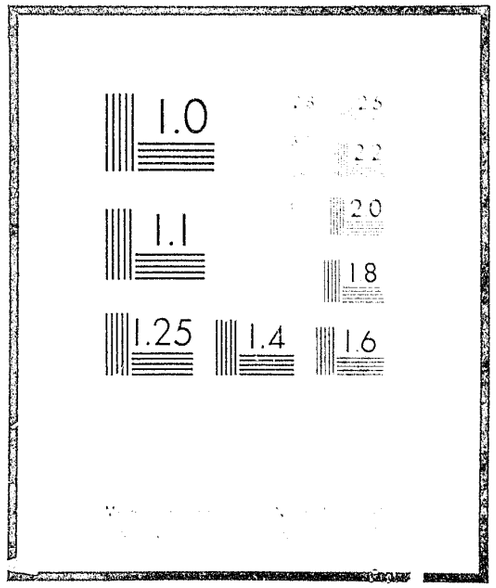

PRISON INMATES IN MEDICAL RESEARCH

HEARINGS

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES, AND THE ADMINISTRATION OF JUSTICE

OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

NINETY-FOURTH CONGRESS

FIRST SESSION

ON

H.R. 3603

TO LIMIT USE OF PRISON INMATES IN MEDICAL RESEARCH

SEPTEMBER 29 AND OCTOBER 1, 1975

Serial No. 31

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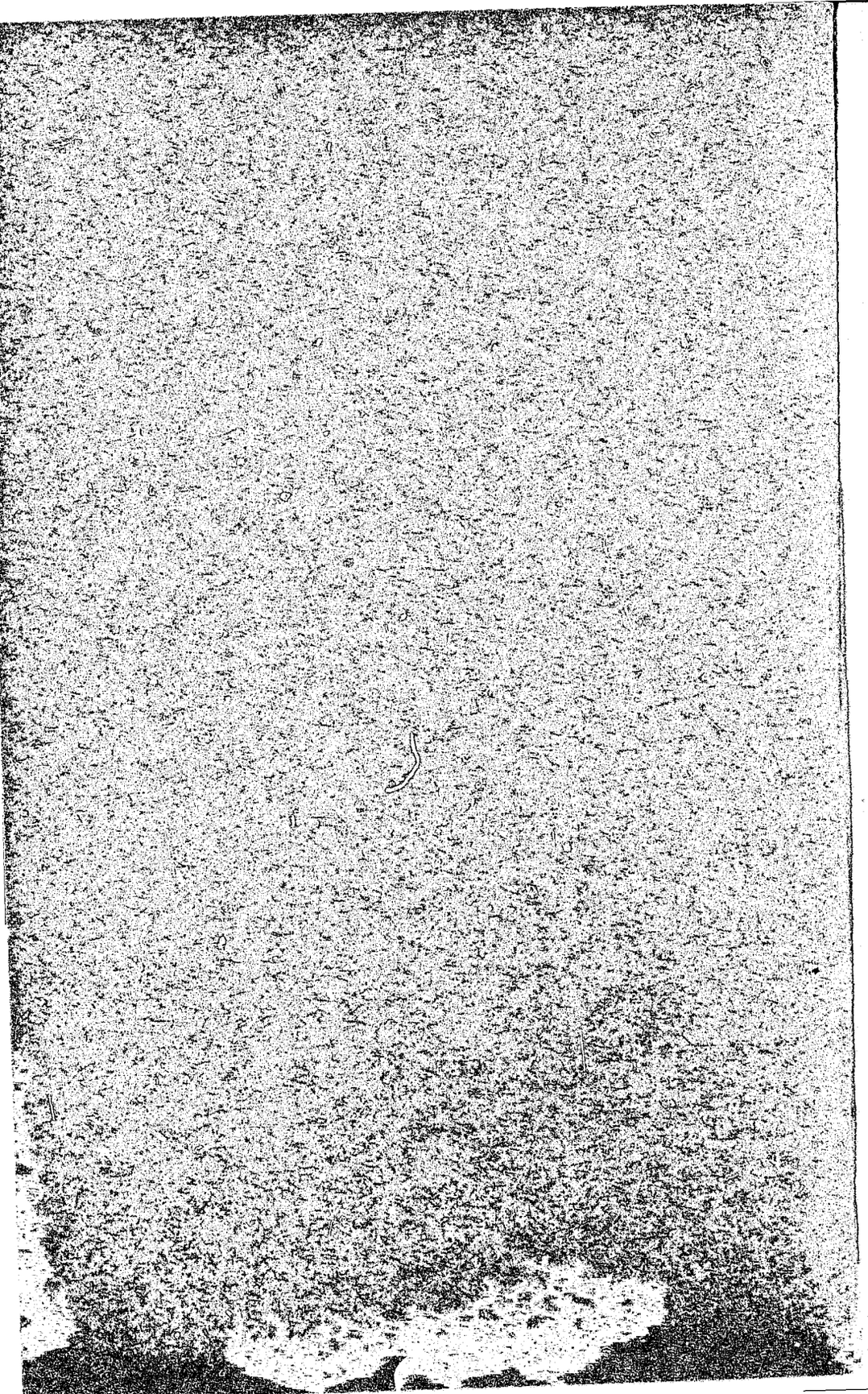

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PRISON INMATES IN MEDICAL RESEARCH

MONDAY, SEPTEMBER 29, 1975

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:15 a.m., in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier [chairman of the subcommittee] presiding.

Present: Representatives Kastenmeier, Pattison, and Drinan.

Also present: Bruce A. Lehman and Gail P. Higgins, counsels; Timothy A. Boggs, professional staff member; and Thomas E. Mooney, associate counsel.

This morning the subcommittee is convened to hear testimony on H.R. 3603, a bill to prohibit medical research on prisoners. The use of prisoners as a subject for medical experimentation by drug companies, medical colleges, and by Government agencies is one of the most ethically questionable practices permitted in this country today.

This issue concerns me and the members of this subcommittee, because we have traveled to some 30 prisons throughout this country in the last few years. One element of prison life which we have come to understand clearly is the constant coercion under which the inmates must live. While there may be coercion in everyday life, coercion in prison life is complete. The person behind bars has virtually no control over his own life. His primary goal is to gain release; thus, his behavior is guided by an ever-present fear of reprisal and hope for reward. Consequently the prisoner is in a uniquely powerless position, and the question of whether it is possible in such a circumstance to give informed consent is confronted.

But beyond the question of whether or not noncoerced and informed consent is possible in prisons, is the question of medical abuses of prisoners while subjects for testing.

While I do not question the motives of drug experiments generally, I am informed that abuses have taken place. The use of Iowa State prisoners in prolonged scurvy tests, later determined to be unnecessary, is well known. In California there are horror stories of the use of prisoners in pain tolerance tests. Addiction Research Center in Lexington, Ky., reports the use of prisoners in a program to test highly addictive drugs. It is reported that no after-care was provided to the subjects of these experiments.

The state of the law on this issue is in considerable flux. Litigation in the courts and agency review of the problems are now underway. I think it is crucial that the Congress move forward with serious consideration of Congressman Mitchell's proposal.

Prior to calling our first witness today, I would like to say that due to time restraints the subcommittee is unable to hear testimony from many groups and individuals who have had an active concern and interest in this issue. We have tried very hard to put together a witness list which will reflect the various points of view on these problems.

In addition to those who appear as witnesses, I have also invited the National Council of Churches, the National Conference of Black Lawyers, the American Pharmaceutical Association, the Clearinghouse in Medical Experimentation on Prisoners, the 50 States attorneys general and the Secretary of Defense to submit written statements for the record.

And in addition to today's witness list on Wednesday, we will hear from Norman Carlson, Director of the Bureau of Prisons, Dr. Alexander Schmidt, Commissioner of the Food and Drug Administration, Dr. William Martin, Addiction Research Center, Lexington, Ky., and a representative of the National Institutes of Health of HEW in the afternoon, Mr. Stetler, Pharmaceutical Manufacturers Association, Dr. Trout, vice president and corporate director of medical affairs, Dr. Opton, Dr. Meyer, and Billy Wayson, director of the Correctional Economics Center of the American Bar Association.

I would like now to open this hearing by calling Hon. Parren Mitchell, who is the author of this legislation, and who has shown a remarkable degree of leadership on this and other issues.

Congressman Mitchell.

[The prepared statement of Hon. Parren J. Mitchell follows:]

STATEMENT OF HON. PARREN J. MITCHELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. Chairman and members of the subcommittee, I am very pleased to appear before you today to take part in these proceedings which hopefully will lead to the end of the exploitation of Federal prisoners in the name of biomedical and behavioral research.

I have introduced H.R. 3603, a Bill which prohibits the use of individuals confined in any Federal or military correctional institution for medical research.

The issue of using prisoners for medical experimentation is significant because of its economic, social, and political implications, as well as the increasing demand for human subjects. In 1970, the National Institute of Health awarded 11,000 research grants of which over 30% involved human subjects. Federal support for biomedical research reached $4.537 million in 1975.

Historically, the abuse of humans in the name of medical experimentation is well established. In ancient times the Persians experimented on condemned criminals. We retain a cruel awareness of the human experimentation performed by the Nazis under the rule of Hitler, and Stalin's abuse of human life, which I might note, bear striking similarities to experiments of recent studies here in the United States.

Currently, eleven States have facilities which participate in biomedical research using prisoners as subjects, including the California Medical Facility, which houses 1,900 inmates, directed primarily by the University of California Medical School faculty members for the purpose of skin sensitivity studies, mild analgesic-sedative tests, and antihistamine studies. In Texas, at the Ramsey Unit Doctors from the University of Texas Medical Branch and Baylor University School of Medicine have been conducting experiments on Cholera Vaccine, Microplasma Pneumonia, and Para-influenza Virus Type 3. In Jessup, Maryland, at the Maryland House of Correction, the University of Maryland School of Medicine has been conducting experiments for new vaccines for such infectious diseases as Malaria, Typhoid, and Cholera. Also conducting research on inmates are the Worcester County Jail in Massachusetts; the State Prison of Southern Michigan, at Jackson, by the Clinics of Upjohn and Parke-Davis; the Montana State Prison, Deer Lodge, by the University of Montana Foundation; the Indiana State Prison by Hill Top Research Inc.; the Cummins Unit in Grady, Arkansas; the Addict Research Center in Lexington, Kentucky, by the National Institutes of Mental Health; Somers Correctional Institution by a private drug company in Connecticut; and the Municipal Correctional Institute in Kansas City, Missouri. Most of the funding for these programs is provided by Federal Government agencies such as the National Institute of Health or by private pharmaceutical firms.[1]

To get to the gut of this issue, let me present you with a couple of hard evidence cases, which are part of the complaint of Bailey vs. Mandel, filed with the U.S. District Court of Baltimore.

Samuel Payne, presently incarcerated at the Maryland House of Correction in Jessup, Maryland, became involved with the Infectious Disease Area because, and I quote, "they pay $2.00 a day, which I used to buy needed items from the Institute Commissary, and had hopes that being a participant in these studies might hold some merit when I was eligible for parole." When Mr. Payne first became involved with the studies, he was assigned to the Institute Woodshop, which paid fifty cents a day.

This man has been subjected to Typhoid, Malaria, Shigella, and Viral Diarrhea studies since September, 1971. He suffered a Typhoid relapse in late 1971, consisting of severe headaches, nausea, fever, loss of appetite and stomach pains. At that time he was refused needed medication because he was told by Infectious Disease Area Staff persons that the study had been completed. Only after the intervention of a security officer was he readmitted to the Infectious Disease Area ward where he was fed intravenously because of severe dehydration. He had lost fourteen pounds and was informed by an Infectious Disease Area technician that his disease would have been fatal if he had not been treated within three days. As a result of this illness, which forced him to stay in the Infectious Disease Area ward, he lost his institutional job.

In May and June of 1974, Mr. Payne's cellmate was a participant in a highly contagious Shigella experiment. During that time period, Samuel Payne became sick for a week where he was nauseous, vomited several times, and suffered from severe headaches. At the time, he was not the subject of any experiments, however, he believed the symptoms of his illness were similar to those of a Shigella infection.

Another illustration is the case of Robert Jones, who is also incarcerated at the Maryland House of Correction. The following is his statement of how he originally became involved with the biomedical experimentation:

"In May, 1970, I was an orderly here at Maryland House of Correction for the IDA. I was asked to go on one of the many tests they have here at the House of Correction. I did not want to do it, but Doctor Miller said it was nothing to it and the money was good. He said the ones who take this test will take some pills first, then you will let some mosquito bite you. This test is a walking Malaria and 9 out of 10 you won't get sick, but for the ones that do we have medication to take care of it, and there won't be any after effects. You will be payed $2.00 a day for about two or three months. How's that? Now, who is going to take it? These are Doctor Miller's words—I'll never forget them as long as I live."

Robert Jones completed the tenth grade. Because of his financial needs, his wife being on welfare and responsible for their two children, he subjected himself to Malaria, May, 1970, by participating in an experiment conducted by the Infectious Disease Area. Despite the assurances of the Infectious Disease Area

[1] This list is provided by the Urban Information Interpreters, Inc., and is current as of June 1975.

Staff that it was very unlikely he would become ill, Mr. Jones, as a direct result of his participation in the experiment, became ill in June, 1970 and again in October, 1970. He was hospitalized after a third relapse for 14 days in January, 1971.

In June, 1971, following his release on parole, he once again became sick while driving a tractor many miles away from a nearby hospital. Before he was able to reach the hospital, he was overcome by violent chills and fever and had to be flown by a State police helicopter to a Baltimore hospital. At the hospital, he was accused by an Infectious Disease Area Staff Director of malingering and complaining for the sake of money. He was subsequently sent a bill for $260.00 from the hospital for the prescribed treatment he received there.

In 1972, while reincarcerated at the Maryland House of Correction, he again, because of a need for funds, subjected himself to Typhoid, Cholera, and Shigella tests. Again, he became sick from all of these tests, and as a result, lost his institutional job. Before each of the above stated tests, the Infectious Disease Area Doctors and male nurses assured him that it would be very unlikely that he would suffer adverse reactions or become ill. During all of these ailments, he was forced to wait for extended periods of time before he received treatment, and then received treatment only because of his insistence that he be cured.

Gentlemen, if you have any sense of humanity, you will, as I do, find these accounts shocking and quite dreadful, to say the least. It is unfortunate, but man in his quest for knowledge, has surrendered his ethical principles.

Equally significant to this issue are the racial, social and political ramifications. It is the poor, the minorities, and the institutionalized that become the "target populations" for risky human experimentation.

I have received many phone calls from people asking if, by introducing this Bill, I am not guilty of "overkill" by not exempting those experiments for which inmates "freely volunteer." These people fail to realize the fact that most prisoners lack the education, expertise, and the technical assistance necessary to exercise informed consent in such complex pharmaceutical studies. The dehumanizing physical and psychological conditions of imprisonment are enough to force some inmates to submit their bodies for experimentation, not to mention the severe economic conditions. The statements from inmates that I have presented, proves that their participation in these experiments is merely a means of escape and in most cases, their only alternative to the severe conditions of imprisonment. To look at this issue from another point of view, if offering one's body for medical research is such a wonderful and great contribution to humanity, then why not solicit volunteers from the free and educated population who are under more desirable circumstances, and therefore, much more capable of exercising their "free will?"

Voluntary or informed consent of a human subject means that the person involved should have the legal capacity to give consent, without the intervention of any element of force, fraud, deceit, duress, or other forms of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This is the first principle of the Nurenburg Code.

The value of health and life of every human being is great. This makes the notion of sacrificing one human being for the welfare of humanity unacceptable, unless that individual is a responsible consenter and exercising his free will to participate in human experimentation, free of ignorance of the consequences, free of coercion of any kind, and free of any undesirable circumstances.

Slowly the public is being made aware of the indefensibility of biomedical experimentation on prisoners, who cannot possibly exercise free choice. The first law suit in the country which has been filed against State and Federal officials to halt experiments on prisoners is now pending in the Federal District Court.

In addition, the National Conference of Black Lawyers is committed to limiting the use of prison inmates in medical research. Towards that end, at their Fifth National Conference scheduled for October 30, 1975, at Howard University, they will conduct a workshop on Behavioral Modification and Experiments on Prisoners.

I firmly believe that passage of the legislation which I have introduced will end abhorrent practices in our prisons and I urge and plead for your support of this legislation.

TESTIMONY OF HON. PARREN J. MITCHELL, U.S. REPRESENTATIVE FROM THE SEVENTH DISTRICT OF THE STATE OF MARYLAND

Mr. MITCHELL. Thank you very much, Mr. Chairman.

First let me say that it is a pleasure to appear before this committee again. I would certainly be remiss if I did not speak to the consistent display of courage that this committee has shown by having hearings and moving forward on very, very controversial issues. I recall earlier in this session of Congress, when you had hearings on the abuse of police power by certain agencies and the matter of the surveillance of citizens who had not really violated the law. I want to publicly thank you Mr. Chairman and the members of the committee and staff for forging ahead in areas which are totally controversial, in many instances, but areas that must be studied if we are to arrive at the proper kind of perspective in this country on these issues.

I would like to introduce the two persons on my left. These are two staff people who have worked not only on the legislation, but have been very active in working with the various groups to set up the legislation.

To my left is Ms. Trisha Irons, and to my far left is Mr. Michael Lipscomb. Both of them are staff members with me.

Mr. Chairman, members of the committee, you have copies of my testimony. There are a large number of witnesses to be heard from. I would ask that my testimony be submitted as it is for the record, and that I be permitted merely to speak to certain portions of it, unless you prefer that I read it in its entirety.

Mr. KASTENMEIER. No. Without objection your statement will be received for the record in full, and you may proceed from it as you wish.

Mr. MITCHELL. Thank you very much, Mr. Chairman.

I think it is important that I give just a little bit of my background and how I got involved in this issue.

Some 20 years ago I worked as a probation officer for the Supreme Bench of Baltimore City, and that brought me into contact with Maryland's prisons quite frequently. What I saw there horrified me. I am convinced that America will not really resolve many of its problems until there is significant prison reform. So, for 20 years I have been more or less involved in working with inmates and trying to do something about the prison system.

I am very proud to say that I have an honorary membership in a number of inmate groups. For the record I would like to point out that one of my best and most highly prized possessions is an award making me an honorary inmate of the Maryland House of Correction. That is framed and is in one of my offices. Quite seriously, that is the background of my involvement. I would further indicate that for as long as I am able, I will continue to maintain that kind of involvement with inmates, trying to reform the prison system.

Quite simply, my bill would have the effect of preventing any inmate in a Federal prison or any inmate in a military prison from being used for biomedical research purposes. That is what it does, in essence, clear, sharp, to the point.

Why is such a bill needed? I would point out to you that in my testimony, beginning on page 2, I cite several examples of cases which

I think demonstrate the abuse of biomedical research. I will call your particular attention to page 3 and the case of Robert Jones on page 3. I would like to read portions of that for the record.

Robert Jones was also incarcerated at the Maryland House of Correction. The following is his statement of how he originally became involved with the biomedical experimentation, and I am quoting from him:

> In May of 1970, I was an orderly here at the Maryland House of Correction for the IDA. I was asked to go on one of the many tests that they have here at the House of Correction. I did not want to do it, but Doctor Miller said it was nothing to it and the money was good. He said, "the ones who take this test will take some pills first, then you will let some mosquito bite you. This test is a walking malaria, and 9 out of 10 you won't get sick, but for the ones that do get sick—

This is the doctor speaking to the inmate—

> we have medication to take care of it, and there won't be any after effects. You will be paid $2 a day for about 2 or 3 months. How's that," the doctor asked. "Now, who is going to take it"? These are Doctor Miller's words, now who is going to take it. These are Doctor Miller's words, and I will never forget them as long as I live.

A little bit about the background on Robert Jones, who completed the 10th grade. Because of his financial needs, his wife being on welfare and responsible for their two children, he subjected himself to malaria in May of 1970, by participating in an experiment conducted by the Infectious Disease Area. Despite the assurances of the Infectious Disease Area staff that it was very unlikely he would become ill, Mr. Jones, as a direct result of his participation in the experiment, became ill in June of 1970, and again in October 1970. He was hospitalized after a third relapse for 14 days in January of 1971.

In June of 1971, following his release on parole, he once again became sick while driving a tractor many miles away from a hospital. Before he was able to reach the hospital, he was overcome by violent chills and fever and had to be flown by a State police helicopter to a Baltimore hospital. At the hospital he was accused by an Infectious Disease Area staff director of malingering and complaining for the sake of money. He was subsequently sent a bill for $260 from the hospital for the prescribed treatment he received there.

In 1972, while reincarcerated at the Maryland House of Correction, he again, because of a need for funds, subjected himself to typhoid, cholera, and the shigella tests. Again, he became sick from all of these tests, and as a result, lost his institutional job. Before each of the above stated tests, the Infectious Disease Area doctors and male nurses assured him that it would be very unlikely that he would suffer any adverse reactions or become ill.

During all of these ailments he was forced to wait for extended periods of time before he received treatment, and then received treatment only because of his insistence that he be cured.

Continuing from my statement, gentlemen, members of the committee, if there is any sense of humanity, if you have it, and I know you do, I think you will find this particular account shocking and the other accounts that I have alluded to in my testimony equally shocking.

In my considered opinion it is unfortunate that man, in his quest for knowledge, has surrendered his ethical principles. I am certain that

there will be those in opposition to my bill. I suspect that three areas of opposition will be raised, the first being the area that the Chairman alluded to earlier; that is, that the inmate really does voluntarily participate in these experimentations. The Chairman questioned the validity of this approach, as I do. In a prison situation there is no free choice. The entire dynamics of prisons, penal institutions, prevent free choice.

You cannot even begin to approach the concept of voluntary participation as long as you are in a prison setting. I think arguments to the contrary are absolutely specious.

The second line of argument that will be raised, I suppose, in opposition to my bill, is that by participating in these experiments, this actually becomes a part of the rehabilitative aspect of the inmates' life. I would consider that a sort of specious argument also. If I am right in maintaining that there can be no voluntary participation, then participation, coerced participation in the biomedical experimentation will in no way have positive rehabilitative effects. Those who would follow that second line of argument would indicate that as a part of being rehabilitated, this man learns that it is to his advantage to do something for the greater good. They would argue that this "voluntary participation" is an act of altruism, an act of humanity, an act for the common good of all the people.

If that kind of altruism is demanded, if that kind of compassion and concern for the need of all people is such an excellent thing, then why can we not have others who can exercise free choice being the experimentees? If that is such a desirable thing, why not college students; why not clergymen; why not housewives who want to participate for the greater good of a larger body?

The third argument that will be raised, and it has already been raised by some who oppose my legislation, is that in order to conduct these experiments you have got to have a very, very controlled situation, a controlled situation in isolation, and prisons represent the best isolated, controlled situation. We are able to create controlled isolated situations outside of prison settings in the various hospitals, in the various universities and colleges. We often conduct experiments, controlled experiments in isolation from the rest of the college population or the hospital population, so I think that that third argument that will be raised against my bill is equally as specious as is argument No. 1 and argument No. 2.

I would, in closing, respectfully suggest to the subcommittee, and really plead with the subcommittee, that swift and favorable action be taken on my legislation. I do not think it ought to be viewed in isolation from the other major objective; that is, significant prison reform.

Obviously until we accomplish significant prison reform, we are going to face rates of recidivism at 70 percent and 80 percent and never dropping much less than 50 percent.

I see the passage of this legislation as being a part of that mosaic in attempting to implement prison reform, and, above and beyond that, I would see the passage of this legislation being an expression from the Congress that we care about human life, whether it be an incarcerated inmate or a person walking the street; that we have not really lost our humanity in terms of using people for medical research;

that we still have some ethics and some values that we think are primary in this country: The one most important value being that that man, that woman, I do not care who he is or where she is, is our most precious commodity. That inmate is still human and is a precious commodity, and to permit him or her to be experimented upon, to be debased and dehumanized in many instances, flies right in the face of our spiritual and moral ethos of this country.

That is my statement in brief, Mr. Chairman and members of the committee, and I will be delighted to try to respond to any questions that you might have.

Mr. KASTENMEIER. We thank our colleague for his statement, and as I said before, for his taking the leadership on this issue. I know that you have a large number of cosponsors for your proposal, and that you are not alone in advancing this proposal.

Let me ask you about your bill, H.R. 3603. It is, limited to the Federal institutions, is that correct?

Mr. MITCHELL. Yes.

Mr. KASTENMEIER. Notwithstanding the fact that most of the abuses cited, if not all of them, have taken place in State systems, State of Maryland and in other places, and we would not therefore reach those abuses by your bill.

Is that correct?

Mr. MITCHELL. That is essentially correct.

I did not attempt to draft the bill to cover the State prisons because unfortunately the Federal Government has very little jurisdiction over the State prison system, save for LEAA funds and other funds which might be contributed to correctional systems.

I would also respectfully suggest to the Chairman that such abuses are not unkown in the Federal prisons, and therefore I think we can start with the Federal prisons, hopefully building that kind of climate in which similar types of legislation would be considered by the various State legislative bodies.

By way of illustration, in the State of Maryland a bill was introduced which is almost comparable to mine.

Unfortunately, it did not get out of committee, but frankly, that is the kind of arrangement I would like to see. It hopefully will become a model by means of which State legislative bodies can begin to tackle this problem.

May I have one word, Mr. Chairman?

Mr. KASTENMEIER. Yes.

Mr. MITCHELL. I have not great pride of authorship in this bill. If any of the members of the subcommitee can find a mechanism by means of which we make it more directly applicable to the State institutions, I would be delighted to support any modifications and changes.

Mr. KASTENMEIER. I appreciate that, and I note that in section 3, reference is made to the withholding of Federal LEAA funds to States which permit medical research on prisoners.

Mr. MITCHELL. That is correct.

Mr. KASTENMEIER. And therefore it would have some effect in certain States.

Furthermore, I take it that you desire this to serve as a model for the States. You feel that the Federal Government should assume the leadership with respect to medical research on prisoners and other similar situated people.

Mr. MITCHELL. Mr. Chairman and members of the committee, I think it is mandatory that the Federal Government assume this responsibility. This is not to suggest that efforts are not being made throughout the country by various State legislative bodies. In Oregon and in Idaho, State law prohibits the use of prisoners in medical research. In my own State of Maryland, there is legislation pending which would prohibit biomedical research on inmates. But I think the major thrust has got to come from this Congress. We are supposed to be closest to the people. We are not supposed to be merely a barometer reflecting the winds that blow in our districts. We are supposed to be advocates in this Congress, and that is why I am suggesting that we take the leadership.

Mr. KASTENMEIER. The Department of Justice Bureau of Prisons—at least the last communication I have for them—states as follows:

> It is against the Bureau of Prisons policy to permit inmates to become involved in medical experimentation projects or drug testing studies which are conducted under the auspices of private agencies or companies, although we frequently receive such requests.

So apparently, they have a very limited policy with respect to use of prisoners presently in the Federal system.

Mr. MITCHELL. Indeed, it is limited, but as I pointed out earlier, I have correspondence in my files in my office indicating that Federal prisoners have needed been used for biomedical experimentation, despite the general policy guidelines.

Mr. KASTENMEIER. Your bill also contains a section which is a limitation on use of military prisoners in medical research. It would not, I take it, rule out ethically or otherwise, the use of military personnel for experimentation.

Mr. MITCHELL. That is different. If a sergeant wants to volunteer, if anyone wants to volunteer who is not presently in a coercive situation, then I think that is his right, just as it would be the right of a housewife in my district; just as would that right be open to a president of a university or college.

Mr. KASTENMEIER. Congressman Mitchell, what do you tell prisoners who say to you, "Look, I want to volunteer. I need the money. I am willing to assume the risks. I thought it through carefully, and your bill would deny us, myself and other prisoners, the right to make this money, the right that other citizens have." What do you tell such prisoners?

Mr. MITCHELL. I think my answer to such inmates would be that in your present setting, you really cannot make an objective determination as to whether or not that is your right. As I pointed out earlier, the whole coercive aspect of the institutionalized really prohibits that right, prohibits that free choice.

Second, Mr. Chairman, members of the committee, I think that you will find that there will be only a tiny percentage of such inmates taking that position. If inmates are able to talk in a situation in which they are not under guard, in which there is not a third party present who is related to the prison structure, you will get a fully different response. I, too, have been in sessions with some inmates

who have said, "Well, I want to be a part of this experiment. It is going to help me get some money for my wife, or it is going to help me get an early parole," but this is done when the prison officials are present. However, when you talk to that same inmate when he is away from the watchful eye of prison officials, and he will tell you, what else would you expect me to say? So I think you are really going to be dealing with a very small percentage of men who would be caught in that kind of situation.

Mr. KASTENMEIER. My last question to you is, if it was possible to end the abuses, to provide a system for overseeing experimentations in prison settings which would not permit the horror stories that you have alluded to, would that be a step forward, or agreeable to you?

Mr. MITCHELL. If you could end the abuses, obviously, it would be agreeable to me, but I would hasten to add, I do not think that, given the present structure of our correctional institutions, that you can end them. I don't think it is physically possible to end the abuses. It is impossible to get the manpower to monitor what happens to prisoners within a given State. For example, if indeed a man at the house of corrections has been abused under this program, and you have, let's say, a Federal agency sending someone over there to check on it, by the time you get to the house of corrections, it is possible that administratively, the man would have been transferred to the Maryland Penitentiary. You have 48 hours in which to follow up on this case, so you go to the Maryland Penitentiary, and he might well have been administratively referred to one of the worksite camps. I just do not think it is possible to end the abuses, in terms of the existing structure.

I also do not think that this Congress nor the States, would have the manpower required to do an effective job of followthrough on each case.

Mr. KASTENMEIER. I yield to the gentleman from Massachusetts.

Mr. DRINAN. Thank you, Mr. Chairman.

Thank you, Congressman Mitchell, for your concern. I am looking forward to hearing all the other witnesses, but just a question or two about the Bureau. On page 3, all experiments are banned, I take it, if they are conducted to determine the safety or effectiveness of any drug, medical device, or medical practice. Do I assume that just every experiment of any nature, even if it is totally harmless to the patients, to the people who take it, would be under the ban?

Mr. MITCHELL. That is correct. That is the only approach we can use, Mr. Congressman.

Mr. DRINAN. So you say inform consent is, under the present circumstances of prisons, is just impossible?

Mr. MITCHELL. It is a euphemistic term which cannot be applied in a prison situation.

Mr. DRINAN. Would you extend that to pretty much every institution, for example, those who are confined for retardation, or mental illness?

Mr. MITCHELL. Yes; I would. It's my understanding that there is some legislation being developed along those lines. If I am not presently cosponsoring that legislation, I certainly will be. I think once again we have a situation in which there is no free choice.

Mr. DRINAN. I assume you thought of extending this to all prisoners, but do you feel that goes beyond the power of the Congress.

Mr. MITCHELL. I think it does. I think the only leverage we can use is to play around with the LEAA constraints, that are LEAA constraints imposed on State institutions. I think we might get into a very, very troublesome area of State jurisdiction versus Federal jurisdiction if we try to legislate directly to cover State prisons.

Mr. DRINAN. Could you, on page 2, tighten it up, and instead of simply stating that the Director of the Federal Prisons shall not allow any Federal prisoner in another institution to be experimented upon—could you say that the Director shall not make any contract with any prison in which such experiments are permitted?

Mr. MITCHELL. Yes; I think that is very good language, and I would be willing to accept it.

Mr. DRINAN. That certainly would strengthen this and would, in effect, ban it in any State institution that did, in fact, take care of Federal prisoners.

Mr. MITCHELL. I thank you.

Mr. DRINAN. I am not certain it is constitutional.

Mr. MITCHELL. Nor am I, but however, you are the astute attorney, and I assume that if it came from you, you would have weighted the possibilities of its constitutionality.

Mr. DRINAN. One last question, Congressman. On page 3, would you spell out what the term drug means? You refer to something in the Federal Food and Drug. What do you really mean by drug, in other words?

Mr. MITCHELL. I am talking about any kind of substance which would induce gross chemical, psychological, physiological changes in human organisms.

Mr. DRINAN. Down to aspirin?

Mr. MITCHELL. Well, aspirin is really not. It is not in that context, in that——

Mr. DRINAN. Well, some experiments would be possible. Suppose they wanted to find out the difference between people who take 12 aspirin and people who take 2.

Mr. MITCHELL. Here, again, you run into some difficulty. It is my understanding, from some medical people, that too many aspirins can be toxic.

Mr. DRINAN. But, technically, aspirin would not be covered?

Mr. MITCHELL. No, I would not consider aspirin——

Mr. DRINAN. If you want to reach that maybe then you ought to broaden the definition. I am not suggesting that you do. I do not know that much about the impact of said nondrugs.

I commend you for your interest, and I look forward to hearing the others. Thank you.

Mr. KASTENMEIER. The gentleman from New York, Mr. Pattison.

Mr. PATTISON. I have no questions.

Mr. MITCHELL. Mr. Chairman, I omitted something from my testimony, and I am sorry. I did want to include it. On the last page, I wanted to pay particular attention to the interest and concern of the National Conference of Black Lawyers. This group is committed to limiting the use of prison inmates, and at their fifth national conference, they are having a workshop on behavioral modification and experiments of prisoners.

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In addition to that, I must mention a group that has worked very, very closely with me and has written this committee on many occasions, I refer to the Urban Information Interpreters, Inc., a Maryland-based organization, a nonprofit organization serving the information needs of the urban poor. I wanted to make sure that this got into the record, because obviously, when you are dealing with medical experimentation on inmates, for the most part, you are dealing with a poor population, and a black population, and I simply wanted to make sure that we had that in the record.

Mr. KASTENMEIER. Yes; without objection, they will be received.

The committee is indebted to you, Congressman Mitchell, for your leadership, and we appreciate your appearance.

Mr. MITCHELL. I thank you very much for letting me appear before you. I am only sorry that my membership on the budget committee, and the Housing and Banking and Currency Committee will prevent me from being here to hear the testimony of the other witnesses.

Thank you very much, Mr. Chairman and members of the committee.

Mr. KASTENMEIER. The Chair would like to call on our colleague who has made a number of contributions to Congress, and to California, who is interested in the question of prisoners and penology; the gentleman from California, the Honorable Leo J. Ryan.

TESTIMONY OF HON. LEO J. RYAN, A REPRESENTATIVE IN CONGRESS FROM THE 11TH CONGRESSIONAL DISTRICT OF THE STATE OF CALIFORNIA

Mr. RYAN. Mr. Chairman, I thank you for the chance to appear here. I preface my remarks—I do not have any degree in penology; I do not have any degree in sociology; I do not have any degree in anything, and I have not taken any courses in some of the things that would probably give me a good deal more broad interpretation of some of the problems today, or more broader knowledge. But there is one area where I feel I have some background that can give, perhaps, some assistance to this subcommittee in considering medical experimentation on prisoners.

I spent 10 years in the California Legislature, and during that time I was on the finance committee for some years. And on my own, and with others, managed to visit almost every prison in the California prison system. I had the dubious distinction, at the time that I was there, of having the largest prison system in the country, with almost 29,000 prisoners at that time in 13 separate prisons.

During that time I also had myself placed in Folsom Prison, as the Chairman knows, for 8 days as a prisoner. I do not know exactly what effect it has if you spend years in prison—it does not mean much—but to me, as a middle-class white American male, it had quite a profound effect on me. And having visited the prison, and having been in that particular prison situation, I did have a chance to listen and to learn. And I have only one, really, I think, important comment to make here, and I feel very strongly about it:

I do not think it would be a good idea to ban completely the use of medical experiments in prison, because I do not think we can define well enough what a medical experiment is. But I think we can say—

and should say—for moral reasons, as well as for very practical reasons, that there should be a ban in the Federal prison system on prisoners getting any kind of time off for being a part of any medical experiment. Because it is my impression from my own experience that, depending upon the circumstances, the prisoner finds himself in—and in many cases, they are desperate for release—oftentimes there are family pressures, there are economic pressures, there are personal internal pressures in the individual to get out. And as a consequence, they simply use their body to buy time off.

Well now, if the purpose of prison is to punish a person by taking away some of their life and putting it in jail, behind steel bars, it seems to me a rather questionable moral practice to allow them to buy time off by having society use their bodies for effects we know of. If they are willing to do so; they should be allowed to do so as anybody outside a prison should do so. But I think it is a very questionable procedure to ask a person—a man, mostly—to jeopardize his health, to jeopardize his life, in order to try and get out after we have put him in, and after society has put him in there.

That, to me, comes very close to the kinds of philosophical and theological problems that are best handled by someone more qualified than I am. But I think that the real flaw—and the most basic flaw—in the present attitude toward this at both the State and Federal level is where we give the prisoner time off for medical experiments on his body.

When he gets out of prison, if he wants to do it, fine. While he is in prison, as an individual with his own personal rights and privacy, if he wishes to volunteer, let him do so. If the medical experiments involve the payment of funds that he thinks are worth it, they are worth the risk to him, if he believes the results of the experiments may provide some kind of long and lasting benefit to mankind as a whole, he may want to become involved in that kind of thing, and I think that is fine.

But if his motivation is—as it usually is—simply to buy time by using his body to get out faster when we put him in there to spend time as a punishment for some past misdeed, then I think the whole matter becomes very questionable. And I just do not believe the State, or any agency of government, should be involved in that kind of, what I would think is trafficking in a very questionable fashion of the use of human bodies for purposes that I think will lead to too many different kinds of abuses, and not all that much in the way of positive benefits to humanity.

That is all I have, Mr. Chairman.

Mr. KASTENMEIER. Congressman Ryan, you are a cosponsor of H.R. 3603, is that correct?

Mr. RYAN. Yes.

Mr. KASTENMEIER. Have you concluded, as Mr. Mitchell has, that we are limited as far as being able to reach the States in terms of this bill?

Mr. RYAN. I am not sure of the legal implications because I am not an attorney. But I think if the Federal Government were to set that kind of pattern, and set that kind of standard, it would be very possible for those who work for prison reform within the various States to point to that as an example, and as a model, and to create that much

greater pressure in the event the Federal Government does not have that kind of jurisdiction, and cannot take that kind of jurisdiction.

Mr. KASTENMEIER. Thank you.

I yield to the gentleman from Massachusetts.

Mr. DRINAN. Thank you, Mr. Chairman.

Mr. Ryan, I wonder if you have had any personal or professional experience in California jails with experimentation.

Mr. RYAN. There have been experiments conducted, I believe, at the Vacaville Medical Facility in Vacaville, northern California. It is a receiving center for northern California, and also, the other half of the facility is the medical facility for psychiatric or psychological problems, convictions and so on. And I am told that there are experiments conducted, the nature of which I am not really that much knowledgeable on. I think that—the dim recollection that I have, and I was there on several occasions—the experiments that I think were conducted were more in the nature of psychological experiments as opposed to the use of the body. Or just trying to find out the mental attitudes, and more in sociological than in a medical sense.

Mr. DRINAN. Thank you.

This, obviously, is a very complicated matter—that we have to have experimentation, if that is the right word. The drug companies apparently have landed on the prisoners. But do I take it that you are firmly behind this bill, and say that no experiments of this kind should be held whatsoever in the Federal prisons?

Mr. RYAN. I would not go quite that far, because I am reluctant to go that last step and say, and ban, any kind of medical experimentation either in prison or outside of prison. I do not have that kind of ability to decide.

I think what we should ban is the business of the Government itself taking the advantage of a situation where we incarcerate a man for an offense which he commits, and after we have got him in there, presumably because he has committed the offense, then we say, well, we will let you out, if you will jeopardize your body, possibly destroy your health, just because we have you in here.

If there is a punishment for the crime, then there ought to be punishment for the crime and there should not be any time off for medical misbehavior. I think that is an extremely important limitation to be placed on the use of a prisoner because the prisoner has so little in prison. The last thing, I think, that he loses—if he can hold on—is his self-respect. If he loses that he loses all that he has.

In the process of losing his self-respect, he no longer cares, and finds that he can buy his way out by using his body to do so; he is liable to do it. In the process of which, two things happen. One is, he may destroy his own health and, from a practical standpoint, place himself—if he lives—in some kind of jeopardy and become a possible expense to the State or Federal Government later on because of his inability to perform as a normal human being.

The other thing is even more important. We become surrogates in a way, I guess, as citizens, as Congressmen, whatever, in approving what is really—what really lends itself, as Mr. Mitchell said before me, to a kind of grisly business over which we have too little control. And the tendency in prison is to begin to treat, in an authoritarian

system, the individual prisoner with a degree of contempt that is hard to describe when you are outside the system.

Mr. DRINAN. Well, Mr. Ryan, the extensive literature about behavior modification, psychiatrists and others say, that they do, in fact, give tranquilizers to prisoners in order to control some type of violence. They are not certain that this particular tranquilizer—which is relatively new—is going to reach this particular form of violence. And they say they would give this to this individual, whether he happens to be in jail or outside.

Now, would Mr. Mitchell's bill actually forbid that in prison, assuming that he is not involved in behavioral modification—that is a whole something else.

Legitimate psychiatrists say that we feel that for this particular type of depression, or this violence prone individual, this tranquilizer might be worthwhile.

Mr. RYAN. I think it is a matter of how that kind of effort is developed. If a particular psychiatrist in a prison facility decides on the basis of his own judgment that the qualities of a particular drug lend themselves to what he thinks he needs for quieting anxieties in prison or outside a prison—either way—and he wants to use it, and finds over a period of time from his experience that it becomes less than satisfactory, that is a matter of more medical judgment; that is experimentation, I think.

Mr. DRINAN. I would feel that you have to modify the language, because the language might well now ban some types of——

Mr. RYAN. That is why I am reluctant to go that last one. The most important thing is to say we are—clearly, you cannot let them buy time.

Mr. DRINAN. What about giving them money for this?

Mr. RYAN. You can do that outside of prison. It is done outside of prison. Students do it; there are all kinds of different groups of people who need funds at a particular point; sell their blood. I do not know whether we can ban that in prison. I do not know whether we should necessarily. But I think if you take away the incentive, it has been my experience and my knowledge, from what I have been able to hear, from what I have been able to observe of my own experience, that the largest number of prisoners that become involved in medical experimentation are the kind that we are talking about, because it is a means of shortening their sentence, and that is what I objected to.

Mr. DRINAN. Thank you very much.

Mr. KASTENMEIER. The gentleman from New York, Mr. Pattison?

Mr. PATTISON. I have no questions at this time, Mr. Chairman.

Mr. KASTENMEIER. In that case, we thank you for your appearance, Mr. Ryan.

Next, the Chair would like to call a panel of witnesses, some of whom are former prisoners. The Chair would like to call Mr. Matthew Myers, who represents the American Civil Liberties Union National Prison Project; and Mr. Richard Alexander, a former prisoner; Mr. Otis Clay, a former prisoner at the Addiction Research Center, and with Mr. Clay his counsel, Mr. Berger and Mr. Helton; also, Mr. Kenneth Matthews, a former prisoner at that center; and Mr. Gary Sabatini, a prisoner in the Maryland House of Correction.

Gentlemen, if you would all come forward, I trust there is room for you. Let me just ask Mr. Clay, where are your counsel?

Mr. BERGER. I am Mr. Berger.

Mr. KASTENMEIER. In no particular order, I would like to call Mr. Kenneth Matthews to briefly—I think each of you have a brief statement of your own experience and your own views. Mr. Matthews?

TESTIMONY OF MATTHEW L. MYERS, ESQ., NATIONAL PRISON PROJECT, AMERICAN CIVIL LIBERTIES UNION; RICHARD ALEXANDER, OTIS CLAY, AND KENNETH MATTHEWS, FORMER PRISONERS, ADDICTION RESEARCH CENTER, LEXINGTON, KY.; GARY SABATINI, FORMER PRISONER, MARYLAND HOUSE OF CORRECTION, JESSUP, MD.; ACCOMPANIED BY ANDREW BERGER, ESQ., AND ARTHUR HELTON, COUNSEL FOR MR. CLAY

Mr. MATTHEWS. Chairman Kastenmeier and members of the committee, in November and January of 1971, I was arrested for the offense of receiving stolen bank money. I was placed in New York City Federal House of Detention.

While I was there, I met Mr. Otis Clay, and he had just come from the Addiction Research Center. I told him of my idea that I would like to go there and receive a television in my room and other comforts that they were giving inmates at Lexington that I knew of. So when I spoke with him, he told me, he said, "If I were you, I wouldn't go." This was a friendly talk between two inmates, and I asked him why he thought I shouldn't go. He said because he had received a stroke while under testing while he was there, and he was back at the present time trying to have something done about it.

I asked him how long he had been there, and he said 2 years. And I said, well, if it took you that long, then I am going down there, too, and see what it is all about. Soon after I was transferred from West Street.

Now, this furthered my decision to go to Lexington, because they told me that they were going to send me to Leavenworth Penitentiary, which is over a thousand miles from where my home is. I knew I could not receive visits. I immediately wanted to get back closer to home, and Lexington is closer than Leavenworth. At Leavenworth I looked on the bulletin board, and there was an announcement that there was going to be some doctors from Lexington to come in and interview us to see if we were eligible to be transferred to this program. From this bulletin, there was about 30 people selected. From these people, there were about 15 people who fit the criteria.

Now, two doctors came up and sort of gave us an idea of what the program consisted of. Now, in Leavenworth, the conditions are: On your gallery, the policeman opens the window, and he lets in the cold, and one night I slept with all my clothes on and newspapers, because you cannot open the window unless the policeman opens it. There is no control of your environment there. In the bathroom, if you go to take a shower, you have wolfpacks—they hang around the shower room and they look for weak guys that they can turn out. So they go in the shower room and see how they fit up, you know—all sorts of things.

So, I said to myself, to avoid this, Lexington sounded like a better environment, because the first thing the doctor told about the conditions is that the correspondence is more lax, that you can receive packages, which you cannot receive in Leavenworth but once a year, and that you could get visits on a more lax basis, as long as they notified them in advance that they were coming; and that you could receive all the records that you could afford to order, you can have a color television in your cell.

Now, we were certified—what you call certified drug addicts. This means that because of our history, we had used drugs, we had abused drugs, a particular drug, to the extent where they felt that we would be serviceable as well as nobody would care anything about us after we got there. So, apart from arriving at Lexington, you go through a physical, a complete physical. I mean, they want to know everything that is wrong with you, only because it relates to their testing.

I thought this was good, up to this point, because I was getting a full physical. Now, after having stayed there for a while, and having gone through some of the tests, I learned that No. 1, in order to take a test, they had to shield certain information from you, because they claimed that if they gave you this information, it would influence your behavior, and that since they were scientists, they had to have accurate, unprejudiced responses. However, I told them, how could I make an intelligent decision if you do not tell me what drug it is I am going to take? And then I said, how can you give me a paper to sign away any responsibility of any effect that this experiment has on me? How can I sign that away, and I do not even know what it is that you are going to give me?

He said, well, listen. Now, you know there is nothing here that is going to hurt you, and as doctors, we could not give you that guarantee, because if you take an aspirin, we cannot guarantee that it will give you no ill effect. And I said, well, under these conditions, does another aspect not arise? Should you not have some concern for me as a patient? I mean, is this thing not illegal if you are not concerned for me all the way?

Well, at that point, you know, we terminated conversation, and he told me that I was going into areas that were premature, and that they had no control over it, because their agreement with the Bureau of Prisons is to borrow our presence, our bodies, and to use us. And then when it is over with, that they have no control over where the Bureau of Prisons sends us, or the medical treatment that we receive.

So this is when I immediately decided that I was not going to take any more chemicals. Then, after this, all of a sudden, another rule came up on the bulletin board. The only way that you can stay there and avoid chemical tests is if you take written tests. Now, before this, there was no limit on the tests that you could take. All of a sudden, now, all you can take is 16 to 18 written tests, and from that point on, you are no longer eligible for written tests. And the only way that you can remain in the program is if you compete, or you get into the program.

So now, this only left the options of a chemical test open to you. So what I would do is, I would begin a test and then stop it, and tell them that I had a headache, so that it would be on record that I was participating in the program because I did not want to lose the showers, the records, and the promise of good time after I had completed my thing at Lexington, when it was time for me to leave.

I asked about aftercare. I said, since I gave up all of this, can I not be sent to an institution that has therapeutic advantages? They told me that they have no control over this, and that I have no right to ask them to interfere with the Bureau of Prisons as far as what happens to me after I leave this building.

So, at this point, I knew that there was no one that I could turn to. So Alexander and myself got into touch with a lawyer in town, and when they saw that he was coming in the building, they tried not to let him in. But since he was legal counsel, they had to. And after I spoke with him, they questioned me as to what we spoke about. I would like to describe one of the tests that I was on. Could I?

Mr. KASTENMEIER. Yes, proceed.

Mr. MATTHEWS. There is a test that the doctors brought around. They asked us if we would volunteer for tests. They called it M–99. Now, the way he advertised this test, he said listen, you know that you are all dope fiends here, and you have a thing with heroin. And this drug is 65 times as strong as heroin. Well, when he said this, because I had a chronic drug abuse problem, and because I was weak for heroin, and because it was only a matter of record that if he offered me heroin, that I would take this test, I said yes; I will take it. And when I took this test in the morning, I never—well, it was 65 times as strong as heroin. It hit me, and sweat came out on my head, and I vomited. And then all of a sudden, like no other drug that I had ever taken, in an hour's time it stopped.

And then, I became violently ill, as if I was going through withdrawal. So I got off of that test. I told him, no, I did not want this any more.

Now, after this, Alexander came to my room, and complained to me about one time that he had taken the test, and they had told him that it was one thing, and that it turned out to be another. So, this is when Alexander and myself decided to go back to Leavenworth, and this is when we started becoming involved with the aftercare.

Now, I was returned to Leavenworth, and when it was time for me to go to parole board, they sent a letter back stating that I was uncooperative in the program. This is for—I notice that the Congressman that just spoke, he said something about them paying in good I use narcotics unprescribed—like, if I do not become involved in a case where I was offered good time. But, I also found out that this good time is also counterfeit, because my parole officer told me when I arrived in New York City that I was sentenced to 8 years by the judge, and irregardless of what I did in that time, that there is no one that could release me from Federal custody before 1979.

So, the time that they promised to give me in Lexington I never received, and, in truth, I never will receive. What it did do was possibly put me on parole early. But I am still in jail, because I am under Federal jurisdiction, and I make reports to my parole officer. And if I use narcotics unprescribed—like, if I do not become involved in a methadone—this is the only provision that they will allow me, methadone; they have not yet given me any avenue to therapy. But they have given me all the narcotics that—that you can have this but no therapy.

Anyway, back to Leavenworth. I was released from Leavenworth into the street and then I was asked to come here to speak as a witness.

Now also, there are booster shots that they give you and they do try to pay you off under the table, of course, in drugs, when they need you, when they think that you are involved or have been involved in the drug for a long time and that you sort of have that expertise. They will offer you a drug payment.

Mr. KASTENMEIER. In your prepared statement you say at the conclusion, I would like to support a ban on prisoner experimentation and ask that aftertherapy be given to those who participated in ARC.

Mr. MATTHEWS. That is my main concern that the people that have gone through this should receive, you know, aftercare concern.

Mr. KASTENMEIER. Thank you very much. You referred to Mr. Alexander. Mr. Alexander.

Mr. ALEXANDER. I have a statement there and I don't think it is necessary to go into it unless you want me to read it.

Mr. KASTENMEIER. Without objection your statement, statements of all those on the panel, will be accepted in their entirety for the record.

And you may proceed as you wish.

Mr. ALEXANDER. My situation was a little bit different than Kenny. I first arrived at Leavenworth, Kans., in 1965 for a charge of bank robbery and I remained in Leavenworth from 1965 to 1969 at which time I was paroled. During the time that I was there I worked for a psychiatrist, Dr. Godfelly and Dr. Joseph Marasen. I worked for them for 4 years, the whole time that I was there at Leavenworth. The first time I went outside, I was on parole for 3½ years. During the 3½ years I had no type of problem, no arrest, nothing. I held a job and I was working and a member of society, although I was still doing other things, I just was not doing it the same way. I was returned to prison on a parole violation, at which time, when I returned there my attitude had changed. And I said, wow, man, this place is ugly.

You know, the first time I did not see how ugly because I was not paying any attention. So I started inquiring about transfers, closer to home, which was denied.

I wrote letters and this and that so one day my caseworker called me to his office and said; "you can go to Lexington, Ky." Up until this time I had very little information on Lexington, Ky., because I was involved in doing other things anyway like we talked about it and after a long conversation I decided and said well, this is not too bad. They're not going to do anything to me that I have not already done to myself as far as drugs. They are going to use heroin, LSD, speed. I had done that myself. I said, hey that is cool. I can go down there to the radio, to TV and play my instrument all day. I said, hey, I will go.

So I went. This was in January. I got there about January 15, 1973. I stayed there until 1974. Kenny was talking about testing when he first came there. You can take a series of written tests. 16 weeks of written tests, examination. I have never been so thoroughly examined in my life, excellent, good, no complaints.

The complaint comes where there was lack of proper concern. The doctor, the first time he approach me to take a speed test, amphetamine, he said, man, you like speed? I would like you to take this test. It is going to last 6 to 8 weeks. It will get you loaded. There is nothing in there that is going to hurt you.

The first time I went back to his office, the next day I said, hey, man, like I have not ever had anything like that. It is not speed.

He said, well, we have some other things in it. And we see that you handle it well. But I said, yes, well, like you have something else in it. And, like, during that time, he was taking notes all the time of how I felt.

So the next time he came up with me he came up again on another amphetamine test. I completed a whole test the first time. I took the next test, supposed to be speed again, amphetamine. It was like acid, LSD, but of a different type of nature. I have also taken a lot of acid on my own. This time, whatever it was, you know, he said it was one thing, but whatever drug he gave me that time, almost blew my sanity. If it was not for Kenny, I don't think I ever would have gotten back. I spent, like, days gone.

Then Kenny and I started questioning him about various different things. Then we had a test to come up and this was a blind. This was supposed to be heroin, speed, M–99 with some elephant tranquilizer and some other drugs and you really did not know what you were going to get. And, like, we were going to talk to a bunch of medical students from the University of Kentucky and like they wanted to get a particular reaction, so we went upstairs early in the morning.

Everybody got a shot of something, but whatever I got that day, it was in my leg and I thought my leg was going to come off within 2 or 3 seconds. Then I had kind of a speed effect and by the time I got into the room to talk to the people, like, I was saying things, man, like, I could my body—I could take my head and put it in my pocket and my hands and I could take people apart. Another form of acid, but not quite like acid, that I ever had. So I told him about that and he didn't do anything and that drug was in a week or so.

During that time, this man and I lost friendship. I went so berserk. Our whole thing just got off base and the problem is, like, they take a man's weakness, find a man that is weak, you know, we are drug addicts, you know, like we have used drugs. We volunteer to go down there as human guinea pigs, yeah OK. These people, do not care about us, the first thing they do, they lie to you. They tell you they are doing one thing, and they are doing something else.

It is harder to prove it. But you have to be there to see it.

Mr. KASTENMEIER. On that question, how do you know they are doing something else.

Mr. ALEXANDER. Certain drugs, like I took a blank test one time, I was on a naline program. When it originally came up in Oakland, I was one of the first people to be on the naline program in Oakland, Calif. And I was in Oakland, then he transferred me to Sacramento.

Naline is supposed to be a drug to determine whether or not you are loaded on heroin. It does something to your pupils. It dilates your pupils, so this is what naline is supposed to be, so he told me about naline and also you can get a load of a rush on naline, a speed type of rush, so I took the test for a doctor. He told a lie, because if he was using naline he had added something else again. Because once again, I was on a trip, that trip must have lasted for 2 weeks. And during that time I went berserk. I started hurting myself. I became very angry, hostile, happy, and various things like that. And the whole issue, like,

Kenny and I started asking for proper concern for once we had left there to go to a place where we could readjust. Everybody would say hey, like, if you do this we will do that, you know. And when it came time, and nothing was done, nobody cared, there was no type of follow-up at all. Once you left Lexington, Ky., just zap, you were through.

Now, there was no way to determine what actually happened to you because there is no research, no followup on what is happening to the people who go there.

The second point, there is no way of them knowing how a particular test would affect you a year from now under different conditions.

And, like, our main concern is the fact that nobody cared. Nobody cared. Like, they would say here, here is a bunch of guys that are social rejects. And we will just do what we want to do. Now how can a person pick up a pencil, sign his name to a document, giving a man consent when back here the man has said it, this man is socially unpurgeable. He is unable to reach a rational decision. But yet, and still at this point you say that this man is capable of giving you consent to use his body and all throughout his history there is no physical evidence where he has made a rational decision about anything. Because if he would have, he couldn't have said it was the first place.

We used to go in there and we asked them, hey, man, you know, we are human beings; we do not know everything; we do not understand the language you are using, but you are playing games, and they would laugh. I wrote to everybody that I possibly could think of, merely to get to a place where I could get my head together.

They sent me back to Leavenworth—zowie—because I refused to participate in their tests any longer. And they called and finally said that I was a troublemaker, and that I was crazy, and I said, yeah, man, I am crazy. I was crazy to come down here and allow you to misuse me as a human being. I said crazy, yeah, you are right; you played the heaviest game in your life, I said. But one day, you have to answer to somebody about misusing human beings.

I am not against experimenting, because a lot of things are necessary. I am concerned with proper concern, like the man said earlier, about if you take a person and put him into a situation that is very ugly, and that is you included, I can almost make you do anything if I first of all, know what it is, that button that I can push that will bring about your weakness.

In a prison like Leavenworth, Atlanta, and other prisons, no man there can make a rational decision about the use of his body and the conditions in prisons. And that is our complaint, is the proper concern.

Mr. KASTENMEIER. Thank you, Mr. Alexander.

Mr. Clay, do you have a statement? I understand all three of these witnesses at one time or another were in the Addiction Research Center.

Mr. CLAY. In 1967, I was sentenced to 10 years in the Atlanta Penitentiary. I stayed there about some 15 months, and while I was there—after that, I saw a notice on the bulletin board saying that volunteers were wanted to participate in experiments at the Addiction Research Center in Lexington, Ky. One of the reasons I was anxious to get away from Atlanta was because I had seen about five murders, about six or seven people getting cut and beat in the head.

Soon, I was transferred to Lexington. In July 1968, I was transferred. They sent about 20 or 29 of us to Lexington, and after we were there about a week, taking physicals and so forth—I was there about a month or so—then they called us up, about 12, 15 members, and asked us if we wanted to participate in what they call a chronic test, in which they said they were going to give us morphine, and this was going to last about 6 or 8 months, and I think—I really do not know the real purpose of it, but I did find some information. I agreed that because as a drug addict, I could not pass it up.

I did go back and get on this test, and once a week, they would ask us to withdraw cold turkey, and do not take any drugs all day, and at the end of that day, they would give us a bonus shot of morphine if we would do that. Everybody agreed to do that. After my 6 to 8 months on that test, I was withdrawn, suffering the usual symptoms of withdrawal, and went back to my living conditions as when I first arrived there.

They called me back to participate in another drug test, 2 or 3 months later. I do not remember how long that was, about 2 or 3 months, and during the time of this test, they injected a drug into me. I would suffer, every injection they gave me. I suffered miserably, terribly. I never knew the names of the drugs. They never told us the purpose of the tests, or any of these tests. They never told us the name of the drugs or the purpose of the tests.

During these tests, I suffered with every shot, and I suffered nervousness, nauseousness, hallucinations, all the time, from every injection. And after that, they called me and asked me, would I participate in electrical experiments, and I agreed to do that.

After that, they took us into a room, and they would place you in a chair, and they would administer shocks. They had two things going. They would have a buzzer. They were sounding the buzzer which would scare you to death. You would never know when anything was going to happen. We could not see anybody. The gentleman was behind you, and the buzzer would sound off.

After the buzzer, you would get an electric shock, and then sometimes, the buzzer would not sound, and you would get an electrical shock. And then sometimes, the buzzer would sound, and nothing else would happen.

And I took two tests, if I remember correctly, and I could not stand it.

And after that, I participated in several other drug experiments. And the last experiment I participated in was the drug they call Naltrexone. They never give you any information about the tests. This Naltrexone, they gave me a pamphlet that stated the short history of this Naltrexone, and this pamphlet stated that this drug had never been tested on a human, but it had been extensively tested in animals, but in some animals that had been tested, it had caused bad heart effects and they explained to us that they kept increasing the doses until the bad effects had been caused in the animals. They asured me that this could not happen to me because the doses that they would give me would be 100 times less than what they gave the animals, and we had nothing to worry about. So I went and signed up for this test. I had no one to put my confidence in, except a doctor, and so, when he told me that, I went and signed up.

And I went up and took an injection of Naltrexone, and the first injection, I aged about 50 years. That is how I felt. And after that, the next week, I took another injection, and the same thing happened. I felt about 100. And just before going up for this third injection, I suffered a nearly fatal heart attack.

And after I suffered the heart attack, they put me in the hospital. They put me in the hospital, and I stayed there for several weeks, and then I transferred back to ARC. When I was in the hospital on the other side, the treatment was pretty good, but when I transferred back to ARC, treatment ceased, because Dr. Martin, the only time he will speak to you—if you were not doing the tests, he would walk by you and not even look at you. But if you are in one of his tests, you are all right.

And I was about ready to leave there when I had the heart attack. If I had followed my mind, I would have left before I had it, and while I was in the hospital, after having the heart attack, one of the doctors would come by to see me every day when I was in the hospital. And one day, he entered the room and I asked him, did he think that that medicine had anything to do with the heart attack that I had, and he said it could have. That was his answer.

Mr. KASTENMEIER. Is that the conclusion of your statement?

Mr. CLAY. That is about it.

Mr. KASTENMEIER. You said you felt about 50 years older—how old are you now?

Mr. CLAY. I was 50 then. I felt about 150 after that second injection. I could hardly move around.

Mr. KASTENMEIER. You are 50 years old?

Mr. CLAY. I am 58 or 59 now.

Mr. KASTENMEIER. Now, Mr. Gary Sabatini.

Mr. Sabatini, you were a prisoner at the Maryland House of Correction in Jessup, Md.?

Mr. SABATINI. Yes, I was, Mr. Chairman.

I would like to thank you, Mr. Chairman, and the committee panel for allowing me to be here to comment on H.R. 3603.

In 1970, I was sentenced for a period of 10 years and sent to the Maryland House of Correction in Jessup, Md. Upon arriving at the house of correction, I learned of an infectious disease program, which was run by the University of Maryland, funded by the Army, in which prisoners could earn a great deal of money. At this time, I had just been incarcerated and found guilty, and I had an appeal in, but I needed money to fight my appeal, money for a transcript, motion fees, et cetera. I had no way of obtaining this money, and the infectious disease department offered me this.

I agreed to participate in a program and was accepted for a malarial study. It was at the beginning of the first tests explained to me that in all probability, I would get sick. I would experience fever, chills, leg and backaches. And for a certain period of time, I would be treated.

I was told that for 2 years following the tests, there was less than a 50 percent chance of relapse, and after 2 years, there would be almost none, that upon my release, I would be given the card that would entitle me to free treatment for any of the relapse of any of the diseases I participated in.

I went on with the test, and became much sicker than the doctor led me to believe I would. After a period of time, I was treated and

released. Within a couple of weeks, I relapsed with malaria, and was treated with a different drug, and released.

A period of time elapsed, and I applied for a typhoid test, maybe a month or so, and was given a physical, and it was learned I had developed infectious hepatitis. I was referred to the institutional hospital, where I was treated and released.

Again, I relapsed with hepatitis within 2 weeks after I was released the first time, and was sent to the penitentiary hospital, treated and released.

After some time I returned to MHC from the camp system. I participated in what I was told was a typhoid test. I was given the germ, but never developed any symptoms. During this test I developed severe stomach problems, including gas, indigestion, attacks of doubling up in which I was unable to breathe. I had to be carried to the hospital for emergency treatment. I complained of these attacks to the Infectious Disease Department. They referred me to the institutional hospital saying that they did not believe that these attacks were a result of their experimentation.

I was put off by the institutional hospital. They said they believed my sickness was a result of my experimentation in infectious disease. Because of a severe and continuing need for money I continued with these tests and was accepted for another malaria test. Two tube swallowings, and a 25-day blood study and two shigella tests, in that order. All the time I was still having stomach problems and complained of it. Both the doctors in the infectious disease studies and the prison doctors continued putting me off. Finally, I was in the University Hospital in Baltimore for tests and I was released.

A short time later relapsed with hepatitis, was treated and released. It is my contention that the hepatitis and the stomach problems are a direct result of these studies.

I was never told that side effects, such as these, would or could occur. They allowed me to continue in these tests knowing of my problem, and I believe this shows that the standards leave something to be desired.

They seemed to be interested in quantity and not quality. The program is a menace to a prisoner's health. I am still having stomach problems. For the following reasons, I feel that this program and others like it should be abolished from prisons.

Infectious disease research for cures is definitely needed. But is it fair to tempt a prisoner with escape from the unbearable noise, confusion, and tension of the prison he has been sentenced to live in by offering him a place that is air conditioned in summer, as opposed to a prison where the heat is stifling; a place that is more than adequately heated in winter, as opposed to a jail where prisoners must go to bed with all their clothes on, including their shoes, with extra blankets, in order to be able to sleep; a place where television, cards, games, freedom of movement and other such reliefs from the drudgery of his day to day life in there, as opposed to working during the day or being idle and stuck in a cell with one other prisoner night after night; a place where he can earn with his body enough money to support himself comfortably in prison, save a few dollars and possibly send money home to needy relatives.

Taking into consideration all the aforementioned pressure, any individual who is faced daily with these facts and is forced to live in a place unfit for dogs where humiliation and degradation, inadequate and poorly prepared food are his steady diet, and to become a subject for these experiments, is infectious disease study fair in a penal institution? I say without hesitation that it is not. I do not believe consent of a prisoner to participate in an infectious disease experiment, taking into consideration the aforementioned, can be considered intelligent, completely voluntary, and without reservation.

To categorize the existence of infectious disease study in a penal institution, without going into detail, I would say it becomes a coercive program. In this atmosphere its benefits on the escapism factor override the intelligence and complete voluntary aspect that should be present in such a situation before an individual consents to participate in these serious and possibly fatal diseases. There is no guarantee that a relapse of these diseases cannot occur, and in the situation where treatment is not available or is undesirable, in all possibility treatment would be put off. This could allow the disease to get to a point beyond cure.

I have seen prisoners ruin their health by participating in test after test. A lot of these tests begin the day after treatment provided for a previous test, and I have seen prisoners on two, sometimes three tests at one time. I have witnessed prisoners who have lied about their health to get on these tests, just to enjoy the benefits and somewhat psychological escape from the prison population at large.

I have seen men who have stayed on these tests and let their bodies run down and who have come very close to death. Some came so close that they had to be rushed to an outside hospital for emergency and prolonged treatment in which complete recovery has taken 6 months to a year or more. For these and other such reasons it is my belief that infectious disease studies and all medical experimentations in penal institutions should be discontinued. I believe that all tests should be discontinued immediately, and that a cleanout operation should be instituted immediately, including a followup program of checking to see that the prisoners presently involved and those who have participated in the past are returned to their original health.

That is all I have to say.

Mr. KASTENMEIER. Thank you, Mr. Sabatini.

Before reaching our last witness on the panel, and the hour is going late, so I ask you to make short answers, if you can. But let me ask all four of you, are all four of you presently on parole?

Mr. BERGER. Mr. Clay is not.

Mr. KASTENMEIER. In any of your cases, or in all four of your cases, was your parole expedited, if you know, by virtue of your participation in these experiments?

Mr. SABATINI. Mine was not.

Mr. MATTHEWS. Mine was almost aborted because of my participation in the program because they sent back a lie. They sent a letter to Senator Kennedy stating that I had written to Senator Kennedy and made a racial issue out of it. I told him that I was being mistreated because I was black, and they took concern for it. He wrote me back a letter that was sent to him by the Bureau stating that I

was manipulative, uncooperative, and a pain in the neck. However, they also gave me 27 commendations for 27 months and the promise of 100, and over 160 good days that I will never receive because, like I said, my parole officer's, you cannot receive any good time.

Mr. KASTENMEIER. Let me get on with the answer to the question.

Mr. Alexander, was your parole expedited or affected in any way by your participation?

Mr. ALEXANDER. I doubt it very seriously because my violation was a very lousy one in the first place, and they made me do 3½ years for nothing, and I was outside for 3½. I do not really know if it did, or if it did not. I doubt it very seriously.

Mr. KASTENMEIER. Mr. Clay?

Mr. CLAY. No.

Mr. KASTENMEIER. One other question.

Do the four of you know of other prisoners, inmates or former inmates, who strongly feel that the research programs should continue because of the payments made? Do some of the people you know who may be out now, or may still be in, feel that the program should be continued?

Mr. MATTHEWS. Yes, I do.

I think that they think that it should be continued because they are still under the influence of coercion. These things, there is still an option of either going back to Atlanta or Leavenworth.

Mr. SABATINI. Mr. Chairman, I do not feel that any man, once he is out in the free world again, would participate in those tests in the free world.

Mr. KASTENMEIER. Your consensus is that there are generally men that would, except that they are still in a prison environment, that outside of the fact that few men know they are participating in this?

Mr. ALEXANDER. I doubt very seriously that there is any guy who is outside now who has been through any other program, would participate under normal conditions, whatever normal conditions are; but under prison conditions, let us take the same person back there, put him under the right conditions, he may do it again. There is no way of knowing that. There is just no way of knowing.

But I know myself, they could take me back to prison tomorrow, and I would never return there under no conditions. They have not got conditions left for me to volunteer to go to Lexington, Ky., again, or anything like that.

Mr. KASTENMEIER. I yield to my colleague from New York, Mr. Pattison.

Mr. PATTISON. I take it you will agree that there is no such thing as a "volunteer" under the circumstances that you described—the word just does not have any meaning.

Mr. ALEXANDER. No.

Mr. PATTISON. Mr. Alexander, I think you make the point that at times you were lied to by doctors as to what they were actually doing to you. Would it have made any difference whether they lied to you or told you the truth?

Mr. ALEXANDER. Yes; it would have. It would have made a great difference. I am a user of drugs. If he would have sat down and told me, if he said, "Hey, Alexander, this is so and so, and so and so, and there is a chance that this may happen," I would have took a gamble, me, personally.

Mr. PATTISON. Of course, the nature of experimentation is such that they are doing things that they really do not understand. It would not be an experiment if they knew what was going to happen, would it?

Mr. ALEXANDER. He could give you a vague outline. He could outline it in such a way where they did that, you know, in such a way, they give you a vague outline in which they thought this particular thing may happen.

Mr. PATTISON. If they were just as honest as they could be, you would still have this same compulsion or coercion as having a TV in your room and the freedom to open and close your window and move around and have all the rest of it. Even if he said this was going to hurt pretty bad, would not that coercion still exist? Would you not be very likely to do it anyway, even if he was being totally honest with you? Under those circumstances you said you would not go back. If you went back you would not volunteer again.

Is it not possible that under certain circumstances if you did go back, you would volunteer again because of the kind of inducements?

Mr. ALEXANDER. Speaking about me personally, they would have to use physical force. They could not do it with terminology. They could not put me in a hole and get me to go back there. If they got me back there, they would have to do it by physical force.

Mr. PATTISON. Of course, you have been through it once.

Mr. ALEXANDER. There would be no way that I would sit down and, like, agree to it. If they did it to me ever again in my life, it would be by force, unless I went totally insane in the next 30 seconds.

Mr. KASTENMEIER. Now we will have Mr. Matthew L. Myers, representing the National Prison Project for the ACLU. I already have your statement here. It will be accepted for the record.

Mr. MYERS. Thank you very much.

I would like to thank you, Mr. Chairman, and the committee for inviting our comments on this issue.

Rather than going through my statement in detail because of the time, I will just try to hit a few points that I think are important.

In 1974, the National Prison Project, filed on behalf of prisoners at the Maryland House of Corrections, what we believe is the first lawsuit challenging the use of prisoners for medical experimentation in the United States. Experiments conducted at the Maryland House of Corrections are run by the University of Maryland Medical School, but are funded almost entirely by various agencies of the Federal Government such as the Department of Defense and the Department of Health, Education, and Welfare.

I point this out because of your concern earlier that the Federal role in medical experimentation is fairly limited. In fact, it is not. We have evidence from the three prisoners who have spoken to you today who participated in the Addiction Center in Lexington. A great majority of funds in prisons—in State prisons—that are used for medical experimentations are Federal funds. And Congress does have jurisdiction over the use of those funds in those institutions.

Finally, almost every prison in the United States receives a substantial amount of money, in one form or another, from LEAA. So, I

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think, this committee does have jurisdiction, and I would urge this committee to make the language in the bill clear that what is being discussed here today is not only the use of Federal prisoners, but the use of Federal funds, in any capacity, for medical experimentation on prisoners.

Our position on the use of prisoners for medical experimentation is clear. We believe that the environment of prisons is so inherently coercive and that the conditions in most of the prisons in the United States are so bad, that a voluntary consent is not possible. Therefore, we are led to conclude that the participation by prisoners is involuntary and in violation of their right to privacy, the right to human dignity and body integrity, their right to be from cruel and unusual punishment. It also amounts to violation of their due process rights.

As I indicated earlier, prisons are inherently coercive. Most experimentation in the United States takes place in medium or maximum security prisons where these conditions are the worst; where the coercion is the greatest and the conditions are the most unbearable. These are the institutions where the State exercises total control over the inmate. The inmate is told when to get up, when to eat, what to eat, what to do, and, most importantly, when he can be released.

The State's role in this process means that the Government is, in effect, identifying certain categories of individuals as less than human; in other words, as fungible and it is disposable.

The issue presented by this bill goes well beyond the issue of the abuses of medical experimentation. The very use of prisoners without a legal and valid consent amounts to the most serious abuse possible.

A number of factors have been addressed by the individuals who have spoken already which contribute to the coercion. I would like to address them very, very briefly.

As all four individuals on the panel have indicated, the most important thing to a prisoner in the United States is his freedom. Most prisoners are sentenced to some form of indeterminate sentence, which means that the date of their release depends largely on the whim and caprice of the prison administration or the parole board. Whether prisoners are actually promised early release, or given early release, I believe it is inevitable that they will always believe that their participation in these programs will lead to their early release, and the statements of the prisoners here today, I think, supports that view.

One of the most severe problems in America's prisons today is idleness. Every official who comes from Europe to view our prisons is astounded at the number of prisoners sitting by with absolutely nothing to do. The first thing you notice when you speak to prisoners is that they are definitely bored.

The second most critical thing you notice as you go into an American prison is the horrible physical conditions most prisoners are forced to live in. They live in noisy, unsanitary, overcrowded cell blocks with no privacy, hostile guards, and in constant fear of homosexual assault, or just plain physical assault.

Participation in these experiments offers an escape, albeit a temporary one, from those unbearable conditions, as indeed, Mr. Matthews and Mr. Alexander said this morning, they literally felt they had no choice but to participate. Under these circumstances, I do not think we can even be coming close to a voluntary consent.

Finally, prisoners in the United States have a desperate need for money. Many are forced to buy the very basic essentials for living—such things like toothpaste or toothbrushes, for example. The opportunity to earn money in most American prisons is almost nonexistent. In fact, six States pay prisoners no wages whether they work or not. Seventeen States pay prisoners less than 50 cents a day no matter how long they work. And 21 additional States pay prisoners less than $1 no matter how long they work.

Thus, even those few prisoners who do have jobs—and in Maryland I am told that over 60 percent have no jobs—that the amount of money they can make by working, or through any other legitimate means, is generally less than one-third of what they can make by participating in a medical experiment: In other words, in selling their body.

One other issue I would like to address is the issue of balancing the risk to the individual versus the benefit to society in deciding whether or not medical experimentation in prisons should be permitted to go on.

We think the issue is irrelevant and cannot be ethically reached, because, until you are able to obtain a legally, voluntary consent, it is pure and simple, you cannot use another individual's body for medical experimentation. As the Nuremburg trials clearly proved, reliance on the risk-benefit rationale can often be used as a substitute for obtaining a legal and voluntary consent.

This rationale allows the State to sacrifice the individual in the name of the State-determined interests of the majority. Application of its utilitarian philosophy to justify involuntary subjection to individuals to medical experiments violates the guaranteed sanctity of the individual by the Constitution and by the Bill of Rights.

We urge this committee to support H.R. 3603, however, we have two suggestions that we feel require additional consideration by the bill. We urge the committee to consider adding a provision to follow up studies and aftercare for those prisoners who have been experimented on in the past, or who may be involved in experiments at the present.

We also urge the committee to enlarge the definition of custody to include those offenders who may be in pretrial or post conviction diversion programs so that they do not become the next wave of subjects. These individuals, who are not in prison, are also under the total control of the State, and many of the same coercion problems exists for them.

As I said earlier, we also recommend that the bill be amended to clarify that the prohibition encompassed by this piece of legislation include not only the use of Federal prisoners, but the use of Federal funds for the use of prisoners for medical experimentation in any Federal or State facility.

I thank you.

Mr. KASTENMEIER. Thank you, Mr. Myers.

In your legal opinion, under the present policy could the Department of Defense or HEW fund the same sort of projects, for example, for Jessup, Md., in the Federal system?

Mr. MYERS. If this legislation was passed, I believe they cannot. Under the present circumstances I believe they can, and I think we have evidence of that by their participation in the program at Lexing-

ton. All that we have is a letter from Mr. Carlson indicating that he prefer it not happen. There is no formal policy, and certainly no legislative policy preventing them from doing so.

Mr. KASTENMEIER. But other than at Lexington, Ky., are there experiments going on, to your knowledge, in the Federal corrections system?

Mr. MYERS. Not nontherapeutic medical experiments to the best of my knowledge.

Mr. KASTENMEIER. If the prisons are removed entirely, as the source of human beings upon which to conduct medical experiments, where ought such experiments be conducted? With what type of population, and how, in your view?

Of course, I am aware that, tongue-in-cheek or otherwise, your colleague, Mr. Bronstein, suggested that they start with the families of pharmaceutical manufacturers and medical researchers.

But apart from that, practically speaking, where would we draw personnel for experiments for medicine?

Mr. MYERS. I believe your next witness, Dr. John Arnold, will address that question directly. He is an individual who has spent many years working in prisons. He finally reached the same conclusions that our organization has reached, and struggled to set up a clinic in the free world to do just what you are suggesting.

He has confronted those very difficult problems, like the use of poor people in the free world, and I believe those questions are best addressed to him.

Nonetheless, let me say that I believe the problems of using individuals in the free world are much less, and until we have tried it—which very few individuals have done—I do not think we can say that individuals in the free world, if offered the proper inducements, the proper medical care, and the promise of proper aftercare, will refuse to participate in medical experiments if they are worthwhile.

I think it is very important to realize that if we cannot convince people in the free world that these experiments are worth doing, maybe we should rethink if, in fact, they are worth doing.

Mr. KASTENMEIER. Mr. Pattison?

Mr. PATTISON. I take it you make a distinction between the setting up and conducting of an experiment and the ordinary treatment of people who run prisons and keep statistics and making observations as to how certain drugs, or certain medical techniques work. And that perhaps there is difficulty in distinguishing between the two.

Mr. MYERS. There is difficuty in distinguishing between the two. All the evidence today, and, I believe, in medical experimentation—which is the focus of this legislation—deals with what is called nontherapeutic medical experimentation. Experiments not for the benefit of the participants. That is the concern that we are discussing today, and I think that is the question which I have no trouble answering.

Mr. PATTISON. But there could be a situation that if you want to learn something medically there is a certain element of experimentation, I guess, in all medical practice or most medical practice. And there could be a situation where you want to learn something about the effects of a drug; you think the drug, when administered under certain circumstances, will achieve a certain result. So you administer it for that purpose, and then you keep records as to what the actual effect is in order to monitor the effectiveness of that drug.

Mr. MYERS. I think we have two issues.

One is the nontherapeutic experiments; the other is experimentation on an individual who already has a disease which you are trying to cure.

It is my opinion, first of all, that a doctor is still under the obligation to do what is best for that patient at that time. So we are not talking about a program of medical experimentation that you would just bring into a prison. What you are talking about is a one-on-one confrontation at that time; whether or not that is the best treatment for the prisoner.

I think I am not prepared to say at this time that we should prohibit the prisoners from getting the benefit of new ideas when they already have the disease. I think that has to be an individual thing. But I think we also have to be extraordinarily careful in institutions not to let that be abused, and not to overlook the need for voluntary consent under the circumstances.

Mr. PATTISON. I have raised the point because the same kind of problem exists to some extent—or, I have heard it exists to some extent in, for instance, medical hospitals or medical teaching centers where you have a medical school and you also have patients. And to some extent there is a learning process going on while you are being cured of something you already have. So there is an element of experimentation.

You are not trying to address that problem at this moment, I take it?

Mr. MYERS. That is correct.

Mr. PATTISON. Thank you.

Mr. ALEXANDER. Mr. Chairman, may I ask Mr. Pattison one thing?

Mr. KASTENMEIER. If Mr. Pattison cares to answer it.

Mr. ALEXANDER. Would you volunteer for anything personally?

Mr. PATTISON. Not a chance.

Mr. ALEXANDER. Do you think that you can be put into a situation where you might volunteer for something?

Mr. PATTISON. Yes; I think I would.

Mr. ALEXANDER. OK. Thank you.

Mr. KASTENMEIER. On behalf of the committee, I would like to thank all members of the panel, Mr. Alexander, Mr. Matthews, Mr. Sabatini, Mr. Clay, and counsel, and representing ACLU, Mr. Myers. Thank you all.

[The prepared statements of Kenneth Matthews, Richard Alexander, Otis Clay, Gary Sabatini, and Matthew L. Myers follow:]

STATEMENT OF KEN MATTHEWS

Thank you, Mr. Chairman, for inviting me to appear today. My name is Ken Matthews and I want to talk about my experience at the Addiction Research Center in Lexington, Kentucky, operated by the Department of Health, Education, and Welfare and the Federal Bureau of Prisons.

I was sentenced in July, 1971. I was sent to West Street House of Detention on my way to Leavenworth, Kansas. While I was in West Street, I spoke with Mr. Otis Clay, who had been a patient in Lexington and he had told me about his experience there. He warned me about Lexington, but when he told me about the living conditions there, I wanted to go anyway.

After I left West Street, I went through Lewisburg and Terre Haute and then when I arrived at Leavenworth, I couldn't believe the conditions there. For example, they put you in a "tank cell" which has double decked bunks with six to eight individuals in a very small area, say 12' x 15'. Because it's a gallery type thing, the windows are lined up against the wall and when they are left open it is cold. In the winter time, I sometimes even slept in my clothes, shoes, pants, coat, to keep warm.

In the shower area at Leavenworth, I noticed that the "wolves" and the people who like to look at men naked in the shower stalls used to hang out around the stalls and look for people who they could make. So I used to try to take my showers when there were not many people in the galleries or in the block. I heard in Lexington that you had facilities where you could take a private shower anytime and there was no crowded condition there.

When I arrived at Lexington I was given a complete physical. Everything was checked: my heart, my teeth, my respiratory system, my limbs, and then I was certified as being physically serviceable to the program and I was officially put in the program as an active participant. Dr. Jasinsky said that periodically I would be asked if I would like to volunteer in research programs that had to do with either written or chemical testing. So I accepted and said that yes, I would periodically like to be involved in this program, especially since some of the drugs mentioned were morphine derivatives.

I was there about from November, 1971, to about December, 1973, or January, 1974. I was there and I took about seven tests. I was noted for being addicted to heroin or morphine type drugs, so when these tests came up I was asked to participate.

When taking a test, I was asked to leave the main floor population where most of the recreation takes place and to come over to another part of the building where the tests take place. I would sit down in a room and the doctor, briefly and generally, would go over the type or the nature of the drug. He wouldn't tell me the exact type or name of the drug in every test. He refused to tell me the side effects. And then he'd ask me if I would like to volunteer to have this drug tested on me. Then he would give me a sheet of paper sort of releasing the doctor from any kind of responsibility in the event of any ill effects. Sometimes if an opiate was to be tested, a lot of the fellows would just sign up on the basis of the fact that it was an opiate-like drug.

They didn't read the release or the paper that was given to get the permission to use this drug. Sometimes they said that it was necessary to keep the nature or the name of the drug from you because it would interfere in their testing.

There have been cases where they have given individuals a drug other than the kind they offered, or in addition to the drug explained. As I think back, one or two times I did get sick when the doctor used a drug—I think it was Naloxon, one of the blocker type drugs and I got a very ill effect. I was told that at any time I decided to have the drug being used on me taken out of my system, or if ever I wanted an antidote, that all I had to do was ask the doctor and it would be taken out of my system. However, I found when this situation did arise in my case, I asked the doctor to take the drug Naloxon out of my system, the doctor immediately began to play a delay game. First, he made me go out and talk to some students about the effects of the drug. I was very sick, and asked the students to hurry the questions. I received no antidote until after two hours had passed, which led me to believe that I had been tricked and misused into completing this test although I wanted to stop.

One of the other tricks they play is that a person cannot be transferred to another institution easily. The staff at ARC will try to delay you there until you either change your mind about wanting a transfer or decide to go along with the program being tested. I went down once myself and asked to be transferred and there was a joke made out of it, since they thought that because of the privileges that you received there that I must be joking. But I was serious. And they stalled it.

Upon leaving ARC, they do give you a physical. But the physical that you receive upon leaving does not compare with the physical that you receive upon entering. I spoke with Dr. Jasinsky once about aftercare, and he said that legally they do not allow a man to go back to an institution until after they have detoxified him and cleaned out his system. Usually this takes three to six months. Dr. Jasinsky said that the reason there was no aftercare is because the government only let him borrow me, and that he had no jurisdiction over me after I left ARC.

This is the extent of their aftercare. There is no followup, so if a man leaves and four years later he drops dead from the tests that he received in Lexington, there is no way to trace it to find out what it was that caused him to die.

While I was in Lexington, an inmate or patient by the name of Carter complained that they had told him that he had contacted something while he was there, and they were sending him to a hospital upon his release from Lexington. But we learned later that he was transferred to Atlanta prison and that the next thing I heard was that he had passed away. But I can witness to the fact that he did complain of ill effects and he did want to make contact with a lawyer named Dean Rivkin who I was in touch with at the time.

Another patient at Lexington was Tatum. He took a year or six-month chronic opiate test, where I think the dosage went to as high as 120 milligrams of morphine a day, in from four to six shots a day. Just recently I heard that he was in the hospital severely sick and suspect he was suffering from the chronic drug usage at ARC.

In conclusion, I would like to support a ban on prisoner experimentation, and ask that aftercare therapy be given to those who participated in ARC.

Statement of Richard Alexander

I was returned to Leavenworth, Kansas, in October, 1972, for parole violation, at which time I started asking various members of the staff if they could help me get a transfer to a more humane institution. I mean humane in the sense that Leavenworth is a very ugly old place with years and years of hate in it, and I didn't want to be in that type of environment anymore. I had remained outside on parole for three and one-half years without any trouble with the law or anyone else.

One day, around the end of November, my caseworker called me to his office and he told me that if I wanted to there was a chance that I could be transferred to Lexington, Kentucky. We talked and I listened and he told me about the use of drugs in research at Lexington. I figured, wow, I could have my own room, tv, radio. I could practice my drums all day. It sounded like a pretty good deal. Also, I figured that they wouldn't do anything to me that I hadn't already done to myself.

My caseworker also said that after completing the experiments there was a very good chance that I could go to an institution of my choice or have a very good chance of being paroled, providing that I completed the program at the institution. No one from Lexington came to interview me. All my interviewing was done by my caseworker, as I just described.

In January, 1973, I arrived at the Addiction Research Center operated by the Department of Health, Education and Welfare and the Bureau of Prisons in Lexington, Kentucky. I was there one year exactly. When I first arrived, Dr. Griffin, Dr. Martin, Dr. Jasinski and Mr. Macklin met me and another man who was traveling with me. Macklin gave us a little speech, took us to the other side of the building and put us to bed. The next day, we started the process of being told what was going on there, that it was researching drugs, mostly heroin and amphetamines, and that they had a new drug M–99, which they weren't talking about much when I first got there. I could do just about anything I wanted to do as long as I participated in the drug program. I was given a complete physical examination.

For 16 weeks I didn't do anything but take written tests and be examined. After that, a doctor, who was a psychiatrist there, called me into his office one day and asked me if I would take a "speed" test for him. I agreed. I went upstairs and went through the process and took the "speed." I told him that it wasn't like any "speed" I ever had before, but he told me that sometimes you don't have the same reaction. Also, another time, I went back up for Dr. Griffin again on a so-called amphetamine study. That time, whatever it was I wouldn't wish that drug on any human being. If it was an amphetamine, it had something else in it, because I started to have hallucinations. It was, in my opinion, LSD of the strongest form. My whole body felt like it was coming apart. It felt like I could take my hand off and put it in my pocket. I became hostile and aggressive. Then I became very happy. It kept changing. I'd be feeling one way for a minute, then it would change and I'd be all right. And that went on for the whole night and the next day.

I told the doctor on numerous occasions that I didn't believe that he was giving me the drug that he said he was giving me, and I'm sure of it. I didn't have any idea what drug he was giving me, but I know that what he told me was speed was not speed. I became very ill in my stomach and chest. I started complaining and after about two or three days they finally decided to take me over to have an examination. I was in the process of taking a "speed" test when this happened. I was given an examination and I was told that there was nothing wrong with me, that they could find no physical evidence of anything being wrong with me and that they were under the impression that I was faking in order to receive drugs.

I took an M–99 test one time, which is an elephant tranquilizer. I had taken acid. I had taken mescaline, but I had never in my life had anything like M–99. It scared me to death.

They always would say after each test they would give you "a bonus"—a shot of morphine or a good shot of speed if you completed the test. And that sounded like a pretty fair deal at the time. Pretty ugly.

They always said that you were able to leave Lexington whenever you wanted to—all you had to do was go to Mr. Macklin and put your papers in and you would leave. But that is not true. Once you put your papers in it may take three or four weeks for him to send them, to Washington, D.C., or wherever he had to send them. Then you might find out that your paper was still there, because he always figured that if you let a dope fiend hang around long enough, if you promise him the right thing, he might change his mind. He was usually right, because by the time it came time to be transferred you would have then decided to take another test. We were paid for tests. Some tests were $5, that's for a week and a day, or $6 in some particular tests, depending on the test you were taking. They ranged from $5 to $6.

I always thought that I would be receiving meritorius time, time that I already had in "the bank." This is statutory good time that I was eligible for. But that also proved to be an illusion. They didn't give up anything. Once you left Lexington, Kentucky, nobody at the institution cared what happened to you at all. There was no type of followup at all. I wrote back a couple of times from Leavenworth to Dr. Griffin, but he was no help.

I know a couple of guys who became ill. I haven't seen them, I only heard about it. There was a guy who was on the morphine study there for a year and all of a sudden something happened in his chest and when he left there they told me he was going to die and I'm kind of sure he is dead. I heard about various other guys who have been there who are not functioning like they should outside, but I couldn't say for sure it was because of what happened there or just the stress of being outside. I know one thing is for sure. No one at Lexington, Kentucky has ever shown any proper concern for human beings. So I'm a drug addict. But that doesn't give anybody the right to misuse me, even with my so-called consent, which in this case was coerced, because if I was to put you in a situation that was ugly and promise you something that you know makes you feel better, you would go for it. I did.

Thank you for the invitation to testify before the Subcommittee on HR 3603. I urge that this legislation be favorably considered by the Subcommittee.

STATEMENT OF OTIS CLAY

To the Members of the Subcommittee on Courts, Civil Liberties and the Administration of Justice: I am very pleased at the opportunity to testify before you with respect to HR 3603 and submit this statement in connection with my testimony:

On or about April 19, 1967 I was sentenced to 10 years for a drug-related offense and was thereafter incarcerated at the Federal prison in Atlanta, Georgia.

At Atlanta I was housed in a small cell with 6 or 7 other inmates, ate food of low quality and was permitted little entertainment to breakup the boredom of prison.

I first learned of the possibility of transfer to the Addiction Research Center at Lexington, Kentucky from a notice posted on a bulletin board at the Atlanta prison. That notice indicated that former drug addicts would be paid $3.00 per

experimental session and one day "good time" for participating in medical experiments at the Addiction Research Center. I also learned from fellow inmates of the better living conditions available at the Center, such as a private room, and of the chance to receive narcotics there. I then filled out an interview form and was later informed of my selection to be transferred to the Center at a group meeting held at Atlanta. At that meeting I was told nothing about the experiments I would be subjected to, or the drugs I would be injected with.

I was transferred to the Addiction Research Center in or about July 1968, was examined by various doctors, and was pronounced in good health.

I then attended a group meeting at which Drs. Martin and Jasinski were present. They informed us that each of us would have a private room, the opportunity to have a radio, television or record player, and that we would be asked to participate in various medical experiments, and take various drugs, for which we would earn $3.00 and one day "good time" for each day of participation. I asked whether the drugs would cause us any harm, and I was assured by the doctors that they would not.

Neither at this meeting, nor at any time thereafter, was I ever told the names of the drugs that I was requested to take nor the purposes of these experiments. In addition, I had no control over the duration of each experiment and understood that if I refused to participate regularly in them I would be sent back to Atlanta.

Following this meeting I was assigned to work as a porter at the Center's laboratory and was given a series of written tests inquiring about my former drug addiction.

MORPHINE EXPERIMENT

After one to two months of answering these tests I, along with some 15 other inmates, was requested to participate in a morphine addiction program. During this program morphine and other related drugs were injected in my arm about three to four times a day for about 6 to 8 months. Before each injection, I was examined by a medical aide who examined my eyes and noted my blood pressure, weight and temperature. Additionally, before each injection I was required to fill out a questionnaire which sought information about the effects of the drugs I was then being given.

At various times during the course of this experiment I was asked by the doctors if I would buy the same drug I was being injected with if I were on the street, or whether that drug had the same effect on me as heroin.

After 6 to 8 months I was then brought down from my addiction to these drugs and suffered withdrawal including nausea, insomnia, chills and anxiety.

SECOND DRUG EXPERIMENT

A few months after my withdrawal I was then asked to take another drug once a week. The night before each injection, I went to the part of the Center where the experiments were conducted and was examined by medical aides. The next day I was injected with a drug whose name I still do not know and my eyes were examined every hour thereafter. The drug made me nervous and miserable all day. The day following the injection I returned to my living quarters and continued normal prison routine until the following week when the next injection was given.

ELECTRICAL SHOCK EXPERIMENT

Sometime thereafter I was requested to subject myself to an electrical shock experiment. During this experiment I was twice strapped to a chair in a cubicle where electrodes and various wires were attached to my arms. A medical aide then stood behind me out of my view and at various times caused electrical shocks to pass through my fingers and arms. At first the shocks were preceded by the sounding of a buzzer in my cubicle. At other times, the buzzer would sound and I would be frightened but not shocked. After two such sessions I was withdrawn from this experiment.

VARIOUS OTHER DRUG EXPERIMENTS

Additionally, I was asked to participate in a series of other drug experiments. In these experiments I was again given various drugs once a week which drugs also caused me to feel miserable and sick.

NALTREXONE EXPERIMENT

Finally, on or about May 27, 1970 Drs. Martin and Jasinski requested that I participate in the experimentation of a drug which they stated had never been given to humans. These doctors provided me with a written statement which indicated that the drug had caused animals to suffer nervousness and convulsions. After reading the statement, I asked the doctors if the drug would cause me any permanent harm. The doctors assured me that I would not be harmed because I would be given smaller doses than the animals had received. Relying on these assurances I signed the statement. The next day I was injected with what I now know to be the drug naltrexone. The injection caused me to feel worse than I had ever felt following any prior injections. I felt about fifty years older. Following examination, I returned to my living quarters and went back to normal prison routine.

On or about June 3, I was injected a second time with naltrexone, and again felt terrible. I continued to feel bad during the week of June 3rd and finally early in the morning on June 8th, I awoke with a severe chest pain. I struggled to the end of the corridor where I was led up to an examination room. A medical aide then phoned Dr. Martin who apparently instructed the aide to give me the electrocardiograph test. Drs. Martin, Jasinski and Mansky then arrived, examined the results of this test and ordered that I be taken to the hospital. On the way to the hospital I was told by one of the doctors that I had suffered a heart attack.

The following day I was taken to the intensive care unit at the hospital and hooked up to a machine that monitored my heart beat. The doctor in charge of the hospital visited me three times a day. Drs. Martin, Mansky and Jasinski came by to see me daily. About one week after the heart attack I asked Dr. Martin if the drug I had just been injected with on May 28th and June 3rd could have caused the heart attack. Dr. Martin replied that it could have. I remained at the hospital for a few weeks.

I was not involved in any more medical experiments at the Addiction Research Center and I was then transferred in September of 1970 to the Federal House of Detention in New York City.

Thereafter in May of 1971 I filed a *pro se* complaint against Drs. Martin, Mansky and Jasinski, as well as the Surgeon General, Attorney General and the director of the Bureau of Prisons seeking damages for the pain, suffering and permanent disability caused by the heart attack. This action by amended complaint now includes the United States and is proceeding to trial at the direction of the United States Court of Appeals for the Second Circuit, who, in an opinion dated January 20, 1975 reversed the district courts dismissal of the complaint.

In summary, based on my long and unfortunate experience as a subject of medical experimentation while an inmate at the Addiction Research Center, I urge such experimentation be banned by the passage of H.R. 3603.

STATEMENT OF GARY SABATINI

I was sentenced in 1970 for a period of 10 years and sent to the Maryland House of Corrections, Jessup, Maryland. Upon arriving at MHC, I learned of an infectious disease program in which prisoners could earn a good deal of money. At the time, I needed money to fight my appeal—money for copies of transcripts, motion fees, etc. I had no other way of obtaining this money and the Infectious Disease Department offered me this. I agreed to participate in the program and was accepted for a malaria study.

It was explained to me that in all probability I would get sick. I would experience fever, chills, leg and back aches and after a certain period of time I would be treated. I was told that for two years following the test there was less than a 50 percent chance that I would relapse and after two years there would be almost no chance.

I went on the test and became much sicker than the doctor led me to believe I would. After a period of time I was treated and released. Within a couple of weeks I relapsed with malaria and was readmitted, treated with a different drug and released.

A period of time elapsed and I applied for a typhoid test. I was given a physical and it was learned that I had developed infectious hepatitis. I was referred to the institutional hospital, where I was treated and released. Within two weeks I

relapsed with hepatitis, was sent to the penitentiary hospital, treated for 16 days and released.

After some time, I returned to MHC from the camp system. I participated in what I was told was a typhoid test. I was given the germ but never developed any symptoms. During this test I developed severe stomach problems, including gas, indigestion and attacks of doubling up in which I was unable to breathe. I had to be carried to the hospital for emergency treatment. I complained of these attacks to the Infectious Disease Department. They referred me to the institutional hospital, saying they didn't believe these attacks were a result of their experimentation. I was put off by the institution hospital. They said they believed my sickness was a result of the experiments.

Because of a severe, continuing need for money, I continued with the tests and was accepted for another malaria test, two tube swallowings, and a 25-day blood study and two shighela tests in that order. All this time I was still having stomach problems and complained of it. Both the doctors in the infectious disease studies and the prison doctors continued putting me off. Finally, I was sent to University Hospital in Baltimore for tests and I was released. A short time later I relapsed with hepatitis, was treated and released.

It is my contention that the hepatitis and stomach problems are a direct result of the studies. I was never told that side effects such as these could occur. They allowed me to continue in these tests, knowing of my problems. I believe this shows that their standards leave something to be desired. They are interested in quantity and not quality. The program is a menace to a prisoner's health. To date, I am still having stomach problems. For the following reasons, I feel that this program and all others like it should be abolished from prisons.

Infectious Disease Research for cures is definitely needed. But, is it fair to tempt a prisoner with escape from the unbearable noise, confusion and tension of the prison he has been sentenced to live in by offering him:

1. a place that is air-conditioned in summer, as opposed to a prison where the heat is stifling;
2. a place that is more than adequately heated in winter as opposed to a jail where prisoners must go to bed with all their clothes on (including their shoes, with extra blankets) in order to be able to sleep;
3. a place where television, cards, games, freedom of movement and other such reliefs from the drudgery of his day-to-day existence are always at his disposal, as opposed to working during the day or being idle and stuck in a cell with one other prisoner night after night;
4. a place where he can earn with his body enough money to support himself comfortably in prison, save a few dollars and possibly send money home to needy relatives.

All of the aforementioned pressure an individual who is faced daily with these facts and is forced to live in a place unfit for dogs, where humiliation, degradation, inadequate and poorly prepared food are his steady diet into becoming a subject for these experiments.

Is Infectious Disease Study fair in a penal institution? I say without hesitation it is not! I don't believe consent of a prisoner to participate in an infectious disease experiment, taking into consideration the aforementioned, can be considered intelligent, completely voluntary and without reservations.

To categorize the existence of infectious disease studying in a penal institution without going into detail, I would say it becomes a coercive program. In this atmosphere, its benefits and the escapism factor override the intelligence and complete voluntary aspect that should be present in such a situation, before an individual consents to participate in these serious and possibly fatal disease. There is no guarantee that a relapse of these diseases cannot occur in a situation where treatment is not available or is undesirable. In all possibility, treatment would be put off and this could allow the disease to get to a point beyond cure.

I've seen prisoners ruin their health by participating in test after test. A lot of these tests begin the day after a treatment period for a previous test ends. I've seen prisoners on two, sometimes three tests at one time. I've witnessed prisoners who have lied about their health to get on these tests, just to enjoy the benefits and a somewhat psychological escape from the prison population at large. I've seen men who have stayed on these tests and let their bodies run down and who have come very close to death. Some came so close that they had to be rushed to an outside hospital for emergency and prolonged treatment in which complete recovery has taken six months to a year, or more

For these and other such reasons, it is my belief that infectious disease studies and all medical experimentation in penal institutions should be discontinued. I believe that all tests should be discontinued immediately and that a clean out operation should be instituted immediately, including a followup program of checking to see that the prisoners presently involved and those who have participated in the past return to their original health.

Thank you for the invitation to comment on HB 3603.

STATEMENT OF MATTHEW L. MYERS, REPRESENTING THE NATIONAL PRISON PROJECT OF THE AMERICAN CIVIL LIBERTIES UNION FOUNDATION

We would like to thank the committee for inviting our comments on H.R. 3603, The National Prison Project of the American Civil Liberties Union Foundation seeks to protect and strengthen prisoners' rights, to improve overall conditions in the nation's prisons and to develop rational, less costly and more humane alternatives to traditional incarceration. In 1974 we filed the first major legal challenge to the use of prisoners as subjects for non-therapeutic medical experimentation in the federal district court in Baltimore, Maryland. The lawsuit, on behalf of Maryland state prisoners, deals with an infectious disease program operated by the University of Maryland School of Medicine, under contracts with the Department of Defense, and the Department of Health, Education and Welfare. A copy of the press release, issued at the time the suit was filed, which provides more details is attached as an appendix to this statement. Further, we have conducted a good deal of research in the past few years which we believe overwhelmingly supports the conclusions that we wish to present to this committee.

Scientists' abuse of the human subjects of their experiments has been well documented. Besides the recent disclosures concerning LSD and other experiments conducted by governmental agencies, one need only recall reports of the untreated syphilis victims in the Tuskegee experiments;[1] the reports of Dr. Austin Stough, the Oklahoma physician who left a trail of hepatitis through the prison systems of several states in the mid-60's while his firm was earning large sums of money testing drugs and selling blood plasma;[2] the reports of Emanuel Mandel, at the time director of medicine and medical education of the Jewish Chronic Disease Hospital in New York, who, without the knowledge or consent of 18 patients and without the knowledge or consent of their doctors, injected those patients with live cancer cells. (Dr. Mandel informed one questioner of his ethics "that he could not get their consent because these patients were incompetent."[3] It is both the actual abuse of captive human subjects, and the potential for abuse which concerns us.

Our position with respect to the use of prisoners in non-therapeutic medical experimentation is simple and we believe legally clear. Our position is that the *de facto* environment of prisons is such that one cannot create an institution in which informed consent without coercion is feasible.[4] That is, given the nature of the institution of prisons, and the degree of intrusion on the individual, his body and his mind, which necessarily results from non-therapeutic medical experimentation, the constitutional rights of the individual prisoner to be free from invasions of privacy, free from invasions of his human dignity, free from cruel and unusual punishment and free from injurious state action without due process, are violated.

In a medium or maximum security institution, of the kind where most medical experimentation on prisoners takes place, the State exercises total control over every moment of the prisoner's life. The State tells the prisoner how he must live, when to sleep, when to get up, when to eat, what to eat, what to do and when to do it, and, most important, when to go free, all adding up to the most oppressive and coercive institution that we have in our society. The State's involvement in human experimentation means that it is identifying some part of the population—prisoners and other institutionalized persons—as less than human, as fungible and as disposable.

[1] See Morris and Mills, *Prisoners as Laboratory Subjects,* The Wall Street Journal, April 2, 1974.

[2] Id.

[3] Jay Katz, *Experimentation With Human Beings,* Russell Sage Foundation (1972), p. 13.

[4] See generally, Jessica Mitford, *Kind and Usual Punishment,* (Knopf, 1973); Ben H. Bagdikian, *The Shame of the Prisons* (Simon & Shuster, 1972); Erving Goffman, *Asylums* (Aldine, 1961).

Imprisonment is the maximum use of the State's power in a free society. The real measure of a free and democratic society is not how it protects the rights of the influential, the strong, the majority but how it protects the rights of the weak, the powerless, the poor and the minority.

The issue of informed consent as a legal doctrine, although not completely settled, can be outlined and discussed. We must keep in mind that it is necessarily a flexible doctrine. Obviously there will be differences between informed consent for a mental patient, or a prisoner or for a college student in the free world who volunteers for an experiment. But it must always consist of three elements. These are competency, knowledge and voluntariness.

The code adopted as a result of the Nuremburg trials concerning the Nazi atrocities, defines voluntary consent and states in pertinent part:

" . . . that the person involved . . . should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved so as to enable him to make an understanding and enlightened decision. . . ."

The nature of prisons and the quality of life in prisons in the United States make it impossible for a prisoner to give a constitutionally valid informed consent. Prisons in this country are closed, secret and inherently coercive institutions. Control and security are the paramount concerns of the prison administrators. Rehabilitation of prisoners is neither the goal nor the practice. More than 90% of all of the monies budgeted for corrections in this country goes for control and security. Less than 10% of the entire corrections budget in the country goes for the generally worthless programs that exist in some prisons.[5] Most experiments using prisoners are conducted in medium or maximum security institutions.[6] These are the institutions where the control is the closest and most coercive and where conditions are most oppressive. These are the institutions where the prisoner has the fewest available options.

The most important thing to most prisoners is their freedom. Indeterminate sentences are widely used in this country and have an extremely coercive effect on prisoners. The prisoner knows that the date of his release from prison, the single most important thing in his life, is subject to the whim and caprice of the prison administration and the parole board. Pleasing the prison administration and the parole board become one of the most important elements of prison life. Prisoners know the economic advantages to prisons of having drug programs. Even for those prisoners who do not have indeterminate sentences, his or her release date is still indeterminate in the sense that it is decided by the parole board.[7]

Whether parole or the date of release is actually affected by a prisoner's participation in experiments, the critical fact is the prisoners inevitably believe that they will enhance their chances for an earlier release and act accordingly. Indeed, federal prisoners with a history of drug-dependency are offered additional good time to reduce their sentence if they will agree to participate in drug testing, including LSD studies, at the Addiction Research Center maintained by the Bureau of Prisons at Lexington, Kentucky. Thus, the promise of early release and the promise of drugs are used to coerce federal prisoners into "volunteering".

The barrenness of prison life is another factor coercing prisoners to participate in experiments. Having drug programs in maximum security institutions helps to continue the existence of these institutions by providing one of the few escapes

[5] See generally, David Rothman, *Decarcerating Prisoners and Patients,* The Civil Liberties Review (Fall 1973); Robert Martinson, *What Works?—Questions and Answers About Prison Reform,* The Public Interest, No. 35, Spring 1974 (To be published in 1975 by Praeger in an expanded version as *The Effectiveness of Correctional Treatment*); Edward M. Opton, Jr., *Psychiatric Violence Against Prisoners: When Therapy Is Punishment,* 45 Miss. L.J. 605 (1974).

[6] For example, State Prison of Southern Michigan at Jackson; Maryland House of Corrections, Jessup, Maryland.

[7] See generally, Alvin J. Bronstein, *Rules for Playing God,* The Civil Liberties Review, Summer 1974.

from the reality of prison life that a prisoner has. If a prisoner were in a community facility or in a very minimum custody facility with a wide range of available activities he would not use the sometimes painful and sometimes dangerous participation in a drug program as the only escape from prison life. Prisoners in almost all American prisons are forced to spend almost all of their time idle. They live in noisy, unsanitary, overcrowded, poorly lit cellblocks with no privacy, subject to hostile guards and in constant fear of assault. Participation in medical experiments provided an escape, albeit temporary, from these unbearable conditions.

Prisoners in most American prisons are forced to purchase, with their own money basic necessities of life, i.e., personal hygiene items. Many prisoners also have families who still look to them for some financial support or have legal expenses which they have incurred. Yet, there is little or no opportunity to earn money within penal institutions. Prison wages generally, or the absence of them, act as another coercive force in prison life. According to recent data, six states pay no prison wages at all, seventeen states pay less than 50 cents a day and twenty-one states pay between 50 cents and $1.00 a day. Only six states pay more than $1.00 a day. In those states that do pay something the estimated percentage of prisoners who earn wages ranges from 10% to 95% so that not all prisoners can earn wages even in those states which pay wages.[8] Although federal prisoners can generally earn more than many state prisoners, it does not significantly affect this element of coercion. In almost every instance, a prisoner is paid far more for participating in a medical experiment than he can obtain any other legitimate way in prison. Often the only way a prisoner can obtain the money he needs to exist is to participate in an experimental medical research program.

Finally, we have the issue of weighing individual risks against the benefits to society. We think that issue is irrelevant and cannot be ethically reached when you are dealing with prisoners, because, as discussed above, one cannot obtain legally voluntary consent from such captive subjects. A physician has stated the matter well:[9]

"Any classification of human experimentation as 'for the good of society' is to be viewed with distaste, even alarm. Undoubtedly, all sound work has this as its ultimate aim, but such high-flown expressions are not necessary, and have been used within living memory as cover for outrageous ends."

The State should not have that power in a free and democratic society. It is dangerous for prisoners. It is dangerous for society. As the Nuremberg trials proved, reliance on the risk-benefit rationale can be and has been used as a substitute for obtaining a legal, voluntary consent from prisoners. This rationale allows the State to sacrifice the individual in the name of the State determined interests of the majority. Application of this utilitarian philosophy to justify involuntary subjection of prisoners to medical experiments violates the guaranteed sanctity of the individual secured by the Constitution and the Bill of Rights.

An increasing number of people, familiar with the quality of prison life, have come to the same conclusion about the use of prisoners for medical experiments. A fair number of states, most recently Pennsylvania, Massachusetts, Alabama and Illinois, have banned the use of prisoners as human subjects because they recognize the impossibility of obtaining a legal informed consent in prison. Similar legislation is now pending in California and Maryland. As one corrections official in Oregon put it: "We are not running a Greek democracy here—no man is a free agent in prison."[10]

We urge the members of this committee to support H.R. 3603. We also urge the committee to consider adding a provision for followup studies and after care for those prisoners and ex-prisoners who have been experimented on in the past and to enlarge the definition of custody to include those offenders who may be in pre-trial or post-conviction diversion programs so that they do not become the next wave of subjects.

It is further recommended that H.R. 3603 be amended to clarify the prohibition against the funding by any Federal agency or department including DHEW and its agencies of non-therapeutic medical research.

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[8] Resource Document No. 4, Parole Corrections Project (American Correctional Association, March 1974), Table IV.

[9] H. K. Beecher in *Clinical Investigation—Medical, Ethical and Moral Aspects*, (Boston University Press, 1963).

[10] Quoted in Morris and Mills, *supra*, note 1.

Appendix

Law Suit Filed Against Maryland and Federal Officials to Halt Experiments on Prisoners

first such suit in the country

The National Prison Project of the American Civil Liberties Union Foundation, Inc., announced a suit filed today against Maryland Governor Marvin Mandel and other state and federal officials for their involvement in the continuation of the Infectious Disease Area (IDA) at the Maryland House of Correction in Jessup. The suit, filed in federal district court in Baltimore is believed to be the first in the country aimed at stopping nontherapeutic medical experimentation on prisoners. The suit also seeks a total of $1,250,000.00 in damages.

The Infectious Disease Area operates under the auspices of the School of Medicine at the University of Maryland in Baltimore and studies the use of new vaccines for treating contagious diseases such as cholera, malaria, typhoid and shigellosis. The use of prisoners as human subjects in bio-medical experimentation has aroused the concern of many local and national prisoner rights and civil libertarian groups because, as the suit claims, the coercive atmosphere in correctional facilities throughout the country, and especially at the Maryland House of Correction, makes voluntary participation in experiments impossible and makes the experiments cruel and unusual punishment. Prisoners at Jessup usually wait 1 to 5 months to receive an institutional paying job and until that time must remain on "idle status," which allows few opportunities to leave a 5×8×7 foot cell which must be shared with another prisoner. In addition to overcrowded conditions there is a severe lack of modern and purposeful rehabilitational, vocational, educational and medical facilities at the 115 year old prison. Because of these poor conditions, and in spite of grave physical risks, prisoners are enticed into participation in the bio-medical experiments by IDA's superior ward conditions. The coercive atmosphere is increased by the fact that a prison job pays on the average of $.65 per day, while a prisoner participating in IDA studies will receive, after the prison deducts an automatic $8.00 "contribution" to the prison hospital, $2.00 per day. Many prisoners at Jessup have families on welfare and therefore must provide for themselves, with whatever means are available, legal transcripts, inflated commissary items and personal hygiene supplies, paper, and extra clothing.

The nine named prisoner plaintiffs claim that exposure of healthy prisoners to serious and debilitating disease is an invasion of the protection of one's bodily integrity secured by the Fourth and Fourteenth Amendments and is forbidden as cruel and unusual punishment by the Eighth Amendment when performed with the cooperation of prison officials. Because defendants have recently contracted to pay non-prisoner participants in similar experimental tests a rate of $20.00 per day, the disparity in the rate of remuneration denies prisoner-subjects equal protection of the law in violation of the Fourteenth Amendment and subjects them to involuntary servitude in violation of the Thirteenth Amendment. Plaintiffs also claim defendants are acting in violation of their First and Ninth Amendment rights to privacy and dignity.

In addition to Governor Mandel, other named defendants are Robert J. Lally, Secretary of the Department of Public Safety & Correctional Services; James Jordan, Commissioner of Correction; Lewis L. Caplan, Chairperson of the Maryland Board of Regents; Dr. Wilson H. Elkins, President of the University of Maryland; Dr. Theodore Woodward, Chairperson of the Department of Medicine at the University of Maryland School of Medicine; Dr. Richard B. Hornick, Director of the IDA at the Maryland House of Corrections; Dr. Neil Solomon, Secretary of the Maryland State Department of Health and Mental Hygiene; Casper Weinberger, Secretary of the U.S. Department of Health, Education and Welfare and James Schlesinger, Secretary of U.S. Department of Defense.

Attorneys for the plaintiffs are Arpiar G. Saunders, Jr. of the National Prison Project, C. Frank Morgan of the Prisoners' Assistance Project, Baltimore Legal Aid Bureau, Lennox S. Hinds of the National Conference of Black Lawyers and Emily Rody of the Maryland Civil Liberties Union Foundation.

The suit seeks an end to the IDA program at the Jessup prison. An overall and extensive improvement in the extremely poor prison conditions is being sought.

The National Prison Project is a national project based in Washington which seeks to broaden prisoners' rights, improve overall prison conditions by using existing administrative, legislative and judicial channels and develop alternatives to incarceration.

Mr. KASTENMEIER. Next the Chair would like to call the gentleman referred to by Mr. Myers. He is Dr. John D. Arnold, medical director of Quincy Research Center, Kansas City, Mo.

Dr. Arnold, you are most welcome.

Your statement is a brief one.

[The prepared statement of Dr. John Arnold follows:]

STATEMENT OF JOHN D. ARNOLD, M.D., MEDICAL DIRECTOR, QUINCY RESEARCH CENTER, KANSAS CITY, MO.

Mr. Chairman, the use of inmates in American prisons for medical research developed primarily during World War II under what was then thought to be the exigencies of wartime. From a scientific point of view, this was an important landmark in that much of the work done in prisons was designed to forestall complications and inadequacies of new drugs, vaccines and procedures for the ultimate consumer, namely, the American soldier, sailor and airman. The idea was relatively new of testing for and resolving complications of medical therapy by relatively controlled and limited trials in volunteers without putting at risk large populations. The morality of the use of prison volunteers bothered some people at the time and we saw a number of committees and commissions addressing themselves to this problem. Most prominent of these was the Ivy Commission.

As the quest for greater consumer safety, as well as more predictable efficacy, of new medicines intensified, so did the use of one special population, namely, prison inmates to predetermine these risks. At the time of the high watermark of prison research several years ago, we could identify over fifty institutions in which some form of medical research was being carried out. It is likely that the majority of these was in connection with the development of new or the re-examination of old pharmaceutical products.

This historical perspective includes a number of elements:

(1) The prison system developed relatively smoothly and easily during wartime.

(2) When the need for human testing escalated, especially after the Harris-Kefauver Act, very little effort went into developing alternate ways of carrying out this research. In other words, the prison system was a ready-made solution to the problem of developing new medicines.

(3) Because the prison system was so successful, it is probable that even if a substantial effort was made to find alternatives, they would have presented too many additional difficulties and too much additional cost to have competed successfully with the prison system.

(4) Until the ethical questions and public disquiet intensified over the use of prison inmates in medical research, there was little incentives to abandon a successful and proven system. In fact, in the minds of many people, it seemed unlikely that an alternative system of cloistered normal volunteers could be developed outside the prison system.

(5) The prison system gave a degree of safety to the volunteer that other non-cloistered populations did not have.

(6) A major defense of the prison system, therefore, was based on the need for clinical trials, on the assumption that there were no alternate possibilities.

Needless to say, the disquiet over medical research in prisons has not ceased and the more recent experience is that more and more penal institutions, for one local reason or another, have discontinued, or have been required to discontinue, their activities in medical research.

As with many other predictions, the prediction that alternate populations were not available has been wrong and we are now at the point where we can re-examine the entire question of prison research from a fresh point of view. We no longer need to propose that important programs be dismantled if we discontinue the use of prison volunteers. This is a critical point in defense of H.R. 3603. I have, accordingly, made a comparison between the prison-system and non-prison volunteers.

COMPARISON OF PRISON VOLUNTEERS WITH CLOISTERED NONPRISON VOLUNTEERS

A. Control of research

One of the early attractions of the prison volunteer was the apparent control of the investigator over diet, other drugs, compliance with the study, the ability to observe closely, and the elimination of parallel hazards, such as driving, etc. All this is true in a relative sense. However, it is true only when we compare this with ambulatory, non-cloistered subjects. When the non-prison but cloistered normal volunteer is compared to the prison volunteer, we can see many problems with the prison setting. For one thing, prisons are run for their own purposes. They were not designed or operated around the needs of medical research. There are many conflicts between the needs of the prison and those of the medical investigator.

In some prisons drugs of abuse circulate widely and complicate observations on new medicines. I do not wish to labor this point, but there is a substantial scientific gain in moving from the prison setting to an arrangement dedicated solely and uncompromisingly to medical research. If this is true of the setting, it also applies to the volunteer.

B. Motivation of volunteer

Without being too self-critical, I think we can admit that medical subjects enter a given study with varying degrees of enthusiasm and commitment. Except for the war years during World War II and part of the Korean War, I have not been especially impressed with a high level of commitment to the research by prison inmates. During those two times, volunteer commitment was impressive. In contrast to this, I can say anecdotally that volunteer commitment is more sustained and more keenly expressed in non-prison cloistered volunteer subjects.

There are inherent problems with the ethics of motivation in captive populations which are not encountered in non-captive volunteer groups. It requires an unusual degree of restraint and circumspection to minimize the coercive forces on prison volunteers. Even under the best of conditions this coercive force is never eliminated.

C. Problems of cost

One of the great advantages of doing medical studies in the prison system has been cost. It is manifestly impossible to generalize about all prisons but the prison setting has often tolerated a very sketchy staff coverage. There have been a number of prison research projects staffed predominantly by inmates. I think most of you will find this morally indefensible and I can assure you it also presents scientific problems. There are instances where inmate staff have seriously abused the power of this role to injure fellow inmates and distort the scientific record. Not only does inmate staff influence cost, but we find prison volunteers being paid at a very low rate, sometimes as low as a dollar or less per day, while the counterpart non-prison volunteer will receive ten to twenty times as much.

This differential in pay has always presented a dilemma. If the rate is relatively large, the coercive force may seem to be large. If the rate is small and on a level with other forms of reimbursement within the prison, then it would seem to be exploitive. The elimination of prison volunteering would resolve these ethical dilemmas.

D. Informed consent

Informed consent is a key to the propriety of any human research. After long and careful study and consideration of the problem of informed consent, I have come to the following conclusions:

(1) Informed consent means different things to different people. We should be talking about the *quality* of informed consent, not just the existence of an informed consent. The modern informed consent requires commitments about care, follow-up and compensation for injury.

(2) The prospective volunteer must have as few constraints on his free decision as possible. I believe that any unique manipulative pressure in the hands of the researcher degrades the quality of informed consent. In this respect, informed consent is less freely given by prisoners, employees, students, or even "captive" patients.

(3) The right of withdrawal: I have not always appreciated this, but I think prisoners, in contrast to free-living volunteers, have often felt less able to with-

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draw at will from the medical study. This unfettered right of withdrawal is at the heart of the quality of informed consent.

(4) In contrast to free-living volunteers, the prison inmate often feels a considerable dependence on the investigator. He never knows when he may wish to call on him for help. This dependence is often subtle and difficult to identify but it makes informed consent of poorer quality.

(5) Compensation for injury: A simple compensation system can be worked out for non-prison volunteers. It is very doubtful that an insurance or compensation system can be applied to prisoners without changes in state and federal laws. Furthermore, there is some question as to whether prisoners seek compensation as readily as non-prisoners. There have been uncompensated injuries to prisoners and this suggests, though it does not prove, that prisoners do not now have adequate compensation potential, nor do they always understand their rights in this matter.

(6) Medical support systems: Volunteers of every category deserve the best medical protection possible. For most modern studies on human volunteers, there are developing requirements for medical support systems that do not exist in prisons and are unlikely to be developed there. A continuation of this practice will ultimately give rise to a double standard with the prison inmate being substantially less well protected than is his free-living counterpart. In fact, some prisons are geographically miles from Class I hospital facilities and remote from physician coverage.

(7) In addition to protection during the course of the study. The volunteer subject deserves follow-up and extended care. The prison setting presents a number of problems with long-term follow-up. It does not require an expert to point out these. For one thing, a volunteer is extremely unlikely to return to a prison for follow-up. Very few programs have provided non-prison locations for follow-up. It also goes without saying that no one can predict whether a former prison inmate *can* report anywhere for medical care after his discharge, even if he knows where or to whom to report.

All too few inmates are given a written record of their informed consent with identification of the physicians or sponsoring institutions. They frequently are unable to identify the individuals or institutions to whom they could or should turn for help after the experiment is over. The only institution they can turn to is the prison and there are problems with this approach.

Where do we go from here? Although I was initially skeptical of the existence of alternate groups, I was wrong. They exist and if they are developed, they will provide sufficient numbers of high quality volunteers to get the job done. Moving from the prisons will make the job harder and more expensive, but it can be done.

In terms of expense, I have made a rough calculation that the non-prison alternative will increase the total cost of new drug development by less than one percent.

In summary, I would say the prison system played a crucial role at one time in medical research. These programs have continued after public concern has made them inappropriate. Public disquiet will continue, I am convinced, if for no other reason than that the research program is relatively hidden in prisons. These medical research programs look best in the clear light of public inspection. This public inspection, so far, has not been easily done in prisons.

The medical community may complain about this bill, but like other "disasters," it has a silver lining. It will force us to develop non-prison alternatives. It will free us of the oppressive restrictions of the prison atmosphere and it will probably substantially improve the research product. In addition, moving out of the prisons will help improve the credibility of certain aspects of clinical research.

TESTIMONY OF JOHN D. ARNOLD, M.D., MEDICAL DIRECTOR, QUINCY RESEARCH CENTER, KANSAS CITY, MO.

Dr. ARNOLD. Thank you, sir. I come here in partial defense of this bill, and I think it may need some modification. And I come here with a background of 30 years—nearly 30 years' experience working in prisons and in nonprison settings with the topic very much like that that you heard previously discussed. And you may find me a strange witness in favor of the bill, but I will give you my reasons.

The paramount reason, I think, that prison research should be discontinued is that there is public disquiet about it. I will repeat that there is public disquiet about this. The larger issues of human experimentation, which are terribly important to all of us, are imperiled by the isolated topic of prison research.

It has not been possible to persuade all of the medical fraternity that this is true, and that the larger issues are endangered by a small issue, and that we can do equally as well outside of prisons as we have been able to do in prisons. In fact, I will even change that; we can do better outside of prisons than we have been able to do in prisons.

We were locked in the prison system by a historic accident. The origins of this practice began in the Second World War. I may be very well the oldest of the prison experimenters, because I began as a young man during the Second World War under Army sponsorship with programs designed to develop drugs and to prove efficacy and safety of these drugs for soldiers, sailors, and airmen before they were put into use in the field. This was a really new idea in the mid-1940's and it was a very effective idea, and the prisons were a very easy and compliant situation in which to develop these problems.

What might have been proper during the war has become less than proper in the present climate of the mid-1970's. This has become politically indefensible, to continue these practices.

I would like to say that we would really like to get out of the prisons and that we can get out of these prisons.

There are lesser matters at stake here. And I do not need to dwell on the abuses and the horror stories to give you an effective argument, as you have just seen. I think it is perfectly clear that the quality of informed consent in a prison leaves something to be desired. You would not have had these gentlemen sitting up here if informed consent had been exercised in the way we would all like to see it exercised.

For whatever reasons, there has been misunderstanding. It has persisted, and it is a frequent complication in prisons, unless extraordinary means are taken to combat it.

Now, I do not believe for a minute that everybody in prison research institutions has lacked proper informed consent. What I am saying is that with that population, it is a much more difficult exercise, and we often fall short of our goals. That is the first reason.

The second reason has not been discussed much here. That is that any person who submits to a medical experiment for the betterment of his fellow human beings and who has an accident or an adverse effect deserves compensation. He deserves some kind of compensation for this bad effect.

Now, it turns out—and this becomes something of a technical matter—that it is difficult to generate compensation schemes to protect the prisoner. I am not an expert on this, but I have spent a great many hours studying this problem. And without some changes in the Federal and State statutes, I really doubt that we can get an insurance scheme that would cover the medical accidents that you know might occur in extensive use of prison volunteers for medical research.

Now, this is not true of the counterpart situation in free-living volunteers. People outside the prison can be covered by compensation schemes that would do all the things that you and I think would be proper under the circumstances.

The third thing that has been a fault of the prison system is that long-term followup and immediate medical care have been defective under some circumstances. It is perfectly obvious that many of the people who have been discharged from prison are not going to go back there to seek medical help for the problems that were started with the medical research.

. No prison—or only one that I know of—ever set up an extramural station to which the prisoner could report, that is, where the former prisoner could report if he had some adverse effect after discharge. Furthermore, a lot of these people are not free to do so because of their involvement with legal processes.

Now, those two problems are right in direct conflict, so that we have a less than satisfactory experimental situation here. We cannot follow them up. We cannot provide them with care for the long-term ill effects that will occur in our experiments. This is an inappropriate population.

And the last thing is that the quality of medical research in prisons is not as good as what can be carried on outside of prisons. We really do not have anything much at stake here. What we have at stake is a historical precedent, the long-term commitment and involvement in these institutions. I can assure you this can be changed.

Now, let's take a look at the various constituencies that are affected by this bill; first, take the public. There is an important body of public opinion which is represented here which is very ill at ease with this process, and I think they should be heard. I think we in the medical profession will do best by being on their side in this civil liberties concept of human experimentation, not in an adversary relationship to them.

I do not know if a public referendum would vote us out of prisons or not, and I really do not care. Enough people care about this so we should get out of prisons.

The other constituency are the prisoners themselves. This is a much more difficult question, I think, than we might expect, because there are some prisoners who will cheerfully and gladly and very happily volunteer for medical experimentation. And there are others that you have seen who believe this is inappropriate. And we have had instances that may be cited later in this committee, actually, where votes have been taken in prison populations to the effect that they would like to continue this.

I do not know how you can accommodate this view. But if seems to me that a large part of the inmate support, that group of inmates who wish to continue medical experimentation, might be just as happy with alternative programs that do not involve research.

In large part, there is a problem of money in prison. Inmates need money and, as you have heard, very few prisons provide programs for the inmate where the inmate can earn money. Certain programs in prisons have done this and they have gotten a constituency for that reason.

I do not know how that should be answered. But I do not think it should be a major stumbling block in the removal of these programs from prisons.

There are, of course, the medical groups who have long used prisons. They are a constituency. There will be some disorder in the medical profession by the abolition of prison research, if that is the will of the committee and the Congress. I would suggest, however, that we will benefit in the long term by this movement, that a short-term disorder would not be too big a price to pay.

It is, if you might visualize it, a complex system of interlocking blocks. The Federal support of the drug company support is interlocked with the investigator, who is interlocked with the prison, and all of these things hook the system together. It is very difficult to get it unhooked and to find alternative programs.

I would originally have feared this movement against prisons, because I saw the complexity of this. I can testify that it takes a long time and a lot of work to get alternative populations into the system to replace the prison system, but it can be done. I suspect that if it is ever going to be done, it is going to be done by some rather striking force.

The size of the programs that you are talking about is not all that great any more. There once, by my estimate, were 50 prisons in which research was being carried out. And now, by the estimate of Mr. Mitchell, there are probably only six who are doing nonfederally supported research. That is quite a reduction in size. I have an idea that they will continue to dwindle away, but I do not see any reason why we should take a chance on this.

As the abuses keep coming forward, they continue to imperil that thing called good will and public credibility, which is what the medical experimenter needs most of all. We are extremely sensitive to the public trust and credibility. If you think about it, you will see why we cannot continue; we can ill afford a tax based on abuses that occur because of the site of our experiments.

Now, I know that almost all, if not all, types of projects that have been carried out in prisons that are unrelated to the prison situation itself—that is, behavioral problems of the prisoner or drug abuse that might be concentrated in the prison—can be carried on outside the prison. It will cost a little more money. I made a little estimate about how much it would cost; it would probably increase the cost of the new drug development by about 1 percent. That is a pretty rough figure.

It will make a lot more work for the medical investigator, but I do not think that is a consideration. I think, above all, our credibility is at stake here.

Thank you, Mr. Chairman.

Mr. KASTENMEIER. Thank you, Dr. Arnold, for a most informed discussion of this problem.

One thing you suggested as a reason for consideration of this was the public disquiet in terms of it being an ethical question. Personally, do you have any problem with use of prisoners in experimentation?

Dr. ARNOLD. Yes; I do. I think we are beginning to see subtleties in use of human volunteers, generally, that we did not see over the years. One of these subtleties—maybe it is not so subtle any more; we are being hit on the head pretty hard with it—is the concept of the captive volunteer. Here is a perfect example.

A captive volunteer is not only one imprisoned, I might add. There are other captives in our society. The medical indigent is captive; the

child is captive. The medical institution is captive, too. Students, interestingly enough, may be one of the more captive groups in our society.

Now, I think that this matter is broader, probably, than your committee wants to look into. But there is a national commission, as you may be aware, looking into the ethics of human experimentation. And I hope that they draw a clear distinction around these captive groups. I think they have less ability to give informed consent.

Mr. KASTENMEIER. This committee is interested in the conclusions of the Commission. Furthermore, we have to be aware of the broader philosophical implications of this issue.

One other question I have, and that is the disorder that this legislation would cause in medical research. Although I gather from what you have said, statistically, that the reliance upon the prisoner, the inmate is decreasing at a very considerable rate, to what dislocation would the termination of all prison research cause?

What percentage of research would have to find other channels?

Dr. ARNOLD. It depends on the speed with which this occurs. I think a 2-year time span would permit suitable alternatives to cover the whole problem, or something of that sort. If it comes tomorrow morning, the dislocation would be fairly severe.

Mr. KASTENMEIER. Certain people have suggested—for example in the dialog, Mr. Hubbard's suggestion for the National Academy of Sciences formally this year. You have heard both sides, and I am paraphrasing it; it is a reiteration of a dilemma. And he put himself in the middle of this presumably, and he thought the answer was "rather to work toward the solution of a problem, preserving personal and social benefits in settings that are designed to be limited, while avoiding the exploitation of the situation of the institutionalized person."

I gather he is suggesting it might still be possible to use an institutionalized person and avoid this exploitation. Do you think that might be possible?

Dr. ARNOLD. Well, I have always thought that the return to prison research might come about after research stopped for a while. And then it could come back into the prisons under the proper settings and the proper controls and in the proper prisons. I am not so sure that is even necessary.

The alternative populations are so much better, from a scientific point of view, except for one thing. If we are studying drug abuse, it might be so limited that it could not be studied outside—not to be an impediment. If you were to just study behavioral modification, say, at some future date, the prospects of behavorial modification would occur, and it would be unfortunate to have a law preventing that from being studied within prisons. But those are very small parts of this whole enterprise.

The great majority of the efforts in prison are not devoted to the prison's own problems anyway. It is toward general medical information.

Mr. KASTENMEIER. Let me ask you about the quality of medical research in prisons. Personal anecdotes creep up when one discusses research with prisoners, not necessarily this morning but otherwise, in which they speak of methods to confound the researcher and avoid taking pills prescribed to them.

I know the literature connected with this is full of that sort of reference.

Dr. ARNOLD. That is a big game.

I recall one investigator who was charged with falsifying his records. It turned out, however, that the staff who did most of the work were just employing another kind of abuse that goes on here and they had been playing games with the numbers, and he commented somewhat—I hope it was—facetiously, whether a bunch of crooks——

This climate has not been of the quality that one would like for the best kinds of scientific results. It was held too tenaciously because it seemed to be the only way to get things done. But that is not so anymore.

Mr. KASTENMEIER. What is the alternative?

Dr. ARNOLD. The alternatives are freedom and people. Although Mr. Pattison would not want to be a scientific subject, there are people who do. And it has been a great surprise to me to find that there are enough such people willing to come off the streets, so to speak, but who have no captive commitment to the investigator to carry out I think all of the needed work that is before us.

Mr. KASTENMEIER. Thank you.

Mr. Pattison?

Mr. PATTISON. Lest I be considered some kind of a monster, I did volunteer one time for a scientific experiment with no problems with it. But it was my free choice and that is really what I meant.

I take it that theoretically if there was some way to distinguish there are some kinds of research programs which would, in fact, be OK. I think, for instance, of a program that wants to test whether the effects of eating organically grown food as opposed to food that is not organically grown, that no matter what happens in the experiment there is no possibility of any long-term effects—bad or good.

And when I say no possibility, I mean no reasonable possibility.

Dr. ARNOLD. Well there are these, but I do not think we need the prisons for those studies.

Mr. PATTISON. I understand that.

My question is, assuming that somebody thinks that that is a reasonable thing and the kind of experiment to do, there are no disastrous kinds of effects. And if the prison wants to do it, and the prisoners want to do it, it may be of betterment to the prisoners.

Dr. ARNOLD. Yes; I could visualize that.

Mr. PATTISON. Dental programs where you are using a different kind of amalgam, or that nature, where they would not get dental treatment otherwise, and where there is no possibility for them to do long-term damage to themselves.

Informed consent becomes less important; in other words, as the ultimate danger becomes less or disappears so that there may be possibilities even though you do not have the informed consent in the true sense, that it is not all that important. And if you design procedures to select the tests which are satisfactory procedures and safeguards go into them, and if you design procedures for obtaining informed consent, such as it is able to be obtained, then there may well be experiments of that nature which would be beneficial to people in prisons. Even in the sense that the prisoners, perhaps, would

be contributing to something and gaining something that way. It might be good therapy for them also.

Dr. ARNOLD. That is possible, yes.

It is hard for me to visualize the language of such a bill.

Mr. PATTISON. I understand that. That is why I said theoretically.

Making those distinctions is very difficult, but all experimentation, for instance, does not all lead to ultimate possible disaster.

Dr. ARNOLD. Right.

Mr. PATTISON. I have no further questions.

Mr. KASTENMEIER. Following up on that, I would think there would be. It would be possible to conceive of experiments that involve no risk whatsoever to the individual, but I understand your point of view in terms that it isn't worth it; in terms of how, generally, it is perceived to be.

In your experience, how much of the possible risks can be, or should be, explained to the potential subject in terms of what is informed consent?

Dr. ARNOLD. That is very difficult.

You need to tell him everything you can, but, as you can see, this can be quite an extended exercise, and it means that some people are probably not suitable for obvious reasons to give informed consent. If they are unable to comprehend, retain and keep all this information clearly in line—I think we have examples before us where, I guess, it probably did not happen. Then we do not have informed consent. This is not that we have not been meticulous enough about this quality.

I cannot set down 12 people at random before me and give them the same spiel about the risks and so on, and get from each of the 12 the same understanding of the risk. So that, I think, is a weakness of the prison system because it is a population which is heavily weighted in favor of lesser educational standards, and lesser capacity—linguistic ability, lesser capacity to understand.

Mr. KASTENMEIER. My final question to you, Dr. Arnold, is, as a partial supporter of the bill before us, what changes, in general terms, would you recommend in such a bill?

Dr. ARNOLD. I would hope that problems of penology and drug abuse and whatever prisons are involved with could be the proper subject of research in prisons. Without that, the people who have ideas and need to investigate the problems would have precious little opportunity to study them.

We would make regular social progress, then, but—and I do not know how to phrase that—but it has to do with a special problem of the prison, of that population. Problems that you would not find immediately outside the prison.

Mr. KASTENMEIER. Thank you. I have no further questions.

On behalf of the committee, Dr. Arnold, we appreciate your coming here.

The Chair will announce that we will reconvene on this subject on Wednesday, next, 10 a.m., in this room, for a morning and afternoon session, during which we will have approximately 10 witnesses. And until that time, the committee stands in recess.

[Whereupon, at 12:35 p.m., the subcommittee recessed, to reconvene on Wednesday, October 1, 1975, at 10 a.m.]

PRISON INMATES IN MEDICAL RESEARCH

WEDNESDAY, OCTOBER 1, 1975

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:05 a.m. in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier [chairman of the subcommittee] presiding.

Present: Representatives Kastenmeier, Badillo, Pattison, and Railsback.

Also present: Gail P. Higgins, counsel; Timothy A. Boggs, professional staff member; and Thomas E. Mooney, associate counsel.

Mr. KASTENMEIER. The committee will come to order.

The subcommittee has convened today to continue our hearings on the use of prisoners as subjects for medical research by drug corporations, Government agencies, and medical schools. Our witnesses this morning represent the Department of Health, Education, and Welfare and two of its branches, the Food and Drug Administration and the National Institutes of Health.

It is fitting that these witnesses comment on the legislation before us because they have played an important role in the development of regulations and guidelines in the area of experimentation with human subjects. HEW serves as a model, both formally and informally, for other Federal and State agencies.

As I noted on Monday, this is an issue on which there is much current discussion, debate, and litigation. And as with many issues of controversy, Congress has established a Commission to study this problem, the National Commission for the Protection of Human Subjects. However, the Commission has met only once to discuss how to approach the problems of the use of prisoners as subjects.

HEW has established regulations which deal with the use of all human subjects, and while proposals have been made for new regulations which recognize the unique situation of prisoners, none have yet been promulgated.

FDA has responsibility for determining the safety and effectiveness of new drugs, and to monitor the testing procedures. It is my understanding that the General Accounting Office is currently investigating the FDA's monitoring techniques. We will have a report from them in the future.

The National Institutes of Health conduct and fund an important segment of medical research in this country. In 1973 they provided approximately 60 percent of the total Federal support of medical research and 40 percent of the nationwide support. The National Institute of Drug Abuse manages the research being conducted at the Federal Addiction Research Center at Lexington, Ky., which the subcommittee learned about on Monday.

So it is fitting that we should have this distinguished panel of witnesses before us today. Before asking them to proceed, I would like to announce that the subcommittee invited testimony on this legislation from the Director of the Federal Bureau of Prisons and the Civil Rights Division of the Justice Department. The subcommittee was initially informed that they would be appearing today. However, I have been subsequently notified that the Justice Department's position on this legislation has not yet been prepared. When their statement is ready, it will be included in the record.

The Chair regretfully observes there is a vote pending on the House floor. Were it a quorum, we would ignore it, but a vote we cannot ignore. Accordingly, the subcommittee will have to recess for approximately 10 minutes, for committee members to make the vote and then return; at which time we will convene the panel's testimony.

The committee stands recessed until approximately 10:25.

[A brief recess was taken.]

Mr. KASTENMEIER. The committee will reconvene.

The Chair regretfully announces that all members of this committee staff, all members of our distinguished panel and their staffs, and many others in the Federal establishment, are limited to 5 percent rather than 8.6 percent pay increase, as a result of the vote that was taken on the floor.

It is a pleasure for me to greet on behalf of the committee, and introduce, Dr. James F. Dickson, who is Acting Deputy Assistant Secretary for Health, for the Department of Health, Education, and Welfare. With Dr. Dickson are Dr. Chalkley, Dr. Crout, Dr. Martin, Mr. Sopper, and Dr. Seal. Gentlemen, you are all welcome.

The Chair should also point out that Dr. Crout is Director of the Bureau of Drugs for the Food and Drug Administration; Dr. Seal is Acting Director for the National Institute of Allergy and Infectious Diseases for NIH; and Dr. Martin is Director of the Addict Research Center, National Institute on Drug Abuse; Dr. Chalkley is Director of the Office for Protection from Research Risks for NIH; Mr. Sopper is Acting Deputy Assistant Secretary for Legislation for the Department of Health, Education, and Welfare. With that, let me greet Dr. Dickson.

TESTIMONY OF JAMES F. DICKSON III, M.D., ACTING DEPUTY ASSISTANT SECRETARY FOR HEALTH, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY: J. RICHARD CROUT, M.D., DIRECTOR, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION, DHEW; D. T. CHALKLEY, PH. D., DIRECTOR, OFFICE FOR PROTECTION FROM RESEARCH RISK, NATIONAL INSTITUTES OF HEALTH, DHEW; WILLIAM R. MARTIN, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, ADDICT RESEARCH CENTER, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION, DHEW; DALE W. SOPPER, ACTING DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DHEW; JOHN R. SEAL, M.D., ACTING DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DHEW; BERTRAM BROWN, M.D., DIRECTOR, NATIONAL INSTITUTE FOR MENTAL HEALTH, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION, DHEW; AND BARBARA MISHKIN, STAFF SPECIALIST FOR BIO-ETHICS, NATIONAL COMMISSION FOR PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

Dr. DICKSON. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, behind me are additional members of the Department who are prepared to respond to your questions as may prove pertinent. It was suggested to me a couple of moments ago that I should reduce my testimony by 3.6 percent, but I think that we do have a lot of good points to make. So we will go ahead as we have prepared.

I am pleased to testify today on H.R. 3603, a bill to limit the use of prison inmates in medical research. We welcome this opportunity to comment on the bill, and to discuss the role and activities of the Department of Health, Education, and Welfare related to the use of prisoners as the subjects of research.

At this time, the Department is opposed to any legislation which would prohibit all medical research on prisoners, the main reason being that other mechanisms have been established for dealing with issues relating to the involvement of prisoners in research. The bill would prohibit certain important research activities which should be judged on their scientific merit and ethical safeguards.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, recently established by Public Law 93-348, is currently operating and has until December 1976 to complete its work. The Commission is charged with examining and making recommendations on a variety of ethical issues related to the Department's biomedical and behavioral research activities. One specific charge to the Commission is to examine the participation of

prisoners in research. The Commission has already begun its work in this area, and is expected to engage in extensive and broad-based public discussion of all issues relating to all research using prisoners. It is our hope that Congress will not act on any legislation establishing limitations on biomedical and behavioral research with human subjects until the work of this legislatively established Commission is complete.

Another arena of continuing discussion and action regarding prisoner research is the Department's effort over the last several years to develop regulations on prisoner research. The Department currently has regulations covering all DHEW-supported research involving human subjects, and has recognized also a need for special principles and protections to apply to research activities involving prisoner subjects. A notice of proposed policy and draft rules dealing with research on prisoners, as well as other special groups, has been published in the Federal Register. We are continuing to evaluate our draft proposals in this area, but would like to share with you some current thinking and tentative positions we have developed.

In both of our previously published draft rules, we have proposed to define permissible conditions for research activities involving prisoner subjects, and to establish additional safeguards to protect the rights and welfare of prisoner subjects. Prisoners would be allowed the opportunity to choose to participate in similar research activities as nonprisoners, and to choose to participate in activities which may potentially benefit them directly or may benefit other prisoners through the development of knowledge useful to understanding and dealing with prisoners' problems.

A possible alternative position, mentioned in comments on our proposed regulations, which might be considered with regard to limiting prisoner research, is to permit use of prisoner subjects only when they may benefit directly, or when the research may benefit other prisoners or persons with similar conditions to the particular subjects.

In addition, we have proposed that institutional review boards—the mechanism used to provide local review of research projects for protection of the rights and welfare of human subjects—assume additional responsibilities to assure that potentially coercive factors are minimized and consent is obtained from each subject in an appropriate manner. Although prisoners are in a custodial situation which is inherently coercive, we believe that given appropriate safeguards, recruitment and participation of prisoner subjects can be controlled to meet ethical standards.

Mr. Chairman, I would like this morning if we may, to insert our proposed regulations into the record.

Mr. KASTENMEIER. Without objection, the proposed regulations you refer to will be received and made part of the record.

[The material referred to follows:]

federal register

FRIDAY, AUGUST 23, 1974

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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

■

PROTECTION OF HUMAN SUBJECTS

Proposed Policy

165—Pt. III——1

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

[45 CFR Part 46]

PROTECTION OF HUMAN SUBJECTS

Proposed Policy

In the FEDERAL REGISTER of May 30, 1974 (39 FR 18914), regulations were published as Part 46 of Title 45 of the Code of Federal Regulations providing generally for the protection of human subjects involved in research, development, or related activities supported by Department grants or contracts. At that time it was indicated that notices of proposed rulemaking would be developed concerning minors, fetuses, abortuses, prisoners, and the institutionalized mentally disabled.

Coincidentally with the development of the notice of proposed rulemaking set forth below, both Houses of Congress reached agreement on the "National Research Act," and the President signed P.L. 93-348 into law. Among other things, the Act establishes an eleven-member National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research to "* * * (1) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the Secretary (I) for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research."

This notice of proposed rulemaking is published today to continue the public dialogue begun in November 1973 when the Director of the National Institutes of Health published draft proposals on these issues in the FEDERAL REGISTER. The comments addressed in this preamble are the result of that issuance.

The comments received as a result of this notice of proposed rulemaking will not only assist the Department to develop final regulations but will also be available to the Commission for their use during the course of their deliberations over the next two years.

In the light of the 450 responses received as a result of the November issuance, largely from grantee and contractor organizations, the Department now proposes that, in addition to the protection afforded generally to all subjects of research, development, and related activities supported by the Department by virtue of Part 46, further protective measures should be provided for those subjects of research whose capability of providing informed consent is or may be absent or limited.

This would be accomplished by amending Part 46 to delete § 46.19 through 46.22, redesignating § 46.1 through 46.18 as Subpart A, and adding new Subparts B through F. If this proposal is accepted, the regulations would be structured as follows:

Subpart A would be the basic regulation, substantially as promulgated on May 30, 1974. This provides that no activity involving any human subject at risk shall be supported by a DHEW grant or contract unless the applicant or offering organization has established an organizational review committee which has reviewed and approved such activity and submitted to DHEW a certification of such review and approval. This subpart also provides that all grant and contract proposals involving human subjects at risk are to be additionally evaluated by the Secretary for compliance with the requirements of said subpart.

Subpart B is reserved for a separate, future proposed rulemaking providing additional protection for children.

Subpart C as described in the present proposed rulemaking would call for the utilization of two special mechanisms for the protection of the pregnant woman and unborn child or fetus, where the pregnant woman participates in a research, development, or related activity. While these mechanisms are designed to allow sufficient flexibility for the pursuit of new information about the perinatal process, they are also designed to provide additional safeguards to assure that the research is acceptable from an ethical standpoint.

Subpart D as described in the present proposed rulemaking would give added responsibilities to an organizational review committee where the contemplated research would involve prisoners as subjects and also would require in such instances that a consent committee be established to supervise the selection and participation of prisoners in the research. Prisoner groups are particularly valuable in properly conducted clinical trials since they provide a stable subject population which can be followed over a period of weeks or months rather than days or hours. From the point of view of the prisoner subject, participation in research offers an opportunity to make a contribution to society and to provide an income, much as other jobs in prison do. Nevertheless, the dangers of abuse of prisoners' rights are obvious. For this reason, the proposed rulemaking calls for additional safeguards for the rights of prisoners whose capability to provide informed consent may be affected by the very fact of their incarceration.

Subpart E as described in the present proposed rulemaking offers additional protections for the rights of the mentally ill, the mentally retarded, the emotionally disturbed, and the senile who are confined to institutions, whether by voluntary or involuntary commitment. Such persons, by the very nature of their disabilities, may be severely limited in their capacity to provide informed consent to their participation in research. At the same time, the nature of their disabilities requires extensive research efforts to the study of the etiology, pathogenesis, and therapy of their conditions. The proposed rulemaking limits the research in which such subjects may be allowed to participate to that which is most likely to be of assistance to them or to persons similarly disabled.

In developing the present proposed rulemaking, the Department has taken into consideration the public's comments relevant to certain parts of the Introduction, Definition, and General Policy Sections of the draft regulations published at 39 FR 18914, November 16, 1973, as well as to the draft regulations themselves. The major comments, and the Department's present proposals, are as follows:

INTRODUCTION, GENERAL POLICY CONSIDERATIONS

A. Commentators suggested, in several different contexts, that the regulations should (i) apply to all research, regardless of the degree of risk or academic discipline concerned, and (ii) provide for the exclusion of certain types of research, particularly behavioral and social science research as distinguished from biomedical research.

The Department, having considered these comments, notes that the applicability provisions of the basic regulations (45 CFR 46.1) permit the Secretary to determine whether specific programs place subjects at risk. Such determination is to be made only after careful study and publication in the FEDERAL REGISTER, providing an opportunity for comment on the merits of each determination. With respect to research in the social sciences, the Department has already indicated its intention of issuing public rulemaking on this matter (see 39 FR 18914, paragraph A).

B. Comments also included suggestions that regulations should be proposed specifically dealing with activities involving students, laboratory employees, seriously ill or terminal patients, the non-institutionalized mentally disabled, and other special groups.

The Department considers that any abuses relating to these groups are less evident and that they are afforded the protection of the existing regulations published in 39 FR 18914.

C. Several comments suggested the provision of additional guidelines with respect to the distinction between established and accepted methods on the one hand and experimental procedures on the other.

While the Department recognizes the theoretical desirability of such guidelines, and that the practical necessity of making such a distinction is arising with increasing frequency, the feasibility of making this distinction on a generalized basis has yet to be demonstrated. At the moment a regulatory approach to this issue does not appear justified.

D. It was suggested that all meetings of organizational review committees and similar groups established pursuant to

these regulations should be open to the public.

The Department notes that since the purpose of these committees is, for the most part, to advise with respect to the conduct of individual projects and proposals by individual investigators, a blanket provision to this effect would appear to be inconsistent with the need to protect the confidentiality of the proceedings and records of institutional review and evaluation committees.

DEFINITIONS

A. Comments on the definition of "Subject at Risk" suggested changes in language that would (i) limit the concept of risk to that encountered only in addition to that normally experienced, (ii) eliminate demonstration projects as a possible source of risk, since these are nominally limited to application of established and accepted methods, (iii) specifically identify failure to maintain confidentiality as a source of risk, and (iv) provide a mechanism for identifying activities essentially free of risk.

These comments are similar to those made with respect to the same definition as incorporated in an earlier proposed rulemaking (38 FR 27882). In responding to the criticism, the Department has already (i) redefined "Subject at Risk" in 45 CFR 46.3(b) so as to exclude any activity which does not increase the ordinary risks of daily life or the recognized risks inherent in a chosen occupation or field of service, (ii) substituted in 45 CFR 46.1(a) the term "development" for "demonstration," (iii) provided in 45 CFR 46.19(b) specific prohibitions against disclosures of information which refers to or can be identified with a particular subject, and (iv) provided in 45 CFR 46.1(b) authority for determination in advance as to whether a particular Federal program or an investigational method or procedure may place subjects at risk.

B. Comments on the definition of "Clinical Research" suggested inclusion in said definition of the behavioral aspects of research and facets of medical research necessarily concerned with diagnosis and other nontherapeutic aspects of research.

Since the term "clinical research" does not occur in the present rulemaking, the Department reserves its opinion with respect to these suggestions. However, the proposed regulations are applicable to all departmental research, development, and related activities except with respect to Subpart C, where applicability is limited to "biomedical research" (§ 46.303(b)).

C. Comments on "Informed Consent" suggested the addition of language concerning (i) full and complete disclosure, (ii) the likelihood of success or failure of the experiment, (iii) the use of placebos or other control procedures, (iv) provision of information as to the progress of the research, (v) publication of names of all persons, institutions, and review committees involved in approval of consent procedures, (vi) provision of legal counsel and technical advice, and (vii) assurance that the subject comprehends the disclosure.

The Department, having considered these comments, notes that "Informed Consent" is presently defined in 45 CFR 46.3(c) and not in the present proposed rulemaking. With respect to the specific suggestions the Department notes that: as far as (i) is concerned, the regulations already call for a "fair explanation" of the procedures and a description of risks and benefits reasonably to be expected; (ii) reflects a basic misunderstanding of the experimental process which begins, essentially, with the comparison of two or more methods, procedures, or modalities on the *a priori* hypothesis that there will be no difference; (iii) is implicit in the existing regulations and is better emphasized in interpretive materials; (iv) would not be an element of informed consent unless interim findings affected the risk of benefit involved; and (v) touches on the subject of a possible future proposed rulemaking and the Department reserves its options for the present. The suggestion in (vi) is met in part by the proposals in the present proposed rulemaking to employ consent committees to advise potential subjects. The last suggestion (vii) goes beyond requirements for informed consent as they have generally been articulated by the courts.

D. Comments also included suggestions for the inclusion of additional definitions of (i) Institutions, (ii) Legal Guardian, (iii) Organizational Review Committee, (iv) Institutionalized Mentally Infirm, and (v) Children (with regard to age of consent), Parents, and Father.

The Department, having reviewed these comments, notes that (i) "Organization" is defined for the purpose of these regulations to include "Institutions" at 45 CFR 46.3(a); (ii) "Legally authorized representative" is defined for the purpose of these regulations to include legal guardian at 45 CFR 46.3(h); (iii) the definition of "organizational review committee" is implicit in 45 CFR 46.6; (iv) "Institutionalized mentally disabled" has been defined in the present proposed rulemaking at 46.503(d) to meet the suggestion; and (v) definition of "Children," "Parents," and "Father" will be reconsidered prior to the issuance of a future rulemaking covering research on children.

E. Several commentators criticized provisions of the draft policy that would have required that activities to be conducted outside the United States satisfy all requirements of the Departments regulations including those based on ethical concepts peculiar to the Judeo-Christian moral heritage or to English common law. It was noted that this would create substantial problems for United States investigators working overseas since these concepts are often inconsistent if not in conflict with normal, ethical, and legal concepts in certain foreign countries. For the same reasons, it was argued that these provisions would create problems for United States citizens assigned, detailed, seconded, or acting as consultants to international organizations or to foreign governmental or private institutions.

Having considered these objections, the Department proposes to retain the basic concept that activities supported by Departmental funds should, in general, be subject to a uniform ethical policy wherever they are conducted, but to permit the Secretary to modify consent procedures if it can be demonstrated to his satisfaction that such procedures, as modified, are acceptable under the legal, social, and ethical standards of the locale in which the activities are to be performed.

FETUSES, ABORTUSES, AND PREGNANT WOMEN

Since comments on the draft provisions in 38 CFR-31738 providing additional protections for fetuses, abortuses, *in vitro* fertilization, and pregnant women were integrated with those on children, it is difficult to identify the communications specifically concerned with these subjects. However, it is estimated that the majority of the more than 400 letters received on research with children, born and unborn, touched on one or more aspects of research with fetuses, abortuses, and pregnant women.

A. A large number of respondents disagreed entirely with the idea of permitting research with the fetus, with the abortus (whether living or dead), or with the pregnant woman if the research might conceivably endanger the fetus.

The Department, having carefully considered these comments and similar proposals reflected in general correspondence and in articles in the public media, notes that their adoption would seriously hamper the development of needed improvements in the health care of the pregnant woman, the fetus, and the newborn. The opposition to research involvement of the fetus and abortus appears to be based in part on the assumption that the needed information can be obtained through research with animal species or with adults. Unfortunately, these assumptions are not valid. While much useful research can be conducted in animals, differences in species are nevertheless so great that any research finding in nonhuman species must ultimately be repeated in man before its general application in human medicine. In addition, the fetus and the newborn are not small adults. They suffer from some diseases not encountered in the adult. They may react differently to the diseases commonly affecting both adult and young, and they may have a different response to the same treatment, both with regard to its effectiveness and to its safety. The Department therefore proposes that (i) the ethical probity of any application or proposal for the support of any activity covered by subpart C be reviewed by an Ethical Advisory Board as described in § 46.304, and (ii) the conduct of any such activity supported by the Department be subject to oversight and monitoring by a consent committee as described in § 46.305.

B. Opinion was divided as to the need for an Ethical Advisory Board. Many respondents called it a welcome addition in the review process. Others felt that it would duplicate the function of the local organizational review committee and that its existence would encourage the organizational review committee to be less critical and would impose an additional roadblock that would delay or prohibit important research while needlessly consuming time, energy, and money, and posing potential danger to a patient waiting for treatment. Complaints were voiced that such decisions should be made locally, not in Washington, and that the investigator should be able to present his case in person. Numerous comments suggested that the Board's function should be limited to advising on policy, guidelines, or procedures, and not be concerned with the review of individual projects. This would avoid duplicating the function of the organizational review committee. Others suggested that the Ethical Advisory Board should serve as an appeal body from the organizational review committee.

There were also numerous comments to the effect that it is unwise and impossible to totally separate ethical and scientific review. Approval based only on ethics would be unethical if the science were bad. Both should be reviewed jointly.

The Department, having reviewed these comments, concludes that Ethical Advisory Board remains, in concept, a useful addition to the review process. It does not duplicate the functions of the local organizational review committee, since the latter is primarily concerned with matters of organizational regulations, local standards of professional practice, applicable law within its jurisdiction, and local community attitudes. The Ethical Advisory Board will be primarily concerned with similar issues at the national level. Applications and proposals should be capable of passing scrutiny at both levels. It is therefore proposed that the Ethical Advisory Board be retained as part of the additional protection mechanism.

Specific comments regarding the establishment of an Ethical Advisory Board touched principally on (i) the possibility that appointment of members at an agency level might lead to "loaded" Boards, while appointment at a higher level, i.e., by a joint Congressional committee or by independent outside bodies, might produce a more objective group, and (ii) disagreement as to the proper balance between scientist and nonscientist members, with a majority of the commentators suggesting that more than one-third of the members should have the scientific expertise necessary to identify risks and their possible consequences. It was specifically suggested that different sizes, compositions, and administrative locations of the Board be tried before selecting a final mechanism. In addition, it was suggested (iii) that a fifteen member Board was too large, (iv) that all members be human geneticists, (v) that at least one member be a psychologist, if behavioral issues were to be considered, (vi) that there be an absolute ban on departmental agency employees, (vii) that all proceedings be confidential, (viii) that all meetings be open to the public, and (ix) that an appeal mechanism be established.

The Department, having considered these views, proposes that while an Ethical Advisory Board to deal with biomedical research involving fetuses, abortuses, pregnant women, and *in vitro* fertilization might logically be established at the National Institutes of Health, (i) the power of appointment should be reserved to the Secretary, (ii) while the membership should include research scientists, physicians, lawyers, clergy or ethicists, and representatives of the general public, the balance between callings should rest with the Secretary as should also (iii) the number of members, so that the membership (iv, v) can be adjusted to the needs of the Board as the workload and the issues before it dictate. The specific suggestion (see vi) that departmental agency employees be excluded is adopted and expanded to include all full-time employees of the Federal Government. The decisions with regard to suggestions (vii) and (viii) will be governed by the provisions of the Federal Advisory Committee Act which generally require that meetings of similar advisory groups be open to the public for the purposes of policy discussion, but closed and confidential for the purpose of review of specific applications and proposals. Since the Board will be advisory to funding agencies, the final action will be that of existing awarding authorities, and appeal mechanisms (ix) will be provided only to the extent available under other existing departmental regulations and policies. These proposals are incorporated into § 46.304.

C. A number of respondents recommended that the policy governing *in vitro* fertilization be strengthened, on the one hand, or liberalized, on the other. The Department has considered these recommendations, and has provisionally chosen not to stipulate at this time protections for the product of *in vitro* fertilization which is not implanted, but rather to leave that series of issues to the Ethical Advisory Board established under § 46.304(a). The Board will be required to weigh, with respect to specific research proposals, the state of the art, legal issues, community standards, and the availability of guidelines to govern each research situation.

Because biomedical research is not yet near the point of being able to maintain for a substantial period the non-implanted product of *in vitro* fertilization, no clear and present danger arises from not stipulating in these regulations the protections for it. Given the state of the research, we believe that such stipulation would be premature.

It is the Department's intent that the definition of the term "fetus" (§ 46.303 (d)) be construed to encompass both the product of *in vivo* conception and the product of *in vitro* fertilization which is subsequently implanted in the donor of the ovum. Whatever the nature of the conception process, it is intended that upon implantation the protections of subpart C apply to all fetuses. It is only with respect to the protections available to the non-implanted product of *in vitro* fertilization that the regulations are silent.

With respect to the fertilization of human ova *in vitro*, it is expected that the Board will consider the extent to which current technology permits the continued development of such ova, as well as the legal and ethical issues surrounding the initiation and disposition of the products of such research.

With respect to implantation of fertilized human ova, it is expected that the Board will consider such factors as the safety of the technique (with respect to offspring) as demonstrated in animal studies, and clarification of the legal responsibilities of the donor and recipient parent(s) as well as the research personnel.

Since the Department does reserve the option of later modifying such protections by regulation, we invite comment on the question of appropriate regulations in the future.

D. The draft proposals included a suggestion for the establishment of a protection committee which elicited numerous comments that the use of the term "protection committee" implies that the Department recognizes a clear, present need for protection against the investigator, the uncertain relation of this committee to the organizational review committee, and the uniform need for and desirability for such protection.

Having reviewed these comments, the Department proposes an extensive revision in this innovative concept. Initially, it acknowledges that the term "protection committee" is pejorative and proposes the term "consent committee" as more appropriate and consistent with the primary purpose of such bodies. Further, it proposes to eliminate specific requirements for the size and composition of such committees. Instead, applicants and offerors are to propose the establishment of such a committee, specifying its size, composition, and rules of procedure. In addition, where the applicant or offeror believes that the activity involves only negligible risks, it may ask the Secretary to waive or modify the requirement for a consent committee. All proposals for the establishment, modification, or waiver of a consent committee shall be subject to review and approval at the local level by the organizational review committee and at the departmental level by the Ethical Advisory Board. The Ethical Advisory Board may prescribe additional duties for the consent committee. These changes are incorporated in § 46.305. In view of this drastic change in concept of the committee, detailed discussion of the many excellent and often thought-provoking comments concerned with details of the original draft seems inappropriate.

E. Many critical comments were addressed to the definitions used in this subpart, specifically:

1. "Pregnancy." It was suggested that pregnancy should be defined (i) conceptually to begin at the time of fertilization of the ovum, and (ii) operationally by actual test unless the woman has been surgically rendered incapable of pregnancy.

While the Department has no argument with the conceptual definition as proposed above, it sees no way of basing regulations on the concept. Rather, in order to provide an administerable policy, the definition must be based on existing medical technology which permits confirmation of pregnancy. This approach is reflected by § 46.303(c).

2. "Viability of the Fetus". Many recommendations were received concerning the definition of viability of the fetus after premature delivery or abortion. Some respondents urged that presence of fetal heartbeat be definitive (whether or not there is respiration) while others urged that identifiable cortical activity be specified as an alternative sign of viability. The Department has concluded that the issue of viability is a function of technological advance, and therefore must be decided with reference to the medical realities of the present time. We reserve the option of redefining the parameters as conditions warrant.

Only upon the basis of a definition which is both precise and consistent with current medical capability can a regulation realistically be interpreted and enforced. Current technology is such that a fetus, given the benefit of available medical therapy, cannot survive unless the lungs can be inflated so that respiration can take place. Without this capability, even if the heart is beating, the fetus is nonviable. In the future, if technology has advanced to the point of sustaining a fetus with non-inflatable lungs, the definition can and should be modified.

The Department has therefore chosen to specify, in the definition of viability of the fetus (§ 46.303(e)), that heart beat and respiration are, jointly, to be the indicator of viability.

3. "Abortus." Various comments noted that this definition is more restrictive than the usual medical definition of the abortus as a "nonviable fetus," and suggested substitution of the broader definition.

The Department proposes to retain the original definition for the purposes of these regulations. There is general agreement that there are distinct ethical problems involved in decisions concerning research use of the intact fetus, or use of organs or tissues obtained from a fetus that has died *in utero* or from an abortus at autopsy. The definition recurs with minor editorial changes in § 46.303(f).

F. Several comments were critical of the draft regulation's provisions limiting activities involving pregnant women to those not adversely affecting the fetus, except where the primary purpose of the activity was to benefit the fetus. It was suggested that the regulations (i) should contain language permitting exceptions for research necessary to meet the health needs of the mother, and (ii) should grant the right to participate in research aimed at improvement of methods of abortion, birth control, and genetic intervention.

The Department concurs with the first suggestion, (i), and proposes that the regulations permit research whose primary interest is to benefit the particular fetus or to respond to the health needs of the pregnant woman. It does not fully accept the second suggestion, (ii), and proposes that the regulations permit fetal research concerned with diagnosis and prevention of perinatal disease, and to offset the effects of genetic abnormality or congenital injury, but only when such research is done as part of a procedure properly performed to terminate a pregnancy. These changes are incorporated into § 46.306(a). The Department has tentatively concluded that consideration of risk vs. benefit with respect to fetal research does not seem to be appropriate.

G. Draft regulation provisions required maternal consent and the consent of the father if he were available and capable of participating in the consent process. This provision was strongly criticized on the grounds that it could permit the father of the fetus to deny needed health care to the woman or to the fetus even though he had no marital obligations, and that it might result in undue delay in the delivery of health care. It was also pointed out that the regulation did not touch on the question of the validity of consent by a pregnant minor.

The Department agrees. It is now proposed that paternal consent be sought only if the activity is not responding to the health needs of the pregnant woman and the father is reasonably available. These changes are reflected by § 46.306(b).

H. The Department has provisionally chosen, in § 46.306(a), to permit research to be undertaken from which there will be risk of harm to the fetus if such research is conducted as part of the abortion procedure. This decision, upon which we invite comment, has been made in the expectation that such research may produce new technology which will enable countless premature infants to live who now cannot.

It is not intended that this provision be construed to permit fetal research in anticipation of abortion prior to the commencement of the termination procedure itself.

While it is true that the class of fetuses for whom abortion is contemplated will be placed at greater research risk than all fetuses in general, such risk can arise only after implementation of the double safeguard of parental consent to the contemplated abortion, and second parental consent to the research procedure itself.

I. Comments regarding activities involving the abortus were concerned with the issue of maintaining vital functions and signs. It was argued that maintaining vital functions at the level of the organ, tissue, or cell is essential to studies and involves no prolongation of the dying of the abortus. At the same time, it was argued that termination of the heart beat should not be prohibited since temporary cardiac arrest has proved essential in the development of surgical techniques necessary to correct congenital heart defects.

Neither of these objections appear valid and no significant changes in § 46.307 are proposed. However, in order to emphasize again the distinction between research with the whole fetus or abortus, functioning as an organism with detectable vital signs, and with the dead fetus or abortus, the Department has added § 46.308, concerning activities involving a dead fetus or abortus, and § 46.309, concerning the abortus as an organ or tissue donor. Also § 46.307(d) has been expanded to permit the artificial maintenance of vital functions of an abortus where the purpose is to develop new methods for enabling the abortus to survive to the point of viability.

The Department feels that there is evident distinction between "termination" and "arrest" of the clinical signs as applied to the fetus or premature infant, but that no such distinction is valid or applicable where the abortus is concerned.

Prisoners

Forty-seven responses spoke to the provisions regarding additional protection for prisoners involved as subjects. Of these, two were from individuals identifying themselves as prisoners, seven were from State correctional institutions or State agencies, and four were from representatives of the pharmaceutical industry.

A. In comments directed at the overall nature of the draft regulations providing additional protection for prisoners, approximately equal numbers of respondents (i) denied that any significant additions were necessary, and (ii) proposed either the exclusion of prisoners from any research or experimentation not intended for the personal benefit of a prisoner, or highly restrictive regulations to accomplish the same purpose.

The Department, having reviewed these comments, has not been persuaded that any change should be made in the initial proposal.

B. A number of comments were concerned with the relationship between the existing organizational review committees and the proposed Protection Committee. It was pointed out by several that, as proposed, the two committees would not only have overlapping functions and authority but could operate independently of each other with conflicting directives and objectives that would not practicably provide additional protection of prisoners used as subjects.

The Department, recognizing the importance of preserving the authority of the organizational review committee as the primary institutional focus for the implementation of the Department of Health, Education, and Welfare regulations, proposes to assign to the organizational review committee the additional duties specified under § 46.404(a).

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A committee auxiliary to the organizational review committee, now designated the consent committee, will have the character and responsibilities specified in § 46.406. In keeping with this modified position it should be noted that when the organizational review committee determines that an activity would involve no risk or negligible risk to any prisoner while serving as a subject, the organization may request the Secretary to consider a modification or waiver of the requirement for a consent committee.

C. Comments on the proposed prohibition of research involvement of persons awaiting arraignment, trial, or sentencing expressed doubts that these individuals should be denied the benefits of innovative procedures, particularly those concerned with sociological research.

The Department agrees that the uniform exclusion of any such person from research should not be mandatory and proposes to permit his participation in an activity as a subject when the risk is negligible and the intent of the activity is therapeutic for him or relates to the nature of his confinement. This modification is incorporated into § 46.406.

D. The draft requirement for DHEW accreditation of prison facilities as sites for the performance of research, development, and related activities involving prisoner subjects was severely criticized, principally because of the jurisdictional problems inherent in any attempt to impose a Federal regulatory requirement on an autonomous State facility.

The Department concludes that this draft proposal was ill-advised. However, in order to attain the objective on an activity basis, certain specific prerequisites for the protection of prisoner subjects within facilities have been added to § 46.404(a) to properly relate conditions in a facility to the issue of undue inducements to participation by prisoners as subjects in an activity.

MENTALLY DISABLED

Over 40 of the responses spoke directly to the section of the draft concerned with the "mentally infirm." Many of these objected initially to the use of the word "infirm" as reflecting an antiquated notion of mental illness.

The Department agrees, and proposes to substitute "disabled" for "infirm," though noting that there is no clearly preferable collective term for the groups described.

A. Comments on the purpose of this section expressed satisfaction with the intent to provide additional protection for this group but dissatisfaction with the actual language employed. Specifically, they noted that not institutionalization but rather the limitation of personal rights and freedom imposed by institutionalization is the determining issue. Similarly, it is not only the potential subject's difficulty in comprehending risks that is at issue, but his ability to comprehend generally.

The Department concurs. Proposed changes in language are incorporated in § 46.52.

B. Many of the respondents objected to one or more of the definitions peculiar to this subpart. The criticisms and the Department's proposed changes are as follows:

1. "Mentally infirm." In addition to requesting substitution of another term for "infirm," respondents raised conflicting objections to the definition's coverage. Some felt that it was overly inclusive; others felt it was too narrow. Some felt that epileptics should be specifically included, as well as those who are temporarily or permanently mentally incapacitated as a result of a physical condition such as stroke, brain damage, trauma, etc.

The Department, having carefully reviewed these comments, proposes no basic change in the definition. It concurs with many reviewers in the opinion that the definition is broad enough to include any category of subjects proposed for specific addition. Minor editorial changes have been made in § 46.503(b).

2. "Institutionalized." Commentators noted that (i) the regulations should cover all mentally disabled persons regardless of institutionalization, (ii) not all involuntary commitments are by order of a court, (iii) the draft refers to "residence" and "confinement" in similar contexts, though the terms do not carry the same connotation, and (iv) the definition does not specify halfway houses, lodges, day/night hospitals, nursing homes, and psychiatric wards of hospitals as places where subjects might be institutionalized.

The Department notes that (i) the non-institutionalized mentally disabled are covered by the existing regulations published as 39 FR 18914 and need not be included under these additional protections. Such individuals are not necessarily subject to all limitations on their freedom and rights as described in § 46.502 of this proposed rulemaking. Consideration will be given, however, to dealing with the noninstitutionalized legally incompetent who are mentally disabled in a subsequent notice of proposed rulemaking. With regard to (ii), the implication that court orders are the sole basis for involuntary confinement is incorrect and should be removed. Editorial changes have been made in § 46.503 to emphasize that concern therein is with those "* * * confined * * * in a residential institution * * *" (see iii) and, in order to designate the type of institutions concerned (see iv), it is proposed to separately define "Institutionalized mentally disabled individuals" in § 46.503 to include examples of such institutions. These changes are incorporated in § 46.503(c) and § 46.503(d).

C. While most respondents endorsed the intent of the draft limitations on activities involving the institutionalized mentally disabled, there were several specific criticisms of the terms used. Several persons suggested that any limitation of research to that related to a particular subject's "impairment" be worded so as to include any illness from which the person suffers so that, for example, an institutionalized mentally disabled person with cancer could not be denied the benefits of research in cancer therapy.

Further, this limitation could exclude the use of such subjects as controls in research which might benefit those suffering from a mental disability other than the specific one from which a particular subject suffers. Still further, mentally disabled people should be involved as subjects in research on infirmities other than their own because of lack of knowledge of the causes of mental and emotional disorders.

Many respondents felt that there was inadequate recognition of the need for research with the mentally disabled on basic psychological processes (e.g., learning, perception, and cognitive functions) which are fundamental to the study of the treatment, etiology, pathogenesis, prevention, and treatment of such disabilities.

The Department agrees that the language of the draft limiting research to the disease entities affecting individual subjects is probably not in the interests of the institutionalized mentally disabled as a class. The Department does not agree that it would be appropriate to permit this class of subjects to be involved in research unrelated to the causes, nature, or circumstances of their institutionalization. While there are possible disadvantages to the institutionalized mentally disabled inherent in this restriction, the possible risks of using the mentally disabled in such research outweigh its advantages. The proposed changes are incorporated in § 46.504(a). Editorial changes are reflected in § 46.504 (b) and § 46.504(c).

D. Criticisms of the draft's suggestion of the establishment or a protection committee in connection with each activity conducted in an institution for the mentally retarded were similar to those aimed at the protection committee to be established in connection with research on the pregnant woman and on the fetus. The Department proposes to change the title of the committee to "consent committee" and to change the regulations governing size, composition, and operating rules to conform to those previously described for § 46.305. Such changes are incorporated in § 46.506.

E. With respect to § 46.603(b), the Department reserves the right to amend this section if legislation now being developed by the Executive Branch on the safe guarding of individually linked data used for statistical and research purposes is enacted.

Written comments concerning the proposed regulation are invited from interested persons. Inquiries may be addressed and data, views, and arguments relating to the proposed regulations may be presented in writing, in triplicate, to the Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. All comments received will be available for inspection at the National Institutes of Health, Room 303, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland, weekdays (Federal holidays excepted) between the hours of 9:00 a.m. and 4:30 p.m. All relevant material received on or before November 21, 1974 will be considered.

Notice is also given that it is proposed to make any amendments that are adopted effective upon publication in the FEDERAL REGISTER.

Dated: August 15, 1974.

CASPAR W. WEINBERGER,
Secretary.

It is therefore proposed to amend Part 46 of Subtitle A of Title 45 of the Code of Federal Regulations by:

1. Revising §§ 46.19 through 46.23 and renumbering them as §§ 46.603 through 46.606, reading as set forth in Subpart F below.

2. Designating §§ 46.1 through 46.18 as Subpart A, renumbering these §§ 46.101 through 46.118, and modifying all references thereto accordingly.

3. Reserving Subpart B.

4. Adding the following new Subparts C through F.

Subpart C—Additional Protections Pertaining to Biomedical Research, Development, and Related Activities Involving Fetuses, Abortuses, Pregnant Women, and in Vitro Fertilization

Sec.
46.301 Applicability.
46.302 Purpose.
46.303 Definitions.
46.304 Ethical Advisory Board.
46.305 Establishment of a consent committee.
46.306 Activities involving fetuses *in utero* or pregnant women.
46.307 Activities involving abortuses.
46.308 Activities involving a dead fetus or abortus.
46.309 Activities involving the abortus as an organ or tissue donor.
46.310 Activities to be performed outside the United States.

Subpart D—Additional Protections Pertaining to Activities Involving Prisoners as Subjects

46.401 Applicability.
46.402 Purpose.
46.403 Definitions.
46.404 Additional duties of the organizational review committee where prisoners are involved.
46.405 Establishment of a consent committee.
46.406 Special restrictions.
46.407 Activities to be performed outside the United States.

Subpart E—Additional Protections Pertaining to Activities Involving the Institutionalized Mentally Disabled as Subjects

46.501 Applicability.
46.502 Purpose.
46.503 Definitions.
46.504 Activities involving the institutionalized mentally disabled.
46.505 Additional duties of the organizational review committee where the institutionalized mentally disabled are involved.
46.506 Establishment of a consent committee.
46.507 Activities to be performed outside the United States.

Subpart F—General Provisions

46.601 Applicability.

Sec.
46.602 Multiple consent committee requirements.
46.603 Organization's record; confidentiality.
46.604 Reports.
46.605 Early termination of awards; evaluation of subsequent applications.
46.606 Conditions.
46.607 Activities conducted by Department employees.

AUTHORITY: 5 U.S.C. 301.

Subpart C—Additional Protections Pertaining to Biomedical Research, Development, and Related Activities Involving Fetuses, Abortuses, Pregnant Women, and in Vitro Fertilization

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting biomedical research, development, and related activities involving: (1) the fetus *in utero*, (2) the abortus, as that term is defined in § 46.303, (3) pregnant women, and (4) *in vitro* fertilization. In addition, these regulations are applicable to all such activities involving women who could become pregnant, except where the applicant or offeror shows to the satisfaction of the Secretary that adequate steps will be taken in the conduct of the activity to avoid involvement of women who are pregnant.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare or any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Biomedical research, development, and related activities" means research, development, or related activities involving biological study (including but not limited to medical or surgical procedures, withdrawal or removal of body tissue or fluid, administration of chemical substances or input of energy, deviation from normal diet or hygiene, and manipulation or observation of bodily processes).

(c) "Pregnancy" encompasses the period of time from confirmation of implantation until delivery.

(d) "Fetus" means the product of conception from the time of implantation to the time of delivery.

(e) "Viability of the fetus" means the ability of the fetus, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. If the fetus has this ability, it is viable and therefore a premature infant.

(f) "Abortus" means a fetus when it is expelled whole, prior to viability, whether spontaneously or as a result of medical or surgical intervention. The term does not apply to the placenta: fetal material which is macerated at the time of expulsion; or cells, tissue, or organs excised from a dead fetus.

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor sperm and ova or by any other means.

§ 46.304 Ethical Advisory Board.

(a) All applications or proposals for the support of activities covered by this subpart shall be reviewed by an Ethical Advisory Board, established by the Secretary within the National Institutes of Health, which shall advise the funding agency concerning the acceptability of such activities from an ethical standpoint.

(b) Members of the Board shall be so selected that the Board will be competent to deal with medical, legal, social, and ethical issues and shall include, for example, research scientists, physicians, lawyers, and clergy and/or ethicists, as well as representatives of the general public. No Board member may be a regular, full-time employee of the Federal Government.

§ 46.305 Establishment of a consent committee.

(a) Except as provided in paragraph (c) of this section, no activity covered by this subpart may be supported unless the applicant or offeror has provided an assurance acceptable to the Secretary that it will establish a consent committee (as provided for in the application or offer and approved by the Secretary) for each such activity, to oversee the actual process by which individual consents required by this subpart are secured, to monitor the progress of the activity and intervene as necessary, and to carry out such other duties as the Secretary (with the advice of the Ethical Advisory Board) may prescribe. The duties of the consent committee may include:

(1) Participation in the actual selection process and securing of consents to assure that all elements of a legally effective informed consent, as outlined in § 46.3, are satisfied. Depending on what may be prescribed in the application or offer approved by the Secretary, this might require approval by the committee of individual participation in the activity or it might simply call for verification (e.g., through sampling) that procedures prescribed in the approved application or offer are being followed.

(2) Monitoring the progress of the activity. Depending on what may be prescribed in the application or offer approved by the Secretary, this might

include: visits to the activity site, identification of one or more committee members who would be available for consultation with those involved in the consent procedure (i.e., participants) at the participant's request, continuing evaluation to determine if any unanticipated risks have arisen and that any such risks are communicated to the participants, periodic contact with the participants to ascertain whether they remain willing to continue in the activity, providing for the withdrawal of any participants who wish to do so, and authority to terminate participation of one or more participants with or without their consent where conditions warrant.

(b) The size and composition of the consent committee must be approved by the Secretary, taking into account such factors as: (1) the scope and nature of the activity; (2) the particular subject groups involved; (3) whether the membership has been so selected as to be competent to deal with the medical, legal, social, and ethical issues involved in the activity; (4) whether the committee includes sufficient members who are unaffiliated with the applicant or offeror apart from membership on the committee; and (5) whether the committee includes sufficient members who are not engaged in research, development, or related activities involving human subjects. The committee shall establish rules of procedure for carrying out its functions and shall conduct its business at convened meetings, with one of the members designated as chairperson.

(c) Where a particular activity, involving fetuses *in utero* or pregnant women, presents negligible risk to the fetus, an applicant or offeror may request the Secretary to modify or waive the requirement in paragraph (a) of this section. If the Secretary finds that the risk is indeed negligible and other adequate controls are provided, he may (with the advice of the Ethical Advisory Board) grant the request in while or in part.

(d) The requirements of this section and § 46.304 do not obviate the need for review and approval of the application or offer by the organizational review committee, to the extent required under Subpart A of this part.

§ 46.306 Activities involving fetuses *in utero* or pregnant women.

(a) No activity to which this subpart is applicable, involving fetuses *in utero* or pregnant women, may be undertaken unless: (1) the purpose of the activity is to benefit the particular fetus or to respond to the health needs of the mother, or (2) the activity conducted as part of (but not prior to the commencement of) a procedure to terminate the pregnancy and is for the purpose of evaluating or improving methods of prenatal diagnosis, methods of prevention of premature birth, or methods of intervention to offset the effects of genetic abnormality or congenital injury.

(b) Activities covered by this subpart which are permissible under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their consent, except that the father's consent need not be secured if: (1) the purpose of the activity is to respond to the health needs of the mother or (2) his identity or whereabouts cannot reasonably be ascertained.

(c) Activities covered by this subpart which are permissible under paragraph (a) (2) of this section may not be undertaken unless individuals engaged in the research will have no part in: (1) any decisions as to the timing, method, or procedures used to terminate the pregnancy, and (2) determining the viability of the fetus at the termination of the pregnancy.

§ 46.307 Activities involving abortuses.

No activity to which this subpart is applicable, involving an abortus, may be undertaken unless:

(a) Appropriate studies on animals have been completed;

(b) The mother and father are legally competent and have given their consent, except that the father's consent need not be secured if his identity or whereabouts cannot reasonably be ascertained;

(c) Individuals engaged in the research will have no part in: (1) any decisions as to the timing, method, or procedures used to terminate the pregnancy, and (2) determining the viability of the fetus at the termination of the pregnancy;

(d) Vital functions of an abortus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling the abortus to survive to the point of viability; and

(e) Experimental procedures which would terminate the heart beat or respiration of the abortus will not be employed.

§ 46.308 Activities involving a dead fetus or abortus.

Activities involving a dead fetus or abortus shall be conducted in accordance with any applicable State or local laws governing autopsy.

§ 46.309 Activities involving the abortus as an organ or tissue donor.

Activities involving the abortus as an organ or tissue donor shall be conducted in accordance with any applicable State or local laws governing transplantation or anatomical gifts.

§ 46.310 Activities to be performed outside the United States.

Activities to which this subpart is applicable, to be conducted outside the United States, are subject to the requirements of this subpart, except that the consent procedures specified herein may be modified if it is shown to the satisfaction of the Secretary that such procedures, as modified, are acceptable under the laws and regulations of the country in which the activities are to be performed and that they comply with the requirements of Subpart A of this part.

Subpart D—Additional Protections Pertaining to Activities Involving Prisoners as Subjects

§ 46.401 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research, development, and related activities involving prisoners as subjects.

(b) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.402 Purpose.

It is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable, inasmuch as, because of their incarceration, they may be under constraints which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate in such activities.

§ 46.403 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare or any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Prisoner" means any individual involuntarily confined in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute and also individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution.

§ 46.404 Additional duties of the organizational review committee where prisoners are involved.

(a) In addition to the responsibilities prescribed for such committees under Subpart A of this part, the applicant's or offeror's organizational review committee shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that there will be no undue inducements to participation by prisoners as subjects in the activity, taking into account such factors as whether the earnings, living conditions, medical care, quality of food, and amenities offered to participants in the activity would be better than those generally available to the prisoners;

(2) Determine that (i) all aspects of the activity would be appropriate for performance on nonprisoners, or (ii) the activity involves negligible risk to the subjects and is for the purpose of studying the effects of incarceration on such subjects;

(3) Determine that the application or proposal contains adequate procedures for selection of subjects, securing consents, monitoring continued subject participation, and assuring withdrawal without prejudice, in accordance with § 46.405 of this subpart;

(4) Determine that rates of remuneration are consistent with the anticipated duration of the activity, but not in excess of that paid for other employment generally available to inmates of the facility in question, and that withdrawal from the project for medical reasons will not result in loss of anticipated remuneration; and

(5) Carry out such other responsibilities as may be assigned by the Secretary.

(b) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an organizational review committee, subject to approval by the Secretary, where no such committee has been established under Subpart A of this part.

(c) No award may be issued until the applicant or offeror has certified to the Secretary that the organizational review committee has made the determinations required under paragraph (a) of this section.

§ 46.405 Establishment of a consent committee.

(a) Except as provided in paragraph (c) of this section, no activity covered by this subpart may be supported unless the applicant or offeror has provided an assurance acceptable to the Secretary that it will establish a consent committee (as provided for in the application or offer and approved by the organizational review committee and the Secretary) for each such activity, to oversee the actual process by which individual subjects are selected and their consents secured, to monitor the progress of the activity (including visits to the activity site on a regular basis) and the continued willingness of the subjects to participate, to intervene on behalf of one or more subjects if conditions warrant, and to carry out such other duties as the Secretary may prescribe. The duties of the consent committee may include:

(1) Participation in the actual process by which individual subjects are selected and their consents secured to assure that all elements of a legally effective informed consent, as outlined in section 46.3 of this part, are satisfied. Depending on what may be prescribed in the application or offer approved by the Secretary, this might require approval by the committee of each individual's participation as a subject in the activity or it might simply call for verification (e.g., through sampling) that procedures prescribed in the approved application or offer are being followed.

(2) Monitoring the progress of the activity and the continued willingness of subjects to participate. Depending on what may be prescribed in the application or offer approved by the Secretary, this might include: visits to the activity site, identification of one or more committee members who would be available for consultation with subjects at the subjects' request, continuing evaluation to determine if any unanticipated risks have arisen and that any such risks are communicated to the subjects, periodic contact with the subjects to ascertain whether they remain willing to continue in the study, providing for the withdrawal of any subjects who wish to do so, and authority to terminate participation of one or more subjects with or without their consent where conditions warrant.

(b) The size and composition of the consent committee must be approved by the Secretary, taking into account such factors as: (1) the scope and nature of the activity; (2) the particular subject groups involved; (3) whether the membership has been so selected as to be competent to deal with the medical, legal, social, and ethical issues involved in the activity; (4) whether the committee includes a prisoner or a representative of an organization having as a primary concern protection of prisoners' interests; (5) whether the committee includes sufficient members who are unaffiliated with the applicant or offeror apart from membership on the committee; and (6) whether the committee includes sufficient members who are not engaged in research, development, or related activities involving human subjects. The committee shall establish rules of procedure for carrying out its functions and shall conduct its business at convened meetings, with one of its members designated as chairperson.

(c) Where a particular activity involves negligible risk to the subjects, an applicant or offeror may request the Secretary to modify or waive the requirement in paragraph (a) of this section. If the Secretary finds that the risk is indeed negligible and other adequate controls are provided, he may grant the request in whole or in part.

§ 46.406 Special restrictions.

Persons detained in a correctional facility pending arraignment, trial, or sentencing or in a hospital facility for pre-arraignment, pre-trial, or pre-sentence diagnostic observation are excluded from participation in activities covered by this subpart, unless (a) the organizational review committee finds that the particular activity involves only negligible risk to the subjects and (b) the activity is therapeutic in intent or relates to the nature of their confinement.

§ 46.407 Activities to be performed outside the United States.

Activities to which this subpart is applicable, to be conducted outside the United States, are subject to the requirements of this subpart, except that the consent procedures specified herein may be modified if it is shown to the satisfaction of the Secretary that such procedures, as modified, are acceptable under the laws and regulations of the country in which the activities are to be performed and that they comply with the requirements of Subpart A of this part.

Subpart E—Additional Protections Pertaining to Activities Involving the Institutionalized Mentally Disabled as Subjects

§ 46.501 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare grants and contracts supporting research, development, and related activities involving the institutionalized mentally disabled as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in such an activity; nor in particular does it obviate the need for court approval of such participation where court approval is required under applicable State or local law in order to obtain a legally effective consent.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.502 Purpose.

It is the purpose of this subpart to provide additional safeguards for the protection of the institutionalized mentally disabled involved in activities to which this subpart is applicable, inasmuch as: (a) they are confined in an institutional setting where their freedom and rights are potentially subject to limitation; (b) they may be unable to comprehend sufficient information to give an informed consent, as that term is defined in § 46.103; and (c) they may be legally incompetent to consent to their participation in such activities.

§ 46.503 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare or any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Mentally disabled" includes those institutionalized individuals who are mentally ill, mentally retarded, emotionally disturbed, or senile, regardless of their legal status or basis of institutionalization.

(c) "Institutionalized" means confined, whether by voluntary admission or involuntary commitment, in a residential institution for the care or treatment of the mentally disabled.

(d) "Institutionalized mentally disabled individuals" includes but is not limited to patients in public or private mental hospitals, psychiatric patients in general hospitals, inpatients of community mental health centers, and mentally disabled individuals who reside in halfway houses or nursing homes.

§ 46.504 Activities involving the institutionalized mentally disabled.

Institutionalized mentally disabled individuals may not be included in an activity covered by this subpart unless:

(a) The proposed activity is related to the etiology, pathogenesis, prevention, diagnosis, or treatment of mental disability or the management, training, or rehabilitation of the mentally disabled and seeks information which cannot be obtained from subjects who are not institutionalized mentally disabled;

(b) The individual's legally effective informed consent to participation in the

activity or, where the individual is legally incompetent, the informed consent of a representative with legal authority so to consent on behalf of the individual has been obtained; and

(c) The individual's assent to such participation has also been secured, when in the judgment of the consent committee he or she has sufficient mental capacity to understand what is proposed and to express an opinion as to his or her participation.

§ 46.505 Additional duties of the organizational review committee where the institutionalized mentally disabled are involved.

(a) In addition to the responsibilities prescribed for such committees under Subpart A of this part, the applicant's or offeror's organizational review committee shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of § 46.50 (a) of this subpart;

(2) Determine that there will be no undue inducements to participation by individuals as subjects in the activity, taking into account such factors as whether the earnings, living conditions, medical care, quality of food, and amenities offered to participants in the activity would be better than those generally available to the mentally disabled at the institutions;

(3) Determine that the application or proposal contains adequate procedures for selection of subjects, securing consents, protecting confidentiality, and monitoring continued subject participation, in accordance with § 46.506 of this subpart; and

(4) Carry out such other responsibilities as may be assigned by the Secretary.

(b) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an organizational review committee, subject to approval by the Secretary, where no such committee has been established under Subpart A of this part.

(c) No award may be issued until the applicant or offeror has certified to the Secretary that the organizational review committee has made the determinations required under paragraph (a) of this section.

§ 46.506 Establishment of a consent committee.

(a) Except as provided in paragraph (c) of this section, no activity covered by this subpart may be supported unless the applicant or offeror has provided a separate assurance acceptable to the Secretary that it will establish a consent committee (as provided for in the application or offer and approved by the organizational review committee and the secretary) for each such activity, to oversee the actual process by which individual subjects are selected and consents required by this subpart are secured, to monitor the progress of the activity (including visits to the activity site on a regular basis) and the continued willingness of the subjects to participate, to intervene on behalf of one or more subjects if conditions warrant, and to carry out such other duties as the Secretary may prescribe. The duties of the consent committee may include:

(1) Participation in the actual process by which individual subjects are selected and their consents secured to assure that all elements of a legally effective informed consent, as outlined in § 46.3, are satisfied. Depending on what may be prescribed in the application or offer approved by the Secretary, this might require approval by the committee of each individual's participation as a subject in the activity or it might simply call for verification (e.g., through sampling) that procedures prescribed in the approved application or offer are being followed.

(2) Monitoring the progress of the activity and the continued willingness of subjects to participate. Depending on what may be prescribed in the application or offer approved by the Secretary, this might include: visits to the activity site, identification of one or more committee members who would be available for consultation with subjects at the subjects' request, continuing evaluation to determine if any unanticipated risks have arisen and that any such risks are communicated to the subjects, periodic contact with the subjects to ascertain whether they remain willing to continue in the study, providing for the withdrawal of any subjects who wish to do so, and authority to terminate participation of one or more subjects with or without their consent where conditions warrant.

(b) The size and composition of the consent committee must be approved by the Secretary, taking into account such factors as: (1) the scope and nature of the activity; (2) the particular subject groups involved; (3) whether the membership has been so selected as to be competent to deal with the medical, legal, social, and ethical issues involved in the activity; (4) whether the committee includes sufficient members who are unaffiliated with the applicant or offeror apart from membership on the committee; and (5) whether the committee includes sufficient members who are not engaged in research, development, or related activities involving human subjects. The committee shall establish rules of procedure for carrying out its functions and shall conduct its business at convened meetings, with one of its members designated as chairperson.

(c) Where a particular activity involves negligible risk to the subjects, an applicant or offeror may request the Secretary to modify or waive the requirement in paragraph (a) of this section. If the Secretary finds that the risk is indeed negligible and other adequate controls are provided, he may grant the request in whole or in part.

§ 46.507 Activities to be performed outside the United States.

Activities to which this subpart is applicable, to be conducted outside the United States, are subject to the requirements of this subpart, except that the consent procedures specified herein may be modified if it is shown to the satisfaction of the Secretary that such procedures, as modified, are acceptable under the laws and regulations of the country in which the activities are to be performed and that they comply with the requirements of Subpart A of this part.

Subpart F—General Provisions

§ 46.601 Applicability.

Sections 46.602 through 46.606 are applicable to all grant or contract supported activities covered by this part.

§ 46.602 Multiple consent committee requirements.

Where an application or proposal would involve human subjects covered by more than one consent committee requirement imposed under this part, upon approval by the Secretary, these multiple requirements may be satisfied through use of a single consent committee appropriately constituted to take account of the nature of the subject group.

§ 46.603 Organization's records; confidentiality.

(a) Copies of all documents presented or required for initial and continuing review by the organization's review committee or consent committee, such as committee minutes, records or subjects' consent, transmittals on actions, instructions, and conditions resulting from committee deliberations addressed to the activity director, are to be retained by the organization, subject to the terms and conditions of grant and contract awards.

(b) Except as otherwise provided by law, information in the records or possession of an organization acquired in connection with an activity covered by this part, which information refers to or can be identified with a particular subject, may not be disclosed except:

(1) With the consent of the subject or his legally authorized representative; or

(2) As may be necessary for the Secretary to carry out his responsibilities under this part in the exercise of oversight for the protection of such subject or class of subjects.

§ 46.604 Reports.

Each organization with an approved assurance shall provide the Secretary with such reports and other information as the Secretary may from time to time prescribe.

§ 46.605 Early termination of awards; evaluation of subsequent applications.

(a) If, in the judgment of the Secretary, an organization has failed materially to comply with the terms of this policy with respect to a particular Department of Health, Education, and Welfare grant or contract, he may require that said grant or contract be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

(b) In evaluating proposals or applications for support of activities covered by this part, the Secretary may take into account, in addition to all other eligibility requirements and program criteria, such factors as: (1) whether the offeror or applicant has been subject to a termination or suspension under paragraph (a) of this section, (2) whether the offeror or applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary failed materially to discharge his, her, or its responsibility for the protection of the rights and welfare of subjects and (3) whether, where past deficiencies have existed in discharging such responsibility, adequate steps have in the judgment of the Secretary been taken to eliminate these deficiencies.

§ 46.606 Conditions.

The Secretary may with respect to any grant or contract or any class of grants or contracts impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary for the protection of human subjects.

§ 46.607 Activities conducted by Department employees.

The regulations of this part (except for this subpart) are applicable as well to all research, development, and related activities conducted by employees of the Department of Health, Education and Welfare, except that: (a) subpart C is applicable only to biomedical research, development, and related activities and (b) each agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint.

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Dr. Dickson. As you know, questions about the use of human subjects, including prisoners, in the investigation of drugs are complex and have been subject to a great deal of recent attention and controversy. Everyone, I believe, would agree that clinical investigation is essential to further advances in medicine, and that mankind has benefited greatly from past investigations. At the same time, no one can be so naive as to think that the use of humans as experimental subjects, and especially those humans with limited freedom, does not create serious legal as well as ethical problems.

As part of the FDA program to monitor clinical investigation, it has conducted inspections of institutional review committees in 19 prisons. It is clear from the other FDA investigations that abuses have occurred.

Although the FDA has been responsible since 1938 for determining whether drugs were safe enough for marketing, it did not have real authority to regulate investigational use of drugs in humans until 1962, following passage of the Kefauver-Harris amendments to the Federal Food, Drug and Cosmetic Act. FDA standards for the conduct of clinical drug trials, which have gradually evolved over the past 13 years, are quite rigorous. These regulations, guidelines, and policies require that, before a new drug is administered to man, the sponsor submit a Notice of Claimed Investigational Exemption for a New Drug, which contains not only the results of chemical tests establishing the purity of the drug and animal tests establishing the safety and efficacy in various species, but also a very detailed plan of each study proposed to be conducted in human beings.

The FDA further requires that if a clinical study is to be done in an institution—which is defined to include prisons, among others—that an institutional review committee be responsible for initial and continuing review and approval of the proposed clinical study. The membership of that committee must be comprised of sufficient members of varying background—that is, lawyers, clergy, or laymen as well as scientists—to assure complete and adequate ethical review of the research project. The membership must possess not only broad competence to comprehend the nature of the project, but also other competencies necessary to judge the acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance.

At the time of submission of the notice of exemption, the FDA has the opportunity to review the proposed study, and has 30 days in which to raise objection to the initiation of the study. After that, the proposed study may begin. At any time, however, the Agency has the option to inform the sponsor that an ongoing study must stop, based on results of the study or new information.

The 1962 amendments and implementing regulations place responsibility for monitoring studies of investigational drugs with the sponsoring drug firms. At the present time, there are about 12,000 active investigators and approximately 1,600 functioning institutional review committees. The FDA cannot possibly police this system directly, since it involves physicians and other scientists throughout the conduct of their professional work.

Although they cannot undertake direct monitoring of all investigators, the FDA over the past several years directed increasing attention to determining whether the present system is working well. This has required a growing effort on their part in the direct monitoring of randomly selected clinical, and more recently, preclinical (animal) studies. At the same time, the FDA continues to investigate any studies about which a suspicion has arisen.

A matter of growing concern to many people is the question of just who participates in drug trials. Consideration of this question requires a distinction between therapeutic and nontherapeutic studies. Early in the development of most drugs, small numbers of normal volunteers are given the drug in nontherapeutic studies—known as phase 1 studies—to evaluate tolerance to the drug, the proper dose, metabolism of the drug, and to detect certain kinds of adverse reactions. Prisoners have represented a large fraction of such normal volunteers.

In certain cases, such as when the drug is highly toxic, as with anticancer agents, these studies are not conducted in normal volunteers, but rather in patients with the disease. Increasingly, initial trials are being conducted in people who have the condition for which the drug is intended, as with high blood pressure, high cholesterol, and the like, rather than in normal volunteers.

The second kind of study is the therapeutic trial, which involves people with a disease or condition to be treated. The use of institutionalized patients in such studies depends to a great extent upon the various groups that might be available to clinical investigators. Many studies, however, are conducted in institutions which draw on all segments of the population.

An FDA review of sample new drug applications indicates that of the various populations involved, prisoners are probably most commonly used in phase I clinical drug trials. The principal advantage offered by prisons to the conduct of clinical research is that prisoners are generally confined. Such confinement permits better monitoring of each subject, meaning that adverse reactions can be detected early in development. This significantly increases the safety of each volunteer.

This ability to monitor the subject closely during and after use of a drug improves the quality of the results derived from each subject. Likewise, the controlled environment—living conditions, diet, exercise, limited source of exposure to infections—reduces the number of variables that might impair the meaningfulness of the results. Better quality of results per subject reduces the number of subjects who would be exposed to any risk. The same advantages that are available in prisoner populations could be obtained in other populations with some cost and effort, that is, with students or paid volunteers.

Although it is obvious that we have benefited from clinical investigation in the past and that we need clinical investigation in the future to answer important questions, we must recognize that all investigations expose subjects to risk. The FDA regulatory requirements for animal testing, for well-trained clinical investigators, for institutional review, and for carefully designed studies are intended to minimize

the risk and make certain that investigational subjects, including prisoners, are fully aware of the risks that do exist.

Research with certain kinds of prisoner subjects is of potential benefit to the prisoners involved, or to persons who may now or in the future be troubled by similar problems. Of particular concern to the Alcohol, Drug Abuse, and Mental Health Administration—ADAMHA—are problems of mental illness, drug addiction and abuse, and alcoholism. Since these are problems sometimes experienced by persons in the general prison population and some persons such as the criminally insane or convicted narcotic addicts are incarcerated specifically because of them, there is interest in research involving prisoners to develop certain needed information about these problems.

Studies involving Federal prisoners related to narcotic addiction and drug abuse have been conducted at the Addiction Research Center in Lexington, Ky. for the last 40 years. Dr. Martin, who is accompanying me here today, is the director of this hospital-research facility, which is part of the National Institute on Drug Abuse within ADAMHA.

Since this program has been in operation, it is estimated that 4,000 to 5,000 volunteer prisoner subjects have participated in research here. In order to be accepted into the Addiction Research Center program, prisoner volunteers must have a history of narcotic addiction. Thus, only those subjects with a history related to the general focus of the Addiction Research Center program are admitted to the facility.

Some of the research in which prisoner subjects at the Addiction Research Center participate may be of direct benefit to them, while other research has potential societal benefit related to the problems of drug abuse and addiction. Past and current studies include efforts to understand the fundamental process of addiction, develop methods for diagnosing drug addiction, understand the biological and psychological bases for narcotic euphoria and the way euphorigenic drugs act, and develop drugs for treatment of narcotic addiction. Thus, these involve research efforts related to understanding and treating problems which the subjects themselves have experienced.

Some studies are conducted to carry out the Secretary of DHEW's statutory responsibility to develop information and advise the Attorney General about the abuse or addictive potentiality of these new narcotic analgesics. These latter activities would be abolished if H.R. 3603 became law, and there is no alternative way this information can be obtained at this time.

Another research area of importance to ADAMHA's mission and related to prisoners is problems of mental health as these are or may be reflected in various types of deviant, aggressive, or violent behavior that frequently involves violation of criminal law. In order to understand and cope with these multifaceted problems, research using diverse methods in a variety of settings is necessary. This includes research with prisoners, using psychosocial and biomedical approaches.

Some information can be obtained only by using prisoner subjects. Among such areas of investigation are certain genetic and other biological aberrations and their possible relationship to criminality and violence; patterns of criminal behavior and various aspects of inmate behavior in prisons; testing and evaluation of new programs for coping

with and preventing criminal behavior; and law and mental health interactions in such areas as the dangerousness of mentally disordered offenders and competency to stand trial.

While H.R. 3603 would not prohibit all these kinds of research, it would eliminate all biomedical research with Federal prisoners, including some which is of potential benefits to prisoner subjects or to other prisoners. Also, it would interfere with attempts to develop a comprehensive explanation, including biological as well as psychosocial and environmental variables, of criminal behavior.

The National Institutes of Health has been and still is supporting some research involving prisoners within the current Department of Health, Education, and Welfare regulations for protection of human subjects. There has been a decline in recent years in the number of such activities. There are now less than a dozen ongoing projects. One project is being conducted at a Federal reformatory, the others at State correctional institutions. No new grants or contracts have been made this year, although renewal contracts and grants have been made for additional years in the support of several projects.

This reduction in support may reflect, at least in part, the increasing difficulty in conducting research in State correctional institutions because of recent rulings by some States prohibiting research not intended for the direct benefit of the prisoners. Most of the past and present research with prisoner subjects supported by the NIH has been for testing the effectiveness of vaccines for infectious, bacterial, and viral agents.

It is evident that the National Institutes of Health is not substantially dependent on prisoner subjects for pursuit of its missions. However, it has proved a valuable research tool. The prison environment with overcrowding, close confinement, and common facilities provides opportunities for the study of institutional epidemic conditions and for the study of certain epidemic transmissible diseases. Such studies would, of course, necessarily include the entire population of the prison environment; that is, guards, administrators, and others having frequent access to the prison.

Studies of the incidence of cancer, heart and vascular diseases, and neurological disorders and the development of chronic and aging disorders in prisoners enduring prison life for extended periods might provide useful information that could be of direct benefit to prisoners as a class.

In sponsoring some of the kinds of prisoner research I have mentioned, we do attempt to assure that the research projects we support are conducted in an ethical manner. As I mentioned earlier, the Department has regulations dealing with the protection of human subjects of all types, including prisoners, in DHEW-supported activities.

Important concepts embodied in these regulations include institutional and agency review of proposed projects, in order to assess the nature and extent of risks, including physical, psychological, and social risks, to determine the adequacy of proposed consent procedures, to assure that rights and welfare will be adequately protected, and to assess potential benefits of the activity. In addition, consent requirements are included which specify elements of informed consent and require that an individual be free to make a choice without undue in-

ducement or any coercion. Also, grant applicants are asked to indicate when special populations such as prisoners are to be used and the rationale for their use, so that we can assess whether the nature of the inquiry is relevant to the group under study. Review groups and agency staff pay special attention to proposals planning to use prisoners in order to assure that adequate protections are afforded and that the research is appropriate for conduct on prisoners.

Researchers at the Addiction Research Center in Lexington also abide by the principles stated in the DHEW regulations, and the ARC has additional requirements relating to prisoner participation. For example, only prisoners are admitted to the program who have a history of narcotic addiction. Further, potential subjects must be in good physical and mental health, be at least 25, and have 18 months remaining to serve in their sentence, so that patients can be appropriately followed up after their participation in research.

Prisoners are admitted to the center who volunteer for the research program there, but consent must be obtained for each individual study and a prisoner may refuse to participate in specific studies. Plans for research projects are reviewed by an organizational review committee to assess technical merit and protections for human subjects.

In summary, the Department is opposed to this legislation which would, in effect, prohibit all medical research on prisoners in Federal, State, and military institutions. While the stated purpose of H.R. 3603 is to limit participation in medical research by the inmates of correctional institutions, its effect is to prohibit all such participation.

Thus, the bill would prohibit involvement of persons in custody, regardless of the beneficial intent to such subjects of certain types of medical research including experimental therapy for prison subjects. Thus, military prisoners might be denied experimental treatment for an unfamiliar disease acquired in the course of foreign service for which there is no standard treatment. Similarly, control of an epidemic in a correctional institution might be forced to rely on older methods, though new, but still experimental, procedures were available.

For the above-stated reasons, we therefore recommend that H.R. 3603 not be favorably considered by the subcommittee.

Mr. Chairman, that concludes my prepared remarks. We will be pleased to respond to any questions you and the members of your subcommittee may have on this complex topic.

Mr. KASTENMEIER. Thank you very much, Dr. Dickson, for a thorough, comprehensive statement on the issue. I think you have anticipated a number of questions that I might have had for you by your statement.

On page 4 of your statement, you state, "The prisoners are in a custodial situation which is inherently coercive." On the next page, you indicate, "It is clear from the FDA's investigation that abuses of prisoner populations in fact occurred."

These statements appear to be inconsistent with your desire to maintain continued clinical research on prisoners.

How can there be an informed consent of free will in an inherently coercive situation?

Dr. DICKSON. I would like to make sort of a general set of remarks on that and then ask for some other members of the panel to comment on that.

I think that the central question here, is: Can prisoners ever actually give free consent? A civil libertarian would say no, for the basic reason that the prisoners are not ever free. I think also that in that situation, the awarding of special considerations of one sort or another, to have people participate in biomedical research is bad.

However, I personally do not believe that prisoners should be excluded from the opportunity to, you might say, contribute to society's advance. In our own culture over the past 25 years, there has been an increase of perception and sensitivities to the prisoner's situation and his rights. And certainly, at the moment, some things are done badly. But I do not believe this should necessarily vitiate against trying to do the right thing.

I do reject a position that someone might take that we cannot insure that the right things can be done. I think we simply ought to try to do it right, and it can be done right.

Because there are current DHEW regulations and proposed new regulations, and the Commission is looking at this situation broadly, we feel that it is well not to make any premature decision with respect to what you might call "a piece of the larger pie" about clinical investigation in general.

If we fail to recognize a valid consent by a prisoner, what is involved here actually is a denial of his personhood and actually a negation of his human capacities, by depriving prisoners of the opportunity to serve as subjects in medical experimentation. There are other classes than those you call classes of human respect. Not the least of these is the opportunity to be of altruistic service to mankind. Even a child at times feels a need to be useful.

In promoting a moratorium prematurely on prison experimentation, we actually would be denying prisoners a satisfaction of this psychic need. We have a moral responsibility to investigate in detail and to not prematurely foreclose on the question of whether prisoners can, under certain conditions, validly consent to experimentation.

It also requires that we do not prevent a researcher from experimenting on the basis of what you might call over-scrupulousness.

Mr. KASTENMEIER. On the point of depriving prisoners of making a societal contribution, in terms of a motivating factor, are there any definitive studies on that?

Do you know that it does, in fact, motivate a prisoner to participate in such experiments?

How certain are you that we might be depriving prisoners of something they consider needful; that is, to be of service to mankind?

Dr. DICKSON. I say, first, that is a personal view I have, as a philosophical moderate, however, I am not sure that view is necessarily correct. I believe the Commission, which will end its activities and submits its report in December of next year, will have thrashed this through a little more thoroughly than it has been thrashed in the past, and as asked to by the Congress. I look forward to hearing what they have to say about it, whether it will correct my personal view or not.

Now, as to specific studies and so forth supporting the comments I have made—I have had occasion to discuss this in the past, and I do know something about it, but I do not know about specific studies to this point. I would like to defer to some of the other people who have

come here today on this point. It is in their area of expertise. They may have the answer you would like to have.

Mr. KASTENMEIER. I would like to hear further, although, of course, we do need to move on to other things. I would hope that answers could be—and I know these are difficult questions—could be reasonably precise.

The questions should be put in the context of the fact that some prisoners, including the panel of last Monday, alluded to other inducements. The fact that the test setting is far preferable to that which they found themselves in, or that in some cases, presumably, the dollar a day or whatever the compensation was, was an inducement, quite apart from a sense of self-worth by virtue of participating in such experiments.

Those that did, the panel—and I grant this is not a scientific sampling or anything else—did suggest that, if one was in a prison setting, one might agree to participate in something of this sort; but if one was not in a prison setting, one would not be inclined to participate in such research. They had changed their minds about the desirability of participating as prisoners in such experiments.

If anyone would care to respond to motivation and perception of prisoners in medical research in the prison setting—Dr. Martin.

Dr. MARTIN. As I understand the argument here, the prisoners felt that the environment at the Addiction Research Center is seductive.

Mr. KASTENMEIER. Compared to that of the other prisons.

Dr. MARTIN. Yes; prisons from which they may have come.

I think this is a question that cannot be clearly decided. Certainly, the environment at Lexington would not be seductive to anyone in this room. The issue here that we have tried to cope with has been to make, insofar as possible, the rewards that they receive for participation in research of comparable magnitude to rewards they can achieve and have received in the Bureau of Prisons.

Both the meritorius compensation, which is the money they receive—and I think there are very few patients that would receive in 1 month over $50 for their participation—and the meritorious good time, which is the amount that their sentence is reduced by, fall within the amount specified by the Bureau of Prisons. Awards that we give are not different in kind or magnitude than they would receive in, say, Leavenworth or Atlanta.

I think another issue is—and this judgment, of course, is always made from a point of perspective—that most of the prisoners that are participating in our study frequently tell me of the environment not being seductive enough while they are with me that we do not give them larger rewards, and that we do not make their living conditions more attractive.

Mr. KASTENMEIER. I understand that position, Dr. Martin.

So long as we are conducting colloquy here, let me go back and ask if you are familiar with the testimony of several witnesses. Three of the four were ARC witnesses; one was not.

On Monday, several of them described their experience at Lexington, and I think referred to you and other doctors there by name.

One witness, Mr. Clay said:

> Sometimes thereafter I was requested to subject myself to an electrical shock experiment. During this experiment, I was twice strapped to a chair, a cubicle where electrodes and various wires were attached to my arms. The medical aide then stood behind me, out of my view, at various times caused electrical shocks to pass through my fingers and arms.
>
> At first the shocks were preceded by the sounding of a buzzer in my cubicle. At other times, the buzzer would sound, and I would be frightened but not shocked. After two such sessions, I was withdrawn from the experiment.

What purpose does this Pavlovian-type experiment have in terms of Mr. Clay?

Dr. MARTIN. The experiment he described was conducted by Dr. Jones. The experimental circumstance was one in which two rubber salinized electrodes were placed on either side of his hand. A moderate shock—one that would produce a tingling sensation—was administered. This was associated with a tone. The end point that was observed was the resistance across his hand, which is called the psychogalvanic skin response.

As you probably know, this is a measure of emotionality and, in a crude way, can be an indication of sweating or phenomena that occur in the skin that would be related to sweating. The reason these studies were conducted is to determine whether drugs of abuse would alter conditioned responses.

We have felt for many years at Lexington that one of the reasons patients relapse to drugs is that they develop a number of conditioned responses. We think that not only the abstinence syndrome can be conditioned, but drug-seeking behavior itself may be a conditioned behavior. These studies were conducted—I believe there were three drugs employed; one of these for morphine, the second was chlorpromazine, and the third was librium—to determine whether any of these drugs alter this conditioned response.

Mr. KASTENMEIER. It was not indicated by the witness last Monday, that this electrical shock was severe, but it was a frightening experience, one that he remembers very vividly.

I am just wondering, to what extent could he have expected that he was consenting in advance to this sort of experiment.

Dr. MARTIN. Before Dr. Jones will accept any patient for this type of experimentation, the patient is taken to the chamber and goes first through a mock run, second through a real run, to determine, indeed, whether this experience is disturbing to the patient and whether he wants to participate in it.

If Mr. Clay did participate in two of these experiments, it was after he had been given an opportunity of experiencing the limited experimental trial, and he could have withdrawn at any time during any part of this experiment without prejudice to him at all.

Mr. KASTENMEIER. Of course, it is not what is known as electrical shock therapy. Indeed, this committee visited Springfield, Mo., chief prison hospital in the Federal system, where the chief physician there told us they were so careful they had not, in many recent years, attempted shock therapy. Many years ago when they did, they would be careful not to do it in a prison setting.

The prisoner inmate, they took him down to the university medical center and had the shock therapy administered by a civilian. Then they were so cautious about not abusing a prisoner, even a mental prisoner, in such a setting.

So when he related this experiment, it reminded me of that. I wondered to what extent this was either necessary or whether he understood what was happening to him, or if he consented to it.

Dr. MARTIN. I think he did understand. We made every effort so that he would understand.

I think it would be important to differentiate the strength of stimuli here. I have had this experiment performed on me, and the strength of stimulus is such that it produces a mild tingling sensation in the palm.

Mr. KASTENMEIER. If you would care to respond to the general complaints that the other prisoners had; I think one of them, to sum it up, was a lack of human concern. "I know one thing for sure; no one at Lexington, Ky. has ever showed any proper concern for human beings."

Of course, that is subjective, and it may or may not be generally the case. But would Dr. Martin care to respond to either these general characterizations or specific characterizations of tests. We invite you to do so, either now or perhaps at a time when you have an opportunity to examine the testimony of those prisoners.

Dr. MARTIN. I would be pleased to respond to it at this time.

I think that the patients' perception of both our motives and our behavior sometimes may be related to their own problem. When patients come to the Addiction Research Center, they have a very high concern for both their mental and physical health. It could be documented, I think, that there are many patients whose physical health unequivocally has benefited by the intensive medical examination they received prior to participation in the study. And every effort—I could document this very readily—is made to correct any physical or psychiatric abnormalities that we would have any power over.

With regard to their participation in the study, these are research studies. Some of these have resulted in discomforting changes in the patient. These are, when we know they will occur, described to the patient prior to his participation. Some drugs we give them we know will produce undesirable subjective changes; these are described, to the best of our ability. The patient is given an opportunity of withdrawing from these studies at any time he wishes, and when the purpose of the study is accomplished, these undesirable changes are always terminated as rapidly as possible.

The undesirable changes that these patients will experience primarily have come from our studies of narcotic antagonists, which were investigated in the effort to find treatment modalities that would be helpful to addicts. Some of these narcotic antagonists produce what is called by the patients racing thoughts. In excessive doses, they may produce frankly disphoric and even hallucinogenic changes. These, as I said, we can terminate quite readily with substances known as narcotic antagonists. When we know that drugs did produce these changes, we terminate these experiments.

We have to know about these changes, because these same things will occur to the patient if he would accept and use the treatment modality. As a consequence of these efforts, we have developed drugs that have been devoid of this undesirable side effect.

Mr. KASTENMEIER. I have many other questions, but I am going to yield to my colleagues, because they have been very patient, and I am sure they will have questions as well. Then I will return with

other questions. First, I would like to yield to the gentleman from Illinois, Mr. Railsback.

Mr. RAILSBACK. Dr. Martin, have you had a chance to visit Leavenworth?

Dr. MARTIN. Yes, sir, I have.

Mr. RAILSBACK. Would you quarrel with a characterization of Leavenworth as a tank cell, which had double-deck bunks, with 6 to 8 individuals in a small area, say 12 by 15 feet. Do you quarrel with that characterization?

Dr. MARTIN. No.

Mr. RAILSBACK. Then do you suppose that part of the seduction that you testified about, part of the seduction would be to get away from that kind of an environment and perhaps go to some place where there is an individual cell with a shower?

Dr. MARTIN. I am sure this is the motive for many patients to come to the Addiction Research Center. I think the question of whether it is already seductive is a moot one. We probably——

Mr. RAILSBACK. If I can interrupt, I agree with you. After hearing you, and after reading the inmates' or the offenders' testimony, I think you are right. They are not overseduced when they get there. The seduction comes, I think, before. The seduction is what they think the promises are; in other words, what Lexington holds out for them. And when they get there, some of them are very disillusioned. I can understand why they are disillusioned.

Let me ask you this. What inducements, exactly what—Dr. Dickson, you can answer—what inducements are offered to get these people to volunteer? Exactly what inducements?

Dr. MARTIN. I will describe the recruiting procedure. We post a notice in the prison newspaper, or it is posted on the prison bulletin board. We have routinely gone to three prisons in the Federal system—Leavenworth, Atlanta, and Lewisburg. Patients then are given an opportunity of signing up for the Lexington program.

Mr. RAILSBACK. Do you have copies of some of those ads?

Dr. MARTIN. I could provide these to the committee.

Mr. RAILSBACK. I think we would like those for the record.

[The material referred to follows:]

INFORMATION RE PROGRAM OF ADDICTION RESEARCH CENTER

Requests for transfer to a special unit of the Addiction Research Center at Lexington, Kentucky, for participation in research studies involving administration of drugs of abuse are being accepted by the Chief of Classification and Parole. To be eligible for transfer you must be 25 years of age or older, in good health, have a history of narcotic addiction, and have at least 18 months of sentence to serve at the time of volunteering. Volunteers who are transferred to the Addiction Research Center for research study participation will receive pay (meritorious compensation) and meritorious good time. They will reside in a special research unit. Dental and medical treatment will be provided. The Addiction Research Center program does not include psychiatric treatment or drug abuse therapy programs. In addition to participating in drug studies, patients will have vocational assignments for which they will also receive pay (meritorious compensation). Participation in research studies will be limited to no more than a two-year period except in special study cases.

Staff members of the Addiction Research Center will be at the institution the last week of June for interviewing and explaining the program to inmates who volunteer.

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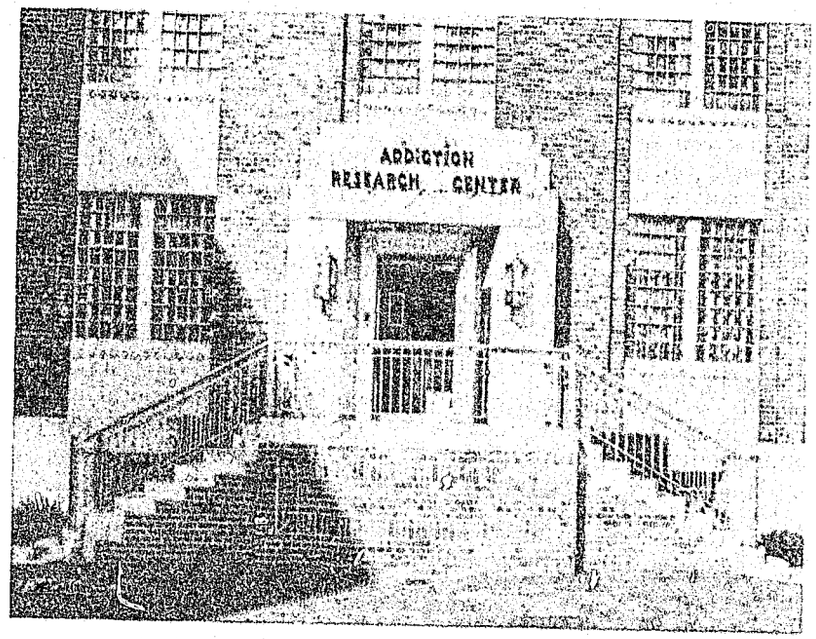
PATIENTS' HANDBOOK



NIDA, ADDICTION RESEARCH CENTER
LEXINGTON, KENTUCKY

ADMISSION ORIENTATION INFORMATION TO ALL INMATES ADMITTED TO THE NATIONAL INSTITUTE ON DRUG ABUSE, ADDICTION RESEARCH CENTER

Welcome to the National Institute on Drug Abuse, Addiction Research Center, Lexington, Kentucky.

As part of a research program in the area of drug addiction, the Addiction Research Center conducts studies in prisoner volunteers to assess the abuse potential of new drugs, to determine the mechanism of action of drugs, to investigate the causes of addiction and to investigate new treatments for addiction. Your purpose at the Addiction Research Center is to participate in these research studies and is not for treatment of your addiction problem. Before coming to the Addiction Research Center, it was explained to you that your participation in this program is voluntary. As a volunteer, you may 1) withdraw from the program at any time whereupon you will be transferred back to a Bureau of Prisons facility, 2) accept or reject participation in any study offered to you, or 3) withdraw from any study at any time. Any of these three actions on your part are without prejudice to you in any way. Through your cooperation and participation, the scientists hope to gain additional insights into problems of addiction and the addictive process.

Following admission and at intervals throughout your stay, you will be examined to determine if there are medical reasons why you should not participate in the research studies. These examinations include a medical history and physical examination and appropriate laboratory tests.

If you wish to participate in a study, you will be screened by the staff. If approved, the study will be explained to you and you will be told about the procedures to be used and the effects expected, and possible harmful effects of

the drugs or the procedures. This description will also be given to you to read and will be read to you. If you agree to participate, you must sign this statement in the presence of a witness. In addition, this informed consent statement will detail the meritorious compensation and meritorious good time awarded for your participation in the study. Before signing, you have the right to ask any questions concerning the study and to have satisfactory answers. In signing the consent form you certify that the study has been explained to you to your satisfaction and that you voluntarily agree to participate.

When you were first admitted to a Bureau of Prisons institution, you were advised in writing of your rights and your responsibilities as a federal prisoner as well as the acts prohibited in the institution and the type of disciplinary action which may be taken. These same rights, responsibilities, and regulations apply to you here at the Addiction Research Center. You are encouraged to ask any questions you may have concerning your participation in the research program.

After approximately two years at the Addiction Research Center or at approximately six months prior to your conditional release date or upon being granted parole, you will be transferred to a Bureau of Prisons facility to allow a drug-free period prior to discharge, as well as to prepare you for release. No mechanism for discharge exists at the Addiction Research Center.

Living Units

At the Center you will reside in an assigned private room on the EN unit. For drug studies, you will be housed in a private room on the ES-3 research ward. When you are on the research ward, your room on the EN unit will be locked until you return. Should you be involved in a chronic drug study, you will reside in a private room on the ES unit until completion of the study.

Your living unit is your home while here. The responsibility for the cleanliness of your room and the ward is yours. The staff will attempt to make your stay here as constructive and pleasant as possible. It is expected that inmates work with one another and the staff to maintain this atmosphere.

Work Assignment

You will be assigned a job within the Center where you will work when not participating in research studies. You will be compensated for your work with meritorious goodtime days and meritorious compensation. Some job assignments involve vocational training in printing, photography, library, plastic sign making, office work and sanitation.

Medical Care

Surgical, medical and dental services are available to you but there is no treatment program for drug addiction. Sick call is on Monday, Wednesday and Friday. Inmates who need medical or dental attention may make an appointment by contacting the Correctional Officer on EN-1. A doctor is always available for emergencies. A caseworker is available for social problems and parole planning.

Recreational Program

Recreational activities include handball, softball, boccie, volley ball, weight lifting, pool, table tennis and movies. In addition basketball and bowling facilities are available at the Federal Correctional Institution during the winter months. Tournaments are conducted in most events semiannually.

Religious Worship

Religious services are conducted by chaplins at the Federal Correctional Institution. If you wish to attend these services, you will be escorted to

and from the chapel and will be separated from residents of the Federal Correctional Institution. Protestant services are conducted Sunday morning and Catholic services Saturday evening.

Food Service

All food is provided by the Federal Correctional Institution and served in a dining room within the Addiction Research Center. Dining hours are 7:00 - 7:15 A.M.; 11:40 - 12:00 Noon; and 5:00 - 5:30 P.M., Monday through Friday. Brunch at 11:00 - 11:30 A.M. replaces the breakfast and lunch meals on Saturdays, Sundays and holidays with coffee, juice and sweet rolls served at the regular breakfast time.

Commissary privileges

Items may be purchased from the Commissary Village Store operated by the Bureau of Prisons and located in the Federal Correctional Institution. You will be escorted to the Village Store on Tuesday and Thursday afternoons at 2:30 P.M. A variety of tobacco, fruit, toiletries, candies, cookies, instant coffee, slippers, watches, radios, etc. are available for purchase. A current price list of all items is available for the asking. Reasonable amounts of items may be kept in your living quarters. You are permitted to spend $45.00 per month at the Village Commissary. Special purpose items, such as watches, radios, television sets and hobbycraft supplies are not deducted from monthly allowance.

Clothing and Laundry

Institutional clothing is furnished; however, you may wear your own shirt, sweater, shoes, socks and under clothing but must wear institution trousers. Laundry service is furnished by the Federal Correctional Institution; however,

articles of personal clothing are completely your own responsibility. A washer and dryer is available for care of personal clothing in the living quarters.

Mail

Incoming and outgoing mail including packages are received at the mail room of the Federal Correctional Institution and after inspection for money or securities are transferred to the staff of the Addiction Research Center for final screening and distribution. Money and securities will be removed from letters and scheduled to your account by the mail supervisor of the Federal Correctional Institution for deposit with the Federal Correctional Institution Agent Cashier. A receipt for the amount of money received will be issued to you.

Money

Your account is maintained in the Commissary Village Store of the Federal Correctional Institution. If your family or approved friends desire to send you funds by mail, urge them to use Postal Money Orders so it may be applied to your account immediately. Checks, personal or other types, usually require thirty (30) days for clearance.

Visitors

Regular supervised visits will be allowed with approved visitors in the ES-1 visiting room. Visiting hours are 9:00 A.M. - 3:30 P.M., seven days per week. Each approved visitor may visit once a month and permission may be granted for up to three consecutive days depending on the distance they have traveled. There will be no visitation between research inmates and residents in the Federal Correctional Institution.

Shakedown and Contraband

It is the policy of the Bureau of Prisons and this Center that any inmate and his property can be searched at any time by a staff member. These procedures are not to harrass you, but are for the necessary care, custody and control of inmates, and are only conducted when circumstances indicate they are necessary and appropriate.

Definition of Contraband in this Center

Contraband is anything that is not purchased in the Village Store, or approved or issued by the institution or a staff member.

Haircuts

It is the policy of the Bureau of Prisons and this center that individual preferences as to style of haircut may be permitted within reasonable limits; mustaches and sideburns are permitted. Beards are prohibited.

Telephone Calls

One collect long-distance telephone call to anyone on your approved visiting list is permitted monthly. Incoming telephone calls are not permitted. Additional calls may be approved in cases of emergency.

Compensation

Meritorious compensation in the form of money and meritorious days is made monthly to you for your participation in research study activities and for your work assignment. Following transfer from the Addiction Research Center, inmates with a satisfactory record are eligible for consideration by the Awards Committee to receive a bonus of meritorious goodtime and $50.00 compensation

for each year of participation in the programs of the Addiction Research Center with a maximum award of $100.00.

RIGHTS AND RESPONSIBILITIES

RIGHT

1. You have the right to expect that as a human being, you will be treated respectfully, impartially, and fairly by all personnel.

RESPONSIBILITY

1. You have the responsibility to treat others, both employees and fellow inmates, in the same manner.

RIGHT

2. You have the right to be informed of the rules, procedures, and schedules concerning the operation of the institution.

RESPONSIBILITY

2. You have the responsibility to know and abide by them.

RIGHT

3. You have the right to freedom of religious affiliation and voluntary religious worship.

RESPONSIBILITY

3. You have the responsibility to recognize and respect the rights of others in this regard.

RIGHT

4. You have the right to health care which includes nutritious meals, proper bedding and clothing, laundry schedule for the cleanliness of same, an opportunity to shower regularly, proper ventilation for warmth and fresh air, a regular exercise period, toiletries, medical and dental treatment.

RESPONSIBILITY

4. It is your responsibility not to waste food, to follow the laundry and shower schedule, to maintain neat and clean living quarters and to seek medical and dental care as you may need it.

RIGHT

5. You have the right to visit and correspond with your family and friends; to correspond with the members of the news media in keeping with the facility rules and schedules.

RESPONSIBILITY

5. It is your responsibility to conduct yourself properly during visits, not accept or pass contraband and not violate the statutes through correspondence.

RIGHT

6. You have the right to unrestricted and confidential access to the courts

by correspondence (on matters such as the legality of your conviction, civil matters, pending criminal cases and to the conditions of your imprisonment.)

RESPONSIBILITY

6. You have the responsibility to present honestly and fairly, your petitions, questions and problems to the court.

RIGHT

7. You have the right to legal counsel from an attorney of your choice by interviews and correspondence.

RESPONSIBILITY

7. It is your responsibility to use the services of an attorney honestly and fairly.

RIGHT

8. You have the right to participate in the use of law reference library resources to assist you in resolving legal problems. You also have the right to receive help when it is available through a legal assistance program.

RESPONSIBILITY

8. It is your responsibility to use these resources in keeping with the procedures and schedule prescribed and to respect the rights of other inmates to the use of this material.

RIGHT

9. You have the right to a wide range of reading material for your own enjoyment. These materials may include magazines and newspapers sent from the publishers.

RESPONSIBILITY

9. It is your responsibility to seek and utilize such materials for your personal benefit, without depriving others of their equal right to the use of this matter.

RIGHT

10. You have the right to participate in education and vocational training as far as resources are available, and in keeping with your interests, needs and abilities.

RESPONSIBILITY

10. You have the responsibility to take advantage of activities which may help you live a successful and law abiding life within the institution and the community. You will be expected to abide by the regulations governing the use of such activities.

PROHIBITED ACTS

IN

FEDERAL PENAL AND CORRECTIONAL INSTITUTIONS

001	Killing
002	Assaulting any person
003	Fighting with another person
004	Threatening another with bodily harm, or with any offense against his person or his property
005	Extortion, blackmail, protection: demanding or receiving money or any thing of value in return for protection against others, to avoid bodily harm, or under threat of informing
051	Engaging in sexual acts with others
052	Making sexual proposals or threats to another
053	Indecent exposure
101	Escape
102	Attempting or planning escape
103	Wearing a disguise or mask
151	Setting a fire
152	Destroying, altering, or damaging government property, or the property of another person
153	Stealing (theft)
154	Tampering with or blocking any locking device
155	Adulteration of any food or drink
201	Possession or introduction of an explosive or any ammunition
202	Possession or introduction of a gun, firearm, weapon, sharpened instrument, knife, or unauthorized tool
203	Possession, introduction, or use of any narcotics, or narcotic paraphernalia, drugs or intoxicants not prescribed for the individual by the medical staff

CONTINUED

1 OF 7

PROHIBITED ACTS (Continued)

204 Misuse of authorized medication

205 Possession of money or currency, unless specifically authorized

206 Possession of property belonging to another person

207 Loaning of property or any thing of value for profit or increased return

208 Possession of any thing not authorized for retention or receipt by the inmate, and not issued to him through regular institution channels

209 Possessing any officer's or staff clothing

210 Possessing unauthorized clothing

211 Mutilating or altering clothing issued by the government

251 Rioting

252 Encouraging others to riot

253 Engaging in, or encouraging, a group demonstration

254 Refusing to work

255 Encouraging others to refuse to work or participation in work stoppage

256 Refusing to obey an order of any staff member

301 Unexcused absence from work, or any assignment

302 Malingering, feigning an illness

303 Failing to perform work as instructed by a supervisor

304 Insolence towards a staff member

305 Lying or providing a false statement to a staff member

306 Conduct which disrupts or interferes with the security or orderly running of the institution

351 Counterfeiting, forging, or unauthorized reproduction of any document, article or official paper

401 Participating in an unauthorized meeting or gathering

402 Being in an unauthorized area

PROHIBITED ACTS (Continued)

451 Failure to follow safety or sanitation regulations

452 Using any equipment or machinery which is not specifically authorized

453 Using any equipment or machinery contrary to instructions or posted safety standards

501 Failing to stand count

502 Interfering with the taking of count

551 Making intoxicants

552 Being intoxicated

553 Smoking where prohibited

554 Using abusive or obscene language

601 Gambling

602 Preparing or conducting a gambling pool

603 Possession of gambling paraphernalia

651 Being unsanitary or untidy: failing to keep one's person and one's quarters in accordance with posted standards

652 Tatooing or self-mutilation

701 Unauthorized use of mail or telephone

702 Unauthorized contacts with the public

703 Correspondence or conduct with a visitor in violation of posted regulations

751 Giving or offering any official or staff member a bribe, or any thing of value

752 Giving money or any thing of value to, or accepting money or any thing of value from, another inmate, a member of his family, or his friend

801 Attempting to commit any of the above offenses, aiding another person to commit any of the above offenses, and making plans to commit any of the above offenses shall be considered the same as a commission of the offense itself

PROHIBITED ACTS (Continued)

Actions which may be taken as a result of violation of the rules of the institution may include, reprimand, restrictions of various kinds, segregation, the recommendation of withholding or forfeiture of good time or the transfer to a Bureau of Prisons facility. The disciplinary action taken will be individualized in keeping with such factors as the offender's past history, institutional adjustment, motivation and attitude.

(A) DERECHOS Y RESPONSABILIDADES

DERECHOS

1. Tiene derecho como ser humano a esperar que sea tratado respetuosa, imparcial y justamente por todo el personal.

RESPONSABILIDADES

1. Tiene la responsabilidad de tratar a los demas, tanto a empleados como a reclusos de la misma manera.

DERECHOS

2. Tiene derecho a ser informado de los reglamentos, procedimientos y horarios concernientes al funcionamiento de la institucion.

RESPONSABILIDADES

2. Tiene la responsabilidad de conocerlos y respeterlos.

DERECHOS

3. Tiene derecho a la libertad de afiliacion religiosa y practica religiosa voluntaria.

RESPONSIBILIDADES

3. Tiene la responsabilidad de reconocer y respetar los derechos de los demas en esta materia.

DERECHOS Y RESPONSABILIDADES (Continua)

DERECHOS

4. Tiene derecho a la atencion de la salud, que incluye comidas nutritivas, cama apropiada y vestido, y un horario de lavanderia para mantenerlo limpio; a tomar banos regularmente; a la ventilacion apropida para tener temperatura adecuada y aire fresco; a un perido regular de ejercicios; tener acceso a articulos de aseo y a tratamiento medico y dental.

RESPONSIBILIDADES

4. Tiene la responsabilidad de no desperdiciar la comida respetar los horarios de lavanderia y banos, mantener ordenado y limpia su celda y solicitar atencion medica y dental en la medida que sea necesario.

DERECHOS

5. Tiene derecho a recibir visitas y a sostener correspondencia con miembros de su familia y amigos y a escribirse con miembros de los medios de difusion, segun los reglamentos y horarios de la institucion.

RESPONSIBILIDADES

5. Tiene la responsabilidad de conducirse apropiadamente durante las visitas, no aceptar o hacer pasar contrabando y no violar los reglamentos a traves de la correspondencia.

DERECHOS

6. Tiene derecho a tener acceso confidencial y sin restriciones a los tribunales de justicia, por correspondencia (sobre asuntos tales como la legalidad de su condena, cuestiones civiles, casos criminales pendientes y condiciones de su reclusion).

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DERECHOS Y RESPONSABILIDADES (Continua)

RESPONSABILIDADES

6. Tiene la responsabilidad de presentar honesta y justamente sus peticiones, preguntas y problemas ante los tribunales.

DERECHOS

7. Tiene derecho a recibir asesoramiento legal de parge de un abogado de su eleccion, por medio de entrevistas y de correspondencia.

RESPONSABILIDADES

7. Tiene la responsabilidad de utilizar los servicios de un abogado de manera honesta y justa.

DERECHOS

8. Tiene derecho a participar en el uso de los materiales de referencia de la biblioteca juridica para ayudar en la solucion de sus problemas legales. Tiene asimismo elderecho de recibir asistencia de parte de un programa de ayuda legal, cuando esta facilidad se halle disponible.

RESPONSIBILIDADES

8. Tiene la responsabilidad de utilizar estos recursos conforme a los procedimientos y horarios establecidos, y a respetar los derechos de los demas reclusos a la utilizacion de los materiales.

DERECHOS

9. Tiene derecho a una amplia gama de material de lectura para propositos educaciona les y para su prpio placer. En este material estan incluidos las revistas y diarios enviados por sus editores.

RESPONSABILIDADES

9. Tiene la responsabilidad de buscar y utilizar dichos materiales para su beneficio personal, sin privar a los demas del ejercicio de iguales derechos respecto de estos materiales.

DERECHOS Y RESPONSABILIDADES (Continua)

DERECHOS

10. Tiene derecho a participar en programas educativos y vocacionales, en la medida que estos se hallen disponibles en nuestra institucion.

RESPONSIBILIDADES

10. Tiene la responsabilidad de participar en las actividades que puendan ayudarle a vivir una vida provechosa y conforme a la ley dentro de la institucion y en la comunidad. Se espera que usted cumpla con los reglamentos que regen tales actividades.

(B) ACTOS PROHIBIDOS EN LAS INSTITUCIONES PENALES Y CORRECCIONALES

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001 Matar

002 Asaltar a otra persona

003 Pelear con otra persona

004 Amenazar a otra a causarle algun dana corporal u ofenderle en su persona o en su propiedad

005 Extorsion, chantaje, proteccion (exigir o recibir dinero o cualquier otra cosa de valor en pago de proteccion contra otros, para evitar dano corporal o bajo la amenaza de informar a las autoridades)

051 Realizar ascots sexuales conotros

052 Proponer o amenazar a otra sexualmente

053 Exponerse indecentemente

101 Fugarse

102 Intentar o planear una fugo

103 Usar mascara o disfraz

151 Incendiar

152 Destruir, alterar o danar cosas de propiedad del gobierno o de propiedad de otras personas

(B) ACTOS PROHIBIDOS EN LAS INSTITUCIONES PENALES Y CORRECCIONALES (Continua)

153 Robar

154 Manosear u obstruir cerraduras

155 Adulteracion de cualquier comida o bebida

201 Posesion o introduccion a la institucion de cualquier explosivo o proyectil

202 Posesion o introduccion de un arma de guego, armas diversas, instrumento cortante, cuchillo o herramienta no autorizada

203 Posesion, introduccion o uso de cualquier narcotico, elementos destinados a su uso, frogas, o intoxicantes no recetados individualmente por el personal medico de la institucion

204 Uso inapropiado de medicamentos autorizados

205 Posesion de dinero, a no ser que sea especificamente autorizado

206 Posesion de articulos que pertence a otra persona

207 Dar en pretamo articulos en cambio de algo de valor, para lucro o valor agregado

208 Posesion de cualquier cosa no autorizada para ser retenida o recibida por un recluso, que no le haya sido entregado por los medios regulares previstos por la institucion

209 Posesion de cualquier vestimenta de oficiales o personal de la institucion

210 Posesion de ropas no autorizadas

211 Cortar o alterar vestimentas entregadas por el gobierno

251 Sedicion

252 Estimular a otros a la sedicion

253 Participar en una demostracion en grupo o estimularla

254 Negarse a trabajar

255 Estimular a otros a negarse a trabajar o participar en paros

256 Negarse a cumplir una orden dada por cualquier miembro del personal de la institucion

(B) ACTOS PROHIBIDOS EN LAS INSTITUCIONES PENALES Y CORRECCIONALES (Continua)

301 Ausencia injustificada del trabaja de o cualquier tarea

302 Fingir estar enfermo

303 No cumplir con el trabajo conforme a las instrucciones de un supervisor

304 Insolencia hacia un miembro del personal de la institucion

305 Mentir o emitir una declaracion falsa a un miembro del personal

306 Adoptar una conducta que pertube o interfiera con la seguridad y functionamiento ordenado de la institucion

351 Falsificacion o reporduccion no autorizada de cualquier documento, articulo de identificacion, dinero, o documento oficial

401 Participar en una reunion o encuentro no autorizado

402 Estar en un lugar no autorizado

451 No cumplir con los reglamentos de seguridad o saneamiento

452 Utilizar cualquier equipo o maquinaria cuyo uso no este especificamente autorizado

453 Utilizar cualquier equipo o maquinaria en contra de las instrucciones o normas de seguridad establecidas

501 Impedir que sea contado

502 Interferir con el conteo de los reclusos

551 Fabricar intoxicantes

552 Estar intoxicado

553 Fumar donde este prohibido hacerlo

554 Emplear lenguaje abusivo y obsceno

601 Jugar por dinero

502 Preparar o dirigir una polla por dinero

603 Posesion de elementos destinados al juego por dinero

(B) ACTOS PROHIBIDOS EN LAS INSTITUCIONES PENALES Y CORRECCIONALES (Continua)

651	Descuidar el aseo y el orden: tanto personalmente como en su habitacion, en disconformidad con los reglamentos establicidos
652	Tatuaje o automutilacion
701	Uso no autorizado del correo o del telefono
702	Contactos no autorizados con el publico
703	Correspondencia o comportamiento con algun visitante en violacion de los reglamentos establecidos
751	Dar u ofrecer a algun oficial o miembro del personal de la institucion algun soborno u objeto de valor
752	Dar dinero o cualquier cosa de valor, o aceptar dinero caulquier cosa de valor de algun recluso, miembro de su familia o amigo
801	Intentar cometer cualquiera de las ofensas antes mencionadas, ayudar a cualquier persona a cometerlas o hacer planes para cometerlas sera considerado tan grave como cometer la ofensa

Medidas disciplinarias, como resultado de la violacion de las reglas de esta institucion, incluyen: reprimendas, varias clases de restricciones, recomendacion de la retencion o perdida de buen tiempo dia. Y translado a una institucion del 'Bereau of Prissons'. La accion disciplinaria sera administrada en una forma individual tomando en consideracion, la conducta de la personal en el pasado, su adaptacion a la institucion y su actitud y deseo de superacion.

Mr. RAILSBACK. Do you have any with you now?

Dr. MARTIN. No; but I can have these forwarded to you.

When patients do volunteer, their jackets are pulled, and myself or several of my staff members will visit the prison and screen each jacket. The screening is done for a variety of purposes; for health considerations, psychiatric considerations, and finally to determine if the patient would be eligible for participation. Dr. Dickson has already spoken to some of these criteria.

At this time, following the screening of the patient's administrative jacket, we then screen his medical jacket. If a patient is found to be acceptable by our criteria, they are further screened by the classification committee of the Bureau of Prisons.

Mr. RAILSBACK. Who sits on that committee?

Dr. MARTIN. It includes social workers, classification officers, and a representative of the Addiction Research Center. Prior to this, we call all of the patients together that are eligible and have indicated an interest in coming to the Addiction Research Center. We describe our program to them as accurately as we possibly can because we wish to avoid patients that come to us and will subsequently be disillusioned or have expectations that cannot be realized.

Mr. RAILSBACK. How is that done? Under what kind of a format?

Dr. MARTIN. We bring them into a room and we talk to them.

Mr. RAILSBACK. Do you do it from a prepared text?

Dr. MARTIN. No. We generally throw it open to questioning. There are a number of points we routinely make. We tell the patient this will not be a therapeutic setting, and we try to describe exactly the types of research they will participate in. We explain the institutional rules. We further explain the nature of the institution. It is a rather small institution. The patients have a relatively confined area. Many patients find this less preferable than they will find the openness of Leavenworth, of Atlanta, which is a much more active community than the Addiction Research Center is.

Now, this determines the patient's eligibility for participation.

Mr. RAILSBACK. May I just add—because I am sure you do not want to mislead—it is true that Leavenworth, for instance, is much more open, perhaps as far as recreation. But as far as the cell blocks, at least when I was there, tremendously overcrowded. This description by that inmate, as far as I am concerned, was right on the point, and you agreed with that.

Dr. MARTIN. There is another aspect.

Mr. RAILSBACK. Six people living in one cell.

Dr. MARTIN. I am not questioning the point you are making at all. You are quite right. But it is a much looser social community, and patients can have many different types of friends and social interactions, much more so than they can——

Mr. RAILSBACK. It is so loose that the guards, because of their number, are afraid to go into the prison blocks after a certain hour at night.

Dr. MARTIN. When the patient comes to the Addiction Research Center, he is given a book describing the program and our regulations. He then is given an intensive physical examination, as well as a psychiatric examination. If we feel he is still eligible for general partici-

pation or for limited participation, he is told this. Many of the experiments we conduct at the Addiction Research Center are nothing but pencil and paper tests. They do not involve drugs at all.

When we initiate an experiment, we let it be known, first of all, that an experiment is going to take place. The first interactions of the patients are with our aides. They tell them, insofar as they can, the general nature of the experiment. If the patient exhibits an interest in the experiment, he is then called up for a briefing by the investigator that is going to conduct the experiment. They are generally briefed in a group, and then there is an individual briefing.

Mr. RAILSBACK. Are they told the effect of the drug that will be administered to them? Because one of the inmates said they were not told what the aftereffects would be. Are they told exactly what the potential effects could be?

Dr. MARTIN. They are told insofar as we know them. Many of the drugs we studied have not been completely investigated. I can give you one example, and I think this may have provided one of the bases for one of the bits of testimony you received. We studied some year and a half ago a drug called fenfluramine, which is an antiobesity appetite suppressant. This drug does not have amphetamine-like characteristics. It was thought that it would probably be a particularly safe replacement for amphetamines for curtailing appetite. This drug, when administered in a few patients, produced a psychotic reaction. This had been described previously in South African literature but had never been confirmed under controlled conditions. I do not think—and I could provide the committee with a copy of our informed consent which describes the actions of the drug as best we know them—we told the patient that it would produce this effect, because we probably had reservations that it might not. But they are told.

Mr. RAILSBACK. But did you think that it might?

Dr. MARTIN. I would have to go back to the study plan and to Dr. Griffith, who conducted the studies, to get an answer to that question.

Mr. RAILSBACK. What about after somebody is released from your institution? What kind of a followup or aftercare do you have, whether they go back to society or back to another prison?

Dr. MARTIN. The followup is that all patients that participate in studies are discharged from the Addiction Research Center at least 6 months before they are discharged from the Bureau of Prisons. During this time, the prisons have an ample opportunity to observe them. The Bureau of Prisons is currently conducting a followup of the patients, and I have received some rather current information that Mr. Carlson will present in more detail when he testifies, indicating that the recidivism, or relapse, rate of addiction research prisoners is significantly lower than any of the other addict patients that are discharged from the Bureau of Prisons.

We are certain at the time that they leave the Addiction Research Center that they do not have any medical disability that is related, or psychiatric disability that is related, to any drug they received.

Mr. RAILSBACK. Thank you.

Dr. Dickson, what is the difference between the pharmaceutical private programs and the Government programs?

I do not think I ever did get all of the inducements. The inducements are what, $5 a week for these people? I asked you to delineate those.

Dr. MARTIN. Essentially, the inducements are 1 day of meritorious good time for every day of experimentation, and I think our going rate of pay is $5.

Mr. RAILSBACK. Five dollars for what?

Dr. MARTIN. Per unit experiment. It would generally be per week. If a patient is in an experiment, he generally will be called once a week to participate, and for this participation he will receive $5 and 1 day of good time.

Mr. RAILSBACK. If he participates in an experiment which is a unit that requires a certain period of time to evaluate his progress, does he get $5 for each of those times, or just $5 total?

Dr. MARTIN. He will get $5 for each participation.

Mr. RAILSBACK. Not for the followup supervision?

Dr. MARTIN. No; once the experiment is completed, he will receive no further remuneration. As an example, let us assume he is in a study that will last for 8 weeks. He will receive $5 per week and 1 day of good time for each week of participation. It is rare that a patient receives over $50 in 1 month's time. I would think that our average rate of meritorious compensation would probably be somewhere between $30 and $35 a month.

Mr. RAILSBACK. I have used up my time, but I hope somebody will pursue the difference in what the private pharmaceuticals pay and what our Government pays, and whether there are different inducements.

Mr. KASTENMEIER. Dr. Crout, did you wish to respond to that?

Dr. CROUT. I think that is an important question.

First, I would say that we do not have in the Food and Drug Administration precise data on that issue. There are no Federal standards for the levels of inducements in particular programs like this——

Mr. RAILSBACK. Why not?

Dr. CROUT. Any more than there are Federal standards for the inducements of any patient into any research.

Maybe I should comment a little more broadly at this point. There is a point I wanted to get to. It goes back to Mr. Kastenmeier's original question, which I think is at the heart of the matter; namely, if a prison is an inherently coercive environment, as testified, how can ethical research ever be done there?

I think that is a fundamental question. However, a prison is not the only inherently coercive environment. From our point of view at the Food and Drug Administration, essentially all research on drugs is done in, to some extent, a coercive environment from the standpoint of the subject. Let me elaborate on that a little.

Drug studies that are done outside of prisons are done in student populations sometimes, and sometimes on the employees of the drug firm making the drug. This is a common situation in Europe, where they do not use prison populations.

Mr. RAILBACK. Is that for more money?

Dr. CROUT. I think you can understand the inherently coercive possibilities of a student doing drug testing for his professor or of an

employee of a drug firm doing it for his firm. The details of exactly what happens in each of these individual arrangements is not known to us at the Food and Drug Administration. That is part of a manufacturer's responsibility to conduct his affairs ethically.

We have never—nor do I know any country that has ever—attempted to get into the details of this and put out by regulations the ethical standards for all those situations.

We are also seeing right now a growing number of private commercial drug testing laboratories that are recruiting people for the testing of drugs. And by and large those people are, as you might suspect, unemployed. They include housewives. I think you can see again that, depending on how much money is offered, improper inducements can occur.

Mr. RAILSBACK. But there is a difference in money?

Dr. CROUT. There may well be a difference in money.

If you have cancer, you have a sudden, sharp inducement to say yes to some drug testing for experimental cancer drugs, which may turn out to do you more harm than good. That can be elaborated on for any other disease.

Mr. KASTENMEIER. That is really phase II.

Dr. CROUT. Yes. But the point is that all human research on drugs, when you think about it, comes out of, in my opinion, more or less of a coercive environment. So that general problem cannot be solved by getting rid of prison research. You simply must address it in a different arena.

I think that is why we are not concerned——

Mr. RAILSBACK. You are not equating paying housewives or other people that are not confined with prisoners, are you?

Dr. CROUT. Let me give you a personal example.

Mr. RAILSBACK. I frankly do not buy that. I would like to see the difference in figures, the remuneration. I would like to see the difference in costs to pharmaceutical suppliers.

Dr. CROUT. I had been in clinical investigation before I came to Food and Drug Administration 4 years ago. I was in the hypertension field. I had a technician in my laboratory who, for a period of time, went to a neighboring laboratory down the hall to a research worker in the field of gastrointestinal diseases.

He would spend all afternoon there, have a tube passed down into his stomach, and samples were drawn from his stomach. This was an uncomfortable but not dangerous procedure. He was paid $125 for this.

I submit that for my technician to be able to take a half a day off from the lab and make $125 was very seductive. And I concede that helped his income a lot, and he did it.

The only point being, it is awfully hard to know what an undue inducement is until you know the exact study and the exact circumstance.

Mr. KASTENMEIER. Before I yield to the gentleman from New York—both the gentlemen from New York have been waiting patiently—because Dr. Crout has raised that question, and I do not want to get into an overly sophisticated analysis of motivation here—one can just go on and on interminably.

But I do agree with the inference drawn by the gentleman from Illinois, that there is a difference between the free person's strict economic motivation, or even for other reasons, and a prisoner. One of the reasons we are convened here is because there is some form of Nuremberg principle, in terms of prisoner experimentation. People are not all of the same character in terms of equality of their disadvantages.

And, indeed, we can conceive of even more disadvantaged groups than prisoners—those in Nazi Germany who were subject to medical experimentation during the war years, for example.

But I can conceive of no other more disadvantaged group on the American scene currently than the American prisoner. There are other groups which you pointed out, and perhaps even the armed services are another, in which coercion is not absent.

But at this point, I yield to the gentleman from New York, Mr. Badillo.

Mr. BADILLO. Dr. Dickson, I have a limited amount of time, and there is an important debate on the CIA going on on the floor, in which I would like to participate. So let me come through so you understand my position.

I do not consider that housewife in the same coercive position as a prisoner, because money is not the same kind of inducement. This committee has jurisdiction over prisoners, who are wards of the State, and with the question of consent as much a different kind of question than a housewife or student.

In addition to that, we have established that abuses of prisoner populations have occurred, and you so testified, in 19 prisons.

Because of that, there are many of us who support H.R. 3603, because we think that this kind of research should be stopped, in view of the previous experience.

Now you come before us and you say you do not support H.R. 3603, but then you come with proposed regulations which seek to meet the problem. I want to tell you why I think these regulations are pure hyprocrisy.

On 46–404, you say the review committee, the Organizational Review Committee is going to determine that there will be no inducements to participation by prisoners as subjects in the activity, no undue inducements, taking into account such factors as whether the earnings, living conditions, medical care, quality of food, and amenities offered to participants would be better than those generally available.

Now, we know they already are better. We know that the ones in Lexington, Ky. are better than Leavenworth. So if you accept these regulations, you will immediately be in violation of them.

How can you expect that these regulations be considered invalid when, in fact, the testimony before this committee indicates that these conditions already exist?

Dr. CHALKLEY. There is no question that these conditions already exist. The anticipation of the Department in putting forth these proposed rules as indicated elsewhere, was that we would be in a position to certify prisons as places in which medical research could be conducted.

Mr. BADILLO. But you know the differences exist already.

Dr. CHALKLEY. We would have to initiate set standards that would undoubtedly bring a substantial halt to the great majority of prison research going on in the country. The original criteria that are listed there were derived principally from a publication by Dr. John Arnold, who has tesified in this committee before.

Mr. BADILLO. I do not disagree with the criteria. I do not think you have any intention of adjusting Federal prisons throughout the country to comply with them, to insure the conditions are equal, because it would cost—I have not seen any budgetary requests being made before this committee to provide the funds necessary to improve, to make the living conditions so comparative in the different prisons that there would not be an undue inducement.

Dr. CHALKLEY. I admit you would probably have to accept initially, essentially low conditions. I admit this is one of the principal objections that was raised against this particular proposal, that this would put the Department of Health, Education, and Welfare in a position in which it would be exercising a lever to raise the living standards in prison.

Mr. BADILLO. I am saying many of us do not consider this a serious proposal, because there is no budgetary amount attached to it. We know that in government nothing gets done unless money comes through. Words do not mean anything unless you are going to back them up with testifying before a committee, asking for additional funds to have these conditions be made comparable throughout the system.

Nothing has been brought forward to indicate that. For that reason, we do not consider that this is a serious proposal.

Let me go on to the other point, the question of the consent committee.

The consent committee is developed by the applicant; the applicant who wants to have the experiment, according to your own regulations, decides on a consent committee. Then the Secretary reviews the applicant's proposal for a consent committee, which may take into account—it does not have to, but it may take into account—the possibility of a prisoner being on it.

If you are really concerned about the consent committee, why do you not have the prisoners select a consent committee, regardless of who the applicant is?

Let each of the prisoners set up their own consent committee. Then, when some applicant comes, whether he comes in an experiment to go to the Moon or go under the ocean, then let the prisoners review it.

Why not have the applicant select the consent committee?

Dr. CHALKLEY. Some of Dr. Arnold's publications, which may or may not have been entered into the testimony here, point out the problem you face when you leave the matter entirely to the prisoners. There is a hierarchy within the prison; there is opportunism in prison relationships.

Mr. BADILLO. You think there is no opportunism on the part of the applicant?

Dr. CHALKLEY. There is opportunism on the part of the applicant. That is clearly subject to review by the Secretary, and the system exists and has existed for years to carry out that review.

Mr. BADILLO. How can you misuse words?

How can you say something is consent when the person who is involved does not have anything to do with establishing the committee which is going to establish consent?

Dr. CHALKLEY. The requirement was that the committee consider including persons who represented the interest of prisoners.

Mr. BADILLO. That is not the requirement, sir. I know how to read. It says it may include; that is not a requirement. May is not must.

Dr. CHALKLEY. May is not must.

Mr. BADILLO. It is not a requirement. It is not true, what you said before.

Dr. CHALKLEY. This is a matter of exercising judgment. A great deal of the research that has gone on, particularly some of that supported by ADAMHA, is directly related to the prisoner, not substantially injurious. And I am speaking here, of course——

Mr. BADILLO. In whose opinion?

How many prisons have you probed?

Dr. CHALKLEY. We have had two extensive petitions in connection with the existence of proposed rules from prisoners to continue the research. We have only one letter of objection. It was from a lawyer in San Quentin for forgery.

Mr. BADILLO. How many prisoners volunteered for these experiments?

Dr. CHALKLEY. I presume, on the basis of past experience, the same percentage that there are in the State prisons.

Mr. BADILLO. Which is what?

Dr. CHALKLEY. It varies, obviously, in the prison system, all the way from approximately 80 percent in the State of New York down to a small fraction in Maine.

Mr. BADILLO. How many of them are poor?

Dr. CHALKLEY. I would say the great majority.

Mr. BADILLO. What is the average level of education?

Dr. CHALKLEY. I had a statistic on that. The average level of education of the prisoner is on the order of about 6 to 7 years.

Mr. BADILLO. What is the level of education of the consent committees that are going to be established by the applicant?

Why do you not have something in there about the ethnic composition of the consent committee?

Dr. CHALKLEY. Again, the problem here is that you are writing regulations at this point that are to be applied broadly across all States, a tremendous mixture of ethnic compositions and also a tremendous variety of prison systems.

Mr. BADILLO. But it would depend on the population of the prison. The committee could reflect the ethnic composition and the educational level and the income level.

Dr. CHALKLEY. The problem is the same one we face with regard to the establishment of these commissions in hospitals. You are dealing with one, admittedly, at best, an average level of sophistication. With your subjects, you have less than the average level of sophistication.

Mr. BADILLO. Is that not how you measure consent?

It is very easy for the more sophisticated person to secure a consent from an unsophisticated one, especially with this kind of a composition.

In other words, the question is, under this coercive atmosphere, how do you establish that there is, in fact, consent?

All I am saying is that a lot of us just do not think this proposal of yours really gives the prisoner a chance. You are putting him in the hands of a committee, a consent committee established by the applicant, and you really do not give him anything at all. You do not give him, in fact, one prisoner on the consent committee. All you say is he may have it.

Dr. CHALKLEY. It should be someone who is representative of the prisoner's interests.

Mr. BADILLO. Do you have any proposals about how a person may withdraw once he is in the thing?

Dr. CHALKLEY. That is part of the basic regulations which are not part of these amendments. The subject must be informed that he is in a position to withdraw at any time.

I might point out——

Mr. BADILLO. The problem is, we have abuses that have been established. That is why you have regulations and we have a bill, because the present procedures have not been followed. And, of course, you know we have had testimony of subjects who have said, for example—here we have Mr. Ken Matthews who said that he was told all he had to do was to ask the doctor and he would be taken out of the system.

However, when I found the situation did arise in my own case, I asked the doctor to take the drug out of my system. And the doctor immediately began to play the delay game. First, he made me go out and talk to some students about the effect of the drug. And it went on and on.

How does the person—if the prisoner is going to negotiate with the doctor who is experimenting on him, does he have another group go and evaluate whether the doctor is, in fact, acting with proper speed in getting him out?

Dr. CHALKLEY. No; we do not have that.

Mr. BADILLO. That is the problem. That is why you have the situation of Congress having to go draw up a bill to take it out. Your own testimony concedes there have been abuses, and you do not really give the ones involved a chance to be on some kind of equal level.

We have not seen any proposed revision of these regulations that would provide a fair opportunity to participate in the establishment of the consent committee or to set up some group that would enable those individuals who wanted to appeal, in case they want to withdraw.

Dr. CHALKLEY. Admittedly, this is one of the problems we face. It is a question of communication, and this is one of the factors we have considered in the issue, as proposed here, of certifying prisons was that of the availability of communication with outside—to communicate with Congressmen or with the Secretary of DHEW, to call attention to abuses.

I admit not all of the mechanism is entirely clear in these regulations, because, as I stated before, they are meant to cover medical research, behavioral research, social research as it goes on in the

prison system. At this point, hopefully, one begins by the least government necessary and learns through experience over the years what constitutes an effective system.

Mr. BADILLO. It does not meet the abuses that have been found. That is the issue. The proposed structure, proposed regulations do not comply with the abuses that I have indicated.

I believe my time is up.

Mr. KASTENMEIER. The gentleman from New York, Mr. Pattison.

Mr. PATTISON. I think I would take issue with Dr. Dickson's statement that civil libertarians would necessarily favor this bill. I say the classc civil libertarian, generally, would take the position that anyone can consent to anything he wants, wise or unwise, as long as he wants to do it, as long as it does not hurt anybody else. And I think that we are really not talking about a civil libertarian issue so much as we are a fairly classic question of what is consent, if you will, almost a law school kind of contractual question as to what makes consent.

Classically, anything short of physical duress was considered to be, to not vitiate consent. But that, of course, has changed over the years, and people—the law has recognized that physical duress is not the only real duress. Although it is more difficult to establish, other kinds of duress are just as real.

I think that is the fundamental question we are trying to deal with here. Would you not agree with that?

Dr. DICKSON. Yes.

Mr. PATTISON. Let me ask you—we have had some testimony about—to follow up on Mr. Badillo's question—we have had some testimony that, although they were told they could get out of the program at any time, that, in fact, when they asked to get out of the program, there was this trying to talk them out of it and delays, et cetera.

Would it not be better, under these circumstances, to have a rule that says when a person wants to get out of the program, whether he is wise or unwise, that no attempt be made whatsoever to convince him? Simply, when he says, I want out, he is out that easily. A very simple kind of rule that, in fact, a prohibition, however much it may damage your experiment, prohibition from even trying to talk him out of it.

Dr. MARTIN. Mr. Pattison, could you tell me which patient claimed that we made efforts to keep him in the program?

Mr. PATTISON. Matthews was one of the ones.

Dr. MARTIN. I can tell you we have encouraged Mr. Matthews to request transfer on a number of occasions.

Mr. PATTISON. I do not want to discuss whether Mr. Matthews perceived the situation to be accurate or not. That is not the point. I am sure Mr. Matthews and the other people we had testify before us the other day were not—were very subjective.

But the point is, would it not be better, when you have an inherently coercive situation—we all recognize it is a coercive situation—would it not be better to have a rule that says, under any circumstance, if a person says he wants out, he gets out right then, no questions about it, no inducements offered, no punishment, et cetera?

Dr. MARTIN. In the operation of a research program at the ARC, we do follow this procedure.

Mr. PATTISON. Good.

Let me ask you about the review board, the institutional review board mechanism, the local review.

What percentage of projects are turned down by the review board?

Do we know about what percentage of projects—do they turn down projects?

Dr. CHALKLEY. Yes, sir. On an average, our data indicates somewhere between 1 and 1½ percent.

Mr. PATTISON. What percentage of projects are stopped once things get under way? The nature of the experiment is that only a certain percentage of them are going to be successful, and you get partly through and—is there oversight by the review board?

Dr. CHALKLEY. There is oversight by the review board. We only know of very few instances since 1966 when a project has been halted or altered in midcourse by our review board. I can say I can number the instances on one hand; very few. Prior to the establishment of the Institutional Review Boards, public health service peer review groups were turning down a little over 2 percent of the applications received on the grounds of undue hazard to the subject or ethical considerations.

At the moment, I would say the Institutional Review Boards are turning down between 1 and 1½ percent. We are still turning down between 1 and 1½ percent after their review.

Mr. PATTISON. These special deals or inducements, the time off, the good time, the money—are these reduced to writing in some way so that a prisoner has the document so he can prove later on he is entitled to it?

We had some testimony the other day—I do not know if it was true or false—that said that they never did get the good time.

Dr. CHALKLEY. I do not know about the Addiction Research Center. Across-the-board, again, these provisions vary tremendously from State system to State system.

I might point out this is the one reason why our regulations do not specify dollar amounts. Obviously, an inducement, rather a financial compensation, not an inducement, if you will, that might be paid to a prisoner in the Connecticut State system, which has a relatively high internal pay rate, as against the same payment to a prisoner in, say, the California or Texas systems, which have very low internal pay rates—there might be no particular inducement in Connecticut and the inducement in California and Texas would be high.

Mr. PATTISON. Are the inducements reduced to writing?

I do not mean two showers a day, but the time off, a very specific kind of thing, how much time off you are entitled to, how much pay you get, things of that nature.

Dr. CHALKLEY. We conducted a brief survey of several prison systems in this country a few years ago, not all of them. We were told by most of them, as far as time off is concerned, that this was not a fixed and absolute guarantee to the prisoner. In other words, they were told that this would be taken into consideration by the parole board. There was no guarantee, because there was no fixed relationship between the investigation and the parole board.

Mr. PATTISON. We had testimony today there was 1 day good time.

Dr. CHALKLEY. This is a specific case.

Mr. PATTISON. Are those specific inducements reduced to writing so that a person, a prisoner, who is basically a pretty defenseless guy when he is in there, and it is rather difficult for him to bang a table and insist upon certain things—are those things reduced to writing?

Dr. MARTIN. Yes. In the informed consent, we state the rewards very specifically. Each of the patients can review the consent firm at any time he wants, and we frequently have many arguments about whether the contract was fulfilled or not. Our records are complete and open for audit at any time.

Mr. PATTISON. So, whatever the deal is, it is in writing and a copy is delivered to the prisoner. He has a copy of it?

Dr. MARTIN. It is on file, and he is free to see it at any time.

Dr. CROUT. My suspicion is that, for the drug studies conducted by pharmaceutical firms in prisons, in the vast majority of cases, that is not so.

Mr. PATTISON. There is no good time?

Dr. CROUT. There will be a written informed consent. But that informed consent does not contain the details of compensation in writing, at least the ones we have seen do not.

Mr. PATTISON. It is pretty hard to have informed consent without having what you are consenting to.

Dr. CROUT. I would say the same situation applies to consent outside of prisons. There may be inducements there, also.

Mr. PATTISON. We are talking about a contractual arrangement here. It is no different from buying an automobile. It would be a heck of a contract if all you had in it; you are going to build me a house for $27,000, and did not specify the size, shape, and space of the house.

Dr. CROUT. The informed consent ethic, and the wording and so on, have focused pretty much on health issues up to this point. The idea that informed consent is a contract, as lawyers view it, with all the details spelled out, is not the prevailing notion in a clinical investigation at this time. Maybe it should be, but it is not.

Mr. PATTISON. I would think—the fact that I am a lawyer does not mean I am very legalistic about those things. But I would think, under the more inherent coercion there is, the more important it is, not only for the prisoner, but for you to have as much of that detail spelled out, the lower the level of intelligence of the person you are dealing with, I would think it would be more important to have that spelled out.

Dr. CHALKLEY. I would heartily agree with that last remark. We have been encouraging the use of written documents and the delivery of written documents to the subject in all cases, prisoners or not. We have run into difficulties on occasion, and advice by legal counsel in various States, that the precedents in those States are such that the provision of a written document specifying certain possible bad effects may, if a bad effect ensues which is not listed, be held as prima facie evidence of negligence. The physician is not likely to put himself in a situation like that, and the question of what constitutes the possible injury is completely open-ended.

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We have courts holding us down now to risks that may be of the order of 1 in 15 million. The consent document is beginning to look like the Encyclopedia Britannica.

Mr. PATTISON. It is essentially the same problem you have in any contract. There are very few contracts where you can specify the quid pro quo, so simply. There are a lot of contracts that get very complicated. But if it is not spelled out, the problem is you are going to be faced with a person who says, look, you told me x, y, and z. You say, no, I did not tell you that at all. But his memory is that you told him x, y, and z, and if you have a blank contract, then these people are going to certainly believe, or likely to believe, that is what you told them.

We had some testimony the other day that the drug addicts were in a way compensated by drugs. In other words, the idea was that they are addicts and they are users, and one of the inducements was that they would be able to get more drugs. They would be paid off in drugs, essentially, not in other compensation; bonus shots.

Dr. MARTIN. There was a time, 20 years ago, that this practice was employed. It has not been for the last 20 years.

Mr. PATTISON. No further questions.

Mr. KASTENMEIER. Thank you.

I have several further questions. I want to assure the panel that we are aware they work collectively in the cause of medicine throughout this country. The contentiousness that sometimes developed is not meant to be anything other than to help us arrive at conclusions. You are invaluable for that purpose. We appreciate your being here.

Dr. Crout, where are drug experiments presently being conducted on prisoners?

Dr. CROUT. I have a list of all the prisons in which drug research, to our knowledge, has at one time been conducted since 1962. When you insert the words "at present," we would have to revise the list downward from the one I have. Let me submit this after some staff work, and try to bring it up to date.

Mr. KASTENMEIER. Fine.

[The material referred to follows:]

FACILITIES EXTENSIVELY USED FOR DRUG TESTING, COMPILED BY FDA

A complete and accurate list of prison sites currently being used for drug testing is not available from our files. To attempt a compilation of such a list would require a manual search of all recent IND's. These IND's number in the thousands and the information compiled in such a search would not necessarily be completely accurate. Changes in sites or temporary suspension of testing is not legally required to be reported to FDA. Furthermore, dormant IND's may be reactivated without prior notice to FDA as long as the IND has not been cancelled or withdrawn.

We know of seven facilities which are extensively used for drug testing. These are:

1. California Medical Facility; Vacaville, California.
2. Connecticut State Prison; Somers, Connecticut.
3. Pendleton Reformatory; Pendleton, Indiana.
4. Worcester County Rehabilitation and Detention Center; W. Boyleston, Massachusetts.
5. Southern Michigan State Prison; Jackson, Michigan.
6. Montana State Prison; Deer Lodge, Montana.
7. Essex County Prison; Caldwell, New Jersey.

These testing sites are used for numerous tests by large drug firms, and probably account for most of the drug testing done in prisons in this country.

TAB A: KNOWN DRUG TESTING SITES—PRISONS

Herewith is a list of prisons where drug testing has been or is currently being conducted. It does not include biological testing prison sites, or sites which by State law are banned from testing drugs.

ARKANAS

Arkansas State Prison, Cummins.

CALIFORNIA

California Institution for Women, Chino.
California Medical Facility, (Vacaville Men's Facility), Vacaville.
Institution for Women, Frontera.

CONNECTICUT

Connecticut Correctional Institution, Montville.
Connecticut State Prison, Somers.

DELAWARE

Delaware State Prison.

GEORGIA

U.S. Federal Penitentiary, Atlanta.

ILLINOIS

Joliet Prison, Joliet.

INDIANA

Indiana State Prison, Michigan City.
Pendleton Reformatory, Pendleton.
Marion County Jail, Indianapolis.

IOWA

Anamosa State Men's Reformatory, Iowa City.

KENTUCKY

Kentucky Correctional Institution for Women, Lexington.

LOUISIANA

Orleans Parish Prison, New Orleans.

MARYLAND

Maryland House of Correction, Jessup.
Maryland Correctional Training Center, Hagerstown.

MASSACHUSETTS

Worcester County Rehabilitation and Detention Center, W. Boyleston.

MICHIGAN

Southern Michigan State Prison, Jackson.
Detroit House of Corrections, Plymouth.

MISSOURI

Missouri State Penitentiary, Jefferson City.
Jackson County Jail, Kansas City.

MONTANA

Montana State Prison, Deer Lodge.

NEW JERSEY

Essex County Prison, Caldwell.

NEW YORK

Attica State Prison, Attica.
Sing Sing Prison, Tarrytown.

OHIO

Cincinnati City Jail, Cincinnati.
Ohio Correctional Institution, Cincinnati.
Ohio Correctional Institution, Lebanon.
Ohio Penitentiary, Columbus.

NEBRASKA

State Penitentiary, Lincoln.

NORTH CAROLINA

Correctional Center for Women, Raleigh.

RHODE ISLAND

Adult Correctional Institution, Howard.

TEXAS

Department of Corrections, Houston.
Texas State Penitentiary, Huntsville.

VERMONT

Vermont State Prison, Windsor.

VIRGINIA

Virginia State Penitentiary, Richmond.
Lorton Reformatory, Lorton.

WEST VIRGINIA

Federal Reformatory—Women, Alderson.

WASHINGTON

Washington State Men's Prison, Shelton.

TAB B

Herewith is a list of prison facilities where drug testing has been banned. It should be noted that prison drug testing has been stopped in the States of Alabama, Florida, Pennsylvania, and Oregon. In addition, prison drug testing has been stopped in Massachusetts State prisons but not in county prisons.

In no case has the Food and Drug Administration been directly responsible for termination of prison testing; however, the ban on prison testing in Pennsylvania and in the Oklahoma State Penitentiary in McAlester, Oklahoma was closely related to FDA inspections.

The list of banned facilities is as follows:

ALABAMA

Alabama State Prison System, Montgomery.

FLORIDA

Avon Park, Avon Park.
Florida State Prison, Raiford.
Glades Correctional Institution, Belle Glades.
Lowell Correctional Institution, Lowell.
Largo Prison Farm, St. Petersburg.

MASSACHUSETTS

Massachusetts Correctional Institution, Norfolk.
Massachusetts Correctional Institution, Walpole.
Massachusetts Correctional Institution, Concord.
Massachusetts Correctional Institution, Framington.

OKLAHOMA

Oklahoma State Penitentiary, McAlester.

OREGON

Oregon State Penitentiary, Salem.

PENNSYLVANIA

Bucks County Prison, Doylestown.
Lancaster County Prison, Lancaster.
Holmesburg Prison, Philadelphia.
Philadelphia House of Corrections, Philadelphia.
Berks County Prison, Reading.
Northampton Prison, Easton.
Chester County Farm, Westchester.
Delaware County Prison, Thornton.
Lebanon County Prison, Lebanon.

Mr. KASTENMEIER. In fact, you note that since 1962, there is a fewer number of institutions than there are now. Are any of these programs suspended, temporarily or otherwise?

Dr. CROUT. A number of them are, in essence, terminated by a combination of public sentiment, our own inspections, State laws, all research being stopped in several States. At the present time, there is no prison I am aware of suspended by Food and Drug Administration action alone. Generally, the situations always involve a combination of local societal factors and our own inspections.

Mr. KASTENMEIER. Dr. Dickson I would like to invite your comment. A witness on Monday, Dr. John Arnold, who has more or less 30 years of experience in governmental institutions and out in conducting biomedical research, indicates it is his view presently that experimentation on prisoners should be ended—I am paraphrasing him—because of what he calls public disquiet.

That is to say, quite apart from all the pragmatic reasons for continuing research on prisoners, he feels the need for prisoners—which he documents—has diminished as a group, and the public concern about the use of prisoners, particularly the abuses which were mentioned, justifies a discontinuance of the use of prisoners, and suggests that other alternatives as subjects are available.

He estimates the cost of reliance on other resources to be about 1 percent increase in cost. Obviously, that is an estimate on his part. I do not think he would characterize it otherwise. I invite your comment.

Dr. DICKSON. I am aware of Dr. Arnold, his career and his writings. I think this is a complex situation in which there are many questions that need answering. I think his views are to the point. I do not think that if you take that view you then conclude you should stop doing medical research on prisoners. Making available to prisoners the opportunity to participate in medical research. I think one of the points that we are trying to make here is part of the problem of the

larger pie of the issue of research on human beings in general, and part of the larger pie of the issue of clinical investigation.

We think it is a mistake—it is so complex; it has moral and legal tones that may never be resolved for some time, even though one comes to a conclusion about what to do immediately—to feel that it is important not to take a piece of the action out of the pie, but rather wait until the Commission has carried out its mandate. Then a better look would be available.

Mr. KASTENMEIER. I appreciate that. That is a plausible answer.

Dr. DICKSON. I think Dr. Brown would like to make a comment.

Dr. BROWN. Just a very brief comment, Mr. Kastenmeier. There are certain types of research which have to do with the prisoner and his behavior. A cessation of such research would be very much to the lack of his or her benefit. Let me give you a dramatic example. The Congress has enacted Public Law 94-63 which, among other provisions, establishes a National Center for the Prevention and Control of Rape. The law mandates research to be conducted on the problem of homosexual rape in prisons. Congress has asked us to do research on this particularly troubling piece of behavior, which is part of the disquiet in prisons. If one were to abolish the use of prisoners in research, we would have been given a double message from Congress.

Mr. KASTENMEIER. I appreciate that point. As a matter of fact, it anticipates a point I was going to make, or at least a dialog on the question. At first, I was going to ask—supposing we put a 2-year moratorium on research in prisons—do you think that is possible, or would it be too upsetting as far as present experimentation goes?

Dr. DICKSON. I do not see how, for example, it would resolve Dr. Brown's problem.

Mr. KASTENMEIER. Let me return to that later, if I may. Let me ask you this. I know you see it in the larger context; that is, particularly with the creation of the National Commission for the Protection of Human Subject, which will not report until December 1976, if then—if the congressional or the national experience with commissions is that it will require additional time to make a final conclusive report. The subcommittee was studying pornography and obscenity while its Commission, the National Commission, was deliberating, and had to reach a legislative conclusion long before that poor Commission ever reported. And when it did, it was discredited in a sense.

Dr. DICKSON. With respect to this immediate point on the performance of the Commission to date, they were asked to report on fetal research in a very short period of time—I believe it was 4 months—and they met the deadline. Based on performance to date, they seem to have things pretty much in order.

I understand in the early part of September, they are discussing the issues that do relate to prisoners. I judge they are well underway.

Mr. KASTENMEIER. It has had one session devoted to prisoners. I do not know in terms of its formulation or being put together, it was designed categorically to deal in part with prisoners, or whether that just happens to be a subject which it happened on by interest in the subject. I would be interested in knowing.

Dr. DICKSON. Ms. Mishkin will comment on that.

Ms. MISHKIN. We have a broad mandate to examine a number of issues, and prison research falls within several sections of our legislation. One has to do with the nature and definition of informed consent in varied research settings. Another has to do with the nature and definition of informed consent with respect to prisoners. There is a question that we must consider the freedom and competence of prisoners to make choices with respect to their participation. There is a whole other section in the charge which requires the Commission to consider not only research conducted and supported by the Secretary of HEW, but research which is not regulated by the Secretary. And by that, we understand it to mean research conducted and supported by other Federal agencies, as well as research conducted and supported by private industry, such as the pharmaceutical manufacturing companies.

That particular section of our charge requires a report to Congress, rather than the Secretary of HEW. We have, in fact, discussed our charges relative to prisoner research on occasions other than the September meeting, and we have a number of various activities we are mapping out, including hearings, papers, and what have you. On this issue, we are going at it in great depth. We can elaborate further, if you so wish.

Mr. KASTENMEIER. The gentleman from New York?

Mr. PATTISON. I think it should be pointed out, relative to Dr. Brown's comment, that the intention of this legislation is not to prohibit the kinds of investigation that takes place by way of interviews, questioning, things of that nature. We are talking primarily about research and testing which is conducted to determine the safety or effect of the main drug, device, or practice. It would not be my intention that—and, I do not think, the rest of this committee's intention—to do away with investigations that deal with behavioral problems, that do not necessarily deal with drugs.

Dr. BROWN. It depends. If you define medical practice to include all psychosocial and psychological research, we do have a serious problem.

Mr. PATTISON. I thought, since initial consideration of this legislation, we should have language or try to develop language which clearly delineates between those things which might cause the physical effects—that is a very difficult thing to delineate, between the mental and physical. I know they are connected. That might be experimentation that smacks, to the public, of Nazi kind of experimentation, as opposed to trying to find out what makes people tick by talking to them and testing them that way; or even, for that matter, by putting them through physical tests which are not in any way injurious.

In other words, they may make you tired, or a variety of other things. But they are not likely to have side effects, the way, for instance, a drug whose effects you are not sure of might have.

Mr. KASTENMEIER. On that point, what I wanted to pursue was a hypothetical situation. I realize that you are presently in a posture of opposing the bill, certainly pending the report of this Commission, and whatever it may be.

Let us assume Congress is disposed to write a bill of some sort, and we may have the value of the commission findings and we may not.

They may be supportive of some sort of restriction on the use of prisoners.

If you were advising us what categories we might retain—and some of these have been alluded to. For example, phase II, we obviously would permit research when it is in fact, therapeutic. That might be one. We might also want to permit categories where prisoners peculiarly are all the beneficiaries of research conducted.

Another category might be, as the gentleman from New York points out, there may be classes or categories where there is not really a risk, a medical risk. For example, the authors of the bill use the term "devices." If you are using a prosthetic device of some sort, where there is no particular risk involved, but is experimental——

Mr. PATTISON. A new kind of toothbrush or something.

Mr. KASTENMEIER. Or a diet, which might not pose a particular problem, or interviews. I think what the gentleman from New York and I had in mind is the type of experiement where the individual would possibly sustain a medical risk if the drug, whether it is toxic or otherwise, could produce some type of result which would be a risk or have a physical impact upon him, or maybe psychological, disorienting, or something.

These are categories which I think we would want to exclude from the possibility, but there may be a list of categories that ought to be included. Can you help us in defining and listing that which, if we went forward which we would not want to exclude?

Dr. DICKSON. Yes; this has been a subject of discussion. I think our position is the same. It is not purposeful to go ahead with legislation at this time for the reasons I said before, but with respect to the question you asked, more specifically, this has been a topic of some discussion. Dr. Chalkley would comment on it.

Dr. CHALKLEY. There is some language in section 46.504 of the proposed rulemaking referring specifically to the mentally disabled, but it is applicable in a sense to prisoners' situations.

The phrase in 46.504 could be paraphrased:

> Residents in correctional institutions may not be included in an activity covered by this sub-part unless the proposed activity is related to the etiology, pathogenesis, prevention, diagnosis, or treatment of a physical or mental disability or condition from which the prisoner is suffering or is related to the management, training, or rehabilitation of a prisoner and seeks information which cannot be obtained from subjects who are not prisoners or residents of correctional institutions.

Basically, then, this would restrict the research to that which was considered to be of direct benefit to the prisoner or the the class of persons as prisoners or residents of correctional institutions.

Mr. KASTENMEIER. Of course I appreciate that exemption still would permit the Lexington experiments on alcoholic and drug abuse which are complained of. It might be a problem for us.

Let me ask you another question. We are considering a bill which would halt medical research in Federal prisons and severely limit such activities in State and local institutions.

What sort of lead time would we want in such a bill? We should not want to prohibit research as of tomorrow. Presumably, we would permit some of these experiments to wind down and permit the pharmaceutical companies to access themselves to other communities of subjects. Would a year or 2 years be required?

Dr. SEAL. As far as winding down things, I do not really think it would make much difference. Once you prohibit research on prisoners altogether, the damage is done. The relatively small number of studies that are currently going on probably will not make a tremendous amount of difference in terms of the eventual outcome of these things.

What I really wanted to speak to was the question of vaccines. This is the end of the research spectrum in which I am involved, some of the problems that might be involved which may be of very much importance to prisoners and the American public—infectious diseases are spread in prisons. Many prisoners have served as volunteers in studies of various vaccines. I would like to point out most of those are done in the prison environment under quite a different setting than moving them from a prison to the ACR. Medical care is provided by the prison's medical system. The people involved in vaccine studies usually come into the prison and are involved in giving the vaccines, conducting studies of reactions to the vaccines, and in the long-term followup of the results.

We have a vaccine under development now, hepatitis vaccine. Most of you know that hepatitis B is a major problem in this country. It is particularly prevalent among drug addicts and homosexuals in institutions and among patients in dialysis centers.

When we get further along with this vaccine, we will very much need to know, when we give the vaccine to an individual who later comes in contact with the virus which causes it, whether there is an adverse effect on that individual. This has occurred with other vaccines.

We are talking of perhaps 5 years to 10 years followup of an individual in a setting where he is likely to encounter hepatitis B virus, and where he will be available for fairly close medical surveillance. We will certainly want to be informed if he becomes ill, if he develops hepatitis, and we will want to be able to follow the course of his hepatitis if he becomes infected after vaccination. We will want to compare the course of the disease in him with that of somebody who never had the vaccine.

Almost the only population we can think of in this country suitable for such studies are prison populations, most probably Federal prison populations. The facts are that prisoners are incarcerated for lengthy periods of time, up to 5 and 10 years; they are subject to the disease at a rate which is considerably higher than the normal population, and the research can be conducted under circumstances in which we think that without coercion we can obtain informed consent for their participation. Prisoners will be asked to volunteer to receive a vaccine which has previously been tested and which is free of immediate adverse effects (insofar as we know). Given the drug culture, the habits of homosexuals, and the high morbidity of much of the American public, it will be virtually impossible to exercise continuing medical surveillance on most of a free-living public.

We think it is going to be important. We would hope that whatever determinations you make, Mr. Chairman, that you would not preclude our capabilities to use a consenting prison population to do this part of this work.

Mr. KASTENMEIER. I appreciate that comment, Dr. Seal, because we have tended to devote ourselves to the Lexington Center, rather than

to some other questions. This brings me back to Dr. Dickson's statement in which he referred to such studies, referring to epidemic-type diseases. These studies would necessarily include the entire population of a prison.

How do you get an informed consent from an entire population? Do you actually attempt to get consent?

Dr. SEAL. I think what you are referring to there is where there is an epidemic in the prison and where you are trying to detect people who are ill, it is not necessarily a research setting. It may be necessary in a particular prison to try to isolate carriers and protect people from contact with the carriers.

Mr. KASTENMEIER. You are referring to another exemption; namely, where you have an epidemic, either incipient or otherwise and in connection with it and with treatment you may also be conducting something which is in the nature of experiment or research.

Dr. SEAL. Let us use hepatitis as an indicator. Hepatitis we know is much more prevalent in prisons than in the normal population. Since hepatitis can be spread from a carrier to other inmates, the individual who is a carrier would be dangerous, more dangerous to other inmates than a noncarrier. It would be quite reasonable to survey and ask on entry into the prison that the individual give a blood sample to be checked to find out if he is a carrier of the hepatitis B virus.

This we would consider a part of preventive medicine, the medical routine, although it may not be the regular practice in the civilian community. In the business of doing research there is no way you can involve or get informed consent from all prison population because, you know, there are always going to be people who are going to say no. We would never anticipate being able to do this in the whole population.

Dr. DICKSON. Mr. Chairman, I recognize there is a time problem here with respect to two of the questions that have been asked, one having to do with the winddown time. Another side to that has to do with industry and that picture. I would like to have a brief comment made on that by Dr. Crout and with respect to the motivation problem, I think Dr. Brown has a brief note to make. It would provide you with a more complete answer.

Dr. CROUT. I would point out that if nontherapeutic testing of drugs is phased out in prisons, the pharmaceutical industry has two options. One is to help build new units in this country of the type that Dr. Arnold has recommended, and from our point of view, that would be perfectly fine and ideal.

Another option the drug industry has is to go overseas, and you and I would be equally interested in whether this is the course the industry is most likely to pursue. I would think you would learn some things by asking for a formal reply from, say, the Pharmaceutical Manufacturers Association on precisely that question: What would the industry do if prison research is stopped? It might be that some domestic problems would simply get shipped overseas.

Mr. KASTENMEIER. May I follow that up by saying—and I should have asked this question really of Dr. Dickson at the outset—it is my understanding that statistically there is decreasing reliance on prison populations for purposes of medical research. Is that correct?

Dr. CROUT. That is correct, but that is probably because of social and regulatory pressures, not because of medical need. It is simply shifting more toward other populations.

Mr. KASTENMEIER. To what other populations is it shifting?

Dr. CROUT. Students, housewives, and drug industry employees.

Mr. KASTENMEIER. What about the armed services? They, I take it, are not involved in this, excepting insofar as service medicine itself is involved.

They are control groups of a very sizable number, not totally dissimilar from prison populations. To what extent, if you know, do the military services rely on military personnel or have access to military personnel for medical research?

Ms. MISHKIN. Our executive director has sent letters to all of the Government agencies and departments requesting information concerning the extent to which they have research ongoing which involves human subjects and the policies and procedures through which they try to protect their subjects.

If I may, while I have your attention, indicate that we do have under preparation a response to your September 24 letter to the Commission asking us about our activities. I am here to answer any questions that you have, but the Commission is not a party to the testimony, which is ongoing today.

Mr. KASTENMEIER. I appreciate that distinction. Indeed, we will look forward to hearing from the Commission.

Dr. SEAL. I would like to elaborate a little bit. We have had some joint work with the Army in connection with some vaccines in those particular settings. The Army really observes essentially the same regulations and rules and practices that we do dealing with military personnel for vaccine studies. They do get informed consent and participation is voluntary.

I think this is a change from the days when I was in the Navy and very much involved in this, but this has been an evolutionary process for everybody. I think I can say the military has evolved essentially in parallel with the rest of the Government.

Mr. KASTENMEIER. Let me ask you this if you know: Does the pharmaceutical industry have the same access to the Military Establishment or military personnel that it would have to other institutional personnel?

Dr. SEAL. No, sir. They cannot come directly in. Any test of a drug within the military has to be because that drug offers promise relevant to a military problem. There can be no trade secrets. The composition of the drug must be divulged and the studies must be approved by the Office of the Surgeon General, depending on which branch is involved. It goes through a review board which is very much like the institutional review boards that we have been talking about, so it would have to be relevant and potentially useful in the military as a particular group.

Those studies can be done, but are done by military personnel, not by the pharmaceutical manufacturers, and the results are published and not provided to the manufacturer as a trade secret or confidential document. They are in the open literature.

Mr. KASTENMEIER. Maybe prison personnel ought to have a similar insulation as military personnel.

I think it is time to conclude. I would like to thank our panel. You have been very patient with the committee. We will look to you for further assistance in this field at some point in the future.

So Dr. Dickson, Dr. Crout, Dr. Chalkley, Dr. Martin, Dr. Seal, and Mr. Sopper, we are pleased to have had you here this morning and are grateful to you.

[The prepared statement of James F. Dickson III, M.D., follows:]

STATEMENT OF JAMES F. DICKSON III, M.D., ACTING DEPUTY ASSISTANT SECRETARY FOR HEALTH

Mr. Chairman and Members of the Subcommittee: I am pleased to testify today on H.R. 3603, a bill to limit the use of prison inmates in medical research. We welcome this opportunity to comment on the bill and to discuss the role and activities of the Department of Health, Education, and Welfare related to the use of prisoners as the subjects of research.

DEPARTMENT'S POSITION ON H.R. 3603

At this time, the Department is opposed to any legislation which would prohibit all medical research on prisoners, because other mechanisms have been established for dealing with issues related to the involvement of prisoners in research. The bill would prohibit certain important research activities which should be judged on their scientific merit and ethical safeguards.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, recently established by Public Law 93-348, is currently operating and has until December 1976 to complete its work. The Commission is charged with examining and making recommendations on a variety of ethical issues related to the Department's biomedical and behavioral research activities. One specific charge to the Commission is to examine the participation of prisoners in research. The Commission has already begun its work in this area, and is expected to engage in extensive and broad-based public discussion of issues relating to all research using prisoners. It is our hope that Congress will not act on any legislation establishing limitations on biomedical and behavioral research with human subjects until the work of this legislatively established Commission is complete.

DEPARTMENTAL REGULATIONS

Another arena of continuing discussion and action regarding prisoner research is the Department's effort over the last several years to develop regulations on prisoner research. The Department currently has regulations covering all DHEW supported research involving human subjects, and has recognized a need for special principles and protections to apply to research activities involving prisoner subjects. A notice of proposed policy and draft rules dealing with research on prisoners, as well as other special groups, has been published in the Federal Register. We are continuing to evaluate our draft proposals in this area, but would like to share with you some current thinking and tentative positions we have developed.

In both of our previously published draft rules we have proposed to define permissible conditions for research activities involving prisoner subjects, and to establish additional safeguards to protect the rights and welfare of prisoner subjects. Prisoners would be allowed the opportunity to choose to participate in similar research activities as nonprisoners, and to choose to participate in activities which may potentially benefit them directly or may benefit other prisoners through the development of knowledge useful to understanding and dealing with prisoners' probelms. A possible alternative position, mentioned in comments on our proposed regulations, which might be considered with regard to limiting prisoner research, is to permit use of prisoner subjects only when they may benefit directly, or when the research may benefit other prisoners or persons with similar conditions to the particular subjects.

In addition, we have proposed that Institutional Review Boards (the mechanism used to provide local review of research projects for protection of the rights and welfare of human subjects) assume additional responsibilities to assure that potentially coercive factors are minimized and consent is obtained from each subject in an appropriate manner. Although prisoners are in a custodial situation which is inherently coercive, we believe that given appropriate safeguards, recruitment and participation of prisoner subjects can be controlled to meet ethical standards.

FOOD AND DRUG ADMINISTRATION

As you know, questions about the use of human subjects, including prisoners, in the investigation of drugs are complex and have been subject to a great deal of recent attention and controversy. Everyone, I believe, would agree that clinical investigation is essential to further advances in medicine and that mankind has benefited greatly from past investigations. As the same time, no one can be so naive as to think that the use of humans as experimental subjects, and especially those humans with limited freedom, does not create serious legal as well as ethical problems.

As part of the FDA program to monitor clinical investigation, it has conducted inspections of institutional review committees in 19 prisons. It is clear from the investigations that abuses of prisoner populations have occurred.

Although the FDA has been responsible since 1938 for determining whether drugs were safe enough for marketing, it did not have real authority to regulate investigational use of drugs in humans until 1962, following passage of the Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act. FDA standards for the conduct of clinical drug trials, which have gradually evolved over the past 13 years, are quite rigorous. These regulations, guidelines, and policies require that, before a new drug is administered to man, the sponsor submit a Notice of Claimed Investigational Exemption for a New Drug (IND) which contains not only the results of chemical tests establishing the purity of the drug and animal tests establishing the safety and efficacy in various species, but also a very detailed plan of each study proposed to be conducted in human beings.

The FDA further requires that if a clinical study is to be done in an institution—which is defined to include prisons, among others that an Institutional Review Committee be responsible for initial and continuing review and approval of the proposed clinical study. The membership of that Committee must be comprised of sufficient members of varying background, i.e., lawyers, clergy, or laymen, as well as scientists to assure complete and adequate ethical review of the research project. The membership must possess not only broad competence to comprehend the nature of the project, but also other competencies necessary to judge the acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance.

At the time of submission to the IND, the FDA has the opportunity to review the proposed study and has 30 days in which to raise objection to the initiation of the study. After that, the proposed study may begin. At any time, however, the Agency has the option to inform the sponsor that an ongoing study must stop, based on results of the study or new information.

The 1962 Amendments and implementing regulations place responsibility for monitoring studies of investigational drugs with the sponsoring drug firms. At the present time, there are about 12,000 active investigators and approximately 1,600 functioning institutional review committees. The FDA cannot possibly police this system directly since it involves physicians and other scientists throughout the conduct of their professional work.

Although they cannot undertake direct monitoring of all investigators, the FDA has over the past several years directed increasing attention to determining whether the present system is working well. This has required a growing effort on their part in the direct monitoring of randomly selected clinical, and more recently, preclinical (animal) studies. At the same time, the FDA continues to investigate any studies about which a suspicion has arisen.

THE SUBJECTS OF CLINICAL INVESTIGATIONS

A matter of growing concern to many people is the question of just who participates in drug trials. Consideration of this question requires a distinction between therapeutic and nontherapeutic studies. Early in the development of most drugs, small numbers of normal volunteers are given the drug in nontherapeutic studies—known as Phase 1 studies—to evaluate tolerance to the drug, the

proper dose, metabolism of the drug, and to detect certain kinds of adverse reactions. Prisoners have represented a large fraction or such normal volunteers. In certain cases, such as when the drug is highly toxic, e.g., anticancer agents, these studies are not conducted in normal volunteers, but rather in patients with the disease. Increasingly, initial trials are being conducted in people who have the condition for which the drug is intended (e.g., high blood pressure, high cholesterol), rather than in normal volunteers.

The second kind of study is the therapeutic trial, which involves people with a disease or condition to be treated. The use of institutionalized patients in such studies depends to a great extent upon the various groups that might be available to clinical investigators. Many studies, however, are conducted in institutions which draw on all segments of the population.

An FDA review of sample new drug applications (NDAs) indicates that of the various populations involved, prisoners are probably most commonly used in Phase I clinical drug trials. The principal advantage offered by prisons to the conduct of clinical research is that prisoners are generally confined. Such confinement permits better monitoring of each subject, meaning that adverse reactions can be detected early in development. This significantly increases the safety of each volunteer. This ability to monitor the subject closely during and after use of a drug improves the quality of results derived from each subject. Likewise, the controlled environment (living conditions, diet, exercise, limited source of exposure to infections) reduces the number of variables that might impair the meaningfulness of the results. Better quality of results per subject reduces the number of subjects who would be exposed to any risk. The same advantages that are available in prisoner populations could be obtained in other populations with some cost and effort, e.g., students or paid volunteers.

Although it is obvious that we have benefited from clinical investigation in the past and that we need clinical investigation in the future to answer important questions, we must recognize that all investigations expose subjects to risk. The FDA regulatory requirements for animal testing, for well-trained clinical investigators, for institutional review and for carefully designed studies, are intended to minimize the risk and make certain that investigational subjects, including prisoners, are fully aware of the risks that exist.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Research with certain kinds of prisoner subjects is of potential benefit to the prisoners involved, or to persons who may now or in the future be troubled by similar problems. Of particular concern to the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are the problems of mental illness, drug addiction and abuse, and alcoholism. Since these are problems sometimes experienced by persons in the general prison population and some persons such as the criminally insane or convicted narcotic addicts are incarcerated specifically because of them, there is interest in research involving prisoners to develop certain needed information about these problems.

Studies involving Federal prisoners related to narcotic addiction and drug abuse have been conducted at the Addiction Research Center, Lexington, Kentucky for the last 40 years. Dr. Martin, who is accompanying me today, is the Director of this hospital-research facility which is part of the National Institute on Drug Abuse, within ADAMHA. Since this program has been in operation, it is estimated that 4,000–5,000 volunteer prisoner subjects have participated in research here. In order to be accepted into the ARC program, prisoner volunteers must have a history of narcotic addiction. Thus, only those subjects with a history related to the general focus of the ARC program are admitted to the facility.

Some of the research in which prisoner subjects at the ARC participate may be of direct therapeutic benefit to them, while other research has potential societal benefit related to the problems of drug abuse and addiction. Past and current studies include efforts to understand the fundamental process of addiction, develop methods for diagnosing drug addiction, understand the biological and psychological bases for narcotic euphoria and the way euphorigenic drugs act, and develop drugs for treatment of narcotic addiction. Thus, these involve research efforts related to understanding and treating problems which the subjects themselves have experienced. Some studies are conducted to carry out the Secretary of DHEW's statutory responsibility to develop information and advise the Attorney General about the abuse, or addictive, potentiality of new narcotic analgesics. These latter activities would be abolished if H.R. 3603 became law, and there is no alternative way this information can be obtained at this time.

Another research area of importance to ADAMHA's mission and related to prisoners is problems of mental health as these are or may be reflected in various types of deviant, aggressive or violent behavior that frequently involves violation of criminal law. In order to understand and cope with these multifaceted problems, research using diverse methods in a variety of settings is necessary. This includes research with prisoners, using psychosocial and biomedical approaches.

Some information can be obtained only by using prisoner subjects. Among such areas of investigation are certain genetic and other biological aberrations and their possible relationship to criminality and violence; patterns of criminal behavior and various aspects of inmate behavior in prisons; testing and evaluation of new programs for coping with and preventing criminal behavior; and law and mental health interactions in such areas as dangerousness of mentally disordered offenders and competency to stand trial.

While H.R. 3603 would not prohibit all these kinds of research, it would eliminate all biomedical research with Federal prisoners, including some which is of potential direct benefit to prisoner subjects or to other prisoners. Also, it would interfere with attempts to develop a comprehensive explanation including biological as well as psychosocial and environmental variables, of criminal behavior.

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health has been and still is supporting some research involving prisoners within the current Department of Health, Education, and Welfare regulations for protection of human subjects. There has been a decline in recent years in the number of such activities.

There are now less than a dozen ongoing projects. One project is being conducted at a Federal reformatory, the others at State correctional institutions. No new grants or contracts have been made this year, although renewal contracts and grants have been made for additional years of support for several projects.

This reduction in support may reflect, at least in part, the increasing difficulty in conducting research in State correctional institutions because of recent rulings by some States prohibiting research not intended for the direct benefit of the prisoners. Most of the past and present research with prisoner subjects supported by the NIH has been for testing the effectiveness of vaccines for infectious, bacterial, and viral agents.

It is evident that the National Institutes of Health is not substantially dependent on prisoner subjects for pursuit of its missions. However, it has proved a valuable research tool. The prison environment with overcrowding, close confinement, and common facilities provide opportunities for the study of institutional epidemic conditions and for the study of certain epidemic transmissible diseases. Such studies would, of course, necessarily include the entire population of the prison environment: guards, administrators, and others having frequent access to the prison. Studies of the incidence of cancer, heart, and vascular diseases and neurological disorders and the development of chronic and aging disorders in prisoners enduring prison life for extended periods might provide useful information that could be of direct benefit to prisoners as a class.

CURRENT ETHICAL SAFEGUARDS FOR PRISONER RESEARCH

In sponsoring some of the kinds of prisoner research I have mentioned, we do attempt to assure that research projects we support are conducted in an ethical manner. As I mentioned earlier, the Department has regulations dealing with the protection of human subjects of all types, including prisoners, in DHEW supported activities. Important concepts embodied in these regulations include

institutional and agency review of proposed projects in order to assess the nature and extent of risks (including physical, psychological and social risks), to determine the adequacy of proposed consent procedures, to assure that rights and welfare will be adequately protected, and to assess potential benefits of the activity. In addition, consent requirements are included which specify elements of informed consent, and require that an individual be free to make a choice without undue inducement or any coercion. Also, grant applicants are asked to indicate when special populations such as prisoners are to be used and the rationale for their use, so that we can assess whether the nature of the inquiry is relevant to the group under study. Review groups and agency staff pay special attention to proposals planning to use prisoners in order to assure that adequate protections are afforded and that the research is appropriate for conduct on prisoners.

Researchers at the Addiction Research Center in Lexington, also abide by the principles stated in the DHEW regulations, and the ARC has additional requirements relating to prisoner participation. For example, only prisoners are admitted to the program who have a history of narcotic addiction. Further, potential subjects must be in good physical and mental health, be at least 25 and have eighteen months remaining to serve in their sentence (so that patients can be appropriately followed up after their participation in research). Prisoners are admitted to the ARC who volunteer for the research program there, but consent must be obtained for each individual study and a prisoner may refuse to participate in specific studies. Plans for research projects are reviewed by an Organizational Review Committee to assess technical merit and protections for human subjects.

SUMMARY

The Department is opposed to this legislation which would, in effect, prohibit all medical research on prisoners in Federal, State, and military institutions. While the stated purpose of H.R. 3603 is to *limit* participation in medical research by the inmates of correctional institutions, its effect is to prohibit all such participation.

Thus, the bill would prohibit involvement of persons in custody, regardless of the beneficial intent to such subjects of certain types of medical research, including experimental therapy for prison subjects. Thus, military prisoners might be denied experimental treatment for an unfamiliar disease acquired in the course of foreign service for which there is no standard treatment. Similarly, control of an epidemic in a correctional institution might be forced to rely on older methods, though newer, but still experimental, procedures were available.

For the above-stated reasons, we therefore recommend that H.R. 3603 not be favorably considered by the Subcommittee.

That concludes my statement, Mr. Chairman. My colleagues and I will be pleased to respond to any questions the Subcommittee may have.

Mr. KASTENMEIER. This concludes this session. The subcommittee will reconvene in 30 minutes for the afternoon session.

[Whereupon, at 12:55 p.m. the subcommittee was recessed, to reconvene at 1:30 p.m. the same day.]

AFTERNOON SESSION

Mr. KASTENMEIER. The committee will come to order for the continuation of hearings on H.R. 3603.

This afternoon we are very pleased to greet as our first witness, or witnesses I should say, C. Joseph Stetler, who is president of the Pharmaceutical Manufacturers Association, and with Mr. Stetler is Dr. Monroe Trout, vice president and corporate director of medical affairs of Winthrop Labs in New York.

Mr. Stetler, you are most welcome and proceed, sir, if you have a statement.

TESTIMONY OF C. JOSEPH STETLER, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY DR. MONROE E. TROUT, VICE PRESIDENT AND CORPORATE DIRECTOR FOR MEDICAL AFFAIRS, WINTHROP LABS, NEW YORK, N.Y.

Mr. STETLER. Thank you, Mr. Chairman and members of the committee.

Dr. Trout and I are here in response to your invitation to present the views of the prescription pharmaceutical industry on H.R. 3603, a bill to bar any inmate in a Federal correctional institution from participating in any form of medical research and to deny Federal assistance to any State or local correctional institution where Federal prisoners are involved in medical research.

Our opposition to the bill is not due to any insensitivity to problems incident to the conduct of certain research in prisons, but rather out of a conviction that drug testing in prisons is desirable, when safeguards for the protection of the medical and civil rights of participants are observed.

Our concern about this subject is longstanding. The PMA's 131 member firms conduct most of the Nation's research and development for prescription pharmaceuticals and for medical devices and diagnostic products. Our companies employ about 23,000 persons in research activities, and our annual commitment to this effort is over $1 billion. We have been sponsoring prison-based drug research for many years, as part of this overall research effort, and to the best of our knowledge, not a single prisoner has died or been permanently injured as a result of a drug firm-sponsored test.

We believe, therefore, that it is essential, in reviewing legislation on this subject, to draw a careful distinction between drug company-sponsored prison tests and those which have resulted in serious injury and death as a result of tests sponsored under other auspices.

The kind of research conducted in prisons by drug firms is almost without exception directed at the collection of information on the general pharmacological and biomedical effects of drug products in normal individuals: How the drug is absorbed, at what rates, and its possible side action. The dosages necessary to obtain these data are generally very low.

Consequently, the likelihood of their producing toxicity is very small, and as the record shows, serious toxicity occurs with extreme rarity in these industry-sponsored studies.

Yet the data obtained from these studies is crucial to the research process. As you know, every candidate drug is subjected to extensive tests in animals before any human is exposed to the substance. But even the most extensive animal testing cannot predict accurately the drug's safety or efficacy in man. It gives only approximate indices. Eventually, a point is reached when it becomes obvious that the only way to test a human drug's potential is in man.

It is at that stage, when the drug's sponsors have adequate animal test data, that they file an investigational new drug exemption, commonly called an IND, with the Food and Drug Administration. The

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application includes all that is known about the drug, together with detailed protocols describing the planned human trials, including such information as the qualifications of the investigators and the scope of the planned investigations. There are, of course, detailed regulations governing this process, including safeguards to insure proper institutional review of the research and preservation of the participant's right to be informed and to withdraw from the experiment at any time.

A 30-day waiting period is observed before the investigation may begin, in order to give FDA time to review the plan and the data submitted and to request any changes or additional information which the agency might consider necessary.

The first trials, called phase I studies, are restricted to a very small number of subjects. Relatively short periods of time are involved, during which overall pharmacological and biochemical characteristics of the compound can be observed. From these observations, parameters essential to the next phase of the research process, the first trials in sick people, are obtained.

The question frequently asked is why should such tests be conducted in prisons? The answer is that if the staff of the testing facility is qualified to conduct the research, if the facilities are adequate, if participation is informed and voluntary, if the experiment is carefully and appropriately monitored, and if the participants are compensated fairly, then the conditions necessary to serve the interests of all concerned are met, whether the facility is a prison or some other research center.

There is no question that a well equipped and staffed prison facility provides a suitable scientific environment, primarily because participants can be closely monitored. Frequently, the studies drug firms conduct call for repetitive procedures, such as frequent body fluid analyses, blood pressure, pulse and respiration tests, and others. Since the participants can be under constant close observation, adherence to dosage routines, test procedures, and reports on reactions can be assured. Relatively few other kinds of populations are practical candidates for these sorts of controlled study. Of major importance is the fact that the prison setting provides maximum safety for test subjects.

These factors, rather than any desire to exploit prisoners, or save money, account for the large number of limited drug trials being conducted in prisons. Given the kinds and amounts of biomedical data required by current standards of research and as reflected in FDA new drug regulations, there are actually few practical alternatives. If we eliminate the prisoner as someone eligible to take part in these carefully controlled trials, we remove another right of choice from his or her already restricted life. We may also delay the development of new drugs which will benefit all people, including the prisoners themselves.

We could understand such a step if there was substantial evidence of misconduct or mismanagement of tests sponsored by drug firms. We are aware of no such evidence. Thus, we believe the actions called for in H.R. 3603 are not in the best interests of either the prisoner or the public in general.

It would be well to consider the implications of a total halt to all research in prisons. As noted, there are few alternative populations which provide healthy persons living in a controlled environment where close observation over periods of weeks or months is possible. As a result, such a step would severely limit the amount of data that could be gathered before a candidate compound is taken into large-scale clinical trials with sick people. On that ground alone, such a course is unacceptable to anyone aware of the scientific and ethical considerations involved.

We could, of course, attempt to conduct all phase I trials, in private or governmental hospitals and clinics. That option, it seems to us, carries its own negative implications. In all likelihood, it would be the underprivileged population groups which would most frequently be enlisted for those studies.

Alternatively, we could limit initial human testing of drugs to patients suffering from the diseases the experimental drugs are designed to treat. Again, serious questions arise, particularly as to the propriety of exposing sick people to drugs which have never before been used in man, without baseline data on their pharmacological and biomedical characteristics in normal volunteers.

Still another alternative is to set up clinics in the community, in which people would participate by moving into the facility for the period of the study. Here too, however, the almost certain outcome is that the unemployed and underprivileged would form the population of such centers. While we certainly do not object to such an approach, we do not see that it erases the basis for at least some of the concerns which motivate the sponsors of this bill.

I want to stress once again that the pharmaceutical industry is well aware of the problems surrounding certain prison testing. But rather than pass Federal legislation barring research, we favor substantive steps to insure acceptable conditions for such testing.

Two years ago, the PMA, in collaboration with the National Council on Crime and Delinquency, sponsored a meeting in order to hear the views of prisoners, correctional authorities, clinical investigators, industry representatives, civil rights authorities, academicians, physicians, lawyers, and Government agencies on prison testing of drugs. Out of that conference, our association developed a series of guidelines and recommendations for our member firms. They are incorporated in a PMA policy statement on clinical research, which I would like to offer for inclusion in the record of these hearings, but which I shall paraphrase briefly.

The policy statement is broad in its coverage and relates to clinical investigation wherever it occurs, in prisons, in institutions for the mentally or physically infirm, with children, and among company employees, as well as in clinical centers and hospitals.

Among the recommendations pertinent to these hearings are the following: One, we support the mandate and mission of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and we are committed to the establishment of expert committees to assist the Commission in its work.

We propose a comprehensive study of the roles and responsibilities of the sponsor and the clinical investigator in drug testing to review,

among other things, the responsibility for long-term followup of participants in drug studies and proper means of insuring compliance with institutional review mechanisms.

We believe that the sponsor of any drug investigation should provide the investigator with a formal document detailing the investigator's responsibilities under law, particularly with respect to patient consent. The investigator should also be given a written description of the facts relevant to the drug under study, prepared in language comprehensible to the participant.

We recognize that pharmaceutical firms are responsible for assisting in and encouraging appropriate followup of participants in investigations involving compounds which may cause toxicity, and we endorse the search for practical, ethical means toward that end.

Not only must pharmaceutical industry research administrators be familiar with regulations and ethical principles relevant to medical research, they must insure that clinicians who undertake studies in their behalf are also qualified and committed to such standards.

We understand our responsibility to protect the subject of any clinical investigation, and we realize that our obligations are even more compelling when the people involved have limited means of protecting their own welfare and civil liberties. Drug firms must therefore take care to assure that facilities and personnel involved in investigations are appropriate to the task and understand their obligations to protect participants.

Also, the necessity of avoiding coercion must be understood.

To that end, we believe that the sponsoring firm must demonstrate a sensitivity to ethical considerations in ways that are plainly evident in its actions. For example, our guidelines suggest that the sponsor should take an interest in the overall medical care quality in the testing facility, and not merely in the portions directly relevant to the experiment.

We realize that every possible effort must be made to guard against coercion in any form, real or implied, in accepting participants in prison tests. The investigator must inform each prospective participant of the nature of the investigation, must disclose all known risks and benefits, and give opportunity for discussion. The written consent form should be explained before the prisoner is asked to sign it, and he or she should be given a copy for personal retention. The prisoner's willingness or refusal to give consent must have no bearing upon his or her penal status or eligibility for parole, and that fact must be made clear.

The manner in which consent is sought has been the subject of long study and legal debate. The procedures outlined in the HEW Policy on Protection of Human Subjects should be carefully observed. In addition, the material presented to the prisoner for the purpose of seeking consent should be reviewed by the institutional review committee. That committee should be asked specifically to look for evidence that the spirit of informed consent is honored.

Prisoners should be informed that they may withdraw from a test at any time, without explanation or justification, and with assurance that such withdrawal will have no bearing on his or her status in the institution.

Under no conditions should a prisoner be asked to waive his or her rights to adequate care and compensation in the event of injury.

An institutional review committee should make an independent critical review of the test program, in accordance with governmental guidelines. The committee should include prisoner representation and should have access to the results of the research, with suitable protections for privacy.

The amount of compensation paid to prisoners should be determined by the correctional institution and the review committee. The nature of the study and alternative methods of earning wages available to the prisoner should be considered in this determination. We feel that whatever rates the authorities set will be acceptable, recognizing that on the one hand they should not be so high as to amount to financial coercion, nor so low as to be penurious. We are willing to consider alternative rates and forms of compensation in the search for an equitable answer to this question.

These are the key points in our policy statement relevant to prison testing, Mr. Chairman. As I said earlier, we do not believe there is any dispute concerning the need to preserve the ethical and legal rights of prisoners. Nor are the contributions that prisoners have made to medical progress being challenged.

What is in question is whether the prisoners' rights are best protected by denying him the right to decide on participating in medical research. It is our view that such a step is unwarranted. I hope that the committee will give careful consideration to modifying the pending proposal to permit such testing, with safeguards, where they are clearly appropriate in light of experience.

We would, of course, be pleased to work with subcommittee members and with your staff in that effort.

Thank you, Mr. Chairman. Dr. Trout and I will be happy to answer your questions.

Mr. KASTENMEIER. Thank you, Mr. Stetler, for an excellent statement. We appreciate your offer to work with the subcommittee.

Presently, in terms of the industry, that is the 131 member firms, is the tendency away from use of prisoners in State and Federal institutions for medical research?

Mr. STETLER. To the best of our knowledge, there is relatively little drug testing being done in the Federal prisons themselves. Most of our testing is in State or local institutions. The great bulk of the testing of prisoners is concentrated on phase I testing. That is important because it has a minimal impact as far as risk is concerned.

I would say of our phase I testing something approaching 80 to 90 percent is done in the prison environment.

Mr. KASTENMEIER. I did not realize it was that high. Of the other 10 or 20 percent then—what sort of population profile does the other 10 or 20 percent compile?

Mr. STETLER. It varies. Some of it is done in student populations and some phase I testing can be done with ill people. In other words, if it is a type of drug that has a particularly bad or serious risk involved, such as a possible cancer cure, then phase I testing may be conducted in ill people. It is not taken into normal, healthy people to begin with because of the risk.

Mr. KASTENMEIER. That would be therapeutic testing?

Mr. STETLER. It would serve both purposes, really. Dr. Arnold testified here that some phase I testing is done in the type of facility he manages. Some is done in government or community hospitals, but obviously 10 percent is the exception rather than the rule.

Mr. KASTENMEIER. What procedure do you go through as far as access to, say, a Federal prison? You have tested the drug on animals in the laboratories. Then you indicated you go to the Food and Drug Administration on an IND basis and have a proposal for them.

Once they approve, how do you actually get that program accepted by either a State or Federal prison, a local, State, or Federal prison?

Mr. STETLER. That is strictly an arrangement between the sponsor or the drug firm and the institution. Frequently it involves an intermediary because they are academic institutions, and other people that have arrangements with the prison institutions in various States and localities for this testing. Our arrangements are often with that intermediary, rather than with the institution itself.

Actually, the Government and the Food and Drug Administration are not involved in arranging for those contracts. They have the authority to review them, but the arrangement is between the sponsor and the prison.

Mr. KASTENMEIER. On page 3 you refer to the staff of the testing facility. You say, "The answer is that if the staff of the testing facility is qualified to conduct the research"—in terms of the testing facility, you are not referring to the staff of the prison institution as such, are you?

Mr. STETLER. In most instances it would be medical personnel that would be brought into the prison environment to conduct the testing. Some prisons would have some minimal capability, but in most instances that is supplemented by additional clinical investigators, persons from a local hospital, or more frequently from a university medical school.

Mr. KASTENMEIER. So it may include the staff of a prison institution. Are they or is the institution compensated in any way for assisting a pharmaceutical house in its program?

Mr. STETLER. Dr. Trout is engaged in these things more specifically.

Dr. TROUT. It varies from State to State. Take the State of Connecticut, for example. There is a percentage of the amount of money that is paid to the prisoner which is turned over to the prison authorities for a prisoner welfare fund.

In addition, there is another percentage which is turned over to the State authorities for administrative and other costs. They set this figure themselves. The State itself sets it.

Mr. KASTENMEIER. Let us take the State of Maryland. Its programs are perhaps better known in this area. What sort of arrangements do you have in the State of Maryland, for example?

Dr. TROUT. We do not have any, that I am aware of.

Mr. KASTENMEIER. None of your 131 member firms?

Dr. TROUT. I do not know.

Mr. STETLER. I am not really familiar enough with the details to say. I assume there is some testing going on in Maryland, but Maryland would be like most every other State. Testing would involve an arrangement between a particular company or this intermediary and the institution. And as indicated, those arrangements vary significantly.

Some have an arrangement whereby a contribution goes to the prison facility. It is so varied that it is hard to say anything as a general rule.

Dr. TROUT. One of the important things is in many of these areas, prisoners themselves are used as they are taught how to become technicians, and they themselves do much of the work. They, of course, are then paid by the investigator for that particular work.

Mr. KASTENMEIER. At the outset, Mr. Stetler said that research conducted in prisons is directed at the collection of information and general pharmacological and biochemical effects of drug products in normal individuals, prefaced that by saying it is almost without exception. What is the exception?

Mr. STETLER. As part of phase I testing I mentioned that on occasion the drug may be used initially in ill persons, that may have the disease entity we are attempting to attack. But phase I testing almost by definition in FDA regulations is a nontherapeutic type of a trial to find out certain baseline data about a particular compound before it is brought into phase II. It is then that you really try to determine its therapeutic effect in ill persons.

Mr. KASTENMEIER. You make a number of recommendations here. One of the recommendations pertinent to these hearings, you are referring to the Pharmaceutical Manufacturers Association policy statement, which incidentally we will be pleased to receive and make part of the record.

[The material referred to follows:]

PHARMACEUTICAL MANUFACTURERS ASSOCIATION POLICY ON CLINICAL RESEARCH, JULY 1975

I. INTRODUCTION

The Pharmaceutical Manufacturers Association (PMA) represents those firms in the pharmaceutical industry that are significantly engaged in the discovery and development of new medicines. In fulfilling this major social and economic function, these firms must of necessity be extensively involved in clinical research. They perform such research because it is only through studies in man that the usefulness, safety and efficacy of a prospective new drug can be demonstrated.

As a result of this activity, the industry has become intimately involved in the humane and ethical issues raised by scientific investigations involving human subjects. This involvement, in turn, requires that the PMA accept the important responsibility of periodically appraising the ethical aspects of clinical research, and offering policy guidance to its members.

As the representative of the pharmaceutical industry, the single most significant institution engaged in the discovery and development of new medicinal products, the PMA is also deeply concerned with those public policies that affect the process by which therapeutic innovations are made. The industry believes it should take an active role in the continuing public reappraisal of the policies, laws, regulations and practices which influence the process of therapeutic innovation.

As is illustrated later in this paper, excessive zeal for the ultimate in technical sophistication in clinical trials can reach the point where the additional information obtained is not worth the risks, however small, encounter in its gathering. Conversely, excessive zeal for absolute safety, if embodied in controls and regulations that are unnecessarily redundant or inflexible, stultify the process by which needed new medicines are discovered and developed—without contributing any significant additional protection to the subjects of the clinical research in question.

If therapeutic progress is to be made, in ways that are both efficient and ethically acceptable, society must adopt policies which assure that both sets of values are protected and upheld.

The policies outlined in this paper, which were endorsed by the Executive Committee of the Board of Directors of the Pharmaceutical Manufacturers Association at its meeting on June 24, 1975, set forth a number of formal positions which delineate the Association's views regarding clinical research on investigational medicines.

II. THE RESEARCH PROCESS AND ITS REGULATION

The importance of protecting the rights of individuals who participate in clinical trials is beyond debate. Similarly, the value of therapeutic innovation is manifest. However, what is not so readily perceived is the critical importance of clinical studies in moving modern medicine forward. It is beyond the scope of this paper to describe in detail how medicines are discovered and developed, but in order to understand the practical context of the policy positions adopted herein, it is essential to appreciate the ways in which clinical trials influence the process of medical innovation.[1]

Furthermore, clinical research with experimental medicines is highly regulated under the Food, Drug, and Cosmetic Act. The impact of these regulations must also be understood, since they represent the foundation upon which the policies and operational practices of the pharmaceutical industry are grounded.[2]

A. The Importance of Clinical Research in the Discovery and Development of New Medicines

Research to discover and determine the properties of new medicines is a complex and sophisticated scientific undertaking.

One of the most pervasive misunderstandings about clinical studies is the belief that this important aspect of modern medicinal research is merely "testing"—implying an empirical exercise to confirm a scientific drug "discovery" that has already been made in the laboratory. In fact, clinical investigation is an integral component of the scientific research process; the early clinical trial ("clinical pharmacology") of a compound with presumptive therapeutic activity is one of the most accepted and fertile methodologies of modern medicinal research.[3] Clinical investigation at early stages of the overall research process can be invaluable in such ways as:

Ascertaining the relevance of findings in animals, particularly in validating the laboratory "model" of the human disease that is the target of the research in question;

Measuring the clinical effectiveness of a biologically active compound that has been selected by laboratory testing;

Assessing the metabolic disposition in man of a prospective drug candidate (species differences are not infrequent causes of non-translatability of findings in animals to man); and

Assessment of certain kinds of drug effects—both desired and undesired—that cannot usually be determined in animal experiments, e.g., headache.

Information of the kinds illustrated above is virtually important to the laboratory research team. Lake of feedback from early stage clinical pharmacology is increasingly the rate-limiting factor in discovering a prospective new medicine. This is particularly true when an experimental compound fails in early clinical studies—a frequent outcome, given the limitations of laboratory methodology—because the circumstances of the clinical failure are frequently an invaluable source of inference to the laboratory teams' effort to find and offer superior candidates. Consequently, a better recognition of the importance of early clinical studies in the implementation of regulatory policies would tend to accelerate the overall process of therapeutic innovation. In addition, since FDA statistics show that early studies are very safe,[4] innovation could be enhanced at no significant risk to the participants in clinical trials.

A candidate compound that survives the critical early clinical studies is further evaluated for therapeutic usefulness and tolerance in progressively larger numbers of patients, by independent physician-investigators, typically associated with medical teaching institutions or major hospitals, and always

Footnotes at end.

in a context that involves systematic recording of the physician's observations and measurements in accord with a formal experimental plan. Subsequent to the establishment of safety and efficacy in these highly structured scientific investigations, later stage controlled clinical trials are undertaken on a broad scale in order to approximate the use of the new medicine in everyday medical practice. Throughout the research process, "feedback" from the clinic is a constant guide to the laboratory program, and vice versa. The research findings from clinical investigation in addition to being reported to the sponsor and by him to the FDA, are normally published by the investigator in the scientific journals.

Research on the established uses of a new medicine is usually looked upon as complete at the time the product is approved for marketing and general use. However, in recent years, there has been a growing awareness of the unique opportunity, and need, for a more systematic assessment of the effects of a newly launched pharmaceutical product—both desirable and adverse—as its usage is broadened. Premarket research of limited scale cannot be expected to reflect the vast range of co-existing illnesses, food and climatic variations, the differing genetic constitutions of the patients treated, and other variables relating to patient, environment and physician, that will be encountered in the real world of general therapeutic use. General use presents, for the first time, a practical opportunity to detect low-incidence or otherwise adventitious effects of a therapeutic agent.

B. The Regulation of Clinical Research

In 1962, the Congress passed amendments to the federal Food, Drug, and Cosmetic Act which initiated a new regulatory era in the discovery, development, manufacture and marketing of pharmaceuticals. The amendments affect the research process generally, and clinical research specifically, in many important ways, for example:

The kind and quantity of experimentation required before the initiation and progression of clinical studies with experimental medicines is regulated through FDA guidelines;[5]

The first human studies with a prospective new medicine are subject to prior regulatory review via the FDA Investigational New Drug (IND) procedures;

All subsequent clinical research is subject to regulatory overview under the IND rules, and may entail FDA requests for clarification, consultation, changes in experimental design, the collection and submittal of additional experimental data, other delays or the termination of the clincial programs;

The regulatory process emphasizes animal and human studies designed to determine the potential risks of side effects or the toxicity of the compound, as well as its effectiveness. In addition to such studies, extensive data with respect to chemistry, formulation, stability, analytical methods and manufacturing and control procedures are required; and

Approval of the new medicine for marketing is carried out under the New Drug Application (NDA) procedures; FDA has the authority to regulate the drug after marketing and to take appropriate actions in the event of further findings relevant to safety and efficacy.

To discharge effectively the many important responsibilities involved in conducting clinical research, the sponsoring firm must assure itself and satisfy the FDA as to the competence of its investigators, the adequacy of the protocol design and the proper conduct of the study.

It is not widely appreciated that FDA regulations incorporate many explicit requirements that bear directly on the ethical and humane aspects of clincial research. Included are provisions specifying the nature of, and procedures for, obtaining informed consent; the role and responsibilities of institutions in which research is undertaken; the responsibilty of the sponsor to report adverse findings; and others. This body of requirements, built up by FDA in the years since 1962, addresses in a substantial way the major ethical concerns that pertain to clinical research with medicines. The additional policy studies proposed in this paper, and the specific policies adopted, are intended to further emphasize and articulate in practical terms the central principles for the conduct of clinical research.

Since the passage of the 1962 Amendments, a substantial number of papers have been published describing—and debating—the impact of regulation on the

Footnotes at end.

process of therapeutic research, and on the rate of therapeutic innovation.[6] Some FDA regulations, guidelines and policies clearly reflect the agency's recognition of this impact.[7] For example, FDA's preclinical guidelines, promulgated some years ago, and clinical guidelines now in draft form, have as one of their purposes the facilitation of research and its regulation through the definition of the general scope and content of research studies of various kinds, and the scientific criteria that should be met by them.[8] FDA has also established modified procedures to expedite the approval of drugs whose early availability is perceived to be important (i.e., L-dopa). In these cases, it is agreed that formal research will continue in the post-marketing period. Currently, FDA is implementing or studying additional procedural changes intended to expedite the regulatory process. Included are such housekeeping matters as a standardized procedure to speed up the distribution of research information sent to the agency by research sponsors, and more substantive proposals that would establish interim reviews and conferences as a new medicine progresses through development—the so-called "Developing NDA" concept.[9]

Finally, it is important to recognize the very substantial amount of peer review of clinical research with new medicines that occurs through instrumentalities other than the sponsor and the FDA. Medical teaching institutions and large hospitals typically maintain Research Review Committees that approve research to be undertaken within the institution; several states have established ethical review committees to approve research to be undertaken in state institutions. These trends have resulted in a multiple "layering" or regulatory review, particularly of the earlier clinical studies. For the reasons discussed earlier, unduly cumbersome regulation of these early studies can strongly suppress the overall rate of progress of medicinal research.

III. PMA RECOMMENDATIONS

The formal PMA recommendations that follow envision constructive, cooperative action by industry, research institutions, the health professions and government, and are designed to encourage creative and workable responses to the important issues raised in the clinical investigation of new medicines, and its regulation.

A. *Policy Studies*

Point 1. Comprehensive Study of the Rights of Individuals in Biomedical and Behavioral Research

In an attempt to define optimum public policy, the Congress recently established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission is charged with making a thorough examination of all aspects of this complex subject, including the impact of government policies and regulations.

Clinical research with new medicines has become increasingly complex in its methodology (under the stimulus of newer medical techniques, procedures and instrumentation) and increasingly demanding and precise with respect to the resulting data. There is thus a danger that the rights and well being of the patient may be inadvertently affected by the intricate requirements of a complex experimental regimen.

This potential conflict of technology and ethics deserves special consideration by the Commission.

The recommendations of the Commission should help assure that public policies on clinical research represent and protect society's best interests. The Commission deserves the support and assistance of all groups and individuals who possess specialized knowledge, skills and experience relating to the protection of human subjects of clinical research.

RECOMMENDATION 1

The Pharmaceutical Manufacturers Association supports the mandate and mission of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In order to further the studies and findings of the Commission, the Association advocates that it and the industry commit themselves to contributing their relevant expertise and their extensive experience in biomedical research with new medicines. To facilitate this, the Association is offering to establish a special committee composed of experts of the

Footnotes at end.

appropriate disciplines familiar with the industry's research methodology to volunteer its service to the Commission.

Point 2. Assessment of the State of Drug Innovation

Government activities and regulations have a profound influence on the conduct of medicinal research and development and on the rate of therapeutic progress. The past decade has seen a steady increase in the scope of regulation governing such research, and concurrently, a decline in the rate of therapeutic progress as measured by the rate of introduction of new medicines, despite a steadily increasing commitment of research resources by industry (Appendix I).

The impact of regulation on the process of clinical research particularly merits a comprehensive reappraisal. In no other field of technology does regulation affect the process of innovation so early in the research sequence. As noted earlier, laboratory models are inherently imperfect surrogates for the realities of medical practice, and clinical research is typically required to validate the presumed useful activity of an experimental compound. Clinical research is a factor in the basic studies of a prospective new medicine, in addition to its more generally recognized function in defining the medical usefulness and limitations of a developing new medicine, and, ultimately, providing the main body of data on which NDA evaluation is predicated.

A reasonable case has been made for the view that the U.S. suffers from unnecessary delays in the process by which medicinal research is regulated here and from disincentives to decision-making in new drug approval (Appendix I). These impediments to therapeutic innovation carry high social and economic costs in delaying the general availability of improved medicines and as a deterrent to investment in pharmaceutical research. Any unnecessary delay in the availability of new and more effective therapeutic agents is a bona fide ethical concern; the suffering of patients who might have been effectively treated is a shared responsibility of persons contributing to the delay. It is axiomatic that therapy delayed is therapy denied.

At present, there exists no effective, broadly representative public body charged with the responsibility of examining the public policies, laws, regulations and procedures that affect therapeutic innovation. The recent appointment of an HEW Review Panel on New Drug Regulation with a limited mandate to examine certain specific FDA policies and practices may be a helpful step toward the ultimate accomplishment of the comprehensive review that is herein suggested. An independent, third party examination with a much broader mandate would be a timely complement to the work of the HEW Panel.

RECOMMENDATION 2

The PMA supports the formation of an independent, expert, broadly based and representative panel to assess the current state of drug innovation and the impact upon it of existing laws, regulations and procedures. This panel should be charged with responsibility to evaluate the effect of governmental activities on drug innovation in light of the beneficial impact which therapeutic advances have on the human, social and economic aspects of national health care. The conclusions and recommendations of such a panel should be published and made available to all interested parties.

Point 3. Drug Innovation Impact Statement Accompanying New Regulations

Since FDA regulations have an important influence on the rate of therapeutic innovation, we believe the Food and Drug Administration should weigh carefully the prospective impact on therapeutic progress of all of its regulatory and policy proposals. FDA has recognized its overall responsibility to encourage therapeutic progress[7,10] and should take steps to ensure that this policy is not defeated by specific regulatory actions. To accomplish this objective, the following proposal is suggested:

RECOMMENDATION 3

When FDA proposes regulations, it should prepare and publish in the Federal Register a detailed statement assessing the impact of those regulations on drug innovation. Such statements should be subject to comment and administrative

Footnotes at end.

review in the same manner as the proposed regulation itself; should estimate the fiscal impact of compliance for the FDA and the pharmaceutical industry; and should clearly set forth the ways in which the proposal encourages or discourages pharmaceutical innovation.

B. *The Rights of Human Subjects in Clinical Drug Investigations*

Point 4. Study of the Relationship Between the Sponsor and the Independent Physician-Investigator

Most studies of investigational new drugs involve the participation of independent clinical investigators, who assume direct responsibility for specific clinical research projects as grantees of the company sponsor. Obviously, when engaged in such research, these doctors must fulfill their primary obligations as physicians to patients participating in investigations.

The physician-patient relationship in the clinical research setting is complex. A need exists to more clearly define the responsibilities of the company sponsor of clinical research and the participating clinician to each other, and to the patient, within the framework of the physician-patient relationship. To accomplish this, the PMA proposes the following study:

RECOMMENDATION 4

The PMA proposes that an appropriately qualified medical organization be encouraged to undertake a comprehensive study of the optimum roles and responsibilities of the sponsor and physician when company-sponsored clinical research is performed by independent clinical investigators. The study should include specific consideration of such important operational matters as the security of medical records, reports by the physician to the sponsor, long-term patient follow-up when required, and appropriate compliance with the several peer review mechanisms that now exist—all with the goal of defining procedures that are practical and effective, yet that also respect the doctor-patient relationship and the patient's well-being and right of privacy.

Point 5. Informed Consent

PMA recognizes that even though a given clinical research study will normally be the direct responsibility of an independent clinician-investigator, the sponsor will possess extensive and intimate knowledge of the therapeutic properties and limitations of the medicine being tested. In addition, the sponsor will frequently provide useful materials to aid the investigator in discharging his important responsibility of properly informing prospective participants in the proposed research program.

Under present regulations, the sponsor is required to make full disclosure to the physician-investigator of all known factors relevant to informed consent and obtain his written certification that he will comply with all regulations pertaining to the securing of informed consent.

RECOMMENDATION 5

PMA recognizes that the physician-investigator has, and should have, the ultimate responsibility for deciding the substance and form of the informed consent to be obtained. However, PMA recommends that the sponsor aid the investigator in discharging this important responsibility by providing (1) a document detailing the investigator's responsibilites under FDA regulations with regard to patient consent, and (2) a written description of the relevant facts about the investigational drug to be studied, in comprehensible lay language.

Point 6. Statement of Principles Concerning Research with Special Groups

The conduct of research with new medicines through the participation of children, the mentally infirm (including the senile aged patient), prisoners and employees of the sponsor presents a distinct set of ethical and legal questions, the answers to many of which require additional consideration by society.

(a) *Testing in Children and the Mentally Infirm.*—The need to conduct research studies in children is clear, for only through such studies can new medicines be developed for the treatment of pediatric illnesses.[11] Similarly, many medicines have been, and continue to be, developed to deal with mental illness and they must, accordingly, be studied in appropriate patient populations.

Footnotes at end.

PMA recognizes that additional study is required to develop optimum public policy in these areas, a matter which should be addressed in the work of the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research. (Recommendation 1 above.)

The following principles are endorsed by PMA:

RECOMMENDATION 6: INFORMED CONSENT ON BEHALF OF CHILDREN

In the case of children, the sponsor must require that informed consent be obtained from a legally appropriate representative of the participant. (Either a parent, guardian or other legally responsible person. In the case of an orphan, the informed consent obtained should be subject to final approval by an Institutional Review Committee.) Voluntary consent of an older child, who may be capable of understanding, in addition to that of a parent, guardian or other legally responsible person, is advisable. Safety of the drug shall have been assessed in adult populations prior to use in children. In the case of efficacy studies in children, the utility of the drug should have been demonstrated in adults where possible. An obvious exception is an investigational product developed exclusively for use in children; but even in this case, early dose tolerance and pharmacokinetic studies in adults are desirable.

RECOMMENDATION 7: INFORMED CONSENT ON BEHALF OF THE MENTALLY INFIRM

PMA endorses the general princple that, in the investigational setting, consent should be sought from both an understanding subject and from a parent or guardian, or in their absence, another legally responsible person. It is also advisable in cases involving the mentally infirm to subject the consent obtained to final approval by an Institutional Review Committee. Where such consent is denied, the investigator should not proceed with the study in that individual, in keeping with the doctrine of voluntary informed consent, unless the experimental medicine is the only appropriate therapy, in a life-threatening situation, or the product is the only available agent of proven benefit. In endorsing this principle, the PMA recognizes that some mentally infirm or psychiatric patients have inherently more capacity to understand and appreciate what is involved in their treatment than others.

Although it may be desirable that information about a new agent be obtained in normal subjects before proceeding to the patient, the response of the patient with a psychiatric disorder may be quite different from that of the normal subject. In most instances, such patients will be sought as specific subjects for a therapeutic trial, but this should not preclude their being enlisted at the same time for studies of doses, tolerance and pharmacokinetics.

(b) *Testing in Prisoners and Sponsor Employees.*—The early stages of clinical drug research are often facilitated by studies in volunteer subjects who are not ill, and who thus do not as a rule derive therapeutic benefits from participation.[12] Such "Phase I" clinical experimentation is a prominent component of modern medical research, and is explicitly called for in FDA guidelines.

Volunteers for such research have included prisoners, students and company employees, who are typically placed under medical supervision in a closely controlled environment for the duration of the experiment.

HEW Secretary Weinberger placed society's need for these experiments in proper perspectiye during an address to the National Academy of Sciences.[13] It is recognized, however, that when dealing with these special categories of normal, volunteer participants, special considerations pertaining to the matter of consent and other special procedures must be employed to protect the rights of the individuals involved.

RECOMMENDATION 8

With regard to the conduct of clinical research in the prison environment, the "Statement of Principles" attached as Exhibit 1 was adopted by the PMA Board of Directors on February 11, 1975.

RECOMMENDATION 9

With regard to the conduct of clinical research through the use of sponsor employee-volunteers, the "Statement on Employee Participation" attached as

Footnotes at end.

Exhibit 2 was adopted by the Executive Committee of the PMA Board of Directors on June 24, 1975.

Point 7. Protection of the Right to Privacy of the Participant in Clinical Research

Modern, sophisticated clinical research requires the collection of large amounts of data relating to the state of the health of participating subjects. FDA regulations, and good scientific practice, require extensive analysis and reporting of these data. Clinical investigators, as well as sponsors and regulators of medical research, share the important responsibility of assuring the confidentiality of the medical and peronal information relating to individual participants in clinical research studies.

The PMA and its member firms are committed to the principle that the identity of patients participating in clinical research, and all information about individual patients derived from such research, be kept confidential in full accord with the tenets of the physician-patient relationship, the fundamental right of privacy of the individual, and the law.

RECOMMENDATION 10

Where the sponsor obtains medical information or data on individuals, it shall be accorded the same confidential status as provided in codes of ethics governing health care professionals. Such information or data will be released only with the consent of the physician and the patient or in a form which conceals the identity of the individual, except as required by law or as necessary in life-threatening situations, and then only to those with a professional or legal obligation to maintain confidentiality.

Point 8. Patient Follow-Up

There are occasions when rare but potentially serious side effects, or animal toxicity of potential clinical relevance, appear during late clinical trials. These are findings of the kind that usually cannot be predicted from animal safety studies of intermediate duration or from early clinical studies, by reason of their low incidence, or because their manifestation requires prolonged administration of the compound. Care should be taken in extrapolating toxicity at inordinately high and prolonged drug levels in animals to man, especially when differences of metabolism and end organ sensitivity occur. A fair balance must be sought between unduly and unnecessarily alarming the patient on one hand, and a proper concern for safety on the other. PMA and its member firms recognize their ethical responsibility to investigate such problems thoroughly, in close consultation with FDA, and of terminating studies if an acceptable benefit/risk ratio no longer exists. In such circumstances, it is believed that when necessary for the protection of the health of the subjects, all individuals who received the investigational drug involved should be adequately monitored for a period of time appropriate to the specific circumstances of the finding in question, and commensurate with accepted medical practice.

Detailed records incorporating patient identification, place of patient residence, etc., must be privileged property of the physician-investigator, in order to safeguard the rights of the patient. (Point 7, above) Hence, the primary responsibility of the sponsor is to provide guidance and assistance to the investigator to assure effective long-term follow-up of patients, when this is necessary.

However, when physicians discontinue their practices, move, or die, or when patients change their residences or otherwise become inaccessible to their former physicians, practical problems are inevitably encountered in retaining contact with the patients for an extended period of time. As mentioned earlier (Point 5), PMA believes that additional practical, professionally acceptable techniques for facilitating long-term follow-up should be sought. The specific techniques finally selected will have to balance the need for retaining patient contact against the dangers to patient privacy inherent in the data systems required to assure such contact.

RECOMMENDATION 11

PMA and its member firms accept responsibility to aid and encourage appropriate follow-up of human subjects who have received investigational medicines that cause latent toxicity in animals or, during their use in clinical investigations, are found to cause unexpected and serious adverse effects. As stated in Recommendation 4, PMA endorses the search for practical, ethically acceptable techniques that would make long-term follow-up of research subjects more effective.

Point 9. Development of Techniques for Systematic Post-Marketing Surveillance

Low-incidence clinical side-effects of a new medicine that may appear under the varied conditions of general medical use are frequently not identifiable until the product has been marketed for an extended period. The manufacturer is responsible, under FDA regulations, for collecting, evaluating and reporting unexpected effects of marketed products.[14] However, methodology for systematic monitoring of the actions of a medicine in general use, in a scientifically meaningful way, has yet to be perfected. PMA believes that member companies, with their substantial medical staffs, nationwide networks of professional representatives, and sophisticated data-processing capability, should actively explore new techniques that might permit more comprehensive, systematic post-marketing monitoring of newly marketed medicines.

RECOMMENDATION 12

PMA supports the exploration and development by its member companies of more systematic surveillance procedures for new medicines after marketing. The continuing study of this issue within the PMA Medical Section and by other appropriately qualified organizations is encouraged.

C. Improving the Efficiency of Therapeutic Research

Hopefully, the above discussion has reinforced the view that clinical research is an ethically sensitive process and one that is so recognized by its practitioners, who work within a comprehensive system of ethical principles, regulations and controls. Substantially because of these ethical constraints, regulations and controls, clinical research is also inherently cumbersome, and hence, the process itself is a factor in limiting therapeutic innovation.

PMA is not aware of any effective or socially acceptable alternatives to the present American system of drug regulation. On the other hand, it seems inconceivable that a process of such complexity, and one that is also so relatively new to science, does not offer many significant opportunities for incremental improvement in efficiency and effectiveness.

Point 10. The "Developing NDA" Concept

A significant proposal for restructuring research and regulatory procedures under IND regulations has been under study by FDA for some time. The proposal is built around a more systematic pattern of sponsor-FDA-Advisory Committee interactions, for pre-review of program plans and overview of program results, and with provisions for the initiation of early formal FDA review of certain units of the New Drug Application as they are completed.

Features such as these, if they are implemented without introducing additional impediments to the flow of research, seem constructive, and PMA supports them in principle—but with the important caveat that any additional, formally mandated delays, or "holds" in the evolution of the overall research program would violate the essential unity of the research process and would certainly further prolong the time required to develop new medicines.

PMA believes it is also important to emphasize that clinical research with a prospective new medicine is an iterative process of hypothesis formation, and hypothesis testing by experiment. Novel findings at mid-point in the research program generally require modification of the plan for subsequent research. Program plans, in truly scientific investigations, must be flexible enough to accommodate change in reaction to such new findings. In the same vein, earlier "completed" units of research may have to be reconsidered later, to properly assess the significance of findings made at later stages of the program.

With these considerations in mind, PMA endorses the following general embodiment of the "developing NDA" idea.

RECOMMENDATION 13

(a) *Development Planning in Consultation with FDA.*—The sponsor's proposed development plan, accompanied by a summary of existing data, would be submitted to FDA when the sponsor concludes from a small number of early clinical trials that development of a basic new agent is likely to continue to an NDA. Following a review of this submission, the FDA, and its Advisory Committee where appropriate, will meet with the sponsor to discuss the development plan.

No formal FDA approval of the submitted data or proposed development plan, and no delays in implementing or continuing research activities, should be

Footnotes at end.

required at this stage or at any time until actual NDA review. Rather, the emphasis should be on identification of potential problems and questions for the sponsor's further study and resolution as the program develops.

(b) *Orderly Paper Flow.*—Routine correspondence and reports relating to a specific medicine in clinical trial would be submitted to FDA at regular quarterly intervals. (Non-routine items, such as new protocols, will be submitted as they are initiated, in accordance with current practice.) Since an appreciable part of the total paper submitted to an IND is of the routine variety, this modification will ease FDA's paper-handling problem considerably without retarding the research process.

(c) *NDA Units Reviewed as Completed.*—NDA review will be facilitated by the sponsor's submission of discrete units of the NDA as they are completed. This process will begin as soon as the sponsor becomes convinced that an NDA is likely to be filed. For example, the manufacturing portions and certain animal toxicology sections are likely to be complete and available for review well before the clinical program is completed.

On completion of the review of each NDA unit submitted, and at the earliest feasible date, FDA will indicate to the sponsor either that the unit is satisfactory (subject to reconsideration in light of relevant later findings), or it will advise as to specific problem areas requiring discussion or action. The usual 180-day period will begin with submission of the final portions of the NDA. Since much of the NDA will have been under review for several months, many problems in these areas will have been resolved by the time the 180-day period begins. Thus, review and approval of the final NDA are more likely to be completed within the statutory time limit.

IV. *Continuing Studies to Define Improved Procedures for Clinical Research and and its Regulation*

The PMA Medical, and Research & Development Sections, the PMA Foundation, as well as various ad hoc committees of the Association, have long been active in seeking improvements in the practice of clinical research, frequently in collaboration with FDA and academic scientists. Such efforts have included the development of guidelines for the clinical evaluation of more than twenty therapeutic classes of drug products; the support of training and research in clinical pharmacology;[15] support of and participation in various symposia and conferences;[16] and many studies of other specific aspects of the clinical research process and its regulation. Further progress in clinical research will require that efforts such as these be continued and expanded.

The PMA will continue to actively encourage the development of improved concepts and methodology for the conduct of clinical research. Timely topics for study mentioned elsewhere in this policy statement include: systematic post-marketing evaluation of new medicines as an alternative to the present practice of prolonged pre-NDA clinical research; modification of existing regulatory procedures to permit rigidly controlled early clinical studies of limited scope and duration with a small number of subjects which will provide an earlier evaluation of safety and efficacy than is possible at the present time; wider acceptance by FDA of the overview function of Institutional Review Committees and other peer review mechanics, as an integral part of the IND and NDA review process. Recommendations forthcoming from these and similar studies will be developed in cooperation with FDA and recognized clinical scientists, and submitted to appropriate scientific and governmental authorities for review and disposition.

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    "Another issue today concerns the use of prisoners for research. Scientists have long viewed prisoners as ideal population groups for controlled studies, because their diets and lifestyles are easily observed and easily controlled. As you know, many beneficial discoveries, particularly in the fields of immunization and microbiological processes, have come from research on prisoner subjects. Clearly, prisoners are needed in research."
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APPENDIX I

A.—TOTAL R. & D. EXPENDITURES AND NUMBER OF NEW DRUG APPLICATIONS

Year	New chemical entities approved [1]												
	1962	1963	1964	1965	1966	1967	1968	1969	1970	1971	1972	1973	1974
Research expenditures [2] (millions of dollars)	$251	$282	$298	$351	$402	$448	$485	$549	$619	$684	$726	$824	[3] $930
New chemical entities approved [4]	19	12	16	17	12	17	10	8	15	13	6	12	15

[1] A new chemical entity (NCE) is defined as a compound of molecular structure not previously used in man in the United States, excluding new salts, vaccines, and diagnostic agents.

[2] Human and veterinary use, ethical pharmaceuticals; amounts spent in the United States and in foreign countries. PMA annual survey reports, 1962–73; starting with 1969, total includes U.S.-Government grants and contracts for company conducted R. & D. This amounts to about $10,000,000 per year. Prior to 1969, U.S.-Government grants and contracts were excluded from the total.

[3] Budgeted for 1974; "PMA Annual Survey Report, 1973–74," ethical pharmaceutical medical device and diagnostic industry operations.

[4] Based on data from Paul de Haen, Inc., excluding new salts, vaccines, and diagnostic agents.

Note: Testimony by Dr. William Wardell, University of Rochester, before the Senate Subcommittee on Health of the Senate Labor and Public Welfare Committee, Sept. 27, 1974. It is noteworthy from the above that the industry's spending for R. & D. from 1962 to 1974 more than tripled. The number of new chemical entities approved remained more or less constant. It is also noteworthy that the United States was the 30th country to approve the antiasthma drug metaproterenol; the 32d country to approve the anticancer drug adriamycin; the 51st country to approve the antituberculous drug rifampin; the 64th country to approve the antiallergenic drug cromolyn; and the 106th country to approve the antibacterial drug cotrimoxazole.

B. R. & D. EXPENDITURES, HUMAN USE DRUGS ADJUSTED TO CONSTANT DOLLARS [1]—1968–73

Year	Funds spent	Implicit price deflator (GNP)	Constant dollars	Percent change
Funds spent in the United States (millions of dollars):				
1968	$410.4	100.0	$410.4	
1969	464.1	105.9	436.7	+6.4
1970	518.6	112.9	451.7	+3.4
1971	576.5	119.3	465.2	+3.0
1972	600.7	123.8	457.7	−1.6
1973	643.8	131.6	440.4	−3.8
Funds spent in foreign countries by U.S. firms (millions of dollars):				
1968	39.1	100.0	39.1	
1969	41.7	105.9	39.2	+.3
1970	47.2	112.9	40.3	+2.8
1971	52.3	119.3	42.2	+4.7
1972	66.1	123.8	50.4	+19.4
1973	108.7	131.6	74.4	+47.6

[1] PMA table, based on annual survey reports, 1968–73; "Implicit Price Deflator," GNP, U.S. Department of Commerce, Statistical Abstract of the United States, 1974, p. 374. Deflator converted to 1968 base (100.0). Amounts spent in foreign countries are measured in U.S. dollars, do not take into account devaluation of dollar, which tends to increase costs abroad.

Note: D. Schwartzman, "Pharmaceutical R. & D. Expenditures and Rate of Return," Center for Health Policy Research, American Enterprise Institute, July 1974. The above table illustrates that U.S. firms are increasing their R. & D. expenditures at a more rapid rate overseas than they are domestically; moreover, the number of U.S. R. & D. personnel in the last several years has remained static, while foreign firms have significantly increased the number of persons employed in R. & D. These trends, together with economic studies which demonstrate that our domestic drug industry has been facing a precipitous decline in its rate to return on R. & D. investment, comes at a time when our own Government is giving consideration to many schemes that would create further disincentives for R. & D. investment in this country.

C.—NEW CHEMICAL AGENTS MARKETED IN UNITED STATES [1]

[In percent]

Origin	1940 through 1970	1971 through 1973
United States firms	70	39
Foreign firms	30	61

[1] Based on data from Paul de Haen, Inc., 1940–1970, PMA Factbook, 1973. 1971–1973, Clymer, H. A., Drug Development and Marketing, American Enterprise Institute, 1975.

EXHIBIT 1

STATEMENT OF PRINCIPLES ON THE CONDUCT OF PHARMACEUTICAL RESEARCH IN THE PRISON ENVIRONMENT, FEBRUARY 11, 1975

INTRODUCTION

The opportunity for careful exploration of new or improved pharmaceuticals for use in the prevention, diagnosis and treatment of disease is essential to the progress of medicine. In recent years, as the scientific standards for judging the safety and efficacy of candidate compounds have evolved, it has become increasingly desirable that early clinical trials be conducted in adequate numbers of individuals, who are under close supervision for sufficient periods, so that their responses to the drugs can be closely monitored. For many studies, it is desirable, even necessary for subjects to be free from recognizable physical illness and to be living under similarly controlled conditions. This has contributed to an increasing interest in the prisoner volunteer as being especially suited for first phase clinical trials and for bioavailability studies of marketed drugs.

At the same time, there has been a parallel rise in society's concern about individual rights. Fundamental questions have been posed about the testing of pharmaceuticals in prisons. Among the issues raised: the possible coercion of prisoners to volunteer for such programs, the adequacy of the protection afforded the volunteers, the right to terminate the experiment, the amount of compensation, the right of the volunteer to withdraw from the experiment, and the safety of experimentation in the prison setting.

The need to preserve the ethical and legal rights of prisoners is not in dispute. Nor is the contribution that prison testing has made to medical progress open to question. At the same time, it is not widely recognized that much of the progress of recent decades has been made possible by normal volunteer subjects, including prisoners. It is abundantly clear that well-controlled studies can be and are conducted in such institutions which contribute to the social rehabilitation of the prisoner, with maximum safety, and with apparent benefits both to inmates and society at large. Indeed, a cogent argument can be made for preserving the prisoner's right to participate in research programs, under appropriate safeguards, as one of the few rights left to the incarcerated individual.

It is clearly not in the province of the pharmaceutical industry to resolve all of the conflicts surrounding this issue. But since it is the industry's conviction that clinical research in correctional institutions in the United States is important to medical progress, the industry believes that it must take certain steps to ensure that prison testing conducted in its behalf by all companies is consistent with the best standards of science, ethics and law.

For that reason, the Board of Directors of the Pharmaceutical Manufacturers Association has adopted the following guidelines for the use of its member firms in the sponsorship or conduct of research in prisons.

1. ADHERENCE TO REGULATORY AND ETHICAL CODES AND SELECTION OF QUALIFIED INVESTIGATORS

Pharmaceutical company research administrators must be completely familiar with official regulations governing clinical investigations, such as those of the Department of Health, Education, and Welfare and the Food and Drug Administration, pertinent state regulations and other statements of principle by professional and other groups, e.g., the Helsinki Declaration, and the Protocol for Medical Experimentation and Pharmaceutical Testing of the American Correctional Association. Moreover, they must ensure that clinicians who undertake studies in their behalf are qualified and familiar with and agree to adhere to such standards.

There should be assurance that a program for the proposed testing of drugs in prison subjects would be appropriate for performance on non-prisoners.

2. ADEQUACY OF FACILITIES

It is recognized that the responsibility for protecting the subject of any clinical evaluation lies with many people, but the obligations are even more compelling when the persons involved have a limited power to protect their own basic welfare and civil liberties. Thus, pharmaceutical manufacturers sponsoring in-

vestigations in prisons must take all reasonable care to assure that the facilities and personnel used in the conduct of the investigations are suitable for the protection of participants, and for the avoidance of coercion, with a respect for basic humanitarian principles. A demonstration of sensitivity to ethical consideration on the part of the sponsor can contribute to a high level of concern by all those associated with the program, and should therefore be plainly evident in every action by the sponsor.

Although the sponsor cannot assume responsibility for medical care in the prison facility, interest in such matters as the overall quality of medical care in the testing facility and the accessibility of medical staff on emergency notice is necessary. In addition, sponsor interest in the quality of equipment and record-keeping systems can be beneficial to the overall prison environment, as well as to the satisfactory completion of the particular investigation.

3. INFORMED CONSENT

The clinical investigator must guard against any form of real or implied coercion and he must inform each prospective participant of the nature of the investigation, including adequate disclosure of all known or likely clinically important risks and benefits, giving an appropriate opportunity for questions to be raised and answered. Consent forms should be fully explained before the prisoner is asked to sign, and he should be permitted to retain a personal copy. The informed consent procedures outlined in the HEW Policy on Protection of Human Subjects (while primarily intended for application to HEW-funded research) offer important guidelines in the conduct of industry-sponsored programs as well. It should always be made clear to the prisoner that willingness or unwillingness to give consent will have no effect upon his or her penal status, and particularly his eligibility for parole.

At a minimum, the document of consent, properly signed and witnessed, will encompass all of the elements of informed consent as outlined in applicable federal regulations.

The material to be presented to the prisoner in the process of seeking consent should be reviewed and approved by a properly constituted institutional review committee. An adequate review can be expected to distinguish motivation from coercion, particularly if the committee is free to make its own inquiries as to how well the spirit of informed consent is honored, through on-site visits to the facility and other means.

4. THE RIGHT TO WITHDRAW

Prisoners should be informed of their right to withdraw from a program at any time. It should be made clear that such a right is not contingent upon their justifying or explaining their decision, nor will their withdrawal be a consideration in any parole application or other matter affecting their status in the institution. It is, however, appropriate on occasion for a prisoner withdrawing from an experiment to undergo further examination for his own health or well-being.

5. WAIVERS

Under no conditions should the prospective participant be asked or permitted to agree, whether in writing or orally, to a waiver of his rights to adequate care and compensation in the event of injury incurred in the course of the investigation.

6. REVIEW OF PROTOCOLS

In addition to voluntary consent, assiduous adherence to properly designed protocols of study, prepared after consideration of pertinent data from preclinical and other clinical testing, is necessary to minimize risk and to protect the rights of the participant. The protocols must be subject to careful review by an independent institutional review committee, composed in accordance with FDA regulations and ideally including prisoner volunteer representation, or representation from the prisoner population. The review committee should review and approve the information presented to volunteers in seeking their consent, and it should also review results of the research.

7. PRISONER COMPENSATION

The amount of compensation paid to the prisoner participant should be determined by the correctional institution and institutional review committee, in

recognition of the nature of the study and the alternative programs available. The administrators are in the best position to know the nature and extent of compensation for other tasks available to the inmate, and to set rates of compensation for drug testing which will be neither penurious nor so high as to constitute an extraordinary inducement. The objective in determining equitable rates should be to give the prospective subject as much autonomy to freely decide on participation as subjects outside the prison enjoy. Sponsors should evince a willingness to respond to alternative rates and forms of compensation in the search for an equitable resolution of this question.

EXHIBIT 2

STATEMENT OF PRINCIPLES ON THE CONDUCT OF PHARMACEUTICAL RESEARCH WITH SPONSOR EMPLOYEES, FEBRUARY 11, 1975

INTRODUCTION

Employees of pharmaceutical firms make an outstanding contribution to pharmaceutical research by participating in non-therapeutic clinical trials of investigational drugs. While in large part the industry has concluded that studies conducted with sponsor employees have been successful, it is also recognized that because of their dedication and motivation, special consideration must be given to the matter of voluntary informed consent.

For this reason, the Executive Committee of the Board of Directors of the Pharmaceutical Manufacturers Association has adopted the following guidelines for the use of PMA member firms in the conduct of pharmaceutical research with employees. In adopting these principles, PMA, on behalf of its member firms, wishes to express its utmost concern for the rights and interests of those involved as subjects in all clinical trials and through these principles seeks to ensure that this concern is carried through specifically to sponsor employee volunteers.

1. MEDICAL RESEARCH COMMITTEE

Sponsors intending to conduct non-therapeutic clinical trials through the participation of employee volunteers should expand the membership and scope of its existing Medical Research Committee, or establish such an internal Medical Research Committee, with responsibility to approve the consent forms of all volunteers, designs, protocols and the scope of the trial. The Committee should also bear responsibility to ensure full compliance with all procedures intended to protect employee volunteers' rights.

Among the criteria to be applied in considering whether a given study should involve sponsor employee volunteers, the Review Committee should consider the following points: (a) the adequacy of available medical facilities and personnel to ensure the safety of the volunteers; and (b) the appropriateness of utilizing normal subject (as opposed, for example, to patients) in the proposed experimental protocol.

The Committee should include company physicians expert in the field to be studied, along with other qualified persons representing the sponsor's personnel and legal departments. Opinions of independent, responsible non-sponsor employees should also be formally obtained, either by including outside representatives on the Committee, or by enlisting the assistance of an Institutional Review Committee from an outside medical institution, or by setting up a special outside panel.

In those instances where employee volunteers are to participate in non-therapeutic trials to be conducted at an academic research hospital, peer review should also be conducted by the Institutional Review Committee of the hospital established for that purpose.

2. INFORMED CONSENT

In implementing clinical studies with sponsor employees, all requirements that pertain in general to informed consent must be scrupulously observed. Accordingly, the sponsor must prepare in strict conformity with all federal and state laws and regulations a statement of informed consent for execution by the employee.

It is recognized when sponsor employees are involved, the issue of "voluntariness" is very sensitive. It is therefore imperative that no coercion on behalf

of the sponsor be engaged in, either overtly or implicitly. Publicity intended to recruit volunteers should be distributed in as objective a manner as possible, preferably by bulletin board notices. Sponsor policy and industry policy should explicitly state that the choice of the employee to volunteer is his or her sole decision and whether the employee participates or not will have no bearing on his or her then current status or future prospects with the sponsor. Managerial personnel should be reminded that they are not to engage in any conduct which could in any manner be construed as coercing personnel for whom they are responsible to volunteer to participate in trials.

Compensation, if any, for employees volunteering for participation in such trials should be separately and appropriately arranged at a scale equivalent to that prevailing locally for similar trials. The scale of compensation should be reviewed and approved by the Medical Research Committee.

3. RECORD RETENTION

The participation or lack of participation by employees in sponsor trials, as well as the results of medical examinations conducted in the course of clinical research should not become a part of the employment record of the volunteer employee unless the employee requests the sponsor in writing to include it in his employment records. Employees who elect to have the information included in their employment records should be given the right at any future time to request that it be deleted.

4. THE RIGHT TO WITHDRAW

Employee volunteers should be informed of their right to withdraw from a program at any time. It should be made clear that such a right is not contingent upon their justifying or explaining their decision, nor will their withdrawal be considered as a factor in their future prospects with the sponsor.

5. WAIVERS

Under no conditions should an employee volunteer be asked or permitted to agree, in writing or orally, to waive his rights to adequate compensation in the event of injury incurred in the course of the investigation.

Mr. KASTENMEIER. And you read about 11 recommendations. The way the recommendations appear, it does not necessarily mean that they have been implemented.

Are these merely proposals, or are your member firms presently implementing these 11 recommendations?

Mr. STETLER. I think you probably have some appreciation of certain trade association limitations, not just in terms of manpower and will to do, but some legal limitations. We are not permitted under the antitrust laws, to enforce certain types of guidelines, no matter how desirable they might be.

I can tell you from personal knowledge of the situation that most of our companies do adhere to these rules, but obviously some do not.

I should add that we are very serious about these recommendations, and if they were to find their way into a statute or into regulations, this is perfectly agreeable with us because we realize the limitations on our capability to enforce them. They were accepted and adopted by our membership, and most of them are being adhered to. Nevertheless, they would be appropriate provisions in a bill that was something short of an absolute bar to use of prisoners in drug testing.

Mr. KASTENMEIER. It is, I think, commonly accepted that the pharmaceutical industry is highly competitive. With 131 member firms, if you were to impose or suggest or make recommendations which were costly to them in terms of research, they might or might not accept those recommendations.

Mr. STETLER. That is right. I should point out, however, that given the large expenditures that are involved in research, phase I testing is relatively inexpensive. It is one of the lesser items and lesser involvements in terms of the total research bill. In phase I we are dealing with a very limited number of people for very short durations, and therefore I can say that it is not the money involved in payment to prisoners, that is important.

Mr. KASTENMEIER. On Monday, Dr. John Arnold—and I quote him on the issue of expense, "in terms of expense, I have made a rough calculation that the nonprison alternative will increase the total cost of new drug development by less than 1 percent."

Do you have any comment?

Mr. STETLER. I have no comment. I have no real reason to doubt him or confirm that figure. It does underscore the point I tried to make, and that is, the cost of prison testing is not really the important factor in our decision, or, I think, in yours in this case.

Mr. KASTENMEIER. In terms of medical research accidents, is it the practice for a firm to carry insurance to protect against claims made against the firm in the conduct of medical research in terms of accidents?

Mr. STETLER. Yes, indeed.

Mr. KASTENMEIER. Let us assume that Congress decided to terminate, as far as we are able to, the use of prisoners in State and local or Federal institutions. How long do you think it would take to permit ongoing experiments to wind up so that a termination date could be effected?

Maybe I should ask Dr. Trout how long that might require?

Mr. STETLER. We could both answer that very easily because these are short-term experiments. If you are only interested in pending experiments, they are all going to be terminated within, let us say, 3 months.

But a much more important issue to us is whether there is a capability now or in a year or 2 years to develop acceptable alternative populations for this important kind of testing? We do not see the alternative at the moment, and therefore that is why we are trying to suggest that maybe there is an answer to the problems that exist—and there are problems—short of an absolute ban. It is not the time required to discontinue tests that is important.

Mr. KASTENMEIER. I yield to the gentleman from New York.

Mr. PATTISON. Thank you for your excellent statement. I was particularly gratified by the summary of your policy statement, and I would hope you would make copies of that available to us other than just in the record. Would that be possible?

Mr. STETLER. Yes, indeed. I would be glad to do that.

Mr. PATTISON. Because I think that the policy statement addresses itself to each of the problems we have in this legislation, and it occurred to me when you were going over those points that many of those statements could easily be suitable for legislation, rather than make them into regulations.

Would it not be helpful to you if indeed legislation were enacted which contained the kind of safeguards that your policy statement contained? Would it not be helpful to you if that were uniform na-

tionwide, in view of the fact that you have very little control over whether or not consent is informed or not, because the local procedures at present, State by State, will vary?

Mr. STETLER. In my opinion, the answer would be yes to that question for several reasons. There are many drug companies some of which are not members of our association and, of course, we are always going to be judged by what might be the exception. If there is a nonconformer, and he is doing a bad job, that is the one that tends to get the publicity.

I do think that even if those sorts of amendments found their way into a Federal bill that might come from this deliberation, it would not have a great impact automatically or right away on the State facilities. I think what it could be useful for, though, in the development of a model State bill. Many of the States are now wrestling with the same questions before this committee as to whether they should bar prison testing, and some have. We do not like it where that has happened, so I think a precedent coming in a proper Federal bill would be a very good development.

Mr. PATTISON. We have the option of going either way on that. We can regulate Federal prisons directly and use that as a model, or we can regulate by prohibiting the use of various Federal funds in prisons if they do not adopt these standards.

Mr. STETLER. I was not quite sure how far that reaches into the State system because I do not know just how dependent the State prison systems are on Federal funding.

Mr. PATTISON. There are Federal questions involved in that, but there are two options. One of your points was one with which I definitely agree, that the consent should have no bearing upon prisoners' penal status or eligibility for parole. We have heard testimony that, in fact, when consent is being obtained that frequently the indication is given that this will be considered when you come up for parole, which undoubtedly it will be.

As a matter of fact, there is just no way to avoid that. I suppose if you have been doing good things, that is part of what parole is all about. To what extent do you feel that is violated?

Mr. STETLER. I heard the testimony Monday, and today, and I was a little suprised at what was said in that regard. I think maybe Lexington may be atypical. In most of the prisons we deal with, there is no giving of good time for involvement in medical experimentation. As a matter of fact, there is a direct prohibition.

Our position is that participation in testing should not be considered for parole purposes, nor for time off. It is the point that Congressman Ryan was making here Monday, and we would agree with that.

Mr. PATTISON. I was interested in your discussion relative to how you go about—and perhaps I should direct this to Dr. Trout—how you go about making the deal with the particular prison and the compensation that is involved. You anticipated one of my questions because I was interested in whether or not compensation, perhaps there is a limit to compensation because of the fact it has the problem of consent also. If you pay somebody $20 a day or something like that, then perhaps you get a lot of people who should not really consent.

The other area of compensation, which is to the prison itself or the prison population itself, which may have some very good social implications, to what extent—how do you make that deal? Is there a bargain that goes on? Is there a fairly uniform kind of standard?

Dr. TROUT. There is no uniform standard, no bargaining that goes on. Much of our research is not done directly by us in the prisons. It is done in most cases by people from universities that are close to a particular prison setup. We contract with the professor in the university to do the study.

As far as the compensation is concerned, it really varies all over the lot, depending on the particular State you are in. Even the contribution to the overall welfare fund of the prison varies. Some States have a set percentage figure; others may just have a dollar amount.

I might add there are other benefits in many of these cases to the prisoners themselves, other than compensation and other than money into the welfare fund. For example, most of our people who are going into the prison setup are experts in particular areas of medicine, and when they are there, they are not just there to do the experiment. They are frequently called upon by the prison doctor or the prison administrator to consult on a patient, a prisoner patient in that particular setup. This is a direct medical benefit to the prisoner.

There are many participants who do not end up as part of a clinical research program who go through a complete physical exam in which things are detected, and they are still not part of a clinical research program. These are added benefits over and above what the prisoner is getting paid in money.

Mr. PATTISON. I suppose you cannot answer this question, representing who you do. Do you suppose that the prisons get enough from the pharmaceutical companies? They have a very difficult time financing prisons these days.

Mr. STETLER. Do the prisons get enough?

Mr. PATTISON. Suppose they doubled the price?

Mr. STETLER. Doubling the price would not be that much of a problem with us. It is not the price. This is a small part of our research bill, relatively.

Mr. PATTISON. I appreciate your frankness. I certainly recommend that they do it.

Mr. STETLER. I would gather the prison systems have many problems.

Mr. PATTISON. Financial concerns is one of the major ones. I have no further questions.

Mr. KASTENMEIER. Apparently the prisoners are in the same position as the Arabs and the oil.

Thank you very much for your testimony here today. We deeply appreciate it. We may have other questions for you, Mr. Stetler, and we would like to pose them in a letter to you.

Mr. STETLER. We would be delighted to respond.

Mr. KASTENMEIER. Next the Chair would like to call Dr. Peter B. Meyer, assistant professor of economic planning from Pennsylvania State University, and Mr. Billy Wayson, who is director of Correctional Economics Center of the American Bar Association.

[The prepared statements of Mr. Billy Wayson and Dr. Peter B. Meyer follow:]

BIOGRAPHICAL INFORMATION: BILLY L. WAYSON

Professional experience

December 1973 to present: Director, Correctional Economics Center, ABA Commission on Correctional Facilities and Services.

December 1971 to December 1973: Special Assistant to the Director, U.S. Bureau of Prisons:

(1) Deputy Director, National Conference on Criminal Justice.
(2) Staff Associate, Corrections Task Force, National Advisory Commission on Criminal Justice Standards and Goals.
(3) Project Director, National Institute of Corrections.
(4) Co-Director, National Conference on Corrections.

May 1970 to December 1971: Program and Management Analyst, U.S. Bureau of Prisons:

(1) Director, Task Force on Performance Measurement.
(2) Project Director, State Correctional Administrators Workshop.
(3) Acting Budget Officer.
(4) Attorney General's Law Enforcement Policy Committee.

March 1969 to May 1970: Administrative Assistant, Office of Law Enforcement Programs, Law Enforcement Assistance Administration.

March 1966 to March 1969: U.S. Bureau of Prisons, various positions.

Education

Graduated magna cum laude from the State University of Iowa in 1965 with a major in philosophy and minor in economics.

Elected to Phi Beta Kappa.

George Washington University, Graduate School of Arts and Sciences from 1968–70 in economics.

Miscellaneous

1973 and 1970: Special Achievement and Outstanding Performance Awards, U.S. Department of Justice.

1974: "Correctional Myths and Economic Realities", Proceedings: Second National Workshop on Corrections and Parole Administration.

"Prison Administration in a time of Change", *Handbook of Criminology*, Daniel Glaser, editor.

"The Economics of Crime and Community" (with Gail S. Monkman), *Law in American Society*, February, 1975.

STATEMENT OF BILLY L. WAYSON, DIRECTOR, CORRECTIONAL ECONOMICS CENTER, AMERICAN BAR ASSOCIATION

Mr. Chairman, members of the subcommittee: Dr. Peter B. Meyer and I thank you for the opportunity to testify before the committee regarding HR 3603.

Much has been written and spoken on the ethical, legal and medical aspects of human subject experimentation, generally, and the use of inmates as experimentees specifically. The perspective we hope to add, however, is that of the economist. The application of economic concepts and analysis to correctional policy issues is a new one; in fact, the Correctional Economics Center of the Commission on Correctional Facilities and Services[1] is the only organization to my knowledge whose sole purpose is such research. There are two ways in which economics may add to the national debate on the use of prison inmates as subjects of medical experimentation.

First, what are the real possibilities for individual choice within the prison context? Analyzing this question from an economic perspective begins to address the issue of coercion and, more specifically, voluntarism.

The second question has two parts and is independent of whether or not the potential subject is, in fact, faced with a choice between comparable alternatives: How large is the implicit subsidy to private corporations resulting from the government's willingness to provide a supply of experimentees, facilities and personnel services? Related to this is the question of who bears the cost of the subsidy and who benefits from its results.

[1] The views expressed in this statement or made before the committee are solely those of the witness and are not intended in any way to represent the official or unofficial views of the American Bar Association, the Commission on Correctional Facilities and Services, or the Foundation sponsoring this research.

I will confine my remarks to the first question which is discussed more fully in the publication provided to the committee titled "Medical Experimentation on Prisoners: Some Economic Considerations."

The concept of choice is a central part of economic theory. An individual has multiple needs or wants but is constrained in fulfilling them because of limited or scarce resources; therefore, a decision must be made between alternatives. While the literature is replete with obtuse, academic discussions of how these choices are made, there are some, not overly simplified, ways of giving a commonsensical appreciation for the decision making process. First, the more one consumes of say, a loaf of bread, the less satisfaction he derives. (This is titled the principle of decreasing marginal utility.) Second, someone given a choice between bread and apples will choose the one which adds the most to total satisfaction—"utility maximization" in the economist's rubric.

Medical experimentation in closed institutions such as prisons complicates the issue of choice, because voluntarism is the operative guideline, but it requires not only the existence of alternatives but also complete information on the consequences (costs and benefits) of choosing one alternative rather than another.

This prelude requires one more theme before elaborating on choice in a prison environment. The Committee's prior efforts in the corrections field have made it aware of the legal and programmatic issues. A convenient summary, however, from a social scientist's viewpoint, is presented in Erving Goffman's landmark book, *Asylums*.[2] Some highlights relevant to the "economics" of informed consent to become a medical experimentee include:

> . . . so little work is required that inmates, often untrained in leisurely pursuits, suffer extremes of boredom. (p. 10)
>
> Paraphrasing: there are house rules, a small number of clearly defined privileges, a set of punishments consisting of the withdrawal of privileges or the right to earn them and an incorporation of release as a privilege. (pp. 48–51)

Perhaps, the formulation appears a bit abstract, but economic analysis and the nature of prison environments present a convergence of ideas which can explain why medical experimentation is conducted with inmate subjects.

The very word "choice" discussed earlier, implies (even mandates) selection among alternatives. Furthermore, these alternatives must display some nearly equal value, or utility to the chooser. Stated somewhat differently, choice implies that the foregone alternative (the opportunity *not* selected) bear a somewhat equal value to the option selected. The "cost" of choosing A is what one could have had by choosing B. If one's opportunity cost is low (i.e., selecting A means that one gives up very little in relationship to what A yields) no real choice has been made.

Information plays another part in choice. Individuals are assumed to possess nearly full information about alternatives, i.e., knowledge of the results of any selection. If information is withheld or otherwise lacking, then, again a realistic assessment of the alternatives is not possible and real choice cannot be said to exist.

THE PRISON ENVIRONMENT AND CHOICE

Given the previous statements regarding the unique nature of a confined population, some observations of inmates' needs may be made:

(1) Relief from coercion (such as an earlier release).
(2) Entertainment or relief of boredom.
(3) Physical amenities, such as better housing or food.
(4) Current and future cash incomes.

To the degree those alternatives are not available to inmates, the more they will pay for an additional unit, that is, the "price" an inmate will pay for this additional unit will be higher than that of his free world counterpart, given the conditions in total institutions described by Goffman. Prisoners do not select from equal alternatives and, in most cases, there is no comparison between option A (participation in experiments) and option B (non-participation).

CASH INCOMES

Economically, the most important feature is the financial remuneration from available alternatives.

[2] Erving Goffman, *Asylums* (Garden City, New York, Doubleday-Anchor, 1961).

Some correctional agencies offer no income-generating opportunities for inmates. This is most dramatically illustrated by pre-trial detainees whose status often makes them ineligible for paid work or industry assignments. In any case, with a nationwide norm for prison wages of well under $1/day, this low opportunity cost will act to obviate choice and force prisoners to "volunteer" for experiments.

It is a perverse irony of "Catch-22" dimensions: Even if remuneration were reduced low enough to eliminate this element of economic coercion, other non-cash forms of remuneration exist and still preclude free choice. (At the same time, the subsidy to experimentors is increasing.)

ENTERTAINMENT AND OTHER AMENITIES

To the extent that participation in medical experiments offers a positive change in physical and nutritional environments, the participation rate will be higher as the inmate "chooses" from vastly unequal alternatives. Even very minor changes in environment may carry great weight if the living conditions are sufficiently adverse.

Unlike the population at large, the inmate ordinarily has few opportunities to relieve the rather sedentary, isolated and empty life associated with incarceration. Breaking this physical routine and the status associated with experiment participation constitute still additional non-monetary inducements to participate.

PAROLE DECISIONS

It is common practice to issue "certificates of appreciation" and other (costless) paper recognition to inmate participants. To the extent that these are viewed by the inmate as favorably influencing his chances for earlier release, participation in experiments will increase. This is obviously a reward *not* applicable to potential subjects in the free world population and thus represents a subtle coercive element peculiar to prisons.

Informed consent—The applicable criterion in medical experimentation—is more complex (even economically) than simple choice. The preceding summary showed that each of the possible forms of remuneration (money, housing, food, entertainment, goodtime or earlier release) involved some degree of coercion, and, more importantly from our perspective, a reasonable dollar value can be estimated for each of these "rewards." Even if there were no rewards (monetary or otherwise), *informed* consent cannot occur because the activities are by definition experimental, and the consequences are unknown. The concept of free choice implies adequate information on all possible options. If consequences are not understood and clarified by experimentors and/or concealed from experimentees, there cannot be an informed decision. Unless the experimentees are compensated for this risk—just as it is for any investor—a subsidy borne by the individual is provided to the corporation conducting the tests.

An economic look at medical experimentation can contribute more than simply whether fifty cents daily are better than nothing. Even if some stroke of fate removed the incentives to participate (e.g., money, better housing, more movies, peer group approbation), there would still remain the question of who pays and who benefits from medical experimentation in prisons. Dr. Meyer will discuss these subsidy aspects and their impact on correctional efficiency.

STATEMENT OF PETER B. MEYER, ASSISTANT PROFESSOR OF ECONOMIC PLANNING, PENNSYLVANIA STATE UNIVERSITY, UNIVERSITY PARK, PENNSYLVANIA

H.R. 3603 is designed to terminate the use of prisoners in medical experiments in the United States. In so far as such experimentation has proven to be of significant economic value to the persons conducting them, termination of experiments is challenged on the basis of their *efficiency* impacts. I will deal with the issues of efficient production in the sections below in which I (a) identify the implicit subsidy provided to pharmaceutical experimenters using the nation's prisons for experimentation purposes, and (b) trace the probable impact on the public welfare of removal of the implicit subsidy. Before addressing these efficiency issues, however, I want to make a statement about *equity* considerations inherent in the problem.

Prisoners will serve as experiment subjects for rates of pay which are minute fractions of prevailing national wages.[1] However, their willingness to serve is in part a reflection of the prevailing prison wage for routine employment, which remains well under $1.00 *a day*. Prisoners, therefore, face much lower "opportunity costs" in the form of foregone incomes associated with service as experiment subjects, and will therefore serve more willingly than most other citizens. More emotionally laden language may carry the identical analytical meaning: "the oppressed condition of prisoners leaves them at the mercy of wage-gauging experimenters." However the argument is phrased, the condition described is one in which costs may be saved by relying on a group of persons with little choice who will serve as experiment subjects. A specialized "class" of willing subjects is thus the most efficient cadre of "volunteers" to use for medical trials.

I object to this specialization on equity, not efficiency, grounds. However, I consider it incumbent upon any person arguing for a change in the status quo to demonstrate that the changes he advocates will enhance the public welfare. Thus the sections below examine the efficiency issues from the perspective of the nation as a whole. (There may be a number of different efficiency perspectives, including those of the experimenters, who are trying to lower the costs of their activity, the correctional systems, which may receive some benefits from experiments, and the like; I have attempted to aggregate across all of those entities to derive a nationally relevant assessment.)

DO EXPERIMENTERS USING PRISONS BENEFIT FROM SUBSIDIES?

The desire of experimenters to maintain their access to prison inmates as subjects derives from a series of very real subsidies to their costs which derive from their practice. A subsidy is typically recognised only when an explicit cash transfer occurs. The prison experimentation subsidy occurs in the form of reduced costs, and therefore does not involve a visible cash transfer.

Despite its invisibility, it is very real. As is demonstrated below, it appears that the subsidy to pharmaceutical development experimentation at Phase One alone has recently averaged $229 million a year.

The Elements of the Subsidy to Experimenters

Subsidies may be associated with each subject employed in experiments or with the number of patient- or subject-days. We shall examine the latter class of subsidies first.

1. *Experiment Staff Savings.*—To the extent that prisoners may serve as experiment staff (such as laboratory technicians, orderlies, and the like), the experimenters may be able to save costs. The apparent cost savings associated with using prisoners in place of free labor market employees for tasks typically assignable to inmates is $2.25 per subject-day or patient-day.

2. *Savings in Facilities Costs.*—In so far as experiments are conducted in buildings maintained by the corrections systems, utilizing utilities, facilities and equipment provided by that system, or in special facilities developed with any assistance from the institutions in which they are housed, savings in the outlay otherwise required for facilities development or maintenance is roughly $1.75 per subject-day or patient-day.

3. *Free Institutional Services.*—Inmates of institutions are housed, fed and clothed by the correctional system. The food and housing would be required by any person who spends some time in a medical institution serving as an experiment subject, so the experimenters are being relieved of the costs for provision of the necessary maintenance of subject services. The apparent value of such housing and food services is $6.00 per resident patient-day.

4. *Subject Salary Savings.*—It costs nothing for inmates to hold themselves available to experimenters who are not certain when they will initiate a given experiment; similarly, it costs them nothing to return for post-experiment check-ups. By contrast, there are real costs to non-incarcerated persons in making themselves available for unknown experiment initiation dates, in terms of work time and pay lost, as well as possible inconvenience. The dollar cost for such "check-in" contact has been estimated to be $25.00 every two days, or $12.50 per subject-day.

5. *Patient Salary Savings.*—Inmates appear to be, on average, capable of earning some $7,000 per annum, if fully employed in legitimate occupations. Therefore, if experimenters would have to hire persons with comparable skills and education to act as subjects, they would have to compensate their subjects for lost pay. Assuming a 240 working-day year, this lost pay would amount to about

[1] These arguments and data are extracted from Peter B. Meyer, "Drug Experiments on Prisoners: Ethical, Economic or Exploitative?" (Lexington, Mass.: Lexington Books, forthcoming, 1975).

$30.00 a day. Thus, the savings enjoyed by experimenters using prison inmates is $30.00 per patient-day of active experimentation.

6. *Insurance for Aftereffects.*—Since experiment subjects, at least in Phase One pharmaceuticals tests, are often the first humans to ingest given substances, aftereffect risks are high. Moreover, the actual occurence of such effects—and their attribution to any given experiment—are very hard to determine according to strict legal principles of proof. Therefore, a generalized insurance provision is appropriate remuneration for the risk incurrence services provided by experiment subjects. At least in part as the result of the concentration of high risk experiments in prison populations, no such insurance for medical damage and/or lost incomes is provided. Were such insurance provided, the coverage would have to be obtained for every person first becoming a subject in medical experiments. Moreover, since the insurance would have to be provided for a person's lifetime, a capitalized stream of probable future insurance premium payments would have to be set aside. The dollar value of this capitalized stream is $10,000 per new subject, now avoided by experimenters.

Figure 1 demonstrates how, given the apparent volume of experimentation on the part of the U.S. pharmaceuticals industry, these subsidy components combine to demonstrate an aggregate subsidy to pharmaceuticals firms adherence to FDA regulations on new drug introductions which amounts to a total of $229 million annually.

FIGURE 1

The elements of the subsidy to experimenters using prisons

Subsidy/subject-day:	
Subject salary savings	$12.50
Experiment staff salary savings	2.25
Saving in facilities costs	1.75
Total per subject day	16.50
Total subject days x 3,030,960	50,010,840
Subsidy/patient-day:	
Patient salary savings	30.00
Experiment staff salary savings	2.25
Savings in facilities costs	1.75
Free institutional services	6.00
Total per patient-day	40.00
Total patient-day	40.00
Total patient days x 473,040	18,921,600
Subsidy/new subject:	
Current dollar value of a discounted stream of insurance payments providing payment for risk incurred and compensation costs of after-effects.	
Total per new subject	10,000
Total new subjects x 16,000	160,000,000
Total subsidy	228,932,440

DOES THE SUBSIDY SERVE THE PUBLIC INTEREST?

The access that experimenters have to prison inmates at subsidized experiment rates and costs affects the public interest directly through two processes: (1) the impact of the transfers on the rate of medical and pharmacological progress and quality and cost of medical care in the United States; and, (2) the impact of the presence of experiments in prisons on the efficiency and effectiveness with which the correctional system produces the outputs for which it is mandated by the public. We can examine the ramifications of subsidized medical experimentation in prisons in each of these areas in turn.

SUBSIDIES AND PROGRESS IN THERAPEUTIC CAPACITIES

Therapeutic capacities incorporate two essential facets: the capacity to diagnose and provide specific medical *services* for given conditions and the capacity to provide medical *products*, or drugs, for specific conditions which will at least alleviate the discomfort of a patient. Thus, therapeutic capacity is enhanced by medical experiments of the disease study and related nature, as well as by FDA required pharmaceuticals experimentation. The importance of the subsidy provided in the process of therapeutic advance lies in the role it may play in promoting a more rapid rate of new medical treatment and/or drug development than would otherwise exist, or, reversing the argument, the extent to which its absence would slow our rate of progress in medical and pharmacological capabilities.

Medical Experimentation

The primary issue with medical experiments is the matter of payment to experiment subjects. If medical experiments are funded and use volunteers, then the funding agents may be willing to pay the true free market costs of volunteers, and the experimenters would be indifferent as to the fees required for payments to subjects. In this sense, therefore, there is no medical experimentation dependence on prisoners as subjects. The major ancillary issue, which may or may not be significant, is that of possible delay in obtaining the necessary volunteer pool. However, to the extent that medical experiments still have access to medical facility clients, subject recruitment should not be a major problem.

Private medical researchers, so long as they can obtain research funding, will continue to experiment, since their activity produces ego gratification, recognition, and other benefits for them. Their contribution to therapeutic advance, therefore, is not associated with access to incarcerated persons, but to subjects in general, and subsidy denials will not reduce their activity level.

Pharmaceuticals Development Experimentation

In order to determine the value to the public at large of the massive subsidies to drug development experimentation which have been provided, we must carefully examine the industry's claim that such subsidies are critical to drug manufacturers' profits.

Profit History.—Drug development is not merely a process of pursuit of knowledge and medical care capacity. It forms one of the critical tools in the competition between drug manufacturers for market and the prescription dollar in an industry with over 700 firms, of which only 28 had fourth quarter, 1974, sales of over $22 million.[1] The observation made in 1970 by the Health Policy Advisory Center (Health-PAC) that, "Control is concentrated in the top fifteen (companies), who sell more than half of all drugs," appears to remain valid.[2] This two-tiered industry, with the bulk of market shares (and profits) controlled by the houses with extensive brand-name prescription items on the market, performed remarkably in the 1960's according to the Health-PAC review:

"For the last ten years, the drug industry has held either first, second or third place among all U.S. industries in terms of profitability, outdistancing such obvious money-makers as the cosmetics, aerospace, recreation and entertainment industries." [3]

We can turn to a more recent look at the profit picture for the drug industry in order to determine its capacity to develop therapeutic capacities in the absence of a subsidy.

Current Performance.—The profitability of the major firms in the pharmaceutical industry may be compared to all-industry average performance data as a means of measuring the capacity of drug firms to adjust to denial of the implicit experimentation subsidies associated with experiments on prisoners. We use data from the quarterly survey of corporate performance prepared by *Business Week* for recent years.

As Table 1 indicates, the major companies in the industry for which *Business Week* gathered data performed at a level which almost doubled the overall profitability and returns evidenced by big business as a whole in the United States.

Denial of the Subsidy.—Despite their outstanding performance in the past, the drug companies may be vulnerable to major profit losses if the implicit subsidy associated with experiments on prisoners is denied to them. We can examine the hypothetical impact of such a denial on the industry's 1974 profits as a means of examining this possibility. The findings of our examination,

[1] *Business Week*, "Survey of Corporate Performance: Fourth Quarter 1974" (March 24, 1975, pp. 57–91).
[2] B. Ehrenreich and J. Ehrenreich, *The American Health Empire*, a Health Policy Advisory Center (Health PAC) Report (New York: Random House, 1970), p. 98.
[3] *Ibid.*, p. 99.

TABLE 1.—DRUG INDUSTRY AND ALL-INDUSTRY PROFITABILITY[1]

[In percent]

	Industrial group	
	Drug industry	All-industry composite
Profit rate (1974)	9.3	5.3
Return on common equity (1965–75 annual average)	16.0	8.0
Growth in per share earnings (1965–75 annual average)	11.0	6.0

[1] Data are all from: "Business Week," "Survey of Corporate Performance: 1st Quarter, 1975" (Mar. 24, 1975, pp. 57–91).

presented in Table 2, make it evident that even without the subsidy, the industry's profit performance is superior to the all industry average. Under the assumption that none of the experiment cost increases can be passed on to customers, the industry still shows average profits three percent above the national industry average.

An adjustment on these figures is, however, in order. The $229 million subsidy denial is in reality to be spread across all the pharmaceutical firms operating in the United States, but the sales and profit data in Table 2 apply only to twenty-eight large, U.S. based firms on which data were available. In addition to the small companies whose size led to their exclusion from the *Business Week* survey, Parke, Davis and Company (perhaps the industry leader in the number of prescription products marketed) was excluded due to the absence of data. Foreign-based enterprises such as the giant Hoffman-La Roche firm (which sold one billion Librium and three billion Valium tablets in the United States in 1974, with a retail value of $670 million and 90% of the U.S. tranquilizer market) are also excluded.[4] Thus, the profit declines attributable to loss of the subsidy derived from experiments on prisoners will, for the industry as a whole, be even smaller than Table 2 suggests.

TABLE 2.—DRUG INDUSTRY PROFITS AND SUBSIDIZED EXPERIMENTS, MAJOR U.S. FIRMS, 1974

[All dollar figures in millions]

	Experience excluding subsidies			
Actual[1]	Constant prices[2]	Constant increase[3]	50 percent coverage price increase[3]	100 percent coverage price increase[4]
Sales	$21,634.9	$21,634.9	$21,749.4	$21,863.9
Profits	$2,013.7	$1,784.7	$1,899.2	$2,013.7
Profit rate (percent)	9.3	8.2	8.7	9.2
Wholesale price increase (percent)[5]	0	.53	.53	1.06

[1] Taken from Business Week, "Survey of Corporate Performance: 4th Quarter, 1974" (Mar. 24, 1975, pp. 57–91).
[2] Derived by elimination of $229,000,000 subsidy reflected in reduction in profits, assuming constant dollar sales.
[3] Derived by elimination of $229,000,000 subsidy, compensated for by a $114,500,000 price increase, reflected in higher sales totals and only a $114,500,000 drop in profits.
[4] Derived by increasing sales by $220,000,000 to compensate for subsidy denial, and leaving dollar profits unchanged.
[5] The hypothesized percentage increase in dollar sales volume given subsidy denial (this estimate, therefore, assumes no change in unit sales).

In conclusion, we can state unequivocally that, even in the total absence of the subsidy now provided to pharmaceutical manufacturers, *and no price increases*, those firms would continue to reap profits at rates which exceed the national industry composite levels and thus would continue their new drug development at comparable levels of effort.

EXPERIMENTS IN PRISONS AND CORRECTIONS EFFICIENCY

However great the contributions to the public interest derived from access to prisoners for tests advancing medical therapeutics, it is possible that such access should not be granted. The primary purpose of correctional institutions is, after all, *not* medical experimentation but "incarceration" and "training." If

[4] *Business Week*, "A Drug Giant's Pricing Under International Attack" (June 16, 1975, p. 51).

the capacity of the correctional system to produce training and incarceration services is sufficiently undermined by the presence of experiments within institutions, then this loss to the public interest may more than offset gains accrued through medical experiments. We need, therefore, to examine the interaction between experiments and corrections efficiency in some detail.

Incarceration Services and Experimentation

Incarceration services in the Avio "model" are two-fold, consisting of removal effects and deterrence effects.[5] A direct corrolary exists under the present process of subsidy grants to experimenters between removal and the magnitude of subsidy granted experimenters: the larger the institutional scale and the more complete the removal, other things being equal, the more constrained will be the opportunity costs of inmates and the larger the subsidy available to experimenters will be. While a positive interaction between removal production and subsidies may be evident, however, the case is far from clear with respect to deterrence.

Deterrence and Resentment.—Deterrence may be seen as consisting of two components: the impact of the prison experience on the individuals undergoing the life behind the walls, and the impact of that experience on persons who have never "served time," but are intimidated from running the risks of ending up in jail. We can address these as "specific" and "general" deterrence. Onerous living conditions may produce specific deterrence for people who decide that they will never voluntarily expose themselves to the experience a second time, but no general deterrence is provided in the absence of publicity about the prison experience. In light of the secrecy which surrounds medical experiments in prisons, the only access that non-inmates will have to information about experiments and their relationship to the life experience in prisons will be through word-of-mouth contact with ex-inmates. It is therefore probable that general deterrence is not affected by the presence or absence of experiments, since publicity about such costs is minimal.

In this book, "The Limits of the Criminal Sanction," Herbert Packer notes that, ". . . the feelings of bitterness, hatred, and desire for revenge on society that are engendered by inhumane treatment may well produce a net loss in crime prevention."[6]

This "backfire" problem is inherent in any activity which introduces a gratuitous negative element into the life of inmates. The issue with respect to experimentation is whether it induces a negative or positive influence: while the subjects may earn money, better living conditions and the like, thus finding themselves experiencing less specific deterrence, the procedures to which they must subject themselves may, in their eyes, be inhumane, with the negative consequences noted by Packer possibly emerging. On the other hand, non-subjects are provided with a new negative element in their prison experience in that they see themselves denied the benefits that accrue to experiment subjects, and their resentment over inequities could elicit responses paralleling reactions to inhumane treatment.

Given medical experiments within the prisons, the persistent distrust of the inmates for all authority behind the walls, and the tendency for the coercive system in a total institution to incorporate any privileges into its armory of tools for coercion, it is highly probable that the presence of the discriminating structured medical tests in prisons *will*, in fact, induce resentment and engender other socially undesirable attitudinal consequences on the part of *all* inmates, whether serving as objects or not. In the absence of any mechanisms to assure general deterrence effects which could overcome these specific negative attitudinal consequences, we can only conclude that the *net deterrence value of the experiments is probably negative.*

Biases Towards Incarceration in Institutions.—Pressure to maintain high incarceration values in the corrections process may emanate from the experimentation pattern. The pharmaceutical manufacturers and other experimenters will prefer the large institutions to community-based corrections on the basis of the greater subsidy made available to them by the larger facilities. They will in the presence of the existing subsidy, be inclined to use such political power as they may wield to further the maintenance of a large scale facility (especially in those instances in which they have made substantial capital investments behind the prison walls).

[5] K. Avio, "An Economic Analysis of Criminal Corrections: The Canadian Case," *Canadian Journal of Economics*, Vol. 6, No. 2 (1973), p. 165.
[6] H. L. Packer, *The Limits of the Criminal Sanction* (Stanford, Cal.: Stanford University Press, 1968), p. 47.

However, the internal system incentives for the maintenance of large scale institutions are even *greater in the absence of subsidies:* if the fees paid for services rendered are paid to the correctional system rather than to general government or inmates, then the increase in the discretionary funds in the agency budget associated with the presence of the experiments will be a function of the difference between the actual cost of rendering the services and the "free market" rates which would apply. Since the external effects of high incarceration include constrained opportunities, high incarceration output will reduce the cost of experiment services. The "discretionary surplus" available to the corrections administration will be higher when experiments are conducted in large scale institutions rather than community-based centers.

This bias does not have any demonstrably major effect on the combined productivity of incarceration and training effects. It is *not* valid, however, to assume that the bias does not materially influence the effectiveness of overall corrections service provision. Given a bias towards maintenance of incarceration at the expense of positive training, the level of incarceration services produced will always exceed that volume which is most efficient, and the production of training services will always lie below the optimal level. Therefore, the corrections system impact on crime will *always be lower than the highest attainable* (optimal) *level.*

Training Services and Experimentation

One form of positive training outcome of experimentation in prisons is skill development of inmates hired as experiment staff. However, such training benefits must be seen to be of minimal current value in so far as the experimenters will not train inmates with short sentences for such jobs, since too much training effort would be required due to a high personnel turnover rate associated with discharges from the institution. Thus, the very persons trained would not be the ones who could use that skill on the "outside," but those expected to remain behind the walls for a protracted period of time. Not even the direct provision of correctional services (training) by the experimenters themselves really seems to end up serving correctional objectives!

Aftereffects and Productivity.—Sequelae of experiments may act to undermine the value of whatever positive training is available. In assessing the benefits of an experimental corrections program in Washington, D.C., John Holahan uses discounted lifetime streams of benefits and costs for experimental program in order to assess its value. He demonstrates that it is the earning capacity and behavior long after discharge from incarceration that determine the net effects of the correctional process and its contributions or costs.[7] Sequelae occur during the course of ex-subjects' lifetimes, and affects the stream of outcomes in two major predictable ways.

First, any aftereffect which causes disability for the subject will tend to reduce the positive value of training. This reduction will take the form of an unanticipated truncation of the lifetime increased income stream due to total disability or early death, or a partial reduction in the stream due to partial incapacitation. In any event, any significant sequelae will undermine positive returns to training for legitimate income earning.

Second, to the extent that sequelae are identified by the ex-subject as associated with experimentation on his/her body, and to the extent that her/his original submission to experimentation was in any manner coerced, the experience of a debilitating aftereffect will raise antagonistic attitudes towards the society which, in the eyes of the individual, caused that negative experience to occur. Thus, the same pattern of desire for revenge, etc., that Packer attributed to the inhumane correctional setting could be stimulated *ex post facto* by the experience of unanticipated and undesirable aftereffects to experiments.

Demonstration Effects.—An explicit *negative* training element may be inherent in experimentation to the extent that subjects perceive themselves to be coerced. Inmates who feel themselves forced into the role of human guinea pigs may interpret the experimentation experience as an object lesson in the principle of competition: "take your fellow man for all he is worth, so long as you can get away with it." This kind of attitude promotes the perception of criminal behavior simply as one of a number of equally appropriate responses to economic conditions and difficulties in earning. While this attitude towards crime may well be wholly rational, it is not conducive to reducing the propensity of ex-inmates

[7] J. Holahan, "Measuring the Benefits of Prison Reform," in R. H. Haveman *et al.* (eds.), *Benefit-Cost and Policy Analysis,* 1973 (Chicago: Aldine, 1974), pp. 491–516.

to engage in behaviors labelled as criminal. David Gordon, a neo-marxist economist, has observed the presence of a common theme in all crime, noting that "most crimes in this country share a single important similarity—they represent rational responses to the competitiveness and inequality of life in capitalist societies."[8]

To the extent that Gordon is right, and/or to the extent that the exposure to medical practitioners' exploitations of their bodies stimulates inmates to concern themselves with the processes of competitive success in a capitalist system, the negative training consequences of medical experimentation in the nation's prisons are indeed of major importance.

On balance, we can safely suggest that the contribution of medical experiments to the capacity of the correctional system to produce "positive training" in the sense of attitude and skill differences which will tend to reduce post-incarceration on criminal behaviors is minimal, at best. Most indications are that such experimentation actually contributes to the production of "negative training," which would tend to increase criminal behaviors following discharge.

Prisons, Experiments and the Productivity of Corrections

As the result of the presence of subsidized experimentation on the bodies of the residents of the nation's correctional institutions, we can identify, in summary, two basic impacts on productivity:

(1) A bias towards more incarceration than would be warranted from the point of view of maximum correctional system efficiency in reducing future crime; and,

(2) A tendency towards negation of positive training through adverse experiment sequelae and promotion of negative training as the result of negative experiences in the correctional institutions, producing more negative and less positive training outcomes from any given volume of "corrections" provided.

IMPACT ON THE PUBLIC AT LARGE

Denial of the subsidy associated with access to prison inmates will not deter therapeutic advance in medical and drug development, while simultaneously contributing to potentially beneficial impacts on correctional institutions and the corrections system as a whole.

Subsidies and access to prisoners have thus been shown to be, at best, *neutral* with respect to medical progress which benefits all members of society, and, under any conditions, *negative* with respect to the capacity of the corrections system to contribute to reduction in the probable future volume of crime. Why, then, does such experimentation continue to be conducted in the prisons of the United States (and no where else in the "free world")?

ABOUT THE AUTHOR

Peter B. Meyer is Assistant Professor of Economic Planning in the Division of Community Development, College of Human Development, the Pennsylvania State University, where he has been since 1968. Holding a Ph.D. in Economics from the University of Wisconsin-Madison, he has been the sole political economist teaching in undergraduate and graduate programs in policy formation and social change which he helped to found. His research has covered aspects of public welfare policy, social services administration and delivery, the problems of optimization as a social goal and more humane alternatives to what is erroneously labelled as "modern capitalism."

Among his publications are *Providing Health and Decency for the Needy in Pennsylvania: A Policy Proposal* (1971, "The Exploitation of the American Growing Class" in D. Gottlieb, ed., *Children's Liberation* (1973); "Differences in Taxation of Households: One Test of a Policy-Relevant Evaluative Technique," *Public Finance/Finances Publiques* (1973); and *Cost-Effectiveness Evaluation of People Processing Networks* (1974). His current research is focused on community-based corrections and correctional services subcontracting.

Dr. Meyer is an active member of the Central Pennsylvania Collective of the Union for Radical Political Economics and directs his research priorities in directions he believes will lead to lasting and meaningful constructive changes in the social order in the United States.

[8] D. M. Gordon, "Class and the Economics of Crime," *Review of Radical Political Economics,* Vol. 3, No. 3 (1971), p. 67.

MEDICAL EXPERIMENTATION ON PRISONERS:

Some Economic Considerations

CORRECTIONAL ECONOMICS CENTER
OF THE
AMERICAN BAR ASSOCIATION

COMMISSION ON CORRECTIONAL FACILITIES & SERVICES

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The Correctional Economics Center is a project of the ABA Commission on Correctional Facilities and Services which has been joined by the Association of State Correctional Administrators, Council of State Governments and National Conference of State Criminal Justice Planning Agency Administrators as cooperating organizations. Initiated in December, 1973, the Center is supported by a discretionary grant from the Edna McConnell Clark Foundation of New York City. The overall goal of the Center is to demonstrate how economic concepts and analysis can be applied to the corrections sector of the criminal justice system.

Implementation of innovations and system reform will require sound economic and cost analysis to help correctional systems and administrators employ limited budget resources to translate proposed innovations into fiscal reality. The Center offers assistance to correctional administrators analyzing the economic and budgetary implications of major policy decisions and seeks to promote economic analysis within corrections by stimulating evaluation by economists, correctional researchers and others. This is achieved through personal contacts, public appearances and publications.

Center staff have participated in workshops and presented papers on correctional economics at the annual meeting of the American Correctional Association, the Second National Workshop on Corrections and Parole Administration, and the California Probation, Parole and Correctional Association's annual meeting. The Center responds to numerous requests for data, information and recommendations from federal, state and local agencies, legislative committees, special commissions, private organizations and independent research projects.

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The Correctional Economics Center has been granted funds from the Law Enforcement Assistance Administration to undertake a Standards and Goals Project. The purpose of this project is to perform a cost analysis of the Corrections Report of the National Advisory Commission on Criminal Justice Standards and Goals, and present it in a form which will aid state and local decision-makers as they set and implement their own standards and goals for corrections. Included in the Report are priorities and standards for upgrading corrections and other criminal justice functions impacting on that process.

Addendum

Dr. Peter Meyers, the author of the ABA Correctional Economics Center Monograph entitled 'Medical Experimentation on Prisoners: Some Economic Considerations" is publishing a book in December or January which will cover additional facts. (The book will be Drug Experiments on Prisoners: Ethical, Economic, or Exploitative?) Although he will discuss the additional facts in his testimony on September 29, 1975, he would like readers to note that at the time the monograph was published he had set 75 million dollars as the annual subsidy given to pharmaceutical manufacturers through the use of prisoner subjects. He has now revised that figure to $279 million annually.

MEDICAL EXPERIMENTATION ON PRISONERS:

Some Economic Considerations

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June, 1975

PREFACE

Medical experimentation on human subjects, particularly institutionalized persons, has been the focus of much recent controversy. The issues which have been raised range from the necessity of the experiments to the conditions under which they are conducted. Reformers maintain, particularly as regards experiments on prisoners, the adequate safeguards are non-existent and that the prisoners are "exploited". Pharmaceutical companies and other experimenters claim that an inexpensive, homogeneous pool of subjects is necessary to hold costs of experimentation (and therefore, prices) to reasonable levels.

It is necessary to extract from this controversy the implications of experimentation (given that it does exist) for the individual, society, and the correctional system. While economic analysis does not represent the only way of identifying and addressing these implications, it can offer concrete insight into two major areas: the concept of "freedom of choice" as it applies to experimentees, and the subsidies rendered to expermenters utilizing the "correctional context". The dollar value of the subsidy can be (and is) estimated. Its magnitude is such that the research issues highlighted in the conclusion warrant serious consideration.

TABLE OF CONTENTS

INTRODUCTION

Medical experimentation on human subjects has been the object of concern and controversy in recent years. In no area has the debate been more intense than with reference to experimentation using incarcerated offenders and detainees. The convenience and economy of using prison inmates as experimental subjects, the peculiar nature and conditions of prison life, an emerging national focus on retained rights of persons in confinement, and the fact that remuneration for participation in experiments, however meager, is often among the highest that convicted offenders can earn within institutional walls, are among the factors which have fired interest and complicated analysis of this problem.

To date, the debates over experimentation on humans and the appropriate safeguards, constraints and compensations have been conducted within the realm of medicine, law, and, at the extreme edges of the argument, ethics. The essential issue, however, is one of choice: alternatives exist, that is, experimentation or the absence of experimentation, with explicit attendant costs and benefits. While the alternatives may be far more complex than this simple dichotomy, and new alternatives, involving different safeguards and compensation principles, may be invented at any point in time, the problem is still one of the exercise of a choice among discrete, identifiable alternatives.

The object of this monograph is the application of what has been called the "science of choice", that is, economics, to perhaps the least tractable of the medical experimentation questions, the issue of medical experimentation on prisoners in correctional institutions. The findings of this study are not new. The data employed and the descriptions of prisons and prisoners, and of experiments and experimenters, are all taken from published sources. The innovation in this analysis is simply that the pieces have been fit together from the perspective of an economist. The analytical and logical focus is on the distribution across all of society's members of the benefits and burdens imposed by the social order in the United States with respect to particular kinds of activity.

The Issue

Is it possible or appropriate for a society to request that one group of people voluntarily make a sacrifice which will benefit only persons other than themselves? The answer to such a question is normally stated in the negative. The presumption underlying such a response is that society should be willing to compensate people for the discomfort or risk they run in order to benefit the rest of the society, and the risk-takers normally would demand such compensation.

How much compensation, and of what sort, should therefore be offered? Brevity again characterizes the response: "enough, and of the right type, to promote the desired behavior". Welfare economics is an entire branch of the science of choice devoted to elaborating upon this theme, and it tends to assume that the rewards demanded for risk-taking do not vary greatly across the population.

What, therefore, should be done if a group of persons in a society, due to the particular conditions under which they live, require much less real compensation for their willingness to undergo risks and discomfort than the mass of society? There is no short answer to this question. The essential problem is one of the appropriate distribution of the "savings" to the society obtained through the use of the people more willing to take risks as experiment subjects.

This last question, however, is the central issue in the argument over medical experimentation on prisoners. Prisoners get paid much less than thier "outside" counterparts for all the work they perform; the lower rates of pay apply not only to experimentation service but also more conventional work as cooks, trashmen, license plate punchers, etc. Does the willingness of prisoners to bear the risk of serving as experiment subjects, insofar as it is a consequence of the coercive setting in which they live, imply that such experiments should be banned from prisons? Does it suggest that the savings due to the willingness of the prisoners to incur risks for low pay logically accrue to the experimenters, the correctional system, or others? These are policy dilemmas which should be resolved, and it is to these matters that this analysis is addressed.

The Findings

This monograph does not provide solutions, but raises questions based on its findings. Still, the findings of an economist who walks where others have not trod may be of some value, despite their tentative nature. The major findings are as follows:

(1) Prisoners, by virtue of their incarceration, are willing to participate in experiments and incur risks at rates in excess of five times the voluntarism exhibited by free persons. Moreover, they will submit to such risks at rates of pay as low as one-tenth what non-prisoners demand.

(2) The constraints under which prisoners exist, as well as the correctional institution's execution of its obligations to feed, clothe and house its inmates, combine to provide a subsidy in lowered costs of experimentation to pharmaceutical companies and other outside experimenters which is estimated to be a minimum of $26.05 per subject-day at current costs. This subsidy is provided at no real cost to the institutions and so constitutes an "efficiency gain" or "savings" which derives from experimenters' access to prisons.

(3) Experimentation, by medical practitioners, social and psychological experts, and the pharmaceutical manufacturers, is pursued at a rate of hundreds of thousands if not millions of subject-days per year, so the "efficiency gains" are large indeed, running to millions of dollars annually.

(4) Experiments in prisons are an activity which inevitably produces a profit for the outside companies and personnel granted access to the institution: pharmaceutical manufacturers sell the drugs and medical devices tested in prisons at a profit, while the other experimenters gain at the least professional kudos for published research, if not direct financial remuneration. Moreover, the entire savings derived from such access to inmates accrues to the experimenters under current policy.

(5) Paritiepation in experiments, especially those involving tests of new drugs, involves risks of long-term aftereffects. The subjects, however, are not provided with insurance or any other coverage to protect them against such post-experiment costs. The cost of complete medical and disability coverage for a "typical" inmate experiment subject for the lifetime that s/he will spend outside the walls of correctional institutions after release is estimated to be close to $10,000 at current rates.

(6) Extensive evidence of unnecessary experimentation has been uncovered in all types of experiments. That is, the purpose of the experiments were such that little value for the society as a whole was to be expected from the work; the efforts, however, benefited the experimenters. It appears that this imbalance between the social and individual benefits from experimentation exists largely because of the exceptionally low cost of subjects to experimenters granted access to prisons. Reduction of the subsidy provided, i.e., having the experimenters bear more of the normal costs of their endeavor, can be seen to reduce this phenomenon.

Resea.ch Issues

In light of the findings uncovered, and within the general rubric of the economics of corrections, three major directions which further research should pursue are raised in the conclusion of this monograph.

Issue 1: Does the presence of experiments within the prisons contribute to or detract from the effectiveness of the corrections process?

Issue 2: Does the presence of experiments in institutions, and the dependence of experimenters on the inmates of large institutions, introduce a societal bias favoring the "big house" over correctional alternatives for reasons having little to do with corrections?

Issue 3: Could the funds produced as "savings" or efficiency gains from allowing prisoners to be used as experiment subjects be employed for purposes other than reducing costs or outlays of experimenters and so as to produce greater value to (a) the corrections process, and (b) society as a whole?

I. ECONOMIC AND SOCIAL CONDITIONS OF PRISONERS

The characteristics of the environment in which radical experiments using inmates are conducted must be understood before the analyst can attempt to apply the logic of economics to the choices facing the institutions, prisoners, and experimenters as regards experimentations. We shall first consider characteristics of total institutions, then address the inmates' needs for income, their possible sources of funds, and the underlying economic dilemmas that the institutions' residents face.

The Total Institution

Two characteristics may be said to constitute the critical dimensions of life in total institutions, insofar as the inmates' capacity for rational choice among economic alternatives is concerned: (1) the shortage of means of entertainment and the accompanying possibilities for freedom and, (2) the ever-present fact of coercion as a critical tool for control of residents and maintenance of the umbrella life control which is the purpose and basis for existence of the total institution, whether medical, mental or criminal corrections in apparent intent.[1]

These features of total institutions immediately can be translated into inmates' demand hierarchies which differ considerably from the need hierarchies which would direct consumer choice outside the institutions. The highest ranking demands of prisoners may be viewed as the relief from (a) boredom and (b) coercion. Simultaneously, since the institutions' employees find maintenance of the degree of total control expected of them to be a difficult-to-unattainable objective, the personnel in a position to allocate favors such as reduction in boredom or in the coercion level experienced by an inmate conceivably might use their power as another coercive tool. Thus prisoners may find that good behavior is required of them in order for them to get entertainment in the form of the right to become medical experiment subjects. Medical experimenters claim to have scrupulously avoided giving false impressions to inmates about the possibility of connections between their willingness to volunteer and their accumulation of "good time" for early parole or release. However, as will be more formally established later, many prisoners continue to believe that their participation in voluntary activities will accelerate their release from the institution. Thus the institutional conditions presage extremely high levels of prisoner acceptance of invitations to participate in experiments, regardless of their nature or the financial remuneration offered. The concern of the institutions' inmates with the boredom and the coercion that they attempt to avoid, however, is not their only reason for wanting to participate in medical experiments. Their residence in total institutions does not imply, as is assumed by many, that their needs are provided for totally, as is shown below.

Prisoners' Needs for Income

Prisoners do not receive all the amenities of life automatically while they are institutionalized. Conversely, they are not automatically denied the amenities, but, rather, they are permitted to "earn" them. Toiletries, cigarettes and other sundries are available at prison commissaries, the profits of whose operations typically are directed into prisoners' welfare funds which are then used for provision of other amenities, possibly movies and the like. Radios and certain other materials for self-entertainment, where permitted, must be purchased. Moreover, access to exercise, the right to hold a prison job and the like are also privileges; these latter amenities, at least, do not require funds for the exercise of the privilege.

Some prisoners, of course, have families which they cannot support due to their incarceration, and may find that these unmet obligations raise their demands for cash beyond the levels necessary for satisfaction of their personal wants within the institutions. Still other prisoners, anticipating furloughs and other short term releases, want to accumulate funds to spend during their released time since no prison contribution is available. Finally, prisoners get at best nominal pocket money upon their release from institutionalization. For those not intent on returning immediately to a life of crime, unless they have family support available upon their release, some augmentation of the monetary allowance received upon discharge may be essential to provide for living expenses until they can locate gainful employment. Many prisoners, therefore, accumulate funds in their personal accounts within general inmate welfare funds.

Both for current expenses and for asset accumulation to assist deinstitutionalization, prisoners are therefore interested in earning income while institutionalized. The sources of funds or income available to inmates are limited, however, as are the amounts they could earn.

Prisoners' Sources of Funds

Prisoners can make money while incarcerated in only a limited manner, excluding activities which are illegal within the institutions. First, and foremost, there are a myriad of jobs associated with institution operations and/or maintenance of physical plant. Next, some prison industries exist and provide employment in manufacture of various products (most typically for direct "sale" to other governmental agencies). Finally, there are medical experiments of diverse sorts in which the inmates of those institutions which permit such experimentation may become involved. In addition to prisoners' earnings, some inmates may be the recipients of funds from friends or relationships "on the outside."

The typical rates of pay for inmates involved in prison industry employment or institutional operations activity have ranged from $0.07 to $2.00 per day in the early 1970's, with days off and other leave provisions available under some circumstances. If all inmates of prisons and jails who were employed received the $2.00 maximum for 365 days, including all days of sick leave and days off, they would acquire $730 per annum in earnings. The manpower value of the average adult inmate has been estimated on the basis of known distributions of education and skill levels, as well as prior occupations of prisoners, to be in excess of $8,000 annually at mid-1972 average pay rates.[2] Thus prisoners who are employed are making substantially less than they could "outside " - even if the cost of prison room, board and supervision is subtracted from the $8,000 figure.[3] Moreover, in many institutions, only a minority of the inmates are employed altogether, leaving a significant proportion of residents with no cash resources from prison employment.

As the Philadelphia Court of Common Pleas noted with reference to Philadelphia county prisons, in April, 1972:

> Substantially the only way in which a prisoner can earn money is by participation in the medical testing program conducted in the prisons by The University of Pennsylvania and the Ivy Research Laboratory.[4]

The major source of funds for prisoners with access to medical experiments derives from their participation in them as subjects. Therefore, any special program or experiment to which the inmates have access and which pays for participation can expect to have a more than adequate supply of "volunteers" for positions as subjects for medical, sociological, psychological or any other research.

The Economic Choices Facing Prisoners

Four basic demands for services, products, or changed conditions can be identified: (1) demand for relief from coercion (demand for earlier release or trial); (2) demand for entertainment (and relief of boredom); (3) demand for physical amenities (including better room and board); and (4) demand for current and future cash incomes. None of these demands are wholly alien to persons not living behind bars, although as noted earlier, the hierarchy of needs seems distorted. However, the degree of severity of needs differs, so the prices prisoners are willing to pay for satisfaction of all or a portion of their demands will be significantly different from the prices evidenced on the "outside."

Two economic concepts must be introduced for the purpose of comparison of the severity of needs felt by inmates and others: (a) the principle of decreasing marginal utility, and (b) the principle of utility maximization

as pursued by consumer balancing of marginal utilities. The marginal utility associated with a good may be said to be the increase in the total satisfaction of desires achieved by a consumer through consumption of one additional unit of a given good. The contribution to a person's utility of any commodity, however, is partially a function of how many units of that commodity the individual already possesses. One traditional example utilized by economists is that of a loaf of bread: the marginal utility of the first loaf will be very high, since the consumer is hungry, but the increase in consumer utility obtained from each additional loaf will be lower than that associated with the first loaf. In a coercive setting, moreover, should the consumer be forced to consume all the bread on the day of receipt, the utility level of the consumer may actually fall with the consumption of the last loaf, as s/he has eaten more than enough: Thus the marginal utility of a loaf of bread falls as the consumer has more loaves, and might even turn negative. The same logic applies to any other good or service which the consumer may feel is needed, and this is the principle of decreasing marginal utility.

The second principle may be illustrated by continuing with the food consumption example: suppose the consumer has eaten one loaf of bread and one pound of apples, and must now choose between another loaf of bread or another apple. What will the choice be, and how can it be anticipated? The operational principle presumed to guide the eater in this instance is the desire to maximize the satisfaction or utility from good consumption. The consumer will, therefore, choose either the bread or the apples, depending on which makes the greatest contribution to total utility. However, for each unit of bread or apples that the consumer acquires, the marginal utility of the subsequent unit will fall, making the other commodity more attractive. The consumer, therefore, will be expected to consume apples until the marginal utility of the next pound of apples falls below the marginal utility of the next loaf of bread (assuming their prices to be identical). Then the consumer will shift to buying bread until the balance of marginal utilities shifts in favor of apples once again, and so on. Eventually, of course, the consumer comes to the end of his/her resources (or discovers the marginal utility of a new pair of socks to exceed the marginal utilities of either food product). In any event, the consumer, insofar as s/he is able, will equate the marginal utility of each good s/he is consuming, and, in so doing, maximize total utility.

The application of this logic to the inmates of institutions is quite straight-forward: given the paucity of entertainment available to them, as well as the extent of the coercion under which they must live, combined with limited income-generating opportunities, it is to be expected that inmates will pay a very high price for want satisfaction. Thus, in light of the extremely high marginal utilities attached to freedom from boredom, reduced coercion, and income, in the virtual absence of any of these "commodities," prisoners will voluntarily subject themselves to experiments in which persons with greater supplies of the critical commodities will not participate,

regardless of the fees to be paid subjects.[5/] The possibility of better quarters associated with becoming an experimental subject simply provides a fourth want satisfaction attainable by prisoners participating in experiments.

In its essential form, then, the critical problem facing analysis of medical experimentation using prisoners is the extent to which conditions inside the institutions preclude the analysis of their decisions as economic choices.

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II. EXPERIMENTATION: A TYPOLOGY OF EXPERIMENTS AND EXPERIMENTERS

Experiments employing prison inmates have involved many inquiries other than those typically associated with medical trials: experiments on choice-making and risk-taking behaviors, behavioral research trials and other activities. Even within the medical experimentation rubric, a range of different types of experimentation on prisoners can be distinguished. The characteristics of the different experiments involve different degrees of active participation by inmates as well as a range of diverse issues as regards their informed consent in the participation decision. Perhaps more importantly, the range of auspices under which experiments can be conducted, and the different persons involved, can significantly affect the impact the tests have on the inmates. Finally, the different purposes of testing with prisoners make diverse demands on the conduct of experimenters which can further affect the degree of inmate voluntarism possible. A careful categorization of experiments and experimenters is, therefore, required in order that the value or problems associated with one mode of experimentation not be inappropriately assigned to tests of a wholly different nature.

The Experimenters and Their Interrelationships

It is possible to distinguish the different sources of experiment funds on the one hand and the actual experimental personnel on the other, although the two will correspond in some instances. Funding sources are essentially twofold: the Federal Government, through the National Science Foundation, the National Institute of Health, or other funding subagent; and the manufacturers and marketers of drugs and other pharmaceutical products who sponsor product testing required by the Food and Drug Administration. It is thus not inappropriate to argue that the ultimate source of all funds for medical experimentation is the United States itself, either through direct disbursement or the coercion of certain expenditures through the requirements of its national government.

The experimenters as a whole are difficult to isolate as to type and interests: prison medical staff, practicing physicians, and researchers from university faculties and research institutes may all be indistinguishable - to the extent that it is possible for a single physician to actually play all four roles.[6/] As is demonstrated below, the pharmaceutical manufacturers and their development and testing laboratories can also be so tied into the network of professional interrelationships as to be virtually impossible to isolate.

The ability to isolate the actors involved in medical experimentation on prisoners is critical to an analysis of the ethics and "honesty" of the

experiments (in terms of the validity of their results, the extent to which the freely given informed consent of prisoners is really obtained, and the like). However, such a separation of participants in the prison experimentation process is of no significant value to the examination of the rationality of the experiments from an economic perspective. Study of the ties between the persons participating in experiments and their regulation in the prison context, however, may be of significant importance in assessing the validity of such charges as the following:

> In the prisons where inmates serve as guinea pigs for the testing of new drugs, the research may have little, if any, scientific or medical value. Such research is frankly commercial, and is solely for the purpose of allowing pharmaceutical companies to meet Government requirements for the introduction of new drugs.[7/]

This charge has both legal and economic significance: commercial activity in prisons is strictly circumscribed by law and public policy; yet, if the primary purpose of experiments is contribution to profits, there is then an implicit subsidy provided to the pharmaceutical manufacturers through the lower costs of experimentation in the institutional context.[8/] Much of the description and discussion below, therefore, is directed towards assessment of the validity of the charge that such experiments are, in fact, commercial endeavors.

The Experiments

Within the medical field, three distinct types of experiments may be isolated for analysis. These different tests have diverse impacts on prisoners and are of different use and importance to the public at large, as well as implying different procedures inside institutions. The largest publicity has been given to inmates used as subjects for tests of new pharmaceuticals, but it is possible that the greatest abuses of the prisoners really emerge in studies of the course of diseases which precede pharmaceutical development, and the use of inmates as subjects in marketing research for patent (over-the-counter) remedies and the like.

1. Disease Studies: The most famous disease study in U.S. history was not conducted with prison inmates but rather on poor black males in Alabama. Representatives of the U.S. Public Health Service monitored the progress of syphilis in a number of men whose condition they had diagnosed, but which diagnosis they did not share with their "subjects," who thus were totally involuntary participants in the project.[9/] Other studies involving the progress of diseases have been conducted on a more open basis, with prisoners and others, in which subjects were intentionally administered toxins or medical conditions otherwise induced in order that the experimenters could evaluate the progress of test medications intended to cure the induced condition. Such studies are claimed to be necessary for

the determination of the dangers inherent in different conditions and for the development of new medications to treat conditions not adequately controlled by available drugs. However, many of these experiments appear to have minimal significance beyond the need for empirical results for adademic publications. One such instance was a study demonstrating the effects of Vitamin C deficiency in men recruited from the inmates of the Iowa State Penitentiary and published in 1971, decades after the discovery that scurvy was caused by such a dietary deficiency.10/ The usefulness of this study was assessed as, "Totally pointless, the cause and cure of scurvy has been well known in the medical profession for generations. Some of the side effects he, the experimenter, lists may well be irreversible..." by a representative of the California Department of Public Health.11/ Despite prisoner voluntarism in the administration of this study, the ethics of its conduct, given the minimal scientific value of the results, is subject to question. From the economist's point of view, the question to be addressed is essentially simpler: do the benefits to society at large of the experiment warrant its costs? Only if the answer is yes should the experiment proceed - and even then the issue of the distribution of benefits produced by the experiments should still be subject to discussion.

2. Marketing Studies: Preliminary testing of consumption appeal, taste, and other aspects of over-the-counter pharmaceutical and toiletry items can be, and frequently is, conducted with inmate populations. Packaging as well as other aspects of marketing appeal may be tested through give-away programs in institutions. These kinds of studies do not require detailed monitoring or explicit voluntary participation determinations, nor do they involve cash payments to prisoners, but only the provision of free goods. Such testing is virtually all-pervasive, especially in light of the financial pressures under which correctional institutions find themselves and the extent to which such provision expands prisoners' real income. One other aspect of such marketing endeavors is the utilization of inmates for side-effects or accidental effect determinations for products not requiring detailed testing for Food and Drug Administration (FDA) approval, but about which manufacturers and marketers want to learn more; this is generally for purposes of including disclaimers in packaging and otherwise anticipating possible litigation about negative unintended consequences of use.

3. Food and Drug Administration (FDA) Required Pharmaceuticals Testing: Tests on "Investigational New Drugs" (INDs), consisting of three distinct phases, must be conducted by law prior to their being declared marketable in the U.S. Before a drug can be declared an IND, some documentation of its expected efficacy and minimal toxicity is to be submitted to the FDA. The three phases of testing on human subjects have been well described by F. Gilbert McMahon, M.D., in an address to a special conference held in 1973 on issues in drug research in prisons:

> Phase One is often conducted in healthy individuals, relatively normal people, and it is for the purpose of

> finding out: Is the pill absorbed? How is it metabolized? And, indeed, how is it tolerated?
>
> One is not interested, in Phase One, in finding out whether the drug works, but whether it gets into the body and whether you are causing side-effects. And, therefore, in Phase One, prisoners are often utilized.
>
> In Phase Two the question is efficacy: Does the drug indeed lower blood pressure by carefully controlled, often double-blind studies? Does the drug have human activity?
>
> Phase Three is often called "clinical trials." In Phase Three the new drug is given to maybe 1000-5000 patients with particular diseases, to assure yourself, to assure the company sponsor, to assure the Food and Drug Administration, that the average practicing doctor can safely and effectively use that drug before it is permitted to get on the market."12/

All three phases have been conducted using prisoners, but the Phase I tests are the experiments which have relied increasingly on the inmate population. Phase I toxicity tests are not only the most onerous experiments in terms of the monitoring medical tests to which the subjects must submit but also the most risky: the express purpose of toxicity and tolerance testing under Phase I trials is to determine the maximum dosage humans can absorb without developing adverse reactions. All subjects of such experiments, therefore, will be subjected to medications never previously administered to humans in sufficient dosages to cause them to exhibit measurable negative reactions. The contributions of Phase I tests, therefore, are screening for excessive toxicity or inordinately low tolerability of particular experimental drugs. Since 90% of all new drugs fall by the wayside in Phases I and II on toxicity grounds, the screening function is of significant value to all users of prescription drugs.13/

The mass tests associated with marketing activity, such as the provision of free toiletries to inmates combined with monitoring of the use of samples, need not constitute a major focus on this section. Such tests exist; they provide inmates with free goods, which, given that such products have already been demonstrated to be safe, are obtained at no real risk to the users. Similarly, conduct of Phase III (clinical trials) tests on new drugs through the simple expedient of prescribing them - handing them out - to prisoners who are ill, may not significantly damage the inmates, although they legally should be informed if they are receiving a drug which is not yet FDA approved. Conduct of Phase I or Phase II testing on new drugs, however, is a different story.

In testimony before the Senate Subcommittee on Health, Mr. C. Joseph Stetler, President of the Pharmaceutical Manufacturers' Association, described the criteria for populations on which Phase I tests should be conducted.

His four points are quoted below, followed by consideration of prospects for satisfying these conditions.

> One would be that relatively homogeneous subjects should be studied in order to facilitate the design of studies from which relatively precise conclusions could be reached in relatively little time.
>
> Second, the study group should be fairly healthy. This allows the research team to study the effects of carefully controlled escalation of dosage under close supervision, with maximum safety.
>
> Third, for the comparison to be valid, only one variable - the drug - should be present. The study group, and the test environment - time, place, diet, exercise, et cetera - should be held constant, insofar as that is possible.
>
> Fourth, attention to detail must be explicit. Phase I studies in particular require many tedious and repetitive procedures, such as frequent blood, urine, blood pressure, pulse and respiration tests.[14]

Mr. Stetler contended in his subsequent argument that inmates of correctional institutions constituted the ideal pool on which to conduct initial tests leading to Food and Drug Administration approval of new drugs. His argument reflects current thinking on the importance of the prison inmate pool to new drug development and testing in the U.S., and the strongest case for the use of inmates for such purposes which is available.

III. MASS TESTING PROTOCOLS: SOME IMPLICATIONS

Two basic types of mass testing can be conducted in correctional institutions with virtually no controls. The first of these two types is rarely, if ever, even recognized to be an experiment by those concerned with inmate well-being and medical care; the second type is one common to all total institutions. Both types are important here, because of the economic implications and interactions regarding individual choice, business subsidies and correctional system efficiency which arise from testing within institutions. We will distinguish between (a) testing of over-the-counter remedies and toiletries, and (b) trials involving prescription compounds.

Mass testing of, utilization of, and response to over-the-counter and toiletry items is relatively simple once a liaison between the manufacturer-marketer and the prison administrative and medical staff is established. As noted above, the prisoners (subjects) get access to a free good. The inmates benefit immediately in that they need not use their supply of cash to buy, say, an underarm deodorant when an experiment making a new product available is ongoing. However, if the commodity is available only on request, albeit at zero cost, the staff responding to the request can monitor demand for the product. Complaints about product efficacy or undesirable side effects (with medical staff involved at this juncture) may also be recorded. Insofar as any staff is involved in monitoring inmate acceptance of a free commodity, staff time is committed to serving the needs of the products' manufacturer or distributor. Such mass testing activity is clearly commercial in its intent and focus. While the response may be made that inmates benefit from a supply of a free product which they need and use, the costs to the correctional system in terms of staff time committed and possible inmate medical reactions to a new product must be regarded as negatives affecting benefits to inmates.

The ultimate question which emerges from such pre-marketing testing in correctional institutions is what the costs are in terms of higher corrections expenditures or less efficient correctional institutions (higher recidivism or criminality on the part of ex-inmates), and who bears such costs, relative to the benefits from such inexpensive pretests which go to the pharmaceuticals manufacturers and marketers and their shareholders.

The mass tests administered in conjunction with prescription compound development may be at odds with administrators' perceptions.[15] It must, however, be noted that the clinical trials phase of new pharmaceuticals testing according to FDA regulations is conducted with minimal information provided subjects even in contexts other than the prisons and jails of the nation. Phase III testing, the clinical trials, is really effectiveness testing. Drugs are administered not to the

healthy persons employed as Phase I and II subjects, but to persons suffering from the medical ailment the drug is supposed to be able to correct. Informed consent is supposed to be elicited from the subjects to whom the experimental drug is administered, but since the patients do not know what they are receiving (since the drugs do not pass through a private pharmacist, no labelling is required by licensing procedures), the validity of such consent must be assumed to be questionable.

In the absence of adequate information, no inmate of a hospital, mental health facility or correctional institution (in fact, no one) can exercise informed consent. That such consent might be appropriately requested is not generally known, nor is the information required for the truly free and informed giving of such consent. To the extent that clinical trials are conducted using patients who do not know the differences between the varied medicines they are receiving, the physicians and pharmaceutical manufacturers may be getting subjects for experiments at zero cost. To the extent that the clinical trial subjects are being administered drugs which can affect a condition for which no remedy previously existed, they are better off, and even might have volunteered freely to be subjects in the clinical trials, given the opportunity to do so. However, if the clinical trials are of a drug produced by one manufacturer intended to compete with another developed, approved and marketed drug which may be superior to the new compound in alleviating a medical condition, the patient endures both more risk and more suffering than had access to the approved medication been made possible.

In any of these contexts, if institution staff are involved in record-keeping with reference to the efficacy or effects of medications administered to ill inmates, the institution is bearing some of the direct costs of the experiments. Mass-testing protocols cannot help but have some negative impacts on institutional efficiency, and similarly, unless all new drugs are assumed to be successes, some negative impact on experimentees should be expected. It may be argued that the institutions benefit since they can provide inmates with expensive medications without having to pay for them, while the inmates benefit on balance from their access to the newest drug on the market. However, regardless of the size of the benefit accruing to the institutions and their residents, the issue of the subsidies provided the experimenters cannot be avoided. The experimenters must be accruing sizable benefits in that they are engaging in the effort directed at wooing and holding contacts with institutions rather than simply advertising for volunteers for a medical or drug experiment in the open market. It is necessary, then, to pursue the issue of to whom this subsidy accrues, its magnitude, and ask whether such a subsidy is in the national socio-economy's, the institutions' and the inmates' interests.

IV. CONTROLLED EXPERIMENTS, THE SUPPLY OF SUBJECTS, AND IMPACTS ON VOLUNTEERS

> ...human research, to be valid, has to have a bundle of people. And where do you find a bundle of people on whom you can collect their blood day and night, on whom you can collect their urine day and night quantitatively, and follow their blood pressure and temperature and pulse and liver function and kidney function for days and weeks? Where do you find such a homogeneous group?
>
> Well, you might find them in the military. You might find nuns, although they are harder to find now than ever before. You might find med students, but they run to class and can't be contained too readily.
>
> A natural evolution since 1945 has been the greater and greater escalation of utilization of prisoners, because they are a relatively healthy young group of people in one place, often anxious...to earn some money... 16/

There is little doubt that the controlled conditions deemed necessary for medical experimentation can be met in the physical environment of a prison.17/ The primary function of correctional institutions, however, is not to act as a source of experimental subjects for physicians and others engaged in medical devices, medical procedure, or drug development. Correctional institutions have as their primary functions the rehabilitation of inmates and the protection of the society at large from those not yet rehabilitated. Such institutions function as agencies of social control, and the interaction between these control and rehabilitation objectives and the goals of experimenters must be examined in order to determine the implications for inmates (who are nominally the primary clients of the institutions) of the presence of medical experimentation within the confines of their residential settings.

Remuneration

The desire for income and other benefits accruing from participation in experiments is such that consent will be virtually inevitably forthcoming when an experiment is proposed. In some instances the perceived benefits of experiment participation are more chimerical than real, but it is the inmate perceptions that must be examined to establish the viability of the application of the doctrine of informed consent or free choice to residents of total institutions. Four major forms of such perceived "remuneration"

for participation may be identified:

1. earlier release or "time off" for good behavior;
2. cash payments and improved economic status;
3. living amenities in the form of better food, quarters and/or more contact with people from the "outside," and,
4. relief from institutional boredom (including the excitement of additional "prestige" among inmates).

The role each of these factors play in motivating inmates is discussed below.

Hope for early release. While we have discussed a range of needs which are expressed by institution inmates, we have not really addressed the primary need, that of getting out of the institution altogether. Nathan Leopold, a convicted murderer in the notorious case of Leopold and Loeb, described his overriding concern as follows:

> We were specifically told we would not be released early because we have been involved in the malaria project but it was a chance we couldn't possibly not take. The most important thing in our life was to get out of prison and anything we thought would influence that decision, no matter how marginally, we would be willing to do.18/

Given the common practice of issuance of "certificates of appreciation" to inmates after completion of experiments, it is certainly understandable that the ex-subjects of medical trials would hope that records of their receipt of such certificates would be in the files reviewed for parole considerations.19/ Even more blatant forms of recognition are known to be available: for example, the procedures described by Drs. Hodges and Bean who worked with inmates at Iowa institutions included a letter routinely sent to wardens thanking them for permitting given inmates to participate in experiments, and "it is possible that this letter in the prisoner's file may favorably influence the parole board."20/ Regardless of intent or actual practice, therefore, evaluation of the economic motivation of prison inmates must recognize the prison population's perception of earlier release as one of the forms of remuneration for participation.

Direct cash remuneration. Needs for income in the institutional setting were discussed above. The relative remuneration of inmates who "volunteer" to be experimental subjects uniformly favors participation in experiments over alternatives. Consider, as an example, the common cold experiments in the Maryland House of Detention:

> Inmates who participate in the medical program are paid $2.00 for their participation. In this prison economic

> system this pittance is riches, for the average pay is $.65 a day and many men until very recently have been on "idle," i.e., have no jobs at all.21/

Extremely detailed schedules of rates of pay for experimental subjects in the Jackson State Prison in Michigan have been developed by Upjohn and Parke-Davis, two pharmaceutical manufacturers which have jointly established a major experimental facility within the institution's walls. They guarantee a minimum of $0.50 per day to all experimental subjects.22/ The cash remuneration for participation in experiments must be considered to be substantial, relative to the other earning opportunities open to prisoners. The pharmaceutical testers may, in some instances, be in the role of monopsonistic employers: there may be quite literally no alternative sources of employment or income (e.g., Texas) for inmates in institutions, so any pay provided is perceived as extremely high relative to the norm of zero earnings.23/ The monopsonistic tendency to hold down wages to whatever extent possible may be said to be constrained only by the public relations problems potentially inherent in low pay scales, and the presence of the prison authorities as potential constraints on excessive "exploitation." The requirements that experimental subjects give a free and informed consent, however, actually could act to restrain potentially higher rates of pay, as the summary of a national conference of medical experimentation on prisoners has noted:

> ...It was agreed that wages for participation in research should not be in excess of the maximum wage available for other prison work, and alternate forms of remunerative work must exist, in order to minimize coercive financial aspects in testings.24/

Financial coercion is inherent in contexts in which alternatives for employment or remuneration are limited, regardless of the cause of the constrained options; moreover, the coercion - and fears of coercion -- ironically act to reduce experiment costs.

Living amenities in the institutions. The more adverse the "normal" living conditions in an institution, the stronger a motivational role will be played by a desire for improved living conditions. Two county institutions have received some attention in this regard, but the conditions described appear to be prevalent in most settings in which large percentages of inmates are detainees awaiting trial, and who are not expected to be long-term residents. Insofar as convicted residents are in a distinct minority, the institution has no rationale for providing rehabilitative programs, and conditions are, therefore, more primitive than in longer-term institutions:

> The Jackson County Jail is on the top four floors of the county courthouse. When we visited it in the summer of 1971, it was hot, and cramped and crowded. Prisoners have little or no recreation. The last meal each day is served at 3:00 p.m...

> But the malaria testing program offered an escape... a six week program that /would/ provide additional food, ice cream, fruit juice, improved quarters and a $50 honorarium.
>
> The program also offered constant contact with female nurses and with doctors or lab technicians who were part of the outside world.25/

The honorarium, taken across the 42 days which comprise six weeks, reduces to $1.19 per diem, a significant wage in a prison context, but an understandably weak incentive compared to the improved living amenities.

The elemental and elementary nature of the amenities which attract inmates into experimental programs derives from the background against which choices are considered. The situation in Philadelphia's Holmesburg Prison has direct health need implications:

> ...it is usually three or four guys jammed in a cell. There is a window in the top of the ceiling. The damp air leaks down. You catch all kinds of colds...There is no hot water in the cells.26/

Volunteering for an experiment in these conditions provides the inmates not only better physical environs, but treatment for medical conditions brought on by the previously experienced living conditions.

Given sufficiently adverse "normal" living conditions in an institution, extremely minor amenities may come to carry great weight.27/ Even more important to the conduct of medical experiments is that such adverse conditions may undermine the very rationale for employing prisoners as subjects, insofar as they may be ill.

Relief of Boredom. The pervasiveness of boredom in institutions has already been addressed above. Relief from boredom, however, may be difficult to separate from provision of amenities as a phenomenon or reward motivating "volunteers." This close interaction should be obvious: if an inmate is moved to better quarters or receives needed attention, he is getting both amenities and relief from a familiar routine. One physician observed the formation of an organization of the participants in a study he conducted in Attica State Prison in New York, with whom he interacted extensively and reported:

> The inmate does not volunteer because he expects his sentence to be shortened, nor does he volunteer for financial reward.
>
> ...Volunteering is an opportunity to break the monotony of his life....

> ...The volunteers were subjects of interest to the entire prison, not only to the other inmates, but also to employees of the prison at all levels. ...They became, at least for a while, the elite of their own society.28/

Achieving elite status in the institution as a whole clearly cannot be described wholly in terms of either relief from boredom or access to amenities. The benefits which could emerge from changed staff attitudes may be massive, but they could not be ascertained without extensive interviewing. To the extent that the phenomena described are broadly experienced, these returns to voluntarism must be added to the tangible payoffs and the perceived effects on length of sentence in determining the utility computations that lead inmates to volunteer themselves.

Free Choice and Informed Consent

Experimenters and correctional administrators alike appear to be concerned about the risk that the privilege of volunteering (and earning relatively good money) might be employed as a coercive tool.29/ The concern here is that the officers whose responsibility it is to maintain institutional discipline not employ the threat of excluding inmates from participation in experiments as a threat to induce desired behaviors. That such participation is deemed a privilege is essentially unchallenged since eligibility to serve as a subject constitutes a real asset to an inmate who has no alternative means of earning equivalent incomes.30/

The previously documented nature of the total institution is the root of the fear of the use of non-participation as a sanction in correctional institutions. The fact that the correctional facility is such a total institution raises a second question, however, that of the possibility of free choice within its walls. Medical experimentation guidelines for federal penitentiaries reflect the common concern of institutional administrators and the Food and Drug Administration that the inmates consent to being subjects, and that the consent be free and informed.31/ Inmates are given consent forms to sign, which they are to fill out only after previous briefings on the nature of the experiments in which they are agreeing to participate. Full opportunity is given the inmates to ask questions and otherwise assure themselves that they understand the nature of the experiments in which they will participate.32/ There is no serious question, however, as to how "free" this choice is, and one of the major services rendered to the experimenters by the correctional institutions, therefore, may be the structuring of an untenable choice situation which permits the aura of informed consent to be claimed, while the outcome of the choice is virtually preordained.

The extent, then, to which consent, even if free, is informed requires some further examination. Dr. Daniel Martin and the team of physicians in Missouri which conducted a malaria study in the Jackson County Jail included in their procedures some steps which enabled them to assess the quality of

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the information on which the inmates were acting in deciding to volunteer or not. Comparing volunteers and non-volunteers for one panel in the Malaria Project, they observed that:

> The volunteers' comprehension of the risks is little different from that of nonvolunteers, and where it does vary, it is certainly not more accurate.33/

In more explicitly examining the understanding of the risk involved on the part of their volunteers, they discovered that:

> Although the physicians had repeatedly explained what the objective risks were (and they were minimal), more than 60% of the volunteers continued to describe the project in terms of "high risk."34/

Given the frequent complaints about the inability of the medical profession to communicate to the population at large, it is not surprising that the level of "informed" action taken by institutional inmates, with below average educational attainment, is relatively low.

The prisoners continue to volunteer to serve as subjects for medical experiments in the United States, the only nation in the non-communist world in which such experiments on prison inmates is legal.

> ...In our opinion, the prisoner is never free to decide, nor is he completely informed and consenting, particularly when facing a doctor proposing to experiment on him.35/

The absence of free and informed consent as regards the detail of the experiments to which prison inmates subject themselves does not provide a prima facie case for the cessation of such experiments, even where the evidence is much stronger than that presented above. However, the presence of any doubt that the ethical standards have been met provides a strong rationale for a detailed, in-depth examination of the services rendered to experimenters by their subjects and host institutions and the implicit economic subsidies thereby provided to the manufacturers and marketers of pharmaceutical products.

V. THE NECESSITY OF EXPERIMENTATION

It is incumbent upon any study of such experimentation to assess the need for experimental subjects in some depth and then direct attention to the extent to which inmates provide the only viable subject pool. The issue of alternative subject pools and some of the reasons why they are or are not employed are the objects of analysis in subsequent sections of this paper. The issue of the volume of experimentation needed and conducted in the United States is the immediate focus below, with emphasis on one primary experimental activity: the testing of new drugs (investigational new drug, or IND research), conducted in conformance with FDA regulations for introduction of new pharmaceutical products in this country. A digression on the structure of the pharmaceutical manufacturing and distribution industry is necessary since an understanding of that industry and the forms that competition has come to take is essential to an appreciation of the extent to which the experimentation conducted in conjunction with new drug development is superfluous. Following the assessment of the industry itself, a review will be made of IND research procedures imposed by the FDA in order to establish the extent to which unnecessary experimentation may be imposed.36/ The final section will constitute an overall assessment of the need for experimental subjects and some consideration of the means by which they might be supplied.

The pharmaceuticals industry is one of the few realms of economic activity in the United States in which the demand for products is independent of price. Insofar as physicians prescribe medications for their patients without having to concern themselves with the costs of purchasing the products, they are minimally responsive to price in their prescription behaviors. However, given the presence of over 7000 prescription products on the market, physicians will respond to information flows in writing prescriptions. Most prescription compounds exist in two forms: the generic- or chemical name-formulae manufactured by a large number of producers and the brand name products which are the property of particular companies.

> ...the major pharmaceutical companies can achieve and hold dominant positions in ethical drug markets solely through promotion of their brand names; further, a firm that has established itself as a leading seller of a drug can enjoy average revenues per unit of output that are two, three, ten and more times those that can be realized by its generic competitors.37/

Patents, trademarks and new drug approvals, therefore, comprise critical tools for the marketing strategies of the manufacturers.

The new drug approval procedures constitute a major concern here since such approval by the Food and Drug Administration is dependent upon the

successful completion of the human trials already described above. However, in more closely reviewing the FDA procedures, it is important to note that any new drug must be authorized for marketing by FDA acceptance of an NDA, or new drug application. There is no constraint, moreover, on the length of time a drug remains in "new drug" status, requiring all manufacturers to hold approved NDA's, so the FDA procedures actually can contribute protection to major manufacturers which extends beyond the 17 year coverage of a patent. The FDA nominally requires repetition of the efficacy tests for each applicant for authorization to manufacture under an NDA. However, it appears that the major manufacturers recognize the cash, and perhaps even the human costs of such repeated experimentation and engage in active trading in "letters of authorization" permitting each other to use prior experimental results in order to satisfy the FDA.38/ But, perhaps, we are overstating the humane nature of the pharmaceutical manufacturers, and the trading in letters of authorization has been no more than a convenient tool in the process of competition through research and development which began in earnest in 1949. The invention of the tetracyclines was accompanied by the successful pursuit of patent coverage for the compounds.

> Here the combination of private patent monopoly and heavy promotional campaigns demonstrated the amazing capacity of new drugs to make profits for their innovators. It was at this point that the major pharmaceutical firms discovered the importance of research and development, not so much for its own sake but as a basic element in competitive strategy.39/

It behooves us, therefore, to pay close attention to the actual characteristics of the new product development and testing efforts, in order to assess the extent to which the NDA's and IND trials (which require human subjects) do, in fact, contribute to the well-being of the American people. As may be expected,

> Few of the new chemical entities marketed in any year are truly original. The majority are congeners (new salts or other molecular variations) of existing drugs. These may, but more often do not, represent any real improvement over the drugs on which they are modeled. What the molecular variants do offer is the basis for additional patents, through which rivals can enter a field from which they would otherwise be foreclosed, and the opportunity for promotion as "significant therapeutic advances".40/

Such duplicative effort is costly in terms of research resources of all sorts, but it is of extreme importance here since this assessment of the nature of new drugs introduced in the nation, if valid, constitutes an explicit statement that some significant proportion of the medical experiments to which prison inmates are asked to subject themselves serve no

portion of the national population other than a dozen or so large pharmaceutical firms and their shareholders.

This argument is of sufficient import that it is necessary to investigate it further. Many observers, both within and outside the drug industry have noted an excessive concentration of production of "me too" drugs.41/ The most telling testimony on behalf of the argument that much of the experimentation is superfluous comes from the pages of a recent review of the condition of the industry in Business Week.42/ The plight of the industry is described (p. 65) as associated with new Health, Education and Welfare rulings requiring that medicare patients be given only generic name drugs and (p. 67) with the increasing costs of experimentation which have held new single-entity drug approvals by the FDA to only 69 in the 1969-73 period (as compared to 20-30 a year in the mid-sixties). Overall, the article sums up, the greater difficulties encountered in conducting experiments and getting FDA approval for drugs, when combined with pressures for generic brand level pricing and the upcoming patent expirations of a string of the major revenue generators for the industry, presage a period of stagnation, if not decline for the industry. (It must be noted in passing, however, that the average return on common equity for the drug industry has hovered at roughly 20% over the 1970-74 period, while steel has rocketed from under 5% to 15%, chemicals have climbed from under 10% to not quite 20% and so on - the industry is still among the most profitable in the nation.)43/

In summary, this review of the economics of the drug industry and the role played by FDA regulation policies suggests strongly that the volume of medical experimentation conducted in this nation is more closely to be associated with the exigencies of non-price competition in the pharmaceuticals industry than with the real rate of advance in therapeutic competency and capacity on the part of the medical profession.

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VI. SERVICES RENDERED TO PHARMACEUTICAL FIRMS BY THE CORRECTIONAL AND CRIMINAL JUSTICE SYSTEMS

Three basic classes of services are provided to pharmaceutical manufacturers who are permitted to conduct experiments in prisons. These classes can be distinguished by the renderer of the service: the inmates who act as subjects, the institutions which provide facilities and personnel, and the system as a whole which fills the institutions and makes the first two service provisions possible. Each will be examined in turn for the specific services rendered, as well as the evidence on the volume of service provided. The value of the services to the drug manufacturers and their representatives is addressed in the next section of this essay.

Inmates as Subjects

Inmates who act as experimental subjects provide a variety of different services to the conductors of experiments. The 1973 pay scale for the Jackson, Michigan State Prison alluded to above, for example, is over four pages in length and specifies seven broad categories of services.44/ These general categories provide a convenient taxonomy of services rendered.

(1) "Routine Sampling Procedures" including stool, urine and blood sample taking;

(2) "Medication" on both inpatient and outpatient bases and including ingestion of drugs for the first time by humans;

(3) "Miscellaneous Clinic Procedures" including such activities as fasting, physical examinations, responding to interviews and the like;

(4) "Special Clinic Procedures" which may include operative insertions, skin grafts, plasma treatments and X-ray examinations;

(5) "Diagnostic Procedures" comprise a lengthy list which is only partially comprehensible to non-physicians, and includes physiological monitoring, exposures to radiation, induced pain, and the like;

(6) "Special Sampling Procedures" include bone marrow aspirations and spinal taps along with minor services such as submissions to nasal washes; and

(7) "Female Subject Pay Scale" which covers such procedures as are specific to female experimental subjects, including pelvic examinations.

Institutional Contributions

An institution with resident inmates provides major services to the efforts of medical experimenters simply as the result of its institutional existence. Moreover, insofar as the institution conforms to those characteristics we have labelled as common to total institutions, the experimental site contributes artifically suppressed wage rates, which affect the price at which not only experimental volunteers but also technicians and laboratory staff may be obtained. In some instances the institutions even offer facilities or space in which to house experiment equipment (although in other cases, as in the Jackson State Prison, the facilities transfer flows from the experimenters to the correctional system). These services may be enumerated for later determination of their cash value, if any:

1. Housing and food service to residents of the institution.

2. Social control of the inmate-subjects.

3. Artifically depressed wage rates and pay scales.

4. Physical facilities in which to conduct experiments.

The fact that such services may be rendered by the institutions at no cost to themselves (which may in no way be the case) would not detract from the real value of the subsidy provided to the medical experimenters who would otherwise have to pay for facilities and other costs associated with experimentation under close supervision "on the outside." The value of such services may be estimated from the probable expenditures required to conduct comparable experiments outside the institutional setting.

Criminal Justice System Contributions

The criminal justice system as a whole makes a not insubstantial contribution to medical experimentation efforts insofar as it places persons in correctional institutions for protracted periods of time. A six month study could not be easily conducted on inmates if none of them were to be incarcerated for more than five months. Similarly, the costs of administering an experiment involving 150 subjects would be significantly greater if all correctional facilities were community based, housing, let us say, no more than 50 persons, than the current case in which all subjects could be drawn from a single cellblock in a major institution. The debt that the experimenters owe the tendencies of the criminal justice system to incarcerate persons for long times in large-scale institutions is recognized by the pharmaceutical industry itself, and some recent attention has been focused on the need to consider alternative sources of experimental subjects:

> ...there are alternatives to prisons, and ... in the long run we will see a disestablishment of prisons.

> In any case, we will probably see a shrinking of the prisoner base in that the state prison population will get smaller and the county prison populations will get larger...45/

The problems that such shifts in prison populations could raise include the need for experimenters to hire "outside" technicians since inmates do not stay institutional residents long enough to warrant on the job training, difficulties in recruitment of longer-term volunteers due to more mobility in the inmate population, and greater administrative costs in conducting experiments in a greater number of smaller settings. Needless to say, the more corrections moves from the provision of total institutional settings to community-based, more open and interactive contexts, the more difficult and expensive it will be for the experimenters to obtain the number of volunteers they need and to control them during the period covered by the experiments.

Whether or not prison inmates are the only source of experimental subjects for the pharmaceutical drug Phase One tests required by the Food and Drug Administration (FDA) may be a moot point, but they are certainly a major asset to the drug developers today, and a significant source of subsidies to the experimentation effort.

VII. SUBSIDIES RENDERED TO PHARMACEUTICAL FIRMS

To the extent that the use of prisoners reduces the costs of experimentation to the sponsoring pharmaceutical firms, a subsidy to new drug or product development is provided by the correctional system. The dollar value of this subsidy is of interest from the perspective of optimization of allocation of societal resources whether or not there is any cost to the correctional process in the provision of this subsidy. In fact, this current distortion of the pricing mechanism does create costs to the system and to the inmate while at the same time providing a sizable subsidy to the pharmaceutical industry. This section will explore the two-tiered nature of the subsidy, calculate its dollar magnitude and offer some policy recommendations.

Subsidies in this instance may be categorized as implicit and either unmeasurable or measurable. The risk, particularly long-term, to experimentees has heretofore been classified as unmeasurable. This will be addressed through the use of appropriate compensation as a measure of incurrence of risk. The direct services provided are more easily quantified and will, in fact, be calculated in dollar terms.

RISK

One service rendered is the acceptance of risk of after-effects associated with participation in, especially, Phase I drug research. This risk acceptance is a service rendered which cannot easily be priced differently for those inside the institutional walls and in the larger society, at least not insofar as the inmates are expected to be paroled and live out their lives in the larger community.

The risk associated with acting as an experimental subject is not incurred exclusively during the time period of the experiment but can be more accurately said to be distributed over the remainder of an individual's lifetime. Such risk derives in part from the unknown long-range effects of ingestion or application of new drugs, but risk is also associated with any medical procedure, so permitting procedures to be conducted on one's body when not required for the purposes of maintenance of health constitutes acceptance of some risk of future aftereffects. Current practice in the experimentation business excludes aftercare responsibility, and inmates are still frequently asked to sign waivers of possible future claims against the institutions, the experimenters, or the drug manufacturers at whose behest experimentation is being conducted.46/

The major risks in experimentation for new drug development are incurred by those to whom drugs are administered, since only short-term effects are observed, and the intent of the drug administration is frequently to increase

dosages until immediate adverse reactions are incurred.47/ These long-term risks constitute a major service rendered for which, at present, no remuneration is offered; specifically, the responsibility for such adverse longer run effects, if not expressly eschewed in the waivers required of subjects, is still evaded insofar as ex-inmates rarely have the financial resources to demonstrate that thier medical conditions derive from experiments in which they participated.

The Jackson State experimentation consortium of Park-Davis and Upjohn was reported a decade ago in Business Week as representing a major breakthrough in the development of efficient means of testing the qualities of a new drug. And indeed it served its purpose, permitting the tests to which outsiders typically would not submit to be conducted with great ease on the inmates of the world's largest correctional facility (with over 4000 inmates):

> ...Tests at the prison are designed primarily to measure the toxicity of a drug, rather than its efficacy.
>
> Initial doses are as low as 1/1000 of LD 50 (the lethal dose for 50 out of 100 laboratory animals, adjusted to man's weight). They are then built up gradually to the point where adverse reactions appear.48/

These testing procedures may be very efficient, and permit gradual build-up of dosages under carefully controlled conditions. However, no knowledge about longer term effects is accumulated in the course of the studies on toxicity, and therefore nothing about the potentially lower doses at which long-term impacts have been induced is uncovered. Inmate-volunteers, of course, do not receive compensation for these longer term risks, and, for that matter, are not informed about the possibility of such effects.49/

As one physician administering Phase I tests readily admits, "the study, at least in Phase One studies, seldom benefits the person who is taking the risk."50/ Whether compensation is forthcoming or not for the incurrence of current risk by the subjects of medical experiments, the acceptance of exposure to long-term risks should be recognized as one of the services rendered by those volunteering for studies.

At the 1973 conference on medical experimentation on prisoners, the President of the Pharmaceutical Manufacturers Association concluded his keynote address with the observation that there exists,

> ...the need to provide guidance on the sponsoring organization's responsibilities to the volunteer who is injured as the result of his participation in the experiment.51/

There is little argument over the need to provide some form of longer term coverage for participants in medical experiments for the potential effects of their ingestion of drugs. Witness A. M. Capron, M.D., a professor in the University of Pennsylvania's Law School:

> We need to consider a program of insurance for the subjects of research to cover all the consequences of their participation, including those arising unforeseeably and without negligence...52/

That experimental subjects as well as experimenters and observers of the experimentation scene perceive a need to pursue coverage for aftereffects of medical experiments is nowhere more clearly defined than in a study of the effectiveness of oral contraceptives in which the "adverse long-term effect" for some subjects was an unwanted child.

In an experiment conducted in a San Antonio, Texas Family Planning Clinic, a "double-blind" experiment was conducted on women who came requesting birth control pills, which required that some of the women be given placebos but be told they had received oral contraceptives. As expected, a significant proportion of the women given placebos became pregnant.

> Among the scores of ethical questions raised by the (contraceptives) study, for example, are the investigators and the Syntex financial supporters of the study prepared to finance the products (the children) of their experiment? It seems to me that the subjects can make a legitimate claim for the full support for the children produced.53/

This experiment lays the problem out very clearly with physical evidence of the long term effects taking the form of children who have entered the world. In most experiments, however, especially those involving Phase I tests which demonstrate excessive toxicity and never proceed to the Phase II test level, the results are not so clear cut. The sample of humans known to have ingested a particular drug will be so small (as few as a dozen persons, for example) that statistical demonstration that a particular medical condition is actually an aftereffect of a long-prior participation in an experiment is impossible.

Compensating for Risk

If aftereffects are known to be present in more than 0.0% of the cases of participation in toxicity studies, but specific attribution of sequelae to given experiments is not possible due to small sample sizes in experiments, then there exists only one means of providing for the possibility of after-effects: generalized insurance coverage. We will examine below some of the parameters of such an insurance policy, and attempt to price the current value of such coverages at the time an experiment is conducted.

The very fact that specific sequelae to given treatments are unknown implies that it is difficult to catalog the sequelae themselves. That is, while it is necessary to identify the possible effects or impacts against which insurance should be taken out, it may be impossible to catalog the full list of possible aftereffects: any attempts at such a catalog will presume to identify certain conditions which are not possibly related to the prior ingestion of drugs of unknown impact on the human body. Some examples may serve to illustrate the problem:

Case I: Individual becomes incoherent and requires intensive psychiatric care at age 50; the care provided appears to be of minimal value and the individual remains totally disabled and not capable of providing for his family, in which he was the prime breadwinner. This individual is known to have been incarcerated while awaiting trial at age 30, and to have participated in Phase I experiments at that time. The experiment in which he participated had ten subjects and was terminated when toxicity became evident after two weeks. Is this condition twenty years later an outcome of the original experiment? Proof is very difficult to ascertain, and would require data on the other nine subjects of the experiment, as well as lengthy and expensive legal proceedings which his family cannot afford.

Case II: Individual was incarcerated and participated in several different Phase I experiments funded by different pharmaceutical manufacturers and conducted by different experimenters. The individual manifests extremely unusual, or even never previously recorded, medical conditions ten years after release. Identification of the condition exhibited as the consequence of any one of the multiple experiments is difficult to pursue without data on all other participants in all of the studies to which the person subjected himself.

Case III: Subject of experiments was a woman whose children were discovered thirty years subsequent to an experiment to share particular abnormal characteristics which render them less healthy than the norm. Such conditions have been demonstrated to constitute sequelae, but only in instances in which the number of women initially exposed or treated numbered in the thousands and significant reliability in statistical data was attainable; no such data are available for participants in experiments which "fail."

In these three cases, we have implicitly identified some of the conditions for which insurance might be desirable, while simultaneously illustrating the difficulty that exists in providing a list of specific aftereffects against which insurance should be available. Avoiding the requirement for a specific list of sequelae for which some compensation or protection should be provided is simple: insurance policies may be purchased and maintained which would cover the specific risks under generalized coverage. Actually, insurance against several classes of sequelae would be in order:

(a) Medical Insurance, including physicians, dentists, and other individual deliverers of services as well as full hospitalization coverages and mental health insurance;

(b) Disability Insurance not tied specifically to hospitalization, to provide for replacement of income lost due to the advent of particular conditions, whether physical or mental in symptom.

(c) Life Insurance, in the event that sequelae lead to early death, to replace lost earning power; and,

(d) Genetic Insurance, which is not now available, but would provide indemnity for offspring who develop conditions in some way identifiable as related to exposures experienced by their parents rather than other factors.

Given the paucity of our knowledge of specific determinants of life expectancy for particular individuals and the extent to which genetic shifts can be induced by medication, the latter two types of insurance coverages may be difficult to design for relevant coverage of experimental sequelae. While one might make comparable arguments for the health and disability coverages, the issue is starker for life and genetic insurance insofar as the probability of impact is so slight and the costs of coverage so variable (for example, for how many subsequent generations should genetic insurance coverage apply?), that these latter insurance provisions may be dropped in favor of a more conservative package.

It may be argued that both health and disability insurance provide broader coverage to the experimental subjects than they deserve if the coverage applies to all medical conditions that they may exhibit subsequent to participation in an experiment. However, while such coverage may be accurately characterized as providing payment in excess of direct compensation for risk incurred, another principle may be said to apply in this context:

> What is the cost of any medical experiment, relative to the threat of danger to the inmate, compared to the benefit to that inmate?54/
>
> Intuitively, it seems unfair to impose the burdens of experimentation on some who do not fully share in the benefits; a violation of their right not to be treated as a means alone, not to be treated as a resource available to other people.55/

Whether treated as just compensation for services rendered or as a way of circumventing the issue of payments for "damages" in the event of identifiable sequelae, the complete insurance coverage, albeit at a higher cost to the conductors of experiments, appears not to be excessive.56/ It must be

remembered that the failure to provide some such insurance coverage implies that the full cost of the medical care and support needs of the family of an adversely affected ex-volunteer will have to be borne by the public fisc, and that the dollar magnitudes in this regard are not insubstantial.

Specifically, the dollar cost of providing for complete physical and mental health costs for a family in conjunction with $350 per month in tax-free income for the household should the ex-subject of an experiment become totally disabled can be estimated for 1974 to be approximately $500 per year.57/ If the experiment for which payment is to be made to the inmate-subject is conducted in 1974, we can allow an additional five years of incarceration before coverage for that inmate must be provided on the outside, but during this time period, the coverage costs (and required disability income levels) may be estimated to have increased by 30%, or to $650.58/ Under the assumptions and principles espoused above, this coverage should extend for the remainder of an individual's lifetime; we will assume that this time period is only 30 years during which the person is not incarcerated and taken care of by an institution.

As a measure of the proper fee to be paid for risk incurred (recognizing that the over-broad medical coverage is partially payment for the risk of future discomfort as well as risk of financial reversals due to health needs), we can take the $650 figure for 30 years and establish the present value of the outlay stream required of the experimenters. Alternatively, we can incorporate the ever-present fact of inflation and assume that the $650 figure in the first of the ex-volunteer's release will increase by 5% per annum for each of the subsequent 29 years.59/ The present value computation is akin to a capitalization formulation, and the critical interest rate employed in these estimations was 7% per annum return on the capital value retained. In the instance of a level payment of $650 for the thirty year period described, the current value of the coverage would be $6534. The more realistic stream of insurance outlays gradually increasing over time would produce a capitalized present value of $11,178 at the time of the experiment.

We, therefore, argue that a fee of between $6500 and $11,200 paid to inmates at the point of their participation in an experiment, or more accurately, escrowed to provide them with medical care coverage in the future, would be a rough measure of the true market price for the risks incurred by subjects. These boundaries are, of course, rough in their derivation and computation. It must further be remembered that the payment constitutes reimbursement for the risk to be incurred in the future, and does not constitute payment for the services rendered at the time of the experiment, which must be added to the risk payment for an approximate measure of the subsidy extracted from the inmates to become evident. This cost, moreover, is invariant with the number of experiments in which a person participates, or the duration of any one clinical experiment. Experimenters can thus save money by using the same subjects more than once if they must pay for risk.

DIRECT SERVICES RENDERED IN EXPERIMENTATION

In reviewing the direct services rendered to the process of establishing and conducting experiments, it may be assumed that, in the absence of access to prisoners, the experiment sponsors would have to construct their own facilities and encourage people to enter them in order to participate in Phase I tests. (While it is true that other institutional settings and the military as well might provide loci for experimentation, these alternative sources of subsidies remain that - sources of subsidies - and we wish to identify the unsubsidized cost of drug trials.) We can then review the services rendered by the correctional institution and the justice system in order, and attempt to price the value of the services made available.

Housing and Food Services

The experimental subjects must be housed and fed, even if we assume that they will reside in the locus of the experiment for only a short period of time and will not require clothing and personal necessities. Given that residency will not be long term, rudimentary housing may be considered sufficient, the more so since no provision for any residents other than single adults need be considered. One simple measure of the cost of provision of such room and board is the fee charged college students for dormitory living and food. Amenities should, as we have argued, be minimal, so the cost of residence at a public university would be preferable to the fees charged at more exclusive and higher priced institutions. The room and board fees for eleven weeks of residency charged undergraduates at The Pennsylvania State University campus at University Park runs from $350 to $395 for a double room with meals, excluding Sunday dinner. The lowest cost residences are the oldest facilities and have the lowest level of amenities; by ignoring the shortfall in food provision of one meal per week, we can be sure that the fee of $350 for eleven weeks, or $4.55 per day, will not overestimate the costs of provision of sustenance and housing for experimental subjects.60/

Social Control of Subjects

The dominant reason for maintaining a centralized housing facility for experimental subjects is the need to control exercise, diet and medication and to have access to persons for the extraction of samples for testing. This need will remain salient on the "outside" but will require some modicum of staffing directed at maintaining minimal control of subjects (especially in terms of assuring that people do not go out and break diet or exercise constraints, and that contagious volunteers do not infect others). Some exercise facilities must, however, be provided for the subjects of the experiments, and this type of facility is lacking in most dormitory facilities.61/ Moreover, some personnel assigned to what may

best be called "door duty" will also be required for maintenance of the minimal level of control described as essential. Assuming the doors will be manned at a rate of 24 hours per day and that there will be one such door-manager per 60 residents, we can assign $1.00 per day for this social control cost (based on wages and fringe benefits for the requisite personnel amounting to not over $2.50 per hour).

Depressed Personnel Pay Scales: The extremely low wage rates prevailing in correctional institution employment normally available to inmates saves experimenters money in two ways: (1) low rates of pay can be offered to experimental subjects who have minimal earning alternatives, and (2) insofar as the experiment staff can be drawn from the inmate population, the cost of such staffing is reduced to typical inmate wages. Admittedly, some staff functions require specific forms of advanced training, most notably the requisite functions of physicians and registered nurses, but other experiment personnel can be hired from the prison resident population. If training must be provided the inmates who serve as staff, the experimenters may recruit only those residents facing long prison terms before they become eligible for parole.62/ Regardless of the pattern by which inmates are recruited, to the extent that they can be trained to take over experiment functions, experimenters can save significant amounts of money which would otherwise be expended on staff hired on the outside.

Measures of the probable dollar volume of the savings available to pharmaceutical manufacturers by virtue of their access to correctional institution inmates as both subjects and staff for Phase One testing can be derived. The fees paid inmate subjects can be compared to fees paid subjects on the outside under the assumption that the requisite subject pool will be made available outside the institutional walls. The probable savings associated with utilization of inmates as sub-professional medical staff in experiments can be derived from known medical staffing patterns and wage rate comparisons.

Data are not readily available on the rates of pay offered non-institutional populations for their participation in Phase One pharmaceuticals testing. However, recent experience in Maryland with experiments conducted on vaccines to control infectious diseases by physicians associated with the University of Maryland provides a neat comparison. Inmates at the Maryland House of Corrections in Jessup have been receiving $2.00 a day for participation in projects which involved their having infectious disease exposures subsequent to receiving vaccinations intended to protect them from contracting the diseases. In the latter half of 1974, the University, with funding and encouragement from the National Institutes of Health, moved to attempt comparable studies with students and other persons in the Baltimore area. These subjects were to have been paid $20 a day, or ten times what was being paid the Jessup inmates for participation in what were, in some cases, identical experiments.63/ It should, however, be noted, at least during the preliminary trials using non-institutionalized populations, no experiments involving serious and potentially recurrent illnesses, such as typhoid

fever, were to be done outside the prison walls. Thus, the diseases to which experiment subjects from the Baltimore population are to expose themselves for $20.00 a day will be less serious than those diseases to which Jessup inmates have been submitting for $2.00 daily. The minimum estimate of the cost savings associated with pharmaceutical manufacturers' access to inmates, as subjects, therefore, may be said to be based on a factor differential of more than 1:10. Assuming equal rates of voluntarism on the part of both institution residents and free living individuals, therefore, the inmates may be expected to cost roughly 1/12 what free subjects would cost for comparable experiments.

In order to more thoroughly examine the differences in the pay demands of inmates relative to persons living outside the walls, the concept of "opportunity costs" facing the individual choosers must be incorporated. The opportunity costs inherent in any choice of activity by an individual are the alternatives foregone by the exercise of that choice, as s/he would price them. The opportunity costs to inmates associated with volunteering for experiments are the prison wages which they lose by not holding their prison jobs (if they had any), and possible other benefits associated with the cell position they hold. The benefit to them, as we have noted, is a higher than average rate of dollar remuneration as well as possible physical and other amenities. The inmate, even at a low rate of pay such as $2.00 per day, must find the benefits from participation exceed the opportunity costs before s/he will participate. By and large, the opportunity cost computation favors becoming an experiment subject, judging by the supply of volunteers. Free-living subjects, by contrast, are faced with much higher opportunity costs: to the extent that participation in experiments requires that they remain within a single facility for days on end, they sacrifice all the benefits associated with freedom to move around in a community; they may sacrifice their income from a job (which unquestionably will pay more per day than the $2.10 which is now the federal minimum wage per hour); their food may decline in quality relative to the ingestion patterns they normally enjoy, etc. Obviously, therefore, they will require more pay to induce them to participate in experiments than do inmates. Under certain conditions, moreover, they may decide that the dangers inherent in their participation, or the extent to which they must subject themselves to losses of freedom, are so great that they will refuse to participate at any price (they perceive themselves as facing virtually infinite opportunity costs). The role played by opportunity cost considerations in the willingness of people to volunteer to serve as experimental subjects is clarified neatly in Table I.

Table 1

VOLUNTARISM IN DIFFERENT POPULATIONS: A MEASURE OF OPPORTUNITY COST[1]

Volunteer Group:	(N) (%)	Experiment: Malaria	Drugs[2]	Cold	Air Pollution[3]
		(Percentage of Group which volunteers)			
		(Group volunteers as % of all volunteers[4])			
ALL PERSONS	154 100.0%	32.5% 100.0%	38.3% 100.0%	46.8% 100.0%	78.6% 100.0%
Prison Inmates[5]:	60 39.0%	66.7% 80.0%	73.3% 74.6%	81.7% 68.0%	83.3% 41.3%
Free Persons:	94 61.0%	10.6% 20.0%	15.9% 25.4%	24.5% 32.0%	75.5% 58.7%
Low Income[6]	26 16.9%	26.9% 14.0%	34.6% 15.3%	38.5% 13.9%	65.4% 14.0%
Police & Firemen	40 26.0%	7.5% 6.0%	12.5% 8.5%	27.5% 15.3%	70.0% 23.1%
Professionals[7]	28 18.2%	0.0% 0.0%	3.6% 1.6%	7.1% 3.8%	92.8% 21.5%

NOTES:

1. Derived from Martin, D. C., et. al., "Human Subjects in Clinical Research - A Report of Three Studies," New England Journal of Medicine, CCLXXIX:26 (12/26/68), Table 1, p. 1428.
2. A new drugs toxicity study or Phase One pharmaceuticals test.
3. Described as involving no more than periodic exhalation into a machine measuring "enzyme efficiency."
4. Totals may not add due to rounding.
5. Included only inmates with sentences of one year or less.
6. Welfare recipients and maintenance personnel were included here.
7. "Scientists, lawyers and educators" were defined as comprising this subsample.

The four experiments for which volunteers were solicited in the tests which underlie Table 1 involve decreasing risk and time commitment as one moves from right to left, from "malaria" to "air pollution." The percentage of all populations volunteering can also be seen to increase as risk declines, while the percentage of the total volunteer pool that prisoners would have had to provide similarly declines as the overall opportunity costs fall. For none of the experiments, however, would the non-incarcerated population as a whole volunteer at a rate equal to the rate at which the inmates would be willing to serve.64/ While the willingness of the free population to participate does appear to decline overall as their incomes rise (from the "low income" through the "police and firemen" to the "professionals"), it is significant to note that the overall willingness to serve in the onerous experiments such as those involving contracting malaria or serving as a guinea pig for Phase One drug testing is better predicted by the respondents' physical state as incarcerated or free than by their income earning capacity. This finding suggests that the opportunity costs associated with loss of freedom exceed those incurred as the result of loss of income. Since the rate of willingness to participate in drug experiments was found to be over 72% for inmates but under 35% for even the poorest of the free subsamples, the assumption made above that the participation rates would be about equal is clearly violated.

Given this difference in participation rates, the cost difference of 1:12 estimated above must also be modified. If it is in fact true that it may be twice as difficult to induce free-living persons to incur the risks and unpleasant effects associated with playing the role of experiment subject as is the case for inmates, some cost allowances for recruitment efforts and other special expenses need to be incorporated. The 1:10 cost ratio finding from the Maryland experience was modified to 1:12 insofar as the infectious diseases to which the inmates subjected themselves were more severe than those induced in the non-inmate subjects. However, it now appears that this minor modification is not sufficient, based on the differential participation rates indicated by Table 1. (Note that the common cold experiments show an even greater disparity of rates of willingness to participate than do the drug experiments in Table 1.) Given the two-to-one greater willingness to participate on the part of inmates, we can suggest that the appropriate cost adjustment factor, to include all recruitment and other special costs associated with using free-living subjects, is 1:20 relative to inmates. Experimentation using inmates appears, therefore, to cost, on average, 1/20 of what similar experimentation would cost in participant fees and related expenses per subject-day were free persons to be so employed. Taking the low figure of $1.00 per subject-day as the payment to inmates for participation in pharmaceuticals testing, the subject fee subsidy provided the manufacturers testing their products may thus be estimated to be $19.00 per subject-day.

The impact on experimentation costs associated with the ability to employ inmates as experiment staff needs to be examined next. While the cost differentials for inmate relative to free-living volunteers was developed using

infectious disease testing, the cost implications of inmates as staff must be derived by a different analogy: this case being one of having to establish probable staffing patterns. The per bed staffing ratios for U. S. hospitals will serve as the frame of reference here, on the assumption that the comparable ratio in experimentation is one half the hospital pattern.

Data on health manpower in hospitals are readily available for different types of staff, and can be employed to approximate the possible number of persons recruited from inmate ranks who could serve on experiments with a minimum of training.65/ We shall consider only three of the ten categories of staff on which records are kept: clinical laboratory services, medical records, and "other." These three classes of personnel require successively less training, since "other" covers maintenance and janitorial personnel, and none of the personnel encompassed in such a body of staff is expected to hold medical or related degrees, as might be expected of the remainder of the typical hospital's staff. Based on U. S. data, we would normally expect to find 10.3 persons per 100 beds providing clinical laboratory services, 4.2 persons per 100 beds, tracking and maintaining medical records, and another 11.9 persons working at miscellaneous maintenance and other tasks for each 100 hospital beds; however, we need half these figures for experimental contexts, which exhibit much higher outpatient ratios.

For the sake of simplicity, we can assume that 27 persons in these categories of employment will be required for every 200 simultaneous subjects employed in an experimental facility. Of these 27 persons, some will be in supervisory roles or otherwise engaged in activities which would not be entrusted to inmates (or require more advanced training than is normally provided to inmates). We can thus postulate the condition that 20 out of the 27 jobs could be held by inmates. Such inmates could be paid at a rate which falls far short of the normal free market wage, regardless of their employment.66/ Thus, some wage cost savings will accrue to experimenters to the extent that they do employ inmates. However, in order to avoid overstatement of our argument, it should not be assumed that all the jobs which inmates could hold are, in fact, made available to them (for whatever reason); assume that 15 of the possible 20 positions are on average actually staffed by inmates and that the inmates so employed are paid $2.00 per day for their services, without running any risk of overstating cost savings.67/ Fifteen such inmate-workers would thus cost the experimenters $30 per day, or $210 per week (whether the seven days' pay is distributed across fifteen or more than fifteen persons).

The Federal minimum wage is now $2.10 an hour, and is rising more rapidly than prison wages have been moving. Hospital workers tend to move towards unionization if their wages are at the minimum level, to judge from the experience of the National Union of Hospital and Health Care Employees; once unionized, they make much more:

> The lowest paid job now brings $3.37 an hour. Beginning next July it will pay $3.62. Examples of some other rates are: nursing assistants - $3.50 now and $3.75 next July; patient unit secretary - $3.58 now and $3.83 next July....68/

The majority of hospitals in the U. S., however, are not unionized. One approximation for the norm for the lowest paid jobs in the nation's hospitals is the minimum wage itself; the presence of unions in the Northeast, which has a high concentration of hospitals, suggests a higher average does, in fact exist. We shall posit average wages for the jobs filled by inmates to be $2.75 an hour on the outside. By this figure, the seven days' work of fifteen persons for which $210 would have to be paid inmates would cost $2,310.

While this differential is a mere 1:11 on the ratio scale on which we found inmates as subjects to permit a 1:20 savings over free persons, it still represents a $2100 savings for every 200 subject-weeks of experimentation. $1.50 for each subject-day of experimentation is the savings incurred if inmates are used as staff while the minimum pay guaranteed subjects remains, in many instances, $0.50 per day. The subsidy provided the experimenters, at least in terms of the incomes and economic conditions of the inmates, is indeed sizable.

Physical Facilities Provision

Experimentation requires some physical loci in which examinations are conducted and tests administered and executed. For the more detailed forms of experimental evaluation, subjects may be placed on metabolic wards for very careful supervision. All experiment procedures require medical apparatus and equipment, which may or may not be provided by the researchers themselves. The patterns of utilization of correctional institution facilities, the donations of equipment or other benefits to institutions, and the sources of maintenance and operations funds for special facilities need to be examined to determine how large a subsidy, if any, may be provided experimenters in the form of low-cost physical facilities.

It was noted previously that sections of correctional institutions may be set aside as dormitories (or separate cell blocks) for experiment subjects. Evidence of such a pattern comes from the descriptions of experiments in Philadelphia's Holmesburg Prison 69/, Maryland's Jessup Correctional Facility 70/, and Jackson County, Missouri's jail 71/. The conversion of such space from typical inmate quarters into more sanitary facilities is typically required, and such conversions are conducted at the expense of the experimenters and their sponsors. The fact of such investment in facilities and equipments does not eliminate the presence of some subsidy provision to the experimenters, even if only the value of the building shell and its support utilities. Whether the improvements and installations of equipment benefit the correctional institution as well as the experimenters, in which case a subsidy to the institution may be identified, is a function of the specific relationship between the experimenters and the facility in which they are operating.

The largest single identifiable investment by experimenters in facilities within the walls of a prison occurred in Michigan in 1964: Upjohn and Parke-Davis constructed buildings housing experiment facilities in the State Prison of Southern Michigan at Jackson 72/. The facility contains two sets of laboratories (one for each company), as well as metabolic wards

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and isolation residential facilities for forty subjects, and was built at a cost of slightly under $500,000 or roughly $12,500 per bed. The per bed figure is employed here to provide for comparison to typical hospitals for provision of health care services on the outside, in order that the subsidy provided by the grant of the land on which the buildings rest to the companies constructing the testing facilities may be identified. The per bed cost for the facilities constructed by the pharmaceutical firms within the correctional institutions should compare closely to the cost per bed in routine hospital construction, since the absence of complex and costly operating room facilities in the testing hospitals is offset by the presence of much more complex diagnostic and chemical laboratories than are routine in small hospitals and by the inevitably higher than average per bed costs in the construction of a smaller than average "hospital."

Comparison to hospital construction costs is therefore appropriate as a basis for extrapolating the value of subsidies rendered to the construction effort. Federal analyses of hospital construction costs indicate that in 1970, "the cost per bed ranged from $14,000 to $72,000."73/ The price deflator for non-residential construction shows a 40.1% increase in construction costs over the 1963-70 period, which means the 1970 equivalent per bed costs for the Jackson experimental facility are $17,500, which is well within the quoted range.74/ However, the specialized nature of the testing facilities are such that their volume of outpatient activity, that is the number of persons "treated" in the Upjohn and Parke-Davis facilities who live, eat, and sleep elsewhere in the institution, is extremely high. It has been estimated that, on average, 1200 of Jackson's over 4000 inmates at any one time are acting as experiment subjects. 75/ This estimate suggests a ratio of outpatient activity is 1160 to 40 or twenty-nine to one, which is a very high figure. The pattern of per bed hospital construction costs evidenced is such that,

> ...Hospitals with large outpatient facilities will have a higher cost per bed than similar hospitals providing more space primarily for inpatient care. 76/

Thus, the cost per bed for the facility built in the Jackson correctional institution may be considered to be very low insofar as the unit exhibits a ratio of outpatient to inpatient activity which far exceeds national norms, and the range of construction costs cited for U. S. hospitals includes, at its lower cost end, hospitals which are little more than convalescent facilities.

The finding that a significant subsidy exists is not unexpected, given the donation of land and the probable participation of prison inmates in the construction labor required to build the experimental facilities. Estimation of the dollar value of such a subsidy is, however, extremely difficult due to a number of factors. First, the average per bed cost for a comparable hospital setting against which the construction costs of the Jackson facility may be measured would have to be derived from the $14,000 to $70,000 range on the basis of a series of complex assumptions, none of which are immediately empirically testable. Second, the Michigan case involved construction of wholly new buildings; the subsidy data on such a construction job would provide little useful data for other contexts in which conversions of existing

buildings and facilities are effected with the donation of the extant structures and equipment to the manufacturers and experimenters. Finally, the cost per bed figures are extremely sensitive to scale of construction or conversion efforts so extrapolation of any specific findings on the known construction efforts, such as that at the Michigan penitentiary, to other institutional contexts would produce very uncertain estimates even were the findings on the Jackson facility 100% accurate.

We conclude this examination of construction subsidies by noting that they unquestionably exist. Furthermore, the capacity of the pharmaceutical firms to provide facilities for experimentation to which the title is transferred to public agencies (or non-profit entities) permits them to acquire tax advantages in addition to subsidies: the immediate write-off as charitable contributions of expenditures which could otherwise only be depreciated over time as investments in experimentation capacity. Thus, the total subsidies identified below may be regarded as major understatements in so far as the implicit price of subsidies to physical facilities is set at zero due to the uncertainties described above, although it is known to be positive.

Direct Services Rendered: In Summary

It is possible to accumulate a minimum subsidy estimate for each subject-day of experimentation using inmates rather than free-living subjects on the basis of the computations and comparisons presented above. In proceeding to such a summation, however, we should note the very real services provided to experimenters by the justice system as a whole, which contribute to the possible accumulation of the subsidies as identified. The system's contributions take two forms: (1) the benefit derived from a steady supply of new subjects, and (2) the low costs attributable to the incarceration of persons in large facilities. We may consider these in order.

Turnover of inmates benefits the experimenters in a variety of manners. It assures a steady supply of persons who do not have the seniority to hold prison jobs, have not heard about the negative effects of experiments, and/or have not been rendered unsuitable for further experimentation on the basis of toxicities evidenced in prior trials.

The size of correctional institutions contributes to the efficiency with which experiments can be conducted within their walls. It is no accident that Upjohn and Parke-Davis elected the facility at Jackson, Michigan as the site for construction of their testing facilities since that institution was, at the time,

> ...rated as the world's largest walled penitentiary, enclosing 57 acres and 4141 prisoners. 77/

Economies of scale apply to any procedures which are standardized across the units over which they are conducted. This is a primary principle in the economics of production, and experimentation may be said to process subjects and produce experimental results. Any process has fixed costs, associated with administration and the provision of the production facilities, and additional costs which are not fixed, but vary with the number of units processed or produced. The larger the number of output units over which the fixed costs may be spread, therefore, the lower will be the costs per unit.

In the case of medical experimentation, the fixed costs are those associated with the experiments direction and supervision and basic facilities provision, while the variable costs are associated with payment to the subjects, provision of the drugs administered, and the conduct of the tests on each subject. The Jackson penitentiary, by virtue of its size, permits a very large number of subjects to be processed in the same facility, under the same central experiment direction, and thus contributes significantly to cost savings. Further development of community-based corrections and other alternatives to incarceration in large-scale institutional facilities for convicted persons could, therefore, deny the current users of the inmate populations of these large institutions a major cost subsidy which they are currently receiving, albeit at no dollar cost to the correctional system.

Given the existing turnover rates for inmates and the presence of the large incarceration facilities within which experimenta are conducted today, the subsidies provided in the form of lower costs for direct services rendered may be accumulated on a subject-day basis as follows:

Housing and Food Services to Inmate-Subjects	$ 4.55
Social Control for Inmate-Subjects	1.00
Depressed Prison Pay Scales	
-as reduced fees to Inmate-Subjects	19.00
-as reduced wages for Inmate-Workers	1.50
Subsidies to Physical Facilities and Equipment (known to exceed zero, but level unknown)	0.00
TOTAL SUBSIDIES CURRENTLY RENDERED PER SUBJECT-DAY	26.05

The annual dollar value of this subject-day subsidy can be computed from data on the volume of experimentation actually ongoing. In so far as such activity is carefully hidden from competitors' view by pharmaceuticals manufacturers (and generally hard to witness due to the closed nature of correctional institutions), little hard data on experimentation activity levels can be obtained. Jessica Mitford, citing R. V. Taylor in Michigan Medicine (see footnote 75), estimated the activity level at the Jackson, Michigan institution to be some 1200 inmates at any given time, but a Parke-Davis representative closely associated with the Jackson facility argues that this figure includes all persons "in the pipelines": persons being screened, persons subject to experiments, persons on whom follow-ups are being continued, etc.78/ It is not at all clear whether or not the total subsidy should or should not be attributed to all such persons, and if a partial subsidy should be applied to people not currently being administered drugs, what the level of that subsidy should be. For the sake of argument, we can assume that half this number, or 600 persons are functioning in contexts which require their institutionalization for the purpose of experimentation and therefore their services provide the full subsidy of $26.05 for each day of service they rendered.

The Jackson facility, therefore, would represent 600 x 365, or 219,000 subject-days of service per annum. This facility is not the only one at which Parke-Davis and Upjohn, the companies using the Michigan site, conduct experiments, and the two companies are neither the largest nor the dominant enterprises in the pharmaceuticals business. The total number of subject days of experimentation, therefore, must be larger than this two hundred-thousand figure, even if we limit our argument to pharmaceuticals manufacturers alone. Recent data on firm sizes and sales for different industries in the United States indicate that there were 21 drug manufacturers in the United States in the 1971-72 period with assets in excess of $250 million, of which Parke-Davis and Upjohn are two.79/ If two of these large drug manufacturers generate 200,000 subject-days of experimentation, then twenty-one of them may be expected to generage 2,100,000. This rough approximation of the total volume of experimentation by pharmaceuticals manufacturers suggests that the annual value of subsidy rendered through direct services provision is on the order of $54,705,000.

TOTAL COST SAVINGS ASSOCIATED WITH PRISON EXPERIMENTATION

We can now merge the cost savings associated with the prison inmates' acceptance of a lifetime of risk of after effects with those associated with subsidized direct experimentation services to arrive at the total value of the prison test sites to the pharmaceutical manufacturers of the nation. Some difficulty may be presented in identifying the number of new participants in experiments who enter the subject ranks annually, in so far as the cost of the insurance coverage is a one-time expenditure, but we can provide for this uncertainty as we estimate the turnover of inmate-subjects.

We estimated above that the annual subject-days of experimentation totalled 2.1 million, representing an average of 6,300 persons functioning as subjects each day. Experimentation protocols often include restrictions on the frequency with which inmates can move from one experiment to another, so the actual number of persons on whom experiments are conducted over the course of a year, even disregarding turnover, will exceed the daily total. If we assume that the drug manufacturers' phase one tests provide for one day off experimentation for every day on as the elapsed time requirement (which implies one month between trials requiring one month of participation, for example), then the minimum number of persons tested in experiments would have doubled the 6,300 figure, or 12,600. In light of inmate turnover, the unwillingness of persons to participate after a "bad" experience associated with revealed toxicity, etc. this figure needs further upward revision. Assuming a 20% turnover rate for the persons who serve as subjects, the number of inmates who would annually come in contact with the experimentation programs of the pharmaceuticals manufacturers would be 16,380. This estimate of the number of inmates contacted is minimal, especially insofar

as the experiment subjects include persons who are not convicted but merely incarcerated while awaiting trial and others who are incarcerated for periods totalling less than one year. Given the posited 20% turnover rate for subjects, 2,520 new entrants into the ranks of experiment subjects would be expected annually at a cost for insurance of between $6,500 and $11,200 per person, or a total of betwen $16,380,000.00 and $28,224,000.00 annually. We assume that the true subsidy lies between these extremes.

The president of the Pharmaceutical Manufacturers Association, when pressed, has admitted the major benefit to the companies derived from the utilization of prison inmates is associated with cost:

"Sen. Kennedy: 'Your position is you couldn't get other citizens in the community, even given financial remuneration, to serve as Phase One drug test subjects?'

"Mr. Stetler: 'I can't say "couldn't" because it has not been tried.'

"Sen. Kennedy: 'It has or has not been tried?'

"Mr. Stetler: 'It has not been tried.'

"Sen. Kennedy: 'Why has it not been tried?'

"Mr. Stetler: 'I suppose because it is too difficult.'

"Sen. Kennedy: 'You haven't tried yet. How do you know it is difficult?'

"Mr. Stetler: 'You get back to the other points I mentioned earlier. When you have others available, you use them.'

"Sen. Kennedy: 'Is that because they are cheaper?'

"Mr. Stetler: 'They are cheaper.' 80/

This is not surprising since we have found that our bare minimum, low-end biased, estimates of the implicit subsidy provided the pharmaceutical firms testing in prisons total some $75 million annually.81/

The sheer magnitude of these subsidies is indication enough that the attention devoted to date to the economics of medical experimentation on prisoners has been woefully inadequate. However, it must be recognized that this $75 million figure may be but the tip of the iceberg. In addition to the pharmaceutical manufacturers and their representatives, large numbers of

other researchers from the medical and related professions continue to experiment on prisoners. Given the low cost of hiring inmates as subjects, some of this experimentation is essentially private, funded directly by the investigators, and no reliable estimate of the volume of such activity is available. Subsidies theoretically represent the explicit decision on the part of participants in a political process to use the power of the state to enhance the economic viability of particular activities which the polity decides should be stimulated. However, in the case of implicit or unrecognized subsidies, activities are being stimulated that have never undergone public scrutiny as regards their desirability. Given the magnitude of the subsidies associated with the access of medical experimenters to the populations in the nation's prisons, further study of the appropriateness of these implicit grants in light of available alternatives is certainly warranted.

The argument which must be examined is whether or not it is efficient for the society as a whole to partially underwrite the costs of new drug development by providing access to experimental subjects in correctional institutions. Presumably, were the decision made that that such underwriting was not efficient, the subsidy provided could be removed by either of two tactics: (a) charge the experimenters using prisons for all the "free goods" and lower cost services provided by the prison setting at the "outside" market rates they would command, thus forcing a reallocation of resources from the manufacturers who underwrite experimentation to the correctional system and its inmates or the public fisc; or (b) ban experimentation in correctional institutions and force the conduct of such trials on the "outside," where, presumably, market rates would again apply.

Either of these approaches could then be augmented by an explicit subsidy provided directly to the experimentation process by the governmental unit which required the trials in the first place. Were such control on subsidies imposed, a variety of outcomes could emerge, all of which impinge on the definition of optimally allocated resources, the rates of new drug development, and the ability of people on the "outside" to contribute to improved social well-being by volunteering to serve as experimental subjects. We can list the major impacts or issues here, although they do not properly fall within the purview of this paper:

1. Given the opportunity to employ prisoners at wages such as $0.50 or $1.00 per experiment day, no experimenters will employ people outside the prisons, thus impinging on the rights of non-prisoners to participate in experiments, since by and large they cannot afford to offer their full time services at competitive rates. Denial of the subsidy would tend to equalize subject costs throughout the socioecomonic system.

2. In so far as most prescription drugs sold under brand names are purchased by the more affluent, the subsidies which reduce the development costs (and thus the selling price of such drugs), comprise transfers to those with above average incomes. Subsidy removal would eliminate this regressive resource reallocation.

3. To the extent that prisoners come from the lower socioeconomic groups in society, limiting experimentation to the prison population (which is what the current subsidy pattern does), forces the costs of the regressive transfers to be borne by those least capable of bearing them. Removal of the patterns which force experiments to be conducted in prisons might more equally distribute the costs of whatever subsidies remain across other groups in the population.

4. To the extent that subsidy allocations will now be based on conscious governmental decisions, not passive permissions, there will be more control over the allocation of the pharmaceutical manufacturers' research dollars (possibly towards more efforts at true therapeutic breakthroughs rather than molecular variant development), which could contribute to increasing the general welfare of the population at large.

5. Such controlled subsidies need not be allocated automatically in proportion to the dollars that drug manufacturers allocated towards experimentation, but could be more equally distributed across the industry, thus ceasing to contribute to increasing concentration among pharmaceutical manufacturers, and possibly lowering costs for prescriptions.

This list could be extended significantly, but the five issues raised above are indicative of the range of issues from which the discussion of subsidies and costs and benefits below has been abstracted. We must mention in passing one of the most significant aspects of subsidy denial strategy (a) above, which is the possibility that permitting experimentation to be conducted in prisons, but at market prices, would so increase the resources of the corrections system as to permit it to execute its functions in a far more successful manner.82/ This possible benefit might well argue in favor of specific selection of the first subsidy control option rather than the second, provided the resources shifted from the drug manufacturers to the corrections process is not simply drained off into general government funds.83/

Regardless of which policy for control and direction of subsidies is to be pursued, and regardless of whether such action as regards the current implicit subsidy provisions is taken to "protect" prison inmates or to control medical experimentation, the level of subsidy, as demonstrated, is not an insignificant issue. Whether the subsidy provided is a simple externality available from the other functioning of the corrections process or a specific cost to the corrections process does not particularly matter in this examination. Externalities result from all collective expenditures or government activities; the presence of such external effects is the rationale for the conduct of such activity as part of the public sector. The particular interest in subsidies emerges only when specific differential rates of external impacts can be isolated for different populations. In the case of the corrections programs of the United States, insofar as medical experiments are permitted within institutional walls, a significant and specific subsidy is provided to experimenters. The dollar magnitude of that subsidy has been identified, but the appropriateness of the grant must now be investigated.84/

VIII. IN CONCLUSION: SOME QUESTIONS

The grant of a subsidy to entities which are not a part of the corrections process is not inherently an inappropriate course of action for the corrections systems of the nation to take. However, any such subsidy should be scrutinized. When the dollar value of subsidy granted (in the case of pharmaceutical manufacturers' experimentation a minimum of $75 million annually) is sufficiently large, serious consideration must be given to utilizing such implicit grants internally, in a manner which might enhance the functioning of the corrections system. Given a total U. S. expenditure for correctional facilitie for adults which is little more than $1 billion per annum, the subsidy to pharmaceuticals experimentation looms extremely large, comprising as it does, some 7.5% of the total budget of the institutions. 85/ A far more detailed study of the uses to which these funds could be put within the corrections system is clearly in order. What we offer in concluding this study of medical experimentation in prisons and jails are some guides to what appear to be the promising issues for this needed additional research.

There exist three basic areas in which additional research in the implications of the presence of medical experimentation in prisons must be pursued, excluding, as we have thus far, the "moral" issue:

(1) Does the presence of implicit grants to medical experimenters, including the pharmaceuticals manufacturers, insofar as such grants are associated with extremely low rates of pay for institutional residents, constitute an effective transfer of income from the relatively poor to the relatively rich? (The argument here would build on the income differentials between the inmates, when not incarcerated, and the average user of prescription drugs.)

(2) Does access to prison and jail residents provide advantages for certain pharmaceutical manufacturers which reduce the competitiveness of the prescription drug industry? (The concern under this rubric would be with the price and supply patterns induced by access to prison and unregulated development of pharmaceuticals accompanied by large subsidies to experimentation.)

(3) What impacts on the success with which large correctional institutions contribute to the administration of justice in the United States (in accordance with their specified correctional and rehabilitative roles) do the experiments now conducted therein have, and could their positive contribution be enhanced? (The focus of this query is strictly limited to the effects of experimentation on the outcomes of the corrections process.)

Insofar as this paper has focused primarily on correctins, with needed, but minimal, digressions into such issues as the structure of the pharmaceuticals industry, we shall limit our discussion below to this third

area, focusing on the opportunity costs associated with different allocations of the subsidy now granted totally to the experimenters in most jurisdictions.

Joint Products and Efficiency

An essential portion of the argument favoring the retention of medical and other experimentation within institutional loci is the assumption, frequently unstated, that such experimentation can be conducted cojointly with correction and rehabilitation; that is, at zero cost to society at large. The contention is that the inmates are incarcerated in any event, and are therefore readily available as an easily accessible experiment subject group, so nothing is to be lost, and all to be gained, by using them as subjects. Obviously, the key assumption is that the presence of experiments within institutions does not impede or otherwise affect the supposedly positive effect institutionalization has on inmates. We can identify a critical issue area as regards this interaction of rehabilitation and experimentation.

> Research Issue 1: What are the effects on correctional and rehabilitative processes of the presence of experimentation within institutional walls?

To the extent that experimentation and correctional efforts appear to be symbiotic within the institutional walls, the continuation of such experiments on inmates may be deemed to be appropriate, although the issue of the most appropriate division of the cost savings (efficiency gains) derived from the joint activity remains unresolved. However, other issues related to correctional processes should still be considered, most notably the availability of alternatives to incarceration. Insofar as the joint production of experiments and rehabilitation can occur most effectively within the prison walls (the assumption granted above), experimentation on inmates is justified, but such a condition does not justify continuation of institutionalization by the correctional system, unless alternatives to incarceration can be proven to be less cost effective than incarceration. If the incarceration of inmates is less effective than their treatment or punishment by different means, any gains incurred in the form of medical experimentation are irrelevant. This leads to a second major issue for further study:

> Research Issue 2: What tendency towards maintenance of the incarceration of individuals in large institutions is induced by the availability of the experimentation joint product, and to what extent does the pursuit of this product occur at the cost of failure to incorporate alternatives to institutions which might reduce recidivism?

The research issues identified above raise questions about the presence of joint products in the correctional system, and the extent of interaction (positive or negative) between the capacity to produce the one output and the other. It is possible, however, to grant fully the presence of a capacity to produce both desirable correctional outcomes and medical experimentation and still question the pattern of allocation of the benefits from such efficient joint product generation. This issue will be dealt with next.

Allocation of Cost Savings

We demonstrated above that the ability to experiment in the correctional institutions of the nation has been worth about $75 million annually to only one of the many classes of experimenters currently using the nation's prisons and jails, the pharmaceutical manufacturers. We further noted that this experimentation cost savings is equivalent to at least 7.5% of the correctional institution budgets, nationwide. There is no a priori reason to assume that the most efficient use of this large savings is not reduction of the correctional institution budgets and denial of all cost savings to the experimenters. What is at issue here is the distribution of the benefits from medical experimentation in prisons and jails, under the assumption that such an effort results in no net negative outcomes. The allocation of any share of this benefit or efficiency gain may be considered to comprise an issue of opportunity cost minimization. That is, we should proceed from the premise that no given or existing allocation of benefits (such as the current pattern in which the cost savings accrue to the experimenters), is sacrosanct and proceed to examine the outcome implications of different allocations of the benefits, in terms of foregone opportunity costs.

On the simplest or lowest level, we could compare the alternatives of leaving the funds where they now lie, with the experimenters, to the requirement that all experimenters be charged market rates or costs for their activities within the institutions. Such a comparison, however, leaves too many questions unanswered, especially regarding the uses to which the institutions, or the correctional system as a whole, may put the additional funds placed at their disposal (and, obviously, obscures the question of who gets the additional resources - the institutional managers or the administrators of the entire corrections system, other agents interested in reduction of criminality and recidivism, or the inmates themselves). Moreover, we can not afford to ignore a problem raised earlier: the development of alternatives means of corrections (community-based and other special programs) could gradually erode the experiment base available in institutions and thus reduce the aggregate efficiency gains now evidenced. The new issues raised under the rubric of the opportunity costs of benefits allocation may be summarized under one major heading:

> Research Issue 3: What are the available or conceivable alternative uses to which the efficiency gains could be put, and what impact on criminality or recidivism would these alternatives exhibit if implemented? (The costs in terms of reduced medical experimentation will have to be addressed, of course, but for the purposes of a primary concern with corrections, we can assume that direct overt subsidization replaces implicit subsidies in those contexts in which correctional concerns dictate the charging of free market rates for services rendered.)

The range of alternatives which would warrant examination is immense; some approximation may be provided by the Corrections report of the National Advisory Commission on Criminal Justice Standards and Goals, which lists 129 standards inadequately met in the corrections process at this time. 86/ Two items may serve to demonstrate the breadth of possibilities available for the

uses of $75 million within the corrections system: (a) Inmates discharged or released on parole typically are provided with "gate money" in the amount of $25, while their average savings for use on release total less than $100; these funds are not sufficient to assure that discharged inmates will not deplete their honestly accumulated resources prior to obtaining legal means of earning more, and may therefore contribute to recidivism. 87/ (b) The costs of maintaining an inmate in an institution range from under $4 to almost $24 per day, averaging $9.99 in the nation; the costs of institutionalization are such that services provision within the walls is minimal, so little rehabilitation may in actuality occur. 88/ Assuming that some 150,000 persons are released annually from all institutions, the savings enjoyed by pharmaceutical manufacturers alone on their experimentation could provide gate money in the amount of $500 to each person so discharged.89/ (If detainees who could not make bail are provided with less money than those discharged after serving prison sentences, or gate monies paid are adjusted to length of institutional stay, other figures would obtain, but the impact of the experiments' efficiency benefits on persons released or paroled would remain extremely sugnificant.) Similarly, if the experimentation cost savings incurred on the activities of the pharmaceutical manufacturers alone were applied to paying for institutionalization at an average cost per day of $10, the efficiency gain could have housed almost 20,625 people for a year, or over 1 1/2 times the number of participants in the experiments producing the efficiency gains. Obviously, partial shares, such as the experimenters paying the costs of incarceration for their subjects, but no more, could also be identified as plausible outcomes. The range of possibility is enormous, but all choices are predicated on the assumption that the full costs of experimentation will be identified and considered as resources to be allocated between the experimenters, the institutions, the inmates, and the correctional system as a whole.

Morality and Money

We have intentionally ignored the issues raised earlier in this paper about "informed consent" and other aspects of the morality of experimentation on inmates (or humans in general). This has been done since the ethical questions to be resolved and the research issues raised here are all based on the assumption that the full cost of experimentation will be identified.

It may be argued that "informed consent" is nonexistent because knowledge is imperfect. (Hotdogs and most canned soups contain carcinogens, for example, and carcinogens have been linked to cancer, but how many housewives are aware of these facts?) Similarly, the argument that no one is free of some form of coercion may be introduced. (The limited alternatives facing any chooser may be said to be the result of some factors over which s/he has no control and may thus be said to be a coercive situation.) However, such broad based lack of information and constrained choice does not appear to cause great moral outcries and concern over the problems of coerced behaviors.

The reason that these generally experienced conditions do not result in moralizing is, perhaps, that they occur in an open and free environment, in which the answers to the questions "how can I do this to another person?" are obvious. The only answer to such a query, other than "I cannot," is

"it is worth it," and this answer is not challenged in an open decision-making context in which the judgment is obvious. When, however, the judgment is made under not fully open conditions, there exists a fear of unknown subsidies which may distort judgments. It is for this reason that we argue that the full cost of experimentation must be identified and the burdens shouldered by different participants in the experimentation process be identified. Without explicit judgment that experimentation activity is "worth it" to all parties concerned, which includes the citizenry at large since taxes and crime affect all persons, this economic analysis would not provide any insight into, nor guides to the resolution of, the moral issues involved.

Finally

Prisoners are used in experimentation to a degree which we really do not know, having only been able to measure experimentation in new drug testing. The fact that prisoners have been, and are now, used, however, in no way warrants the position expressed by Secretary Weinberger of the Department of Health, Education and Welfare at a recent scientific meeting that "...prisoners are needed in research. Their diets and life styles are easily observed and easily controlled...." 90/ Whatever contributions prisoners have made to medical advance, there exists no question that other human bodies, had they been available and employed, could have done as much. The argument that inmates are critical to the research effort is one based on economic cost considerations.

Such an argument presumes the desirability and necessity of exploitation of prisoners' limited choices, and such a claim of essential need should always be challenged. We can do no better than to quote William Pitt, who observed that, "Necessity is the plea for every infringement of human freedom. It is the argument of tyrants; it is the creed of slaves."91/ Prisoner experimentation is not necessary; given direct subsidies, all current experimenters on inmates could continue their work with free living persons. Whether such subsidies should be provided or not, and whether experimentation itself should continue to be permitted in the jails and prisons of the nation, should not be a matter of rhetoric, but of conscious examination of the available alternatives for the experimenters, the institutions, and, above all, for the inmates and the population at large.

FOOTNOTES

1. "A total institution may be defined as a place of residence and work where a large number of like-situated individuals, cut off from the wider society for an appreciable amount of time, together lead an enclosed, formally administered round of life." Goffman, Erving, Asylums (Garden City, New York: Doubleday-Anchor, 1961), p. xiii.

   Goffman's book lies at the foundation of extensive subsequent analysis of, and theorizing about, such institutions as jails and mental hospitals, and his characterization of the institutions has been reinforced repeatedly. Some of Goffman's observations are salient to our characterization of prisons. On work:

   > "...so little work is required that inmates often untrained in leisurely pursuits, suffer extremes of boredom. Work that is required may be carried on at a very slow pace...." (p. 10)

   On priviledge, and, therefore coercion:

   > "First, there are the 'house rules', a relatively explicit and formal set of prescriptions and proscriptions that lays out the main requirements of inmate conduct. These rules spell out the austere round of life of the inmate...
   >
   > "Secondly, against this stark background, a small number of clearly defined rewards or privileges are held out in exchange for obedience to staff in action and spirit...
   >
   > "The third element in the privilege system is punishments; these are designated as the consequence of breaking the rules. One set of these punishments consists of the temporary or permanent withdrawal of privileges or the abrogation of the right to try to earn them...
   >
   > "There are some special features of the privilege system which should be noted.
   >
   > "First, punishments and privileges are themselves modes of organization peculiar to total institutions...
   >
   > "Second, the question of release from the total institution is elaborated into the privilege system...." (pp. 48-51)

2. Singer, Neil M., "The Value of Adult Inmate Manpower", Correctional Economic Analyses Series, (Washington, D. C.: ABA Commission on Correctional Facilities and Services, 1973), p.11.

3. We are avoiding a specific dollar projection for the "room, board and supervision" costs insofar as the actual situation now involves the inmates as involuntary recipients of services provided by a monopolist, whose capacity to charge above the rates which would obtain on the "outside" for comparable housing and meals is effectively unchallenged. The appropriate subtraction for housing and food services would be the rates existing in the free market, but no price for "supervision" could really be obtained, the more so since the inmates have no option to reject this (dubious) "service".

4. Decision of a three judge panel in Jackson vs. Hendricks (Philadelphia Court of Common Pleas, April, 1972), cited by Allen H. Lawson in testimony before the Subcommittee on Health of the U. S. Senate Committee on Labor and Public Welfare, March 7, 1973 ("Quality of Health Care - Human Experimentation, 1973," HEARINGS, March 7 and 8, 1973, Part 3, p. 823, (Washington, D. C.: U.S. G.P.O., 1973)). Future references to the hearings record will identify the author(s), whether the citation is made with reference to testimony or documentary submissions, and "HEARINGS, op. cit.," followed by a page number citation.

5. The additional issue of the opportunity costs of voluntarism is addressed in some detail below (see section VII).

6. These roles may be played either sequentially (over the course of a physician's professional career) or simultaneously. While the simultaneous playing of these roles is ethically questionable, at the very least, such activity does go on, as one case uncovered in Florida attests:

   > "Pharmaceutical firms experimenting with Florida prison inmates pay thousands of dollars each year to prison doctors and hospital supervisors who help with the tests and sometimes judge their effectiveness.
   >
   > "Drug firms reported paying one hospital supervisor more than $7,000 during a two-year period while he was passing judgement on the safety of their tests, State Correctional Division records show."
   >
   > Raum, T., "Prison Drug Tests Benefit Supervisors", Tallahassee Democrat, December 24, 1972, documentary submission, HEARINGS, op. cit., pp. 872-3.

A legal vehicle for physicians wanting to serve several roles simultaneously was developed in California; a nonprofit corporation called the Solano Institute for Medical and Psychiatric Research, organized primarily for the purpose of conducting research in the California Medical Facility and Vacaville (Mitford, J., Kind and Usual Punishment, New York: Alfred A. Knopf, 1973, p. 157 ff.). Most impressive of all, two pharmaceutical manufacturers have actually constructed a mini-hospital expressly for the purposes of expediting medical experimentation within the walls of the Jackson, Michigan correctional facility (which houses 4000 inmates). Parke-Davis and Upjohn, therefore, have actually invested in physical facilities designed to minimize the discrete roles played by physicians in the provision of authorization for, the conduct of and the evaluation of medical experiments with prisoners. ("Drug Tests Behind Bars", Business Week, June 27, 1964, pp. 58, 60, 62.)

7. Bernard L. Diamond, M.D., Psychiatrist and Professor in School of Law and School of Criminology, University of California - Berkeley, in testimony, HEARINGS, op. cit., p. 838.

8. Singer, op. cit., describes the constraints; the subsidies take the form of any aspects of working with prison populations which lowers the experiments' costs. (Section VI and VII below address the elements of the subsidy provided and the dollar costs thereof.)

9. While the study was reviewed by the U. S. Public Health Service in 1969, it took public disclosure of the experimentation of non-treatment for syphillis, which occurred in 1972, before a panel of non-Public Health Service persons was created to review the situation. Immediate provision of medical care for participants, as well as payment of some financial restitution, was recommended by the ad-hoc advisory committee after its review of the case. (C.f.: documentary submission, HEARINGS, op. cit., pp. 1108-1118.)

10. Mitford, J., op. cit., p. 147, calls attention to the experimental procedures which led to the eventual publication of "Clinical Manifestations of Ascorbic Acid Deficiency in Man" by Dr. R. E. Hodges in April, 1971 issue of the American Journal of Clinical Nutrition.

11. Dr. Ephraim Kahn, quoted by Mitford, ibid, p. 149.

12. Pharmaceutical Manufacturers Association and the National Council of Crime and Delinquency, Proceedings of the Conference on Drug Research in Prisons, (Davis, Cal.: Research Center, National Council on Crime

and Delinquency, 1973), p. 15 (F. G. McMahon, M.D.). Further citations of this source will be identified as "PROCEEDINGS, op. cit.," followed by page number, and author identified in parenthesis. (Note that a conference summary, paginated separately from the proceedings, also exists; it will be cited as "PROCEEDINGS, op. cit., summary," followed by a page number.)

13. Figure cited by Mitford, op. cit., p. 140, quoting Dr. Robert Batterman.

14. Joseph Stetler, in testimony, HEARINGS, op. cit., p. 865.

15. Data on informal drug testing and market research trials in correctional institutions, largely because of the casual nature of such experiments, are virtually impossible to obtain. These qualitative narratives are based upon descriptions provided the author by ex-inmates and colleagues specializing in correctional institutions and processes in the Division of Community Development, Pennsylvania State University.

16. PROCEEDINGS, op. cit., p. 17 (F. McMahon, M.D.).

17. There is one proviso, however, which must be added: the inmates do not necessarily conform to the requirement that the subject pool be healthy. Consider the following observations:

    "According to the (U. S.) Bureau of Prisons, the typical inmate is incarcerated with a 95% chance that he needs medical care". (A. Adams, testimony, HEARINGS, op. cit., p. 809);

    "Each volunteer gets a physical and about half are eliminated from testing." (Business Week, June 27, 1964, photo caption, p. 62, emphasis added).

18. Quoted by Michael Mills, in PROCEEDINGS, op. cit., p. 175, emphasis added.

19. One such certificate was part of the appeal of a malaria study described by Aileen Adams and Geoffrey Cowan, in "The Human Guinea Pig: How We Test New Drugs, World, December 15, 1972, pp. 20-24; photograph of the certificate appears p. 23.

20. Hodges, R. E., and W. B. Bean, "The Use of Prisoners for Medical Research", Journal of the American Medical Association, CCII:6, cited by Mitford, op. cit., p. 146.

21. Burger, L., and M. L. Bundy, "Secrecy and Medical Experimentation on Prisoners", mimeo, Baltimore, Maryland: Urban Information Interpreters, Inc., July, 1974, p. 2. Bowers, J., "Medical Research in Prisons", Clearinghouse Review, VI:3, July, 1972), notes (p. 151) that somewhat broader pay scale difference existed in California, where an inmate in 1972 had jobs available "earning him anywhere from two cents to $0.40 per hour."

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22. The fee schedules appear as documentary submissions, HEARINGS, op. cit., pp. 933-37.

23. This situation obtains in Philadelphia PA's Holmesburg Prison, at least for the 85% of inmates who are detainees awaiting trial (and who are therefore ineligible for any of the "real" prison jobs available to convicted inmates during the entire time period of their detention, which runs as long as 30 months). Exchange between Senator Kennedy and Mr. Lawson, HEARINGS, op. cit., p. 822.

24. PROCEEDINGS, op. cit., summary, p. 19.

25. Geoffrey Cowan testimony, HEARINGS, op. cit., pp. 803-4.

26. Lawson testimony, HEARINGS, op. cit., p. 827.

27. Bowers, J., op. cit., p. 152, notes that legally conditions in the institutions cannot be so bad that the choice as regards participation is forced.

28. McDonald, J. C., "Why Prisoners Volunteer to be Experimental Subjects", Journal of the American Medical Association, CCII:6, pp. 175-6.

29. The major importance to an inmate of the right to elect participation in an experiment has been described as follows:

> "...the opportunity to participate in drug research and testing offers the prisoner a rare and important thing: the chance to make a real, effective decision about some matter affecting his life in prison. When clothing daily life, movement, sound and sometimes communication are under the control of someone else -- the prison institution -- even the seemingly small choice of whether or not to sign up for a new drug test in an important one." PROCEEDINGS, op. cit., p. 45 (Report of Ethics, Rights and Laws Work Group).

Observations on the problem of participation rights at the Conference on Drug Research in Prisons by individual conferees is also indicative of this concern:

> "...we are all concerned about the right to participate, the right to not participate and the existence of coercion as a function of poor prison conditions." p. 116 (Mervin Clark, M.D.).

> "Should one who has had so many rights removed from him by law still retain the right to consent to a procedure not for his own benefit but for the benefit of someone else?" p. 139 (Victor Henderson).

> "At the present time, the departments of corrections and the administrators of the prisons have the power, and the prisoners don't. The option to participate in or not participate in research activities is filtered to the prisoners through the administration. And I think only when that power is passed directly by the drug research operatives to the prisoners can we then begin talking about voluntariness." p. 142 (Paul Dunn).

30. In some contexts, the capacity to authorize inmate participation in experiments devolves to "trustees" and other longer-term institutional inmates. One major cause celebre associated with medical experimentation emerged out of Holmesburg Prison, one of three institutions in the Philadelphia County correctional system, in which an inmate used his powers to authorize experimental participation to garner huge quantities of funds (by prison standards, at least) in payoffs for authorizations, as well as a steady supply of homosexual partners. (Cf., Philadelphia Inquirer, articles reproduced as documentary submissions, HEARINGS, op. cit., pp. 998-1001.)

31. "It is a firm principle that no one should be subject to arbitrary risks against his will and informed consent is required of all participants in research projects. This requires obtaining a consent and release statement from each participant which statement must include the stipulation that the subject may freely withdraw from participation at any time without penalty of any kind." U. S. Bureau of Prisons, "Research", Policy Statement-#6110.0, issued October 31, 1967, p. 1, emphasis added.

This clause, if fully implented, could require that full payment equivalent to the amount which would be earned by persons staying in an experiment for its entire course be paid to individuals who dropped out after being accepted for the experiment but prior to receiving any drugs.

32. Such consent forms appear as documentary submissions in HEARINGS, op. cit., pp. 929, 938-9, 940-41, 942, 952 and 991. However, one observation on the language in such forms should be noted:

> "You have informed consent waivers, but that, to most of the men in a penitentiary, is like reading hieroglyphics". Lawson, A. H., in testimony HEARINGS, op. cit., p. 824. The problem encountered

by the possible subjects is a combination of two factors: the description of possible side effects in medical jargon and the low educational level of the inmates. (Singer, op. cit., Table 1, p. 4, finds the educational attainment distribution of adult inmates to be as follows: less than 8 years of school, 24.9%; eight years, 14.8%; some high school, 33.6%; finished high school, 20%; some college, 5.3%; finished college, 1.4%; for 1970.)

33. Martin, D. G., et. al., "Human Subjects in Clinical Research - A Report of Three Studies", The New England Journal of Medicine, CCLXXIX:26 (December 26, 1968), p. 1427.

34. Idem.

35. Klein, M., "Problems Arising from Biological Experimentation in Prisons", Ciba Foundation Series 16 (New Series), Medical Care of Prisoners and Detainees, (Amsterdam: Associated Scientific Publishers, 1973), p. 67.

36. It should be obvious that the simplest way to mediate the conflict currently extant over the utilization of prison inmates for medical experimentation is to first lower the level of conflict by reducing, wherever possible, the pressures for such experimentation. While we do not necessarily contend that such action will fully resolve the conflicts, the scale of experimentation, and thus associated conflict, might be significantly reduced.

37. Moore, T. G., "The Pharmaceutical Industry", pp. 156-188 in W. Adams (ed.), The Structure of American Industry, Fourth Edition (New York: The MacMillan Company, 1973), p. 171. This chapter forms a dominant underpinning for this review of the structure of the pharmaceuticals industry.

38. Ibid, p. 172: Moore points out that the only parties damaged by such procedures are the smaller pharmaceutical manufacturers locked out by the bigger companies' internal trading in the letters, and the consumers of prescription drugs, who do not benefit from the downward pressures on prices which would result from a higher level of competition in the pharmaceutical industry.

39. Ibid, p. 173.

40. Ibid, p. 174.

41. First, a drug manufacturer's Director of Research: "In viewing the congener-drug developments of recent years, I have often wondered why medicinal chemists in so many laboratories had chosen to devote their efforts onto molecular modification of new drugs developed by others. Although this massive surge has created new knowledge for the medicinal

chemist at an almost explosive rate, its productiveness in the field of medicine can be questioned." Task Force on Prescription Drugs, "The Drug Markers and the Drug Distributors," Background Papers (Washington, D. C.: U. S. Government Printing Office, 1968), p. 22.

A second example is provided by a physician holding a law school chair in medical law:

"Senator Kennedy: 'What would it take to involve you in one of these drug programs?'"

"Dr. Capron: 'Some sort of convincing evidence that the drug was something that was needed and not a duplication, which is what most or many of the new drugs that come out are.'"

Exchange in HEARINGS, op. cit., p. 850.

42. "The Drug Industry's Clouded Future", Business Week, November 23, 1974, pp. 64-68, 73.

43. Data from ibid, p. 64. Moore, op. cit., (p. 182) notes further that, while industry economists explain the risks inherent in new drug development efforts as a rationale for the profit returns exhibited by the industry, their argument is specious since, "if this were so, over a reasonable period of time, losses would presumably offset extreme profits..." which has not occured.

44. The taxonomy of services rendered by patients is derived from a detailed fee schedule for roughly 100 different procedures executed, documentary submission, HEARINGS, op. cit., pp. 933-37.

45. Proceedings, op. cit., p. 143 (P. Dunn).

46. Several such waivers appear as documentary submissions, HEARINGS, op. cit., p. 928 (Michigan), p. 989 (Connecticut), and p. 991 (Philadelphia, PA).

47. "Tolerance" examination is one of the objectives of Phase I testing, and is the avowed purpose of one Connecticut experiment, for example (ibid, p. 989).

48. Business Week, July 27, 1964, p. 60.

49. C. f.; waivers cited in fn. 46 supra. Also see consent forms in HEARINGS, op. cit., pp. 929, 938, 942 and 944.

50. PROCEEDINGS, op. cit., p. 113 (A. W. Czerwinsky, M.D.).

51. Ibid., p. 8 (C. J. Stetler).

52. Capron testimony, HEARINGS, op. cit., p. 849, emphasis added.

53. Example raised by Dr. G. K. Beecher, M.D., testimony, HEARINGS, op. cit., pp. 1059-1067 ; quotation is from p. 1063.

54. PROCEEDINGS, op. cit., p. 31, (D. T. Kirkpatrick, Ph.D. At the time he made this comment, Dr. Kirkpatrick was Director for Treatment of the Texas Department of Corrections).

55. Fried, C., Medical Experimentation (Amsterdam: North-Holland Publishing Company, 1974), p. 61.

56. While this author claims no expertise in the probability of successful pursuit of damage suits as regards sequelae of medical treatments and experiments, it appears to him to be intuitively probable that complete insurance coverage, excluding by its provision suits for damages, would end up less costly for experimenters, especially when the costs of pursuing legal defenses and the dollar value of successful large damage suits are considered. (C.f.: discussion below on willingness to serve as a subject and the probable market price of the inmate "volunteers" outside the institution.)

57. This estimate is based on Pennsylvania Blue Cross-Blue Shield rates, the current quotations for an office worker for disability coverages to age 65 for a 35 year old man, and an additional $100 allowance for other medical expenses, including some of these funds as escrowed against the deductable provisions in the policy and the 20% contribution required under major medical coverages.

58. We are intentially inducing a conservative bias here by taking an extremely low estimate of the costs of such a policy. Recent inflationary increases in medical care costs have averaged 7% per annum, while overall inflation has been solidly in excess of 10%; the 30% increase projected is under 6% per year, compounded.

59. For the sake of simplicity in the current value computations (which involve discounting the future for the facts that money will be worth less then and that the experimenters will be able to earn interest on their capital prior to the points in time at which they have to disburse their funds), all computations assume experiments occur in year 1, inmates are released in year 5, and are covered by insurance for years 6-35. A discount rate of 7% is used throughout.

60. This computation ignores (a) the economies of scale which may permit food service for several hundred students in a dormitory to be provided for far less than a small number of persons would require per capita, and (b) the fact that some percentage of the experimental subjects may live on metabolic wards in small hospital-like installations rather than dormitory-type facilities. We are assuming that the upward cost bias which introducing the first consideration would impose is roughly counterbalanced by retaining a room charge for those not in the dormitory but on the wards.

61. While dormitory fees at some institutions cover athletic and other facilities, at the Pennsylvania State University athletic facilities are constructed and maintained through profits on the money-making intercollegiate sports and special donations to that end. The dormitory fee, therefore, does not really cover these costs. In order to further protect against overstatement, we will assume the dormitory fees will cover recreation costs.

62. And, to the extent that the experimenters attempt to reduce turnover in the jobs that they give inmates as members of their staffs, they therefore undercut the potential value, in terms of manpower training for jobs on the outside, that the correctional system as a whole might otherwise reap from their presence in the institutions. Obviously, moreover, to the extent that the experimenters consider their presence in a given institution to be transitory, they would be less concerned with the longevity of availability of the inmate staff they have trained. It is ironic to note, therefore, that, to the extent that Parke-Davis and Upjohn wish to make their activity in the Michigan's Jackson State Penitentiary as efficient as possible, they may actually contribute less overall to prison rehabilitative goals than might a much more transitory relationship between the penitentiary and pharmaceutical manufacturers desiring to conduct experiments.

63. Drug Research Reports, Inc., The Blue Sheet, XVII:36 (9/4/74), pp. 6 - 8, reports on the NIH sponsored experimental use of Baltimore residents as alternatives to employing prisoners as experimental subjects.

64. The extraordinarily high voluntarism rate for professionals in the relatively non-demanding air pollution study may be explained, perhaps, by some form of guilt-based conscience-saving activity on the part of those who know they are reaping the benefits of society to an above-average degree.

65. U. S. Department of Health, Education and Welfare, National Institutes of Health, Division of Manpower Intelligence, Health Manpower in Hospitals (Washington, D. C.: US G.P.O., 1970). The data referred to in the text are drawn primarily from Table 14, p. 54. It should be noted

that the data employed here are average figures for non-governmental hospitals, which excludes long-term maintenance units such as exist in the Veteran's Administration system. Our estimates, however, are well below those provided for hospitals in the Northeastern U. S. (Table 19, pp. 64-5) or for hospitals with over 200 beds (Table 27, pp. 77-8). These two subsets contain a higher percentage of teaching and research units than would the national average. Therefore, the staffing per 100 beds taken as a base in our cost computations is an understatement of the probable ratios which would obtain in a primarily inpatient unit with a high research component attached.

66. Footnote 21 supra suggests the wage rates in prisons have ranged from under 20 cents to roughly $4.00 per day (since overtime is paid, but at the constant hourly rate, and many inmates may select overtime work).

67. Mitford, op. cit., p. 156, quotes rates of pay ranging up to $1.25 per day for shifts of up to 16 hours for such experiment staff positions.

68. Report on new contract won at Strong Memorial Hospital in Rochester, N. Y., "National Hospital Union is First to Win Contract under New Law," 1199 News, IX:12 (December, 1974), p. 3.

69. Lawson testimony, HEARINGS, op. cit., pp. 822-27 and his prepared statement, ibid, pp. 828-35.

70. Gilchrist, I. (ed.), Medical Experimentation on Prisoners Must Stop! (College Park, Md.: Urban Information Interpreters, Inc., 1974), esp. p. 2.

71. Adams, A. and G. Cowan, op. cit.

72. C.f.: footnote 6, supra. Dollar figures are from the Business Week article.

73. U. S. Comptroller General, Report to Congress: Study of Health Facilities Construction Costs (Washington, D. C.: US G.P.O., 1973), p. 12.

74. U. S. President, Economic Report of the President (Washington, D. C.: U. S. G.P.O., 1974, Table C-3, "Implicit Price Deflators for Gross National Product," p. 252.

75. Taylor, R. V., et. al., "A Research Protocol Review Committee for the State of Michigan", Michigan Medicine, Vol. LXVIII; (October, 1969), pp. 1023-1028.

This reviews the Jackson experimentation site. The 1200 man estimate appears on page 1028.

76. U. S. Comptroller General, op. cit., p. 13.

77. BUSINESS WEEK, June 27, 1964, p. 58.

78. Dave Wood, Manager of the Parke-Davis operation in the Jackson Facility, was interviewed by telephone in May, 1975; he argues only 200 persons were actively subject to experiments at any one time, but this figure is suspect on a number of grounds, and involves multiple experiments on the same person. (Further citations from Woods' interview will be noted as Woods, Interview". Actually, according to Moore, op. cit., p. 174, 42 major firms accounted for 97% of all research and development outlays in 1964. Arguing that Upjohn and Parke-Davis accounted for 9.52% between them may severely overstate their share, and thus under estimate experimentation by pharmaceutical firms.

79. Almanac of Business and Industrial Financial Ratios, 1975 Edition, (Englewood Cliffs, N. J.: Prentice-Hall, Inc., 1975), p. 46, "Manufacturing: Chemicals and Allied Products: DRUGS", number of establishments by size of assets for accounting period July, 1971 through June, 1972.

80. Exchange, HEARINGS, op. cit., p. 866.

81. These estimates of subsidies are limited to the cost savings associated with the actual conduct of the experiments. The profitability contributions of the access to inmates also include the implications of a more rapid move from the filing of an investigational new drug patent to its marketing, which provides more years of exclusive marketing rights to the drug developers and thus more monopoly profits. Such subsidies to the marketing operation do not directly affect the corrections system and its inmates, however, except insofar as they raise the costs of the pharmaceutical products which the institutions must purchase for the provision of medical care to their residents. They do, however, affect the rest of the population through their effects on the costs of medications.

82. At the moment, it must be noted, one major contribution to improved institutional operations is readily admitted: increase in the quality of medical care actually provided to, or available for, inmates: "...We don't even have enough money to hire full-time doctors in some Louisiana prisons. That is why I think the money ought to spill over and help medical care inside of the prison." PROCEEDINGS, op. cit., p. 112 (F. G. McMahon, M.D.).

83. An ancillary argument in favor of maintaining experiments in prisons is that ability to participate in experiments in part of the correctional therapeutic process; it is deemed important by many observers that prisoners be capable of expiating their sins in such a manner. Consider the following:

> "...Inmates benefit from...feelings of self-worth resulting from participation in research...." Ibid, p. 21 (Report of Work Group on Corrections).
>
> "The opportunity to participate in a wholesome activity, such as research holding the promise of advancing knowledge and capability, is considered to be sufficient incentive for inmate participation." U. S. Bureau of Prisons, op. cit., p. 2.
>
> "...drug trials involving prisoners can and do serve an essential purpose. They...provide the prisoner with an opportunity to contribute something back to society..." Alabama, State of, Board of Corrections, Report Of Special Committee Of Medical Association of Alabama to Investigate The Use Of Prisoners For Drug Trials In Alabama, May, 1969, p. 14.

84. The major reason for examination of the subsidy is in order to pursue the secondary issue of what could otherwise be done with the funds retained by the pharmaceutical manufacturers which underwrite the experiments. Obviously, the funds could be channelled to general government, specifically to the correctional institution, or to the inmate-subjects themselves, among other options. The detailed study of the appropriate allocation of these funds is beyond the purview of this review of issues in the economics of medical experimentation on prisoners, albeit a critical and interesting issue.

85. U. S. Law Enforcement Assistance Administration and U. S. Bureau of the Census, Expenditure and Employment Data for the Criminal Justice System: 1972-73, (Washington, D. C.: U. S. G. P. O., 1975), p. 270, (Table 50), showed national corrections expenditure totalled $2.6 billion for the 1972-73 fiscal year. Data on states, 312 counties and 384 large cities (Tables 40, 42, and 44) demonstrate that correctional institution spending, excluding juvenile facilities, comprised about half the total spending for corrections in those jurisdictions, or at most $1.3 billion.

86. U. S. Law Enforcement Assistance Administration, National Advisory Commission on Criminal Justice Standards and Goals, Report on Corrections, (Washington, D. C.: U. S. G. P. O., 1973).

87. Lenihan, K. J., "The Financial Resources of Released Prisoners, "Report, prepared under Manpower Administration Grant No. 91-11-71-32, mimeo, (Washington, D. C.: Bureau of Social Science Research, Inc., 1974), Table II, p. 9 and p. 18.

88. Ibid, p. 25 and Table IX, p. 27.

89. Citing 1967 data, Lenihan (ibid, p. 16) notes 80,000 or more annual discharges from state institutions; allowing for growth in inmate populations and institutions other than state facilities, we arrived at a 150,000 discharge per year estimate. (It should be noted, in light of this volume of turnover, that the assumptions regarding turnover which entered into the cost computations for insurance covering sequelae for experiment subjects (supra, p. 42) appear to greatly understate subject turnover and thus true experiment subsidies).

90. Cited in Drug Research Reports, Inc., The Blue Sheet, XXVIII:9, (February 26, 1975), p. 2. Secretary Weinberger was addressing the National Academy of Sciences' Forum on Human Experimentation in New York on February 19, 1975, when he made the remarks quoted.

91. William Pitt, in the House of Commons, 1763, arguing against the right of the king's agents to search private homes on the basis of general warrants issued by the king himself (quoted in Washington Watch, II:35 (March 15, 1975), p. 3.

TESTIMONY OF DR. PETER B. MEYER, ASSISTANT PROFESSOR OF ECONOMIC PLANNING, PENNSYLVANIA STATE UNIVERSITY, ACCOMPANIED BY BILLY L. WAYSON, DIRECTOR, CORRECTIONAL ECONOMICS CENTER, AMERICAN BAR ASSOCIATION

Mr. WAYSON. Thank you, Mr. Chairman. I will proceed first, with your permission, Mr. Chairman. I would like to submit my statement for the record and simply summarize it.

Mr. KASTENMEIER. Without objection, your statement will be accepted and printed in its entirety in the record. It is not a particularly long statement, but you may proceed as you wish.

Mr. WAYSON. Dr. Meyer and I thank you for the opportunity to testify before the committee today regarding the proposed H.R. 3603. I suppose that, as the committee is well aware, much has been written on the ethical, legal, and medical aspects of human subject experimentation. You have taken testimony in the last few days along each of those dimensions.

I would like to bring an additional perspective to this discussion. Many of the questions which were asked of the previous witness, including the testimony, are really economic kinds of questions. There are two kinds of ways I believe that economic analysis and economic concepts can perhaps shed some additional light on this issue.

The first, and the one which I will deal with in my statement, is whether or not there is a real possibility for individual choice within the prison context. That question then begins to address the one of coercion and voluntarism.

The second question is more complex and will be the subject of Dr. Meyer's testimony. That really relates to how large is the implicit subsidy to private corporations resulting from the Government's willingness to supply a relatively large pool of experimentees, facilities, and personnel services?

The second question then is followed up by another, and that is, who pays that subsidy and who benefits from it? I believe that the committee has a copy of Dr. Meyer's monograph on medical experimentation on prisoners, and each of our testimony is elaborated more fully in that document.

Mr. KASTENMEIER. We do have that, and we are very appreciative of your presenting it.

Mr. WAYSON. The concept of choice, individual choice, is really a central one in economic theory. While there is a lot written by academicians about what that is, it is really relatively straightforward: We all have many things we want or need; we all have limited resources; and, given those conditions, we have to make a choice between buying a Cadillac or buying a Volkswagen or riding the bus.

The committee's prior work in the area of prisons make it fully aware of the programmatic and legal issues in prisons. A prison is a closed institution. It is questionable whether or not under any conditions there can be real voluntarism, either psychologically or financially.

Our interest, of course, is in the financial aspect. The prison's conditions can best be summarized by Irving Goffman's book "Asylums." He indicates really what are the kinds of payoffs that are possible by

concentrating on what the negative aspects of prison life are. The fact that there is little work, and there are few leisure time activities. There is boredom, a set of rules, privileges, punishments consisting of withdrawal of privileges, incorporation of release as a privilege. The parole discussion earlier certainly relates to that last kind of item.

Economic analysis and the sociological dimension in prisons represents a convergence of ideas which explain why medical experimentation is conducted with inmate subjects. There is coercion—not that "coercion" is necessarily a negative term—and the individual seeks relief from that. He seeks relief from boredom, improved physical amenities such as better housing, better food, and so forth, and finally current and future cash income, money in other words.

Most importantly from our perspective because it is our area of expertise, essentially there are no income-generating alternatives; or, if there are, they are of such a small amount that they really do not represent what can be considered an alternative. The national norm of pay in prisons runs roughly around a dolar a day, but in many cases there is no pay. If the choice is zero or $2, then that represents a very large increment, so whether the payment is $2 or $26, the nature of the prison environment and tl. limited number of opportunities still has the element of coercion.

But even if there were no cash, assuming they did not compete for anything, experimentation or otherwise, the other noncash forms of pay, I think, would still exist and preclude free choice. Those were mentioned earlier: Better housing, better food, privileges, and certainly the question of parole or the impact on parole decisions. Regardless of the good intent and sincere attempts of experimenters to preclude that kind of information from the parole decision, I think it is simply not possible.

In the case of medical experimentation, informed consent is the operative principle. But even if there were no rewards, not even favorable parole decisions, I think there is a question about whether or not there can be informed consent. By definition, the purpose of the activity is to experiment and gain more knowledge.

An economic look, I think, at experimentation can say more than simply whether it should be 50 cents, $2, or what-have-you. Even with all the incentives, it would still remain a question of who pays and who benefits. That is really when we start discussing what is the level of implicit subsidy provided both by the correctional agency and by the individual experimentee to private industry?

If there are no questions, Dr. Meyer will speak directly to that question.

Mr. KASTENMEIER. Dr. Meyer, please proceed with the discussion of the subsidy aspects.

Dr. MEYER. Thank you, Mr. Chairman.

Permit me to explain. The argument I am about to offer is derived from a book which is forthcoming, and, therefore, I felt it necessary to provide you with a lengthy supplemental statement in an attempt to provide some background. I wish to apologize for the typing and the general form of my submission. I would like to believe I am a somewhat better economic analyst than I am a typist.

Basically, I contend that experimenters wish to maintain access to prisoners for very real reasons: the subsidies they enjoy as a result of

such access. The subsidy takes the form of reduced cost and is essentially invisible, but still very real. My estimate is that such subsidies are worth, at a bare minimum, some $229 million annually. I find that——

Mr. Kastenmeier. What was that statement of the amount?

Dr. Meyer. The amount, $229 million annually.

There are basically six components to the subsidy. First, there are savings in experiment staff costs. Prisoners may serve as experiment staff in place of free-market employees, permitting a cost savings in the amount of some $2.25 per patient- or subject-day.

Second, we have savings in facilities costs. Experiments are conducted in buildings maintained by the corrections system, thus relieving experimenters of facilities development and maintenance costs which would amount to roughly $1.75 per subject- or patient-day.

Third, there are free institutional services. Inmates, of course, are clothed, housed, and fed by the corrections system. The experimenters are thus free from having to provide such housing and food service to inmates, and thus avoid a cost of at least $6 per subject- or patient-day.

Fourth, there are subject salary savings. Experiment subjects not actively undergoing experimentation may be on standby awaiting the start of a project or may be returning for preventative post-experiment checkups. Nonincarcerated persons experience real costs in making themselves available in this manner. The cost to inmates is effectively zero. Experimenters thus enjoy cost savings in avoiding remuneration for lost worktime, and so on, of some $12.50 per subject-day.

Fifth, we have patient-salary savings, Those individuals on whom the experiment is actively being conducted would lose all their potential work income while they are resident in some facility and being subjected to tests. Inmates are capable of earning some $7,000 annually in legitimate occupations, if you look at their education and occupational skills. Thus, if experimenters have to hire people off the street with comparable earning abilities, they would have to compensate their experimentation patients at least $30 per patient-day for income losses for the days they might work.

Now, these first five subsidy elements are associated with current services delivered. They were computed one way or another on an experiment-day basis.

A sixth subsidy, however, derives from the impact of freedom of responsibility for long-term experiment aftereffects, or sequelae, which pharmaceutical manufacturers and experimenters now enjoy. At least in phase I drug tests, subjects are the first humans to be administered a substance. Long-term aftereffect risks are, therefore, high. Moreover, establishing the presence of, and assigning causality for such sequelae is extremely difficult under the normal rules of evidence, especially given the very small number of people who may be the subject of any one experiment.

Therefore, generalized insurance policies are an appropriate form of remuneration for the lifetime risk incurrence services provided by subjects. This generalized coverage would be required for each person first serving as an experiment subject since, once the policy has been bought, it would protect the covered individual against all future aftereffects of any future experiments.

The capitalized stream of probable insurance premiums for such a policy which would have to be set aside at the time of this first experiment would be some $10,000 per new subject. This total is now avoided by all experimenters.

Given these six components and the apparent volume of experimentation on the part of the pharmaceutical industry experimenters in prisons, I find that the subsidy elements combine to form an aggregate which amounts, as I said earlier, to a total of $229 million annually.

This subsidy is substantial, but it does not follow that it is necessary or desirable to maintain the subsidy. Denial of the subsidy does not necessarily damage the public interest or the public welfare. On the contrary, I believe that removal of the subsidy, that is to say banning access to prisoners, which is one way of doing this, is in the public interest.

Permit me to elaborate. The access experimenters have to prison inmates at subsidized costs affects the public interest through two processes quite directly. First is the impact of the transfers on the rate of medical and pharmacological progress and the quality and cost of medical care in the Nation. Second, there is the impact of the presence of experiments on the prisons in which they are conducted. Therefore, there is an impact on the efficiency or effectiveness with which the correctional system itself produces the outputs for which it is mandated by the public.

The importance of the subsidy provision in the process of therapeutic advance lies in the role it plays in promoting a more rapid rate of new medical treatment and/or drug development than would otherwise exist. However, if physicians' medical experiments were funded by foundations or Government agencies, and these funding agents are willing to pay the true free market cost of recruiting subjects, then physicians who engage in the development of new medical procedures would be indifferent as to the fee they have to pay to get these subjects, so long as they continue to receive adequate funding. In this sense, there is no real medical experimentation dependence on prisoners as subjects.

The private medical researcher's contribution to therapeutic advance then is not associated with access to prisoners, but to subjects in general, and nonincarcerated subjects could be found providing the experimenters got the requisite research funding.

Turning to pharmaceuticals development experimentation, we must examine the extent to which subsidized access to prisoners is critical to, among other things, drug manufacturers' profits. To do so, we need only look at recent Business Week quarterly surveys of corporate performance. The major companies in the industry for which Business Week gathered data outperformed Business Week's all-industry composite on three major critical scales.

First, if we look at 1974, profits on sales for the drug industry were 9.3 percent. Profits on sales for the all-industry composite were 5.3 percent.

On the other hand, we could look at the return on common equity over the period from 1965 to the present. The annual average return on common equity for the drug industry is 16 percent. The all-industry composite return is 8 percent.

Yet another measure is the growth in per-share earnings over the same decade. Annual average growth in per-share earnings was 11 percent for the drug industry, 6 percent for the all-industry composite. It seems the drug industry has performed rather well.

However, despite the performance of the past, the drug companies may be vulnerable to major profit losses if the implicit subsidy associated with experiments on prisoners is denied to them. We can examine the hypothetical impact of such a denial on the industry's 1974 profits. The 1974 profits actually experienced were slightly over $2 billion on a sales volume which fell slightly short of $22 billion. If we took the entire subsidy, roughly $230 million, and subtracted it from the profits, profits would fall to under $1.8 billion. The profit rate would fall from 9.3 percent to 8.2 percent, assuming constant prices and a constant dollar sales volume.

While the pharmaceutical industry contains not just the 131 members of the Pharmaceutical Manufacturers Association, but rather something closer apparently to 700 companies, 15 of those 700 companies account for one-half of all sales. So it is a relatively concentrated industry; therefore, it is probably capable of pushing prices up. We can assume prices would go up by $229 million, covering the increased operating costs. Profits then would be diluted slightly down to 9.2 percent.

More importantly, since we live in an inflationary period, the wholesale price increase resulting from this denial of the subsidy associated with the experiments on prisoners would be something on the order of 1 percent for drugs. This would be an increase occurring at one point in time, at the initial denial of the subsidy. Thereafter, increases could not be attributed to subsidy denial.

However, the $229 million subsidy denial applies to the entire industry. The Business Week data that I was just reviewing covers only 28 firms based in the United States from which data were available. Thus, the actual profit declines or the inflationary pressures would be lower than the figures I have just cited.

On balance, then, both medical and drug therapeutic advances could easily be continued at comparable rates without access to prisoners and the associated subsidies.

Next, we must look at the corrections process itself. It may be that the capacity of the corrections system to produce its mandated outputs is adversely affected by the presence of the experiments in the prisons. If this is in fact the case, then a concern for correctional effectiveness becomes a basis for denying access to prisons. If we look first at incarceration, we can divide it into removal effects and deterrence effects.

There exists a direct corollary between the degree of removal and the available subsidy to experimenters. The more removed inmates are—that is to say, the larger the institution—the more constrained are their opportunity costs because they are living in a very coercive environment, and the larger will be the subsidy to experimenters. Outside pressure to maintain such high incarceration values, which might

derive from the close association between a subsidy that has got very real value and institutionalization, may well bias the correctional system toward more incarceration than would otherwise be appropriate from the pure corrections perspective. To the extent that this bias emerges, the level of incarceration that we maintain would tend to be higher than that level which is optimally efficient, and the correction system's overall impact on crime then will always be lower than it could be.

This is a very heavy price that all of us pay for experimentation which could be conducted outside of the prison walls.

Turning to deterrence in experimentation, I would like to draw on Herbert Packard's book, "The Limits of the Criminal Sanction." Packard notes, "The feelings of bitterness, hatred, and desire for revenge on society that are engendered by inhumane treatment may well produce a net loss in crime prevention." This backfire problem is inherent in any activity which introduces a gratuitous negative element into the lives of inmates.

The issue with respect to experimentation is whether it induces a negative or a positive influence. The subjects may earn money; they may get better living conditions and the like, thus finding themselves experiencing fewer sanctions and somewhat less deterrence. However, the procedures to which they must subject themselves in the experiments themselves may, in their eyes, be inhumane. [The issue, parenthetically, is their interpretation. If they perceive these procedures to be inhumane, then the negative consequences noted by Packard might possibly emerge.]

Moreover, the nonsubjects, most especially people who volunteered but were not accepted as participants in experiments, are provided with a new negative element in the prison experience. They see themselves denied the benefit that accrued to experiment subjects. Their resentment over inequities could elicit responses paralleling reactions to inhumane treatment.

If we look beyond the issue of incarceration to correctional training services and their relationship to experimentation, we find one form of positive training emerging from experimentation, which is skill development on the part of inmates that may be hired as experiment staff.

However, experimenters will not train inmates with very short sentences for experiment staff jobs since too much training effort would be required, due to a high turnover of personnel rate associated with the discharges from the institution. The very persons trained would thus not be the ones who could use their skills on the outside because they will remain behind the walls for a protracted period of time. Therefore, not even the direct provision of correctional training services by the experimenters themselves really seems to end up serving correctional objectives!

The emergence of sequelae of experiments at a later date in an individual's life may act to undermine the value of whatever positive training may in fact be available. First, any aftereffect which causes a disability will tend to reduce the positive value of training if the individual can no longer work. Second, to the extent the sequelae and aftereffects are identified by the ex-subject with the fact of experimenta-

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tion, and to the extent the ex-subject feels that he or she was coerced, he or she will bear antagonistic attitudes toward the society which caused the negative experience and might very well develop a desire for revenge along the lines of that which Packard attributes to inhumane correctional settings. This desire for revenge, then, could be stimulated at a significantly later date ex post facto by the experience of unanticipated and undesirable aftereffects to experiments.

Finally, an explicitly negative training element may be inherent in experimentation to the extent that subjects perceive themselves to be coerced. Inmates who feel themselves forced into the role of human guinea pigs may well interpret the experimentation experiences an object lesson in the principle of competition along the lines of, "take your fellow man for all he is worth so long as you can get away with it."

On balance then, experimentation on the bodies of the residents of the Nation's correctional institutions results in two basic impacts on correctional productivity. First, a bias toward more incarceration than would be warranted from the point of view of maximum correctional proficiency in reducing future crime; and, second, the tendency toward negation of positive training through adverse sequelae and the promotion of negative training as the result of experiences in the correctional institutions.

In conclusion, my investigations lead me to the finding that denial of the subsidy associated with access to prison inmates for medical experiments: (1) will not deter advances in medical and drug therapeutics; and (2) will contribute to decreased productivity on the part of correctional institutions and the correctional system as a whole.

Thus, access to prisoners should be denied to all experimenters, and we would all be better off as a result.

Thank you.

Mr. KASTENMEIER. Thank you, Dr. Meyer.

I think you will agree there is such a wide discrepancy between your analysis that there is currently approximately $229 million in subsidies being affected, and the testimony of the preceding witness, Mr. Stetler, who suggested that in behalf of the Pharmaceutical Manufacturers Association, a rather nominal amount is involved. It is not of great concern to these manufacturers.

How do you account for that? Do you think he is unaware of your type of analysis and what it might mean to his industry?

Dr. MEYER. That may in fact be the case, I do not know. I think I can account for it in several ways. First, the actual outlay by the pharmaceutical manufacturers today for experimentation in prisons is a completely different datum from the total value of services provided to the pharmaceutical manufacturers by inmates in the correction system. That is to say, it may cost the manufacturers today, let us say, $50 or $100 million to experiment in prisons. I am arguing that in addition to that amount of money, there would be required some $229 million in addition to experiment outside prisons.

The actual outlay that they must expend now may in fact be significantly lower than what they would have to spend were they to operate outside of prisons.

Mr. KASTENMEIER. We have heard testimony that a surprisingly high percentage, 80 or 90 percent, of the subjects of medical research

are in prison populations somewhere. They know what that cost is presumably. They almost must know what the cost is for the 10 or 20 percent who are outside, and they can certainly project nonaccess to a prison population to figure out what it would cost them if they conducted more or less the same degree of research with a nonprison population.

I do not know whether it would come out anything like you suggested or not, but if it would, it would be significant, it seems to me, and Mr. Stetler would have to consider that important aspect, if not of his testimony at least of his computations.

Dr. MEYER. What Mr. Stetler was testifying to was the actual outlay that the manufacturers currently incur for medical experimentation. That is a very different number from what it might cost them if they did suffer the denial of access to prisoners, item 1. And, item 2, as I understand it from my review of Dr. Arnold's testimony, as well as Mr. Stetler's testimony, there is currently no active program that does remunerate subjects for the fact that they incur a lifetime of aftereffect risk, and the cost of that insurance program is a substantial portion of my $229 million estimate.

Mr. KASTENMEIER. I asked him, without having access to your statement, whether they carried insurance to cover this sort of risk, he said they did. I did not pursue it with respect to how much that might be, whether there would be an elevated premium because these were not prisoner subjects. I suppose we could go into it in great detail, and maybe we should pursue that.

Mr. RAILSBACK. Would you yield please?

Mr. KASTENMEIER. Yes.

Mr. RAILSBACK. I remember your insurance projection. I think it is $10,000 or something like that, and I think that is significant as to what kind of insurance we are talking about.

For instance, when a company is talking about liability insurance or whether it is insurance that would really cover somebody that in any event whether he proved liability or not, that would make a difference what kind of insurance we are talking about.

Dr. MEYER. May I provide you with sort of an anecdotal kind of example by way of trying to illustrate the problem, because I think that Congressman Railsback is 100 percent correct. We have, for example, in a particular experiment, a dozen persons who serve as subjects for a week or 2 weeks. The drug is found to be excessively toxic and does not go on to phase II or phase III development. There are three phases of human experimentation.

One of the subjects of this experiment 20 years later develops some symptoms that have not been previously evidenced, or we do not know where the symptoms come from. The individual wishes to make a claim, let us say for damages, and it may be a 20-year later aftereffect. That is part of the problem we confront. It is statistically virtually impossible for an individual to establish his case on the basis of a dozen persons who were subjected to the drug, in the first place.

In addition to which, by and large—and I am drawing now from the conference that the manufacturers had with the National Council on Crime and Delinquency to which Mr. Stetler made reference earlier—we suffer from an inability to trace prison inmates after they

were released. Thus it would probably be impossible for that one person who suffered aftereffects to in fact even locate the other 11 subjects to find out whether they also had suffered aftereffects. Of course, we are assuming the individual has got the resources to engage in that kind of an investigation and can obtain a lawyer and is sufficiently conversant with how to establish liability.

The insurance policy I am talking about, the $10,000 figure, obviously goes way beyond workmen's compensation, which is provided, as I understand it, in Dr. Arnold's operation in Kansas City. The $10,000 is a combination of an overall medical, major medical insurance policy and a disability income policy, trying to protect the individual from loss of income and all medical costs.

The logic is for a total coverage, that is to say, all medical and major medical, not just those items associated with the experimentation itself. The logic behind that is twofold: (1) you cannot establish liability, as I understand the rules of evidence, although I am not an attorney; and (2) if in fact all you did is remunerate someone for the damages experienced as a result of aftereffects actually occurring, then in fact you are not paying the subject for a very real service which has been rendered. This service is the individual rendering himself or herself open to a potential lifetime of aftereffects. They have accepted a long-run risk, and in some manner, shape, or form, they should be paid for providing that service.

That is not a function of how many days they are in the experiment, but the fact they took a substance which has never been administered to a human being before. That is a very real service. That is the logic behind the combined policy, and that is where the $10,000 figure comes from.

Mr. KASTENMEIER. Where does your figure come from on total subject-days, 3,030,960? Obviously, you need to know presently how many subjects and how many days the average subject during any given calendar year.

Dr. MEYER. Basically these data are derived from information that is available on the activities of two pharmaceutical firms based in Michigan—Upjohn and Parke-Davis—that maintain fairly elaborate facilities that are built within the walls of the State prison of southern Michigan at Jackson. These are two of the larger pharmaceutical firms that would fit within the 15 I mentioned earlier that account for 50 percent of all sales, and there is detailed data on their levels of experimentation: How many persons they have either waiting to go into experiments, being processed in aftereffects checks in the short term and currently actually residing in the experiment facility.

I can go into some detail on the way in which I arrived at the numbers, but basically I took the figures for those two companies and said, OK, those two companies account for between them roughly one-eighth of all of the pharmacological products that are actually pictured in the color section of the Physician's Desk Reference, which is a crude kind of an approximation on one level.

Next, they are 2 of the 15 largest, as I just said earlier, which is slightly more than one-eighth of the big group.

As I looked at some of the figures on sales, they seemed to fit again at roughly the one-eighth level. I guess they came in at about 11 or

12 percent of the large group. I simply took that figure, then, their level of experimentation, assuming that the proportion of experiments to sales was roughly constant and used that figure then, multiplied by eight to account for the fact that they are at most one-eighth, I can give you the derivation in greater detail. It is actually contained in the book manuscript, not in the report.

I guess the one point I should add is that, the estimate only expands estimated experimentation from 2 companies to 16. Even in the case of Pharmaceutical Manufacturers Association, there are 131 members. If anything, 3 million is an underestimate in the number of subject-days.

Mr. KASTENMEIER. I think if we knew that it were a reliable figure for total subject-days in the United States prisons, 3,030,960 for the year, that would be a rather interesting number to deal with. As far as generally the subject of subsidy I remember the last time Dr. Walter many years ago in discussions of the cost of a volunteer army versus a conscript army, the cost to the individual and the societal cost was in fact a large subsidy. That is any differential between paying a conscript versus paying a free man to enlist is the subsidy that the conscript bears on his back, bearing that subsidy for society.

So society would make up the difference by moving to a volunteer army, the argument goes. That is a similar argument, I think, you made, using somewhat different terms.

Mr. Wayson, I wanted to ask you a question or two. I know you have had a great deal of background with corrections. How would a prison administrator generally react to a medical research program in his institution? Is it useful as an alternative method for diverting, for preoccupying prisoners, or is it a problem in terms of having to give access to medical investigators? What elements enter into it in terms of the prison administrator?

Mr. WAYSON. I believe in the earlier discussion it was indicated the economic plight, I guess, of correctional administrators. I know the committee is well aware of that. I think they tend to be very ingenious and very well meaning kinds of people. When they have an opportunity to improve prison conditions, I think they will take that advantage.

There is a problem, of course, which the committee is well aware of, of the fantastic idleness in prisons. In our studies by the Economics Center, we estimate that roughly 38,000 probably of the 200,000 incarcerated people in State institutions are in some form of work program, paid work program in prison industries. Depending on which figures you use, it was from 17,000 to 38,000, a relatively small percentage of the total inmate population.

So I guess what I am saying is, given again the economic constraints that the prison administrator faces, it is very natural and reasonable for him to try to supplement those wherever he can.

I roughly calculated that there are probably 73 million prisoner-days in the United States, so the 3 million I believe Dr. Meyer used seems large absolutely, but against the total is relatively small.

Mr. KASTENMEIER. I yield to the gentleman from Illinois.

Mr. RAILSBACK. Dr. Meyer, referring back to page 12 of your statement, I am wondering if your loss of profit projection might not be

accurate in the sense that instead of losing a subsidy, as the thrust of your statement seems to suggest, I wonder if it would not be more likely that the drug industry would simply pass on its increased cost to the public, to the consuming public. I wonder from an economic standpoint. Perhaps what we are wrestling with is whether we should balance the nonincarcerated society, with those who are incarcerated and because of the problems existing, we must face up to the fact that prisoner experimentation might be a bad thing from a social standpoint?

Dr. MEYER. First of all, I did consider the very real possibility that the total cost associated with the loss of this subsidy would be passed on as higher prices. That accounts for the fourth column on page 12.

I also consider it to be fully appropriate for the nonincarcerated population to bear that increased cost, which, let me remind you is at most a 1-percent increase in wholesale prices, which would only occur once.

Very simply, I mentioned earlier that prisoners on average, if fully employed, would be capable of earning about $7,000 per annum in 1973. I suspect the total population of the United States was capable of earning on average something more on the order of $10,000, not $7,000. By and large, prisoners are poorer than nonprisoners. Therefore, if in fact we shift the burden to the nonprisoners, then in fact that constitutes a progressive move. The subsidy as it stands is regressive.

The other point I might make is that actual purchases of pharmaceutical products do increase significantly with income, both absolutely and as a proportion of total medical expenditures, and therefore, once again, the burden in terms of who is going to pay higher prices for pharmaceutical products will be distributed in a progressive manner.

The material I presented in my supplemental statement is drawn from a chapter in my book dealing with the subsidy and public interest, and I just felt I could not go much further. The next one dealt with the private interest.

Mr. RAILSBACK. I agree with your response. It kind of bothers me that as far as drugs are concerned one factor to be taken into accout is who uses drugs, what part of our population? Usually it is the senior citizens.

Dr. MEYER. You see, if in fact the price of pharmaceutical product is borne by public agency, whether you deal with medicare, medicaid, or something on that order—if in fact you cover pharmaceuticals, then this burden does not shift to the elderly, Pennsylvania medical assistance program, for example, does cover pharmaceuticals.

Mr. RAILSBACK. Many drugs are not covered.

Dr. MEYER. In the case of Pennsylvania, we are fairly well covered. You get into a combination problem there.

Mr. RAILSBACK. I am not really quarreling with your analysis. I am simply saying that instead of just loss of subsidy to the drug industry, we are also talking about increased costs to the pharmaceutical consumer.

Let me ask you this: What other differences and inducements are there between the pharmaceutical industry and the Government? I understand that much of the experimentation occurs in State institutions. How much do they pay them? What is the per capita?

Dr. MEYER. It varies all over the map. In Maryland, it was—at least the data I was looking at—$2 per day.

Mr. RAILSBACK. Per day, or per unit experiment?

Dr. MEYER. Per day that the individual is in the experiment.

Mr. RAILSBACK. So if that is true, you are paying substantially more than the Federal Government?

Dr. MEYER. I did not hear that testimony, so I cannot respond on that basis, but certainly there exists the possibility.

I will go back to Michigan. The example I raised earlier, where inmates were making in excess of $10 in 1 day, admittedly that would also involve subjecting themselves to a bone marrow aspiration or some other form of operative procedure.

Mr. RAILSBACK. Where is that again?

Dr. MEYER. It is the State Prison of Southern Michigan in Jackson. If you remember the newspaper stories sometime this summer, I believe, of the prisoner who recreated the "Great Escape,"—got out of this prison with a helicopter. It is that particular prison, the largest institution in the United States. It is the largest institution, largest walled prison in the United States. Upjohn and Parke-Davis are both Michigan-based and were invited to experiment within the walls.

Mr. RAILSBACK. In making your computation as to profits and revenues and subsidies, you are not really using empirical data, actual per capita payments made by the pharmaceuticals. I was not here when Mr. Stetler testified, but I am interested to see what the difference is in amount of payments by the Federal Government. I am also interested in seeing what the difference is in the pharmaceutical company payments to a nonincarcerated person.

Dr. MEYER. I can give you some specific information on that. I cannot address the former question. I can definitely address the latter, that is to say, remuneration to nonincarcerated versus incarcerated. I may be replicating some things that were said on Monday. My apologies, if I do.

The Department of Health, Education, and Welfare—and I do not remember through which one of its subunits—is participating in a program at the University of Maryland in which some common cold experiments were being conducted, using noninmate populations recruited in Baltimore. They are paying $20 a day.

Inmates in the Jessup facility in Maryland were getting paid $2 a day for roughly comparable procedures. There is an outfit called Health Sciences Association, I believe Maryland-based—I could get the details for you—that has been paying $50 to $100 a day to experiment subjects above and beyond covering their lost pay, providing them with transportation and room and board, and so on for a number of days.

Mr. RAILSBACK. For what phase experiment?

Dr. MEYER. Phase I.

Mr. RAILSBACK. What bothers me is that they are paying the prisoners less money per capita than the nonincarcerated person, despite the fact, if we believe your testimony, that there are also big subsidies that go into using incarcerated people.

In other words, even the salary paid out is much less for the incarcerated, despite the fact that all of these other costs are being subsidized.

Dr. MEYER. I think that is correct, but let me sort of come to the defense of the experimenters on that particular issue because I do not think it is a matter of their choice. I think it is a constraint imposed upon them by the prison settings. Very simply, there is a limit. You cannot pay $100 a day to subjects in an institution in which, if people are lucky enough to find other work, they get paid 50 cents a day. You create too much disparity.

Obviously, if you attempted to pay the $100, you would have to pay a much higher wage for the nonexperiment work conducted in prisons as well, and we were just talking about the problems in the correctional budget.

Mr. RAILSBACK. However, am I correct that some of the payments made for experimentation do not go to the inmates, anyway? Some of them go to the prison to improve the conditions?

Dr. MEYER. That is correct.

Mr. RAILSBACK. There would not be a constraint there.

Dr. MEYER. No; I do not know what those dollar figures are. In the Michigan case—if I can go back to it because it is one of the most interesting ones, simply because of the volume—the two pharmaceutical firms built what basically are two minihospitals of 40 beds with a very elaborate metabolic ward in each, rather expensive installations within the walls of the prison. Those installations are at least nominally now the property of the State of Michigan, so in that sense the experimenters made a contribution. Whether that contribution can be used for purposes other than experimentation is something that I really do not have that much detail on. I do not know how badly needed those medical facilities were prior to the construction.

Mr. RAILSBACK. Thank you

Mr. KASTENMEIER. Thank you. We have one more witness, I might say, but we have a vote on the House floor, I believe. It is on the final passage of the Defense appropriations bill.

On behalf of the committee, I thank Dr. Peter Meyer, a product of the University of Wisconsin, I am pleased to say, and Mr. Billy Wayson for their testimony.

Dr. Edward Opton is here, and if you are agreeable—you have been patiently waiting all afternoon—to a 15-minute recess, we will be back to hear your testimony, sir.

Thank you very much. We will stand recessed for 15 minutes.

[A brief recess was taken.]

Mr. KASTENMEIER. The committee will come to order, and we will call as our last witness, Dr. Edward M. Opton, Jr., who is a senior research psychologist of the Wright Institute in Berkeley, and also a fellow of the American Psychological Association.

I apologize for reaching you so late this afternoon, but I am sure you will be able to conclude these hearings and make a contribution to the work of the committee.

Dr. Opton.

[The prepared statement of Dr. Edward Opton, Jr., follows:]

STATEMENT OF DR. EDWARD M. OPTON, JR., ASSOCIATE DEAN, GRADUATE SCHOOL, WRIGHT INSTITUTE, BERKELEY, CALIF.

My name is Edward Opton, Jr., I am Senior Research Psychologist and Associate Dean of the Graduate School at The Wright Institute, Berkeley. I am also a Fellow of the American Psychological Association and Chairperson of

the Committee on Coercive Modes of Therapy of the Society for the Psychological Study of Social Issues, a division of the American Psychological Association. In my statement today I represent none of these organizations, but only myself as a concerned citizen and a constituent of one of the sponsors of H.R. 3603, Mr. Dellums.

It would belabor the obvious to explain why medical experimentation can be extremely dangerous. It is less obvious that medical experimentation seldom need be dangerous. Caution, patience, and the money to implement them can almost always reduce the risk of necessary research to levels which we would willingly bear.

But safety costs money, and medicine is a business as well as a profession and a science. Medical research, whether pharmaceutical, surgical, psychiatric, or otherwise, is expensive, and any organization conducting it faces an inescapable conflict between the interests of its patients and its financial balance sheets. This is only slightly less the case for nonprofit organizations like the National Institutes of Health than for profit-oriented enterprises like Squibb, Upjohn or Merck.

Someone always must decide how much time, patience and dollars to invest in safety. Someone always must decide whether to cut the same corners as one's most aggressive competitors, or to be more careful. Insofar as our economic system works according to its theory, enterprises that maximize their dollar efficiency, at no matter what human cost, will prosper and grow. The whole process is lubricated when those who make the crucial financial decisions are insulated by several layers of bureaucratic subordination from those who might have an opportunity to observe the shattering of human lives that can result.

I doubt that this is news to you.

Let us consider, then, sources of protection, potential and actual, for the subjects of medical experimentation. There are four basic possibilities.

I. INDIVIDUAL CONSCIENCE

The first protection is the conscience of medical experimenters. You will hear much from spokesmen for drug manufacturers and perhaps from the National Institutes of Health or other segments of organized medicine about medical ethics, professional standards, self-policing, peer review committees, and so forth.

I suggest to you that these appeals to conscience alone are an extremely frail reed from which to weave a support for the men and women whose safety in prison is the responsibility of this subcommittee and of Congress.

There is a plain and consistent pattern of failure of unaided conscience in this area. In Europe the pattern of failure did not begin at Dachau and Bergen-Belsen, nor did it end with the awful catastrophe of Thalidomide. In the United States the pattern was well established before the infamous Tuskegee syphilis experiments, nor has it ended with the recent revelation that physicians in New York have systematically inoculated retarded children with a deadly virus, hepatitis, at the so-called "school" at Willowbrook.

I think there are at least two important reasons for the failure of self-regulation and conscience. One is that the medical personnel who do prison-based research work for organizations. They are not entirely free to follow their own consciences. In the pharmaceutical industry financial executives hire and fire physicians, not the other way around. Physicians whose personal ethical standards are financially inconvenient are unlikely to be assigned responsibility for financial important projects.

Even when money is a secondary consideration, ambition for recognition and prestige is an equally powerful temptation.

The second reason why unaided conscience is a weak reed is that conscience is unequally distributed among medical people. It would be no protection at all if 99 percent of all experiments were the ethical peers of such giants as Dr. Walter Reed or Dr. William Osler. Only a fraction of one percent of all experimenters are needed to direct all the medical experiments that will ever be profitable to conduct in prisons. And if I may mix metaphors, one is likely to come up with a higher than average proportion of rotten apples when one scrapes the bottom of the barrel. We must face the fact that our prisons are the bottom of the prestige barrel among physicians as well as in other respects. I do not mean to imply that all prison medical personnel are rotten apples. Some are dedicated, honorable people; they deserve recognition for doing an unpleasant job under impossible conditions. But the abuses at which H.R. 3603 is directed do not require that all the "apples" be rotten, only that a small number be a bit overripe.

In these comments on the reasons why the unaided individual conscience is an inadequate protection for human experimental subjects, I may have emphasized economic considerations more than they deserve, for a number of factors in the social organization and nature of medical training and practice are also important. For example, there is a nearly impassable barrier of social class between most researchers and most subjects, no to mention the presently unbridgeable gulf of race. Also, the psychological pressures of responsibility for others' lives and the repeated exposure to others' suffering forces many physicians to insulate themselves, psychologically speaking, to stand back from their patients, viewing them less as human individuals than as collections of individual organs assembled into a biological machine. That outlook is healthy and functional—it is virtually necessary—when one steps up to the operating table or the autopsy table. But that stance makes it harder for physicians than for others to consider fully the human dimension of their work. That psychic insulation may make it all too easy to forget that when a patient becomes a research subject, the physician's interests and the patient's interests are no longer nearly identical; they begin to diverge radically.

I would like to give you some examples from my personal experience which illustrate the inadequacy of relying on individual ethical standards. The first occurred when I was an intern at the Duke University Medical Center. One day a colleague, a psychiatry resident, proposed that we collaborate on a drug research project which had been offered to him, unsolicited, in a letter from the Upjohn Co. of Kalamazoo, Michigan. He showed me a research plan which Upjohn had enclosed. The experimental drug was identified only by a number and the information that it was intended for psychiatric patients suffering from anxiety. We were asked to administer it to a run-of-the-mine sample of outpatients, to note whether they "improved," remained "unchanged," or became worse. As best I recall, the protocol said nothing whatever about consent, informed or otherwise; it was up to us to decide whether to get a signed consent, or indeed, whether to inform the patients that they were our, and Upjohn's, guinea pigs.

The psychiatric resident, having done no research, sought me out as his research expert. I knew no more than he about drug research, so I repaired to the library to educate myself. I soon discovered that the research design Upjohn was suggesting would prove nothing about the efficacy of the drug, and it would reveal little about the possible major and minor side effects. Nevertheless, I can see why Upjohn was motivated to suggest the work to us: they would have gotten a publishable clinical trial which they could have submitted to the FDA and which they could have cited in the footnotes to their medical advertising.

I could also see clear advantages to us in accepting Upjohn's proposition. They offered us $5,000 to carry out work that would have taken, perhaps, two hours extra per week for about eight weeks. Five thousand dollars was more money then than now. It was more than my entire salary for the year. In addition, we would have gotten a publishable article, which Upjohn would help us to edit, that would look good on our résumés at job-application time.

Had we done the experiment and reported results favorable to Upjohn's drug, perhaps we would have been offered additional, equally lucrative contracts. Had we reported negative results, perhaps we would have been offered additional contracts anyway. Or perhaps not. As it happened, we declined, and we never heard from Upjohn again. But I have no doubt that they found someone to do that particular clinical trial. Their generous offer was not an offer we could not refuse, but it was not easy to refuse. I have always wondered if that drug, which we knew only as a number, could have been Thalidomide.

I would ask you to keep in mind that the mail-order research situation I am describing was to take place in an out-patient clinic, and although most of the patients would have been black, our clinic was still a clinic, not a prison. If the problems of undue influence on medical personnel are so pervasive in a setting where the subjects of research are free citizens, you may imagine how much augmented those problems are in prisons, where the official rule is that the inmates have few rights, and where the near-universal practice is that they have virtually none.

The second example comes from California, where, on November 19, 1970, I attended a conference as the guest of the California Department of Corrections. Their invitation solicited my views as a scientist on the sorts of research and treatment that might best be implemented in the new Maximum Psychiatric Diagnostic Unit, then under construction at the prison at Vacaville.

Throughout the morning of the conference I, and a group of about twenty other scientists and physicians, sat through a program of descriptions of the new facility which told us exactly nothing about what research or treatment the Department was planning. The Department of Corrections therefore learned nothing whatever from the people it had gathered from all over the state to advise it. I wondered why we were there.

At lunchtime I turned to my neighbor in the cafeteria line and asked, "Do you have any idea what they are planning for this new unit?" He told me he was the research psychiatrist for the unit, and that he planned a comparison of the results of psychosurgery with the results of chemical castration. The idea had come from the work of two surgeons, Drs. William Sweet and Vernon Mark, and a psychiatrist, Dr. Frank Ervin, with whom he had formerly been associated in Boston. An application for federal funds to pay for the surgery was already prepared.

At the afternoon session I asked if my luncheon companion's reports were accurate. The reaction of the medical and other personnel from the Department of Corrections was dramatic. They were embarrassed, intensely flustered, and unwilling to confirm or deny it. They quickly adjourned the meeting, and soon thereafter, in the wake of modest publicity in the local press, they cancelled the project.

Two years later a similar plan, again to be supported by public funds, was proposed in two widely separated institutions, the University of California, Los Angeles, and the Lafayette Clinic in Detroit. In both cases the physicians attempted to keep it secret, and in both cases the story leaked out, at first as rumor, then backed up by irrefutable documents. In both cases the project was halted. The U.C.L.A. project is described in the November, 1974, report of former Senator Sam Ervin's Subcommittee on Constitutional Rights. The Detroit project was halted by the well-known psychosurgery lawsuit, *Kaimowitz* v. *Rodin*, but not before the so-called "consent" of the first prospective research subject had been obtained by the physicians telling him that he would never get out alive unless "I get either your brains or your balls." The offer was one the prisoner could not refuse, so he signed.

Incidents like these are inevitable under our present non-system. The restraints of unaided conscience are not enough.

II. SELF-PROTECTION: INFORMED CONSENT

The second line of defense against improper and dangerous medical research is such defense as the prospective subject can make in his or her own behalf, for example, refusal to participate. It has long been recognized that a person who does not understand what is being proposed, or who is confined under such oppressive conditions that, in effect, the offer is one he cannot refuse, is in no position to look after his or her interests. The "consent," so-called, is not "informed."

Needless to say, there are times when it would be cheaper or more convenient to conduct research without the trouble of obtaining informed consent. That is a major reason why medical research is conducted in prisons and other total institutions.

You have already heard convincing testimony on the reasons why informed consent in a prison setting is a logical impossibility, a contradiction in terms. I will not take up your time with a repetition of the message you heard on September 29th from the ex-prisoners. Moreover, I have not shared their experiences; only they can speak for themselves. I hope you will have occasion to solicit additional information from them and from other ex-prisoners and current prisoners.

I expect that experts like Professors Katz and Capron will also be communicating with you about informed consent. I know they have written on it wisely and at length. For me the issue in the prison is a simple one: informed consent is not possible. Some scholars believe it would be possible in some hypothetical prison system; some think not. I note that the Congress must legislate for the prison system we have now, and which we will have for years to come, and not for some ideal system. And so I pass on to other protections against dangerous experimentation that might be more substantial.

III. BUREAUCRATIC REGULATION

Administrative regulation, with or without the mandate of legislation, is the classic way to manage our social institutions. In the case of medical research

in American prisons, it is an almost hopeless exercise in futility. Greenburg and Stender,[1] as well as many others, have demonstrated that our prisons are at least as lawless in their administration as in their clientele. That situation is not about to change, for the beyond-the-law quality of prison administration is necessary. Prisons, as we know them, could not operate within the lawful limits of democracy.[2] Their isolation, their secrecy, and above all, the total power of the administration and the total powerlessness of the prisoners ensures lawlessness. Experience has shown the accuracy of Lord Acton's aphorism about the corrupting effects of great disparities in power.

Anyone who still entertains hopes of dealing with the abuses of medical experimentation in prisons by regulations and rules should consider the psychiatric prison at Patuxent, Maryland, only about 30 miles from this committee room. There, a so-called "goon squad" has in recent times roamed the institution in the dark of night, using clubs and fists and feet to take care of disciplinary "business" left over from the day. The goon squad resembles the quasi-official Brazilian "death squads" of off-duty policemen, and it has a similar function: to suppress vocal malcontents, social troublemakers, and dissidents, to compel docility through terror.

During the daytime, and the nighttime too, Patuxent has used torture as one of its standard forms of discipline. One form of torture which I observed in June of last year takes the form of the "strap-sheet," a hospital gurney equipped with handcuffs at one end, foot cuffs at the other, and a canvas "sheet" which is tied down to immobilize the prisoner's torso. The prisoner is left to stew in his own bodily juices until he learns to behave himself to suit the administration and guards. As befits an institution designed specifically for therapy, and whose superintendent is by law a physician, this device is called a "treatment."

The important fact about Patuxent is not that its practices are particularly malodorous. Unfortunately, there exist even more oppressive prisons in America. What is noteworthy is the result, or non-result, of the extensive efforts that have been made to reform it. There have been numerous lawsuits, some of them reaching the Supreme Court. Yearly newspaper exposés have horrified, disgusted, and entertained the public in the Baltimore-Washington area. Patuxent has been the subject of both legislative and administrative investigations; it has been the subject, perhaps, of more sustained pressure from reform groups than any other prison in our nation. Yet the efforts have made essentially no difference; the situation is basically as bad today as it was twenty years ago.

If the best efforts our political process can muster at this moment in history are unable to affect even the most blatant barbarisms, how can we expect mere rules and regulations to protect our prisoner citizens from the more subtle exploitations of medical experimentation improperly conducted?

An additional factor which makes bureaucratic regulation an unreliable protection for prisoners subject to medical experiments is the conflict of interest of administrators and staff in institutions where the experiments are conducted. Experiments in prison require extra work by prison executives and guards; the researchers must negotiate pay for this time. As Dr. Meyer has indicated in his report, the pay may be quite lucrative, and it may be one of the few sources of extra income for prison personnel. Prison employees thus find themselves in a serious conflict of interest situation when questions might be raised about experiments on their prisoners. The employees' personal financial interest pulls one way; their responsibility for the prisoners' welfare pulls the other. We should not permit public employees to carry the burden of this sort of conflict of interest.

IV. PROHIBITION

The remaining possibility for protection from abuse of medical experimentation in prisons is prohibition. It is simple. It would be effective. Other countries have done it without any adverse effect on their citizens' health. It is the only method that will work. You have heard testimony from Dr. Meyer and Dr. Arnold that the additional costs it would impose on our pharmaceutical manufacturers and our public would be quite modest. Mr. Mitchell's bill, H.R. 3603, would go far towards prohibiting medical experimentation in prisons. I recommend its passage.

[1] The Prison as a Lawless Agency, 21 Buffalo Law Review 799 (1972).
[2] Opton, Psychiatric Violence Against Prisoners: When Therapy Is Punishment, 45 Mississippi Law Journal 605, 632–35 (1974).

I would also recommend augmentation of H.R. 3603 in at least this one respect: it is important that research and experimental therapy not be concealed under the label "treatment." Under the bill in its present form both the Detroit and the U.C.L.A. psychosurgery programs might have gone forward, for their proponents adeptly switched from a "research" to a "treatment" rationale as the situation required.

I would like to thank the committee for inviting my comments on H.R. 3603.

TESTIMONY OF DR. EDWARD OPTON, JR., ASSOCIATE DEAN, GRADUATE SCHOOL, WRIGHT INSTITUTE, BERKELEY, CALIF.

Dr. OPTON. Mr. Chairman, I understand you would like to wrap things up this afternoon early, so I will be governed by your wishes insofar as you let me know about them.

I have a 12-page statement and also some thoughts on the testimony that was given earlier.

Mr. KASTENMEIER. Without objection, your statement will be received for the record and printed in full. You may proceed as you wish.

Dr. OPTON. It would belabor the obvious to explain why medical experimentation can be extremely dangerous. It is less obvious that medical experimentation seldom need be dangerous. Caution, patience, and the money to implement them can almost always reduce the risk of necessary research to levels which we would willingly bear.

But safety costs money, and medicine is a business as well as a profession and a science. Medical research, whether pharmaceutical, surgical, psychiatric, or otherwise, is expensive, and any organization conducting it faces an inescapable conflict between the interests of its patients and the interest of its balance sheet. This is only slightly less the case for nonprofit organizations like the National Institutes of Health than for profit-oriented enterprises like Squibb, Upjohn, or Merck.

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Let us think, then, about the sources of protection, potential and actual, for the subjects of medical experimentation. There are four basic loci of protection.

The first is individual conscience, the conscience of the medical experimenters. You will hear from spokesmen for drug manufacturers and perhaps from the National Institutes of Health and other segments of organized medicine about medical ethics, professional standards, self-policing, institutional and peer review committees, and so forth.

I suggest to you that these appeals to conscience alone are an extremely frail reed from which to weave a support for the men and women whose safety in prison is the responsibility of this subcommittee and of Congress.

There is a plain and consistent pattern of failure of unaided conscience in this area. In Europe the pattern of failure did not begin at Dachau and Bergen-Belsen, nor did it end with the awful, but profitable, catastrophe of Thalidomide. In the United States the pattern was well establishesd before the infamous Tuskegee syphilis experiments, nor has it ended with the recent revelation that physicians in New York have systematically inoculated retarded children with a deadly virus, hepatitis, at the so-called school at Willowbrook.

I think there are at least two important reasons for the failure of self-regulation and conscience. One is that the medical personnel who do prison-based research work for organizations. They are not entirely free to follow their own consciences. In the pharmaceutical industry financial executives hire and fire physicians, not the other way around. Physicians whose personal ethical standards are financially inconvenient are unlikely to be assigned responsibility for financially important projects.

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Also, the psychological pressures of responsibility for others' lives and the repeated exposure to others' suffering force many physicians to insulate themselves, psychologically speaking, to stand back from their patients, viewing them less as human individuals than as collections of individual organs assembled into biological machines.

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subject, the physician's interests and the patient's interests are no longer nearly identical; they begin to diverge radically.

I would like to give you some examples from my personal experience which illustrate the inadequacy of relying on individual ethical standards. The first occurred when I was an intern at the Duke University Medical Center. One day, a colleague, a psychiatry resident, proposed that we collaborate on a drug research project which had been offered to him, unsolicited, in a letter from the Upjohn Co. He showed me a research plan which Upjohn had enclosed.

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I would ask you to keep in mind that the mail-order research situation I am describing was to take place in an outpatient clinic, and although most of the patients would have been black, as would most prison subjects, our clinic was still a clinic, not a prison. If the problems of undue influence on medical personnel are so pervasive in a setting where the subjects of research are free citizens, you may imagine how much augmented those problems are in prisons, where the official rule is that the inmates have few rights, and where the near-universal practice is that they have virtually none.

The second example comes from California, where, on November 19, 1970, I attended a conference as the guest of the California Department of Corrections. Their invitation solicited my views as a scientist on the sorts of research and treatment that might best be implemented in the new maximum psychiatric diagnostic unit, then under construction at the prison at Vacaville.

Throughout the morning of the conference, I, and a group of about 20 other scientists and physicians, sat through a program of descriptions of the new facility which told us exactly nothing about what research or treatment the Department was planning. The Department of Corrections, therefore, learned nothing whatever from the people it had gathered from all over the State to advise it. I wondered why we were there.

At lunchtime, I turned to my neighbor in the cafeteria line and asked, "Do you have any idea what they are planning for this new unit?" He told me he was the research psychiatrist for the unit, and that he planned a comparison of the results of psychosurgery with the results of chemical castration. The idea had come from the work of a surgeon and a psychiatrist with whom he had formerly been associated in Boston, who also did research in prisons. An application for Federal funds to pay for the surgery was already prepared.

At the afternoon session, I asked if my luncheon companion's report were accurate. The reaction of the medical and other personnel from the Department of Corrections was dramatic. They were embarrassed, intensely flustered, and unwilling to confirm or deny it. They quickly adjourned the meeting, and soon thereafter, in the wake of modest publicity in the local press, they canceled the project.

Two years later, the same plan, again to be supported by public funds, was proposed in two widely separated institutions, the University of California, Los Angeles, and the Lafayette Clinic in Detroit. In both cases, the physicians attempted to keep it secret, and in both cases the story leaked out, at first as rumor, then backed up by documents.

In both cases, the project was halted. The UCLA project is described in the November 1974, report of former Senator Sam Ervin's Subcommittee on Constitutional Rights. The Detroit project was halted by the well-known psychosurgery lawsuit, *Kaimowitz* v. *Rodin*, but not before the so-called consent of the first prospective research subject had been obtained by the physician's telling him that he would never get out alive unless "I get either your brains or your balls." The offer was one the prisoner could not refuse, so he signed.

Incidents like these are, I think, inevitable under our present nonsystem. The restraints of unaided conscience are not enough.

The second line of defense against improper and dangerous medical research is such defense as the prospective subject can make in his or her own behalf—for example, refusal to participate. It has long been recognized that a person who does not understand what is being proposed, or who is confined under such oppressive conditions that, in effect, the offer is one he cannot refuse, is in no position to look after his or her interests. The "consent," so-called, is not "informed."

Needless to say, there are times when it would be cheaper or more convenient to conduct research without the trouble of obtaining informed consent. That is a major reason, I believe, why medical research is conducted in prisons and other total institutions.

You have already heard convincing testimony on the reasons why informed consent in a prison setting is a logical impossibility, a contradiction in terms. I will not take up your time with a repetition of the message you heard on September 29 from the ex-prisoners. Moreover, I have not shared their experiences; only they can speak for themselves. I hope you will have occasion to solicit additional information from them and from other ex-prisoners and current prisoners.

I expect that experts like Professors Katz and Capron will also be communicating with you about informed consent. I know they have written on it wisely and at length. For me the issue in the prison is a simple one: Informed consent is not possible. Some scholars believe it would be possible in some hypothetical prison system; some think not. I note that the Congress must legislate for the prison system we have now, and which we will have for years to come, and not for some ideal system.

And so I pass on to other protections against dangerous experimentation that might be more substantial.

Administrative regulation, with or without the mandate of legislation, is the classic way to manage our social institutions. In the case of medical research in American prisons, it is an almost hopeless exercise in futility. Greenburg and Stender, as well as many others, have demonstrated that our prisons are at least as lawless in their administration as in their clientele. That situation is not about to change, for the beyond-the-law quality of prison administration is necessary.

Prisons, as we know them, could not operate within the lawful limits of democracy. Their isolation, their secrecy, and above all, the total power of the administration and the total powerlessness of the prisoners insures lawlessness. Experience has shown the accuracy of Lord Acton's aphorism about absolute power corrupting absolutely.

Anyone who still entertains hopes of dealing with the abuses of medical experimentation in prisons by regulations and rules should consider the psychiatric prison at Patuxent, Md., only about 30 miles from this committee room. There a so-called goon squad has in recent times roamed the institution in the dark of night, using clubs and fists and feet to take care of disciplinary business left over from the day. The goon squad resembles the quasi-official Brazilian death squads of off-duty policemen, and it has a similar function: To suppress vocal malcontents, social troublemakers, and dissidents, to compel docility through terror.

During the daytime, and the nighttime too, Patuxent has used torture as one of its standard forms of discipline. One form of torture which I observed in June of last year takes the form of the "strapsheet," a hospital gurney equipped with handcuffs at one end, foot cuffs at the other, and a canvas sheet which is tied down to immobilize the prisoner's torso. The prisoner is left to stew in his own bodily juices until he learns to behave himself to suit the administration. As befits an institution designed specifically for therapy, and whose superintendent is by law a physician, this device is called a "treatment."

The important fact about Patuxent is not that its practices are particularly malodorous. Unfortunately, it is not the most oppressive

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prison in America. What is noteworthy is the result, or nonresult, of the extensive efforts that have been made to reform it. There have been numerous lawsuits. Yearly newspaper exposés have horrified, disgusted, and entertained the public in the Baltimore-Washington area. Patuxent has been the subject of both legislative and administrative investigations and of more sustained pressure from reform groups than any other prison in the Nation.

Yet the efforts have made essentially no difference; the situation is basically as bad today as it was 20 years ago.

If the best efforts our political process can muster at this moment in history are unable to affect even the most blatant barbarisms, we cannot expect mere rules and regulations to protect our prisoner citizens from the more subtle exploitations of medical experimentation improperly conducted.

We have had talk of economics today, very properly. One of the aspects of that economics we have not talked about is payments of various kinds to the officials who run the prisons from the pharmaceutical companies and others who find it convenient to do research there. I am not talking about payments to the prisoner welfare fund or contributions of hospital beds that might at some date in the future be helpful for the prisoners.

I am talking about cash payments to prison officials. For example, at the California Medical Facility, a prison at Vacaville, Calif., where a great deal of contract drug research is done, it is done through a corporation called the Solano Institute. The head—or former head—of the institute was Dr. William C. Keating, Jr. At the time he founded the institute and went on to its board of directors he was also the superintendent of the prison at Vacaville.

Through that institute flow hundreds of thousands a year. Many of those thousands of dollars go to pay moonlighting prison personnel. They receive extra wages which are not so easy to come by when you are a prison guard or administrator, and of course Dr. Keating is or was well situated to control the flow of those dollars. I have no idea what goes on in other prisons, but it seems to me there has to be some incentive to the prison administration to bring such programs in.

The remaining possibility for protection from abuse of medical experimentation in prisons is prohibition. It is simple. It would be effective. Other countries have done it without any adverse effect on their citizenry's health. It is the only method that will work. You have heard testimony from Dr. Meyer and Dr. Arnold that the additional costs it would impose on our pharmaceutical manufacturers and our public would be quite modest. In spite of the $229 million estimate of Dr. Meyer, that is only a small portion of the drug companies' profits, and I think that under certain other assumptions about what alternatives the pharmaceutical manufacturers would use, one might come up with a lesser figure.

Mr. Mitchell's bill, H.R. 3603, would go far toward prohibiting medical experimentation in prisons. I recommend its passage.

I would also recommend augmentation of H.R. 3603 in at least this one respect: It is important that research and experimental therapy not be concealed under the label "treatment." Under the bill in its present form both the Detroit and the UCLA psychosurgery programs

might have gone forward, for their proponents adeptly switched from a "research" to a "treatment" rationale as the situation required.

That is my prepared statement. I have some comments on what has been said earlier today. I would also be happy to respond to your questions.

Mr. KASTENMEIER. If you care to briefly comment further, you may do so at this point.

Dr. OPTON. I would like first to comment on the Addiction Research Center. I think one aspect of that Center that would be worthy of Congress' attention is the possible failure of the research there, quite apart from the ethical aspects. I note that Dr. Mitchell said he has had 4,000 to 5,000 of what he called "patients." I believe he termed them "patients" quite improperly. They should be called "prisoners." They are not his patients. The work that is done there is of no therapeutic value to them.

He has had between 4,000 and 5,000 prisoners go through his installation, and he has 18 doctoral level staff in the program, he told me. I estimated the cost of that program over the past 20 years by multiplying the number of professional staff times about $60,000 per researcher per year. That is about what it costs to keep a researcher in business. I also based the estimate on $5,000 per prisoner per year, as additional cost beyond what it would cost to keep the man in prison anyway. The two methods of estimate produced figures ranging from about $20 million to over $33 million for the total Federal Government moneys that have gone into that research center over the years.

I wonder what value has come out of it. I asked Dr. Mitchell for a bibliography of his publications. He does not have one, but there are other ways that research results or their absence might be found out, as for example, through the annual reports.

One thing that makes me have some skepticism about the value of the ARC research is the prisoners' testimony, which certainly sounds inconsistent with a high degree of competence. Also, the report of the galvanic skin response experiment that we heard about this morning leads me to be dubious about the ARC research. I worked on basic research on galvanic skin response and psychophysiology for 6 years at the University of California at Berkeley, yet I could not see even the germ of any worthwhile experiment in the description Dr. Mitchell gave of the ARC experiment. I would like to see what valuable results to the Government came out of work like that.

Mr. KASTENMEIER. You are referring to Dr. Martin?

Dr. OPTON. Right. He was describing research done by one of his staff. Dr. Jones was the man or woman who did the GSR research.

Dr. Dickson gave several reasons why he thinks research in prisons is valuable and should be continued. He said, "The principal advantage of using prisoners as subjects is that prisoners are generally confined," and he went on to amplify what he meant by that.

He said, "Such research is safer for the subject, gives you better data because of uniform environment of the people, and fewer subjects need be at risk."

I think all of those are very questionable assumptions. Prisoners are generally locked up for long periods, often from 4 o'clock in the afternoon until the next morning, quite out of touch with medical or

any other kind of personnel, and therefore unsafe during those hours, as compared to free people who can, if they find themselves getting in trouble at night, summon help.

The fact that you get more uniform data from people who are in a uniform environment is to my mind a disadvantage in medical research, not an advantage. It is true, the data comes out more similar than it might if some people were physically active and some were sedentary, if some were eating steaks and some were eating beans, and so forth. But it makes the results of the research less generalizable. If everyone is on the same diet, having about the same amount of activity, approximately the same age, generally young men, it is very hard to generalize to the effects of a drug on people who are engaging in different kinds of activity, eating different kinds of diets, and of a different age, such as old people—who are in fact the main consumers of drugs—or to children or to women.

If Thalidomide, for example, had been tested on free people rather than on prisoners, assuming it was tested on prisoners, as it appears that 80 to 90 percent of drugs are, its mutagenic effects might have been discovered much earlier, and you might not have 7,000 or 8,000 adolescents running around in the world today with flippers instead of arms.

Dr. Dickson also said that some of the research is potentially valuable to the prisoner himself or to other prisoners. He mentioned alcohol, narcotics, and mental health as specific instances. These are areas that I know something about. I do not claim to be an expert in all of them, but I know something about them. I know of no research done in prisons that has been particularly valuable in any of these specific areas, alcohol, narcotics, or mental health, and I would like to be informed of it if it exists.

Finally, Dr. Dickson said it would be a shame to deprive prisoners of the opportunity to contribute on society's behalf. Perhaps so, but then is it not a terrible deprivation of the prison guards and prison wardens to deprive them of the opportunity to contribute on society's behalf? Yet I see no programs for them. I think it might be nice to run medical research on insurance company employees. They certainly are people who are in an excellent position to give informed consent because they are in the business of estimating risks, and certainly they should be as motivated as people in our prisons to contribute on society's behalf. There are a lot of groups that ought to have that opportunity.

I think that is all the comments on today's testimony that I have.

Mr. KASTENMEIER. Thank you, Dr. Opton.

I would first like to congratulate you on your testimony, which I consider excellent, and then I will yield to my friend from Illinois.

Mr. RAILSBACK. Doctor, what evidence do you have about money paid to the heads of penal institutions?

Dr. OPTON. I have no evidence other than what I told you about Vacaville, where, as I said, the former superintendent of the institution was also a founder and director of the separate corporation through which all the drug money is funneled into the institution and out of which prison employees were paid for their work in conjunction with the drug and medical experiments.

I also speculate—I have no evidence—that in other institutions there must be some sort of incentives to the institutions to engage in this cooperation.

Mr. RAILSBACK. We cannot consider that. Do you have any evidence of that?

Dr. OPTON. No; that is all I know about.

Mr. RAILSBACK. I think that that would be very interesting to develop if you could produce evidence that prison administrators or others are being paid, receiving some kind of money to participate.

Dr. OPTON. I think it would be, but I suppose that is the sort of evidence that you would be in a better position to develop than I, if you wanted to ask the pharmaceutical manufacturers about it, and so forth.

Mr. RAILSBACK. I see that two of your preceding witnesses are here—Mr. Chairman, I wonder if somehow we might consider that.

Mr. KASTENMEIER. What information is that you want?

Mr. RAILSBACK. I am talking about money that was paid or some kind of compensation to the heads of penal institutions by the pharmaceutical suppliers.

Dr. OPTON. Also, the line level of employees who work as guards and in other functions, the line level employees like guards who do extra work in connection with this research and may at times be paid from funds other than State funds.

Mr. KASTENMEIER. Do either of the preceding witnesses wish to come forward and testify to that point?

Dr. MEYER. If I may.

Mr. KASTENMEIER. Very concisely. The person answering is Dr. Peter Meyer.

Dr. MEYER. My apologies. In one case of experimentation by pharmaceutical manufacturers in using Florida prison inmates, the firms were reported to have paid one hospital supervisor—that is to say, an individual in charge of a prison hospital facility. The firms were reported as paying one hospital supervisor something in excess of $7,000 over a 2-year period.

Mr. RAILSBACK. For what and what firms?

Dr. MEYER. I do not have the detail in front of me, but I can tell you the material to which I am referring. It is contained in the hearings held by the Senate Subcommittee on Health of the Committee on Labor and Public Welfare in 1973 upon which a lot of the material in my monograph is based, and it has to do with a series of articles that appeared in a Tallahassee newspaper with some further documentation relating to it that appear in that hearing.

Mr. RAILSBACK. Is there any other evidence or information that you know of that payments have been made to penal officials or authorities that have conducted experiments?

Dr. MEYER. That is the only instance I can think of immediately of an example of a payment to a prison authority. I need only to go to Philadelphia, however, for yet another form of payoff, which is internal to a prison—prisoners kicking back 50 percent of their proceeds from experimentation to one of the long-term prison inmates, a trustee, who was a critical gatekeeper, recommending people to serve as subjects or not to serve as subjects.

Again, an extensive exposé on that appeared in the Philadelphia Inquirer with yet further documentation in that instance. I refer you

back again to those Senate hearings. The Senate hearings have got an extensive body of data relevant to these types of abuses.

Dr. OPTON. In my discussion of payments, I was not necessarily implying any improprieties. We do not consider it improper if a policeman works on his time off as a guard in a bank. I was pointing to the fact that if money passes to people working after hours, it provides an incentive which produces a conflict-of-interest for the prison administration and its employees vis-a-vis their responsibility to protect the interests of the men in their charge.

Mr. RAILSBACK. If an official of an institution were to benefit from such payments, it would seem to me very likely that that institution or the people in charge of it would want to see that people did participate in a program.

Dr. OPTON. One would think so.

Mr. RAILSBACK. Thank you. That is all I have.

Mr. KASTENMEIER. If we ban access to prisoners in this country as volunteers in medical research, to what groups would you permit access for medical research as such? To what extent would such groups in fact be noncoerced?

Dr. OPTON. I think there are others who are in a much better position to answer that. I am not familiar with the other groups on which the pharmaceutical companies and other sorts of medical experimentors do rely in addition to prisoners.

I think that people who are experienced with that could tell you better. I would guess that, unless your legislation includes rules to the contrary, a good deal of the work might go out of this country to be done in the prisons of other countries, like Chile, for example, or Spain.

Mr. KASTENMEIER. Would we have any less moral or ethical responsibility for how it might be conducted there than we would here?

Dr. OPTON. I think not. I think the Congress ought to take the responsibility for controlling it as best it can. I think that as to the coercion that other groups might be under, we heard testimony this morning about use of drug company employees as subjects, which is certainly not ideal. Probably we will never have the ideal situation. Ideals are seldom reached, but I think there is nothing further from the ideal that we would like to see, at least that I would like to see, than the use of prisoners, and the use of any noninstitutionalized group would be better than the use of prisoners, mental patients, and profoundly retarded children.

Mr. KASTENMEIER. The reason, of course, I ask the question is because if we reach legislative judgment on this, on the proposal before us, we have to be willing to assume the implications of that in terms of medical research, effect on other population groups, and we have to be reaching judgments presumably that other groups are appropriate as subjects as this group may not be.

Dr. OPTON. It is certainly a very researchable question. It can be researched in terms of asking pharmaceutical companies what they would do. It can be researched historically, for we did not do much research in prisons before World War II. We could look back to see how it was done before World War II. We could look to the ways medical research is done in those many countries which do not use prisoners as subjects. It certainly can be found out.

Mr. KASTENMEIER. We may be, in effect, prisoners of our own scientific and technological development—that is to say, of standards of testing that have been, let us say, "upgraded" by the FDA and by the medical research community to the point where an accommodation with those standards, if we think it is essential to do so, may get very difficult for us to find alternatives. Might it be a result that we will have perhaps less research, perhaps research in terms of pharmaceuticals would be more selective in terms of use of human beings?

Dr. OPTON. On that question, I am strictly a layman. It is an economic question whether we would have less research. You could form estimates from previous testimony. Dr. Arnold, I believe, estimated that the extra costs of using nonprisoners would run to about 1 percent, and I think he referred to the research budget, not the total budget, of all drug company expenses. That would be a very minimal increase, and so I suppose that imposing it would not produce any particular decrease in the amount of research done.

Dr. Meyer's estimate of $229 million a year would be a substantial expense although not a crippling one by any means. I think there are other assumptions that could be plugged into his calculations that might produce a lower figure. For example, his figure on the cost of facilities, the implicit cost of the prison providing free physical facilities for the research to be done in, is based, I presume, on what it would cost the drug companies to recreate or rent these facilities themselves. But I think it is possible that if they were not doing these experiments on prisoners, they would find other sources of subsidy, for example, universities, at which the space for research might be obtained without their paying for it.

Dr. Meyer also estimated that it would cost $10,000 to buy the best sort of insurance to cover patients. Yet I think if we look to historic costs for what drug companies have paid for insurance when they have done their experiments on nonprisoner populations, it might turn out to be very much less. I am not saying it should be less, but perhaps it would be less.

Mr. KASTENMEIER. One question I had, and I do not want to quibble about it, but on page 3 and 4 you are talking about physicians, particularly physicians who are institutional corrections type physicians, with respect to their ranking in the total community of physicians or researchers.

My point is to what extent is the conduct of research relying on such individuals as opposed to the design of the pharmaceutical house, as they present it to the FDA for approval, and it goes to the medical school who uses the prison? What I am suggesting is, it is not really to that extent in the hands of these several individuals who may be permanent medical personnel at the prison so much as it is the design in the hands of others who control the experiment.

Dr. OPTON. I think that would vary from place to place. Usually the research would not be in the hands of the regular prison physician, but would be in the hands of other physicians who work on these projects specially. I think the crucial decisions would be very much down at the level where the prisoners are worked with, both in terms of the physician who is seeing them and also with the personnel who are carrying out the work, who often are other prisoners.

In my university research projects, and from what I know about my colleagues' work, I know that the experimental protocol—what the person reports to his sponsoring agency that he is going to do in his research—often, in fact usually, varies substantially from what he actually does. Exigencies of the particular situation require one to make changes. Ethical standards and all other kinds of standards, quality control, depends very much on the people actually administering the drugs, looking at the subjects' symptoms, and keeping the records.

Mr. KASTENMEIER. In conclusion, I would like to say you are very well advised to caution us on, if there is any language in any bill, 3603 or any other, about permitting certain medical treatment to be conducted, that it ought not to be medical research through the guise of medical treatment, that in fact it ought to be therapeutic and not nontherapeutic in institutions, because it is suggested that if such a bill passed that it contain certain exemptions, and if it does, I think we would have to very carefully consider those exemptions to insure that this sort of abuse could not take place that has been referred to, and this sort of relationship does not continue between the prisoner as a coerced subject of a medical experiment under the present system, and the prisoner as a bona fide patient, or in another capacity in which in fact more risks may be assumed by him.

In any event, if there are no further questions, I wish on the behalf of the subcommittee to thank Dr. Opton and recall the fact that we have collaborated at least on one other enterprise in conference together, a different moral and ethical question, and we hope that you may be of further service to us one day.

Thank you.

Dr. OPTON. Thank you.

Mr. KASTENMEIER. This concludes the subcommittee's hearings on the questions of medical research and prisoners, and with the possible exception of the Department of Justice, which has not as yet testified—this will conclude these hearings.

The record will be open for the balance of this month for additional statements.

The committee stands adjourned.

[Whereupon, at 4:35 o'clock p.m., the subcommittee was adjourned, subject to the call of the Chair.]

[Subsequent to the hearing the following material was received for the record:]

THE PENNSYLVANIA STATE UNIVERSITY,
University Park, Pa., October 10, 1975.

Representative ROBERT KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, House Committee on the Judiciary, Washington, D.C.

DEAR REPRESENTATIVE KASTENMEIER: Thank you for the opportunity to testify before your subcommittee on October 1, 1975 with reference to H.R. 3603, a bill to limit use of prison inmates in medical research. The extension of your hearings into an afternoon session indicated to me the concern you had for this important issue. I would like to extend my remarks with the comments below, most of which are directed at the statement of the Pharmaceutical Manufacturers' Association's representative, Mr. C. Joseph Stetler.

A. Mr. Stetler observes that, "We have been sponsoring prison based drug research for many years . . . and to the best of our knowledge, not a single prisoner has died or been permanently injured as a result of a drug-firm-sponsored test." (p. 1)

This is easily understood, since No Follow Up is present. Under Phase One tests persons are administered substances never given to humans before. *Toxicity* in the short run is tested at Phase One, but if a substance has been administered at dosages producing short-run reactions, there exists a significant probability of long-term experiment sequelae. These aftereffects are, conveniently, unknown because no follow-up is conducted. Mr. Stetler's comment thus reflects his organization's intentionally maintained ignorance, no more.

B. Mr. Stetler further observes, ". . . serious Toxicity occurs with extreme rarity . . ." (p. 2)

Low Level toxicity is to be defined by the tests, after which the tests are supposed to be terminated. The fact remains that some 90 percent of all IND's are terminated at Phase One or Phase Two, so extensive toxicity is, in fact experienced, even if it is not medically "serious."

C. On page 3 of his statement, Mr. Stetler notes Five "conditions necessary to serve the interests of all concerned" in experiments:

(*a*) "if the staff of the testing facility is qualified to conduct the research,"
(*b*) "if the facilities are adequate,"
(*c*) "if participation is informed and voluntary,"
(*d*) "if the experiment is carefully and appropriately monitored,"
(*e*) "if participants are compensated fairly."

Given the characteristics of total institutions such as prisons we can never be certain we meet conditions (a) and (b) in correctional settings.

Given the coercion inherent in prisons, condition (c) cannot, by definition, be met for experiments using inmates.

Given the closed nature of a prison, monitoring of an experiment is exceedingly difficult; the "appropriateness" of any monitoring effort, moreover, is in the eyes of the monitors and cannot serve the public welfare, so condition (d) may be meaningless.

At wage rates one-tenth of those prevailing outside the prison walls, prisoners will never be "compensated fairly," the more so since experimenters enhance their profits by exploiting prisoners, so condition (e) will never be met.

The majority of the conditions which Mr. Stetler himself argues Must Be Met before experiments in prisons can be deemed acceptable are thus regularly violated. Mr. Stetler's own conditions of acceptability, therefore, become grounds for termination of prison-based experiments.

D. Mr. Stetler has argued that termination of experimentation in prisons implies that "we remove another right of choice from" the prisoner's "already-restricted life." (p. 4)

He obviously assumes that participation in experiments is a process of free choice. To counter his argument, I offer the observations of Nathan Leopold, an articulate inmate of long standing, who had to face the so-called choice:

"We were specifically told we would not be released early because we had been involved in the . . . [experiment] . . . but it was a chance we couldn't possibly not take. The most important thing in our life was to get out of prison and anything we thought would influence that decision, no matter how marginally, we would be willing to do."

Perhaps, since all of us have somewhat restricted lives within the law, we should all be granted "another right of choice:" an encounter with a holdup artist offering the option, Your Money Or Your Life.

I should stress that the Leopold statement cited above was read at the 1973 conference on prison testing of drugs which Pharmaceutical Manufacturers' Association cosponsored, and to which Mr. Stetler refers on page 5 of his testimony. Other critical observations were presented at that conference (and several are cited in my monograph, which was submitted for the record), but Mr. Stetler and his associates are making the same claims now about the value of experiments to inmates that they uttered prior to their conference.

E. Dwelling on the necessity of utilization of prisoners, Mr. Stetler noted that. "There are few alternative populations which provide healthy persons living in controlled environments where close observation over periods of weeks or months is possible," and then argues that, without such populations, the collectible data would be limited. (p. 4)

There is a critical question to be asked of Mr. Stetler: Could such populations be recruited from the free population given adequate pay? Dr. Arnold, in his testimony before you, answered this query in the affirmative. The cost of such recruitment is, of course, avoidable if inmates may be employed as subjects.

F. If prisoners could no longer serve as subjects, hospitals and clinics could be used as test sites, according to Mr. Stetler, with the negative implication that "it would be the underprivileged population groups which would most frequently be entitled for these studies." (p. 4)

This is true; but are prisoners less underprivileged than the unimprisoned poor? Or are prisoners less human? One of the ethical premises underlying doctrines of informed consent as well as challenges to experiments on prisoners is that we must learn to experiment on human beings not human bodies. Mr. Stetler's remarks underlie the relevance of this premise.

G. The detailed Pharmaceutical Manufacturers' Association policy statement on human research, summarized by Mr. Stetler on pages 5–8 of his prepared testimony, contains a number of propositions on which I have commented in some detail in my monograph, Medical Experimentation on Prisoners: Some Economic Considerations, which is reproduced in the hearing record. I offer below page references to the sections of the monograph which are relevant to the PMA statement for your use in examining the logic of the PMA case and other arguments favoring experiments on prisoners. (I have noted only these items in the policy statement on which I have commented.)

Item 3—Physicians experimenting with prisoners, as well as inmates themselves, believe informed consent to be unattainable. See pp. 17–18 and footnote 32, pp. 55–56.

Item 4—All tested drugs may cause toxicity, and follow-ups do not provide compensation for damages or remuneration for risk. See pp. 8–9, 25–30.

Item 6—It is the nature of correctional institutions to be coercive and to expect the absence of coercion in any action taken behind the walls is wishful thinking. See pp. 1–5 and footnote 1, p. 50.

Item 7—Long term risks are, by definition, unknown, so disclosure of "known risks" is inherently inadequate. See pp. 8, 9. Choices in prisons are inherently coercive. See pp. 13–22.

Item 8—The crude fact is that withdrawal from experiment participation can affect an inmate's status in the institution. Telling an inmate that she/he is free to withdraw from tests without altering his/her status is thus a misleading statement.

Item 9—Granted that waiver of rights should not be requested, the issue of guaranteeing rights to care and compensation in the event of injury remains. It appears impossible to rely on litigation initiated by ex-subjects as a means of providing such a guarantee, especially in light of inmates' relative poverty. This "recommendation" is thus merely window dressing. See pp. 25–30.

Item 11—Remuneration, according to Stetler, "should not be so high as to amount to financial coercion, not so low as to be penurious." Since prevailing prison wages average 50¢ a day, this condition cannot be met: prisoners will either be paid penurious wages for participation in experiments or will be under financial coercion. See pp. 32–37.

H. There remain two critical issues which require some resolution if experimentation in prisons is to continue. To my mind, neither subject was addressed in adequate detail in testimony.

1. Remuneration to Prison Authorities for Services Rendered. No experiment conducted within an institution will fail to utilize some services routinely rendered within the prisons, and yet no requirement regarding remuneration of prison authorities has been imposed. Such a legislated requirement could increase funds available for corrections programs while merely removing a minor portion of the subsidy experimenters now receive.

2. Distribution of Efficiency Gains. The PMA, NIH, HEW and other experiment sponsors all favor the continued utilization of prisoners as medical test subjects on the grounds of efficiency. We can grant their arguments and yet disagree on experimentation policy on the grounds that the efficiency gains or benefits from such procedures should not accrue exclusively to the experimenters. In fact, the implicit subsidy to drug experiments alone is so large that "gate money" grants to discharged inmates of $50 per month of incarceration could easily be financed through accurate billing for real cost savings. Such a grant to discharged prisoners could help them to readapt to the outside world more easily than the below $25 total allowance now provided, on average in the United States. Recidivism associated with readaptation to the "outside" could thus be reduced by reallocation of efficiency gains.

Finally, in concluding this note of amplification, permit me to stress a point which your hearings have not had the opportunity to cover in any real detail:

The impact of experiments conducted in prisons on correctional institution effectiveness may be highly deleterious. If this is the case, which I believe it to be, then we may be buying experiment efficiency with higher crime and recidivism rates.

Once again, I heartily support the intent of H.R. 3603, favoring termination of prison experiments. Should regulated experimentation be continued, however, I urge your subcommittee to frame legislation assuring a more egalitarian distribution of monies so saved for purposes of enhancing correctional effectiveness. Needless to say, I stand ready to assist you further in your work on this most important measure.

Cordially yours,

PETER B. MEYER,
Assistant Professor of Economic Planning.

AMERICAN BAR ASSOCIATION,
Washington, D.C., October 13, 1975.

Hon. ROBERT W. KASTENMEIER,
Member, U.S. Congress,
Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: In reviewing the October 1st. transcript of the Committee's hearing on H.R. 3603, there were several comments and suggestions I wanted to bring to your attention.

There are three places in H.R. 3603 where ambiguity arises: Page 2, lines 9–10 require the Attorney General to establish "appropriate procedures" for complying with paragraph 1. In principle, I believe administrative procedures should not be legally mandated, but the word "appropriate" is subject to wide variations in meaning, particularly when the regulations involve Federal/State relations. Is a simple declaration of non-experimentation sufficient? Will verification be required? Is on-going monitoring "appropriate"? How are violations to be enforced?

Second, subsection (b) does not preclude Federal contracts with political subdivisions for so-called rehabilitation and treatment, only "imprisonment, subsistence care and proper employment". Hypothetically, a political subdivision could allow medical experimentation on Federal prisoners held under a contract for rehabilitation or treatment. Again, "assurances satisfactory to the Director" (lines 16 and 17) is simply too vague by not specifying the types of assurance, sanction or enforcement mechanism.

Finally, it is my personal feeling that the term "medical experimentation" (page 3, lines 3–8) is much too narrowly defined. If "medical" encompasses physical and mental health, there is no language which describes what is included in the latter. If the intent is to exclude psychological or psychiatric practices, H.R. 3603 is silent on what may potentially be the most deleterious form of human subject experimentation.

In reviewing Dr. Meyer's testimony and the Committee's questions, the economic analysis and subsidy estimates are admittedly complex; therefore, it would be useful to include the entire monograph, "Medical Experimentation on Prisoners: Some Economic Considerations" as a part of the Committee's printed record. This would enable any interested parties to examine the arguments and calculations in detail and, perhaps, prevent possible misunderstandings from reading only those parts discussed in the oral testimony.

Thank you, again, for inviting us to testify before the Committee. We would welcome the opportunity to provide other assistance in this or other matters.

Sincerely,

BILLY L. WAYSON,
Director.

LEXINGTON, KY., *November 3, 1975.*

Hon. ROBERT W. KASTENMEIER,
House of Representatives
Washington, D.C.

DEAR MR. KASTENMEIER: We wish to personally comment on the testimony of former prisoner patients of the Addiction Research Center before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice. These comments are our own and have not been subject to the clearance process of DHEW.

We have only recently had the opportunity of reviewing the statements of former prisoner patients who participated in research studies at the Addiction Research Center. We have not yet seen the transcripts of their testimony. However, we have learned that the staff of your Subcommittee was aware of the content of these prisoners' testimonies prior to it being given in open hearing. These patients made several very serious allegations: (1) That their participation in the experimental program of the Addiction Research Center was not voluntary; (2) that scientists at the Addiction Research Center deliberately misled them concerning the nature of the experiments and thus denied them the opportunity of giving an informed consent; (3) that requests for transfer from the Addiction Research Center were denied; (4) that drugs were administered to patients that subsequently caused death or serious illness; and (5) that unethical rewards were given to patients who participated in research studies. These accusations are, at the very least, derogatory to both the program of the Addiction Research Center and to the physicians who conducted the studies. Since these studies were conducted in fulfilling our statutory responsibilities, it is fitting to determine whether these allegations are true and for the responsible physicians to respond.

The purpose of these prisoners' testimonies as we understand it was to establish that unethical research was being conducted at the Addiction Research Center that was harmful to participants. Both these prisoner patients and segments of the news media have characterized our treatment of prisoner patients as inhumane. Since I was not aware of the content of the prisoners' testimonies at the time I appeared before your Subcommittee, my colleagues, Drs. Donald R. Jasinski and John D. Griffith, and I wish to respond to the allegations in their statements.

Otis Clay's Testimony

With regard to the electric shock experiments, Mr. Clay was not strapped to a chair. Electrodes were placed on his fingers. He was placed in a chair and his movements were not restricted. At the end of the study, Mr. Clay was asked to characterize the effects of the drugs and the shock using a standardized questionnaire. During his first participation, he characterized the shocks as "not painful" and "weak." During the second experiment, he characterized the shocks as "slightly painful" and "of average strength." As I indicated in my testimony, these types of stimuli were not discomforting to me and apparently my reaction to them was not greatly different than that of Mr. Clay. Several people who have talked with me about Mr. Clay's testimony have wondered whether electroconvulsive shock treatments were used in these experiments. Finally, Mr. Clay states that he was withdrawn from this experiment. Again, this statement has a degree of ambiguity that may be somewhat misleading. This study, for which he volunteered, consisted of two experimental trials. Mr. Clay completed both experimental trials and was not withdrawn. Mr. Clay's statements to your Subcommittee have been interpreted as indicating that he was restrained while painful and harmful stimuli were involuntarily inflicted upon him, whereupon he was then heartlessly rejected. These interpretations are not correct.

In another experiment, Mr. Clay (second drug experiment) received dextromethorphan (Romilar) which is an over-the-counter cough preparation that is freely available. There had been some reports that this drug was being abused and attempts were made to determine if it did indeed have addictive properties. Our experiments indicated that dextromethorphan was devoid of addictive activity.

Further, as Mr. Clay indicated, he has brought suit for damages against Dr. Donald R. Jasinski, Dr. Peter Mansky and myself, and this suit is still before the court. I have been advised by attorneys not to discuss this case and for this reason cannot speak to Mr. Clay's further allegations with regard to this case. Mr. Clay has made allegations before the Subcommittee that could be prejudicial to my position and to which I cannot respond. Whether Mr. Clay's allegations have substance or not will eventually be decided by the court. It is inappropriate that his derogatory testimony be used either as partial basis for a legislative decision, as an assessment of our professional conduct, or as a commentary on the nature of the Addiction Research Center's research program.

Kenneth Matthews' Testimony

Mr. Matthews has stated that we did not tell him the nature of the drugs that he received nor their side effects. As indicated in my testimony, patients are given a consent form to read which describes the properties of the drugs to be administered. To facilitate an informed consent, the consent form is also read to them by the investigator. Then, the subject is given the opportunity of asking questions and discussing any aspect of the experiment. The consent forms for each study are a matter of record and copies of not only our protocols but our consent forms are approved by our Organizational Review Committee, sent to the Division of Research, National Institute on Drug Abuse, FDA and the Bureau of Prisons before initiating our studies. Mr. Matthews has further stated that he signed a form releasing doctors from responsibility. The statement in the consent form is: "I further fully understand that the drug treatment to be performed is experimental and unproven by medical experience and that there may be unpredictable consequences."

Mr. Matthews further alleges that we told him that he would receive one drug and then received another. He cites an example. Each year we have conducted experiments for the University of Kentucky Medical Center sophomore class to give them experience in identifying signs of drug intoxication using common clinical methods. Patients are given an opportunity of voluntering for participation in these demonstrations. These demonstrations are very popular among the patients and the students. The experiment that we frequently conduct is to give one of four patients either a saline placebo, a 30 mg dose of morphine, a 250 mg dose of pentobarbital or a commonly used narcotic antagonist, nalorphine (30 mg). The effects produced by nalorphine are not greatly different than those produced by the commonly prescribed analgesic Talwin (pentazocine). I think that it is improbable that Mr. Matthews' rememberances of the effects of the drug are completely accurate nor does his rhetoric agree with his performance. Mr. Matthews agreed to participate in these demonstrations on two successive years. The second year he was told that he could possibly receive the same drug he received the year before. In these studies, Mr. Matthews was informed that disturbing subjective effects would, if possible be treated. The actions of nalorphine could be terminated with the narcotic antagonist naloxone or could alternatively be treated with a sedative such as pentobarbital. Following the completion of the demonstration, these could have been administered if Matthews requested them.

During Mr. Matthews' stay at the Addiction Research Center, he frequently requested transfer and then would withdraw his request on the same day. Our records do show, however, that on November 9, 1973 Mr. Matthews sent a note to Dr. Harold Conrad, Medical Officer in Charge, Clinical Research Center, inquiring if he would be eligible for employment at the Clinical Research Center. This note was referred back to Mr. Robert Maclin, Administrative Officer, who informed Mr. Matthews on November 14, 1973, that there were no openings at the Clinical Research Center for which he would be eligible. Following this, Mr. Matthews again requested transfer and this request was promptly forwarded to the Bureau of Prisons. On November 19, 1973 travel orders were issued by the Department of Justice and Mr. Matthews was placed in prisoner coordination for transfer. There was, however, a delay and he was not transferred until January 14, 1974. Delays of this duration are not atypical. Prisoners are opportunistically transferred from one Federal institution to another. The time of transfer is contingent on the availability of marshals or the availability of space on interprison buses. During the period of time that Mr. Matthews was awaiting transfer, he was not eligible for participation in drug studies.

Mr. Matthews is correct in his allegation that the physicians of the Addiction Research Center have no medical responsibilities for patients when they leave the Addiction Research Center. In this regard, no prisoner is discharged from the Addiction Research Center. All are returned to a Bureau of Prisons facilities. He further is correct that no systematic followup of their health status is made following their transfer from the Addiction Research Center. Although this at face value seems to be both a reasonable and a correctable criticism of the Addiction Research Center's program, it in fact is not. We have never been requested nor have we been authorized to conduct followups. Further, the design problem in determining causes of deaths is extremely difficult even in the best of designed experiments. The death rate among addicts on the street is 1 to 2 percent per year. Many of these deaths are violent in nature. As addicts, many of our patients have had a history prior to coming to the Addiction Research Center of ingesting many toxic substances including unknown contaminants. It is difficult to attribute death at any time to any specific antecedent event including the administration of experimental drugs. However, while at the Addiction Research Center, patients are under continuing medical scrutiny with repeated physical

and laboratory examinations. Every effort is made to treat disorders or to have patients transferred to institutions where their disorders can be treated in the event the Addiction Research Center does not have appropriate facilities.

I can state emphatically that I know of no evidence of any patient at the Addiction Research Center being harmed as a consequence of drugs administered during its 40 years of experimentation. A case in point is the patient mentioned by Mr. Matthews. When this patient came to the Addiction Research Center, he had a normal chest X-ray. During one of our routine chest X-ray surveys, some enlargement of hilar lymph nodes in the lung was detected. An extensive medical workup was performed on this patient which included consultation with the staff of the University of Kentucky Medical Center and the Veterans Administration Hospital. He had no symptoms and did not feel ill. A tentative diagnosis of histoplasmosis was made which is endemic and self-limited disease in Kentucky. There was, however, a remote possibility that he may have had a lymphoma (i.e., Hodgkin's disease). We consulted with Dr. Harry M. Weller, Deputy Medical Director, Bureau of Prisons, who arranged for the patient's transfer to the U.S. Penitentiary, Atlanta, Georgia, where he could receive further diagnostic workups at Emory University or the Communicable Disease Center. Because of the Privacy Act of 1974, we have not been able to obtain detailed information on this patient but believe that he was released on parole in March, 1974 in good health. We have gone over all of the drugs that this patient received while at the Addiction Research Center. All of the drugs that he received are medicines extensively prescribed. There is no evidence at all that any of these drugs cause a lymphoma, if indeed this is the disease from which this patient was suffering. Histoplasmosis is an infectious disease and not drug-induced.

The second patient to whom Mr. Matthews referred was granted parole while he was at the Addiction Research Center. He was transferred to the Federal Detention Headquarters, New York City, by court order. Subsequently, he was placed in a treatment program as part of his parole. He was in good health at the time of his transfer. We thus take exception to Mr. Matthews' characterization of the medical treatment administered at the Addiction Research Center.

Richard Alexander's Testimony

Mr. Alexander received two drugs, amphetamine (30 mg) and fenfluramine (120 mg) while participating in drug studies. Mr. Alexander reported no reaction at all to fenfluramine and, therefore, the reactions that he describes must be due to amphetamine. Mr. Alexander received amphetamine on two occasions and his responses were totally inconsistent. Mr. Alexander did not receive M-99, the so-called elephant tranquilizer. Neither Mr. Alexander nor any other subject at the Addiction Research Center has during my tenure as Director ever been given drugs as a reward for participating in studies. Undesirable subjective effects when they occur in our patients are usually terminated by appropriate antidotes. These are therapeutic medications prescribed by a physician. In this regard, our drug records are open for inspection. No medications are given at the Addiction Research Center without a doctor's orders, and thus we have an accurate record of all drugs given.

Dr. Griffith regularly corresponds with inmates at Leavenworth but no letter from Mr. Alexander has ever been received.

We believe that we can identify the patient whom Mr. Alexander describes as dead. This patient complained of abdominal and chest pains. He was then given an extensive diagnostic workup. X-rays revealed a lesion in one of his ribs. He transferred to the Medical Center for Federal Prisoners, Springfield, Missouri, where the rib was surgically excised and a histological diagnosis of enchondroma was made. This is a benign tumor. The patient, subsequent to his surgery, recovered uneventfully, made parole and was discharged in good health.

Mr. Alexander claims that he was coerced into participating in drug studies. Mr. Alexander participated in his last drug study on June 7, 1973. He participated in student demonstrations on October 16, 1973. Mr. Alexander requested transfer from the Addiction Research Center in January 1974. A request was prepared on January 14, 1974. Transfer orders were issued on January 29, 1974. He was transferred by a Federal marshal on March 15, 1974. Thus, for a period of almost a year Mr. Alexander did not participate in drug studies. During this time, however, he participated in many psychologic studies. During his stay at the Addiction Research Center he did not receive any narcotic analgesics. The fact of the matter is that not only was he not coerced to participate in drug studies,

he did not participate in drug studies at all during his year's stay at the Addiction Research Center except on five occasions.

I think there is little question that the testimonies of the three prisoner patients was derogatory to the Addiction Research Center and the physicians who conducted the experiments. All of the physicians on my staff are highly reputable, internationally recognized authorities on drug addiction, who have conducted experiments fulfilling a Congressional mandate and statutory responsibilities. All experiments at the Addiction Research Center have been conducted in accordance with DHEW regulations and FDA guidelines. As I have previously indicated to your Subcommittee, the studies conducted at the Addiction Research Center have been published in the most reputable journals and you have been furnished with a bibliography of these publications. Through an examination of our records it can be established that patients were not misled when they volunteered for experiments, that harm did not come to them, that they were not detained at the Addiction Research Center by scientists, and that they did not receive unethical rewards. Whether any patient, prisoner or not, can give a truly informed consent is a matter of debate. The staff of the Addiction Research Center has been especially concerned about this issue and procedures have been evolved which provide our patients with a high degree of protection against excessive inducements and harmful effects. In performing its statutory responsibilities in determining the abuse potentiality of new drugs, of understanding the psychopathology and pathophysiology of drug addiction and in the development of new treatment modalities, the Addiction Research Center has very likely prevented tens of thousands of persons from abusing new addicting analgesics and has been responsible for saving thousands of lives as a consequence of our studies concerning the detoxification of overdosed and dependent patients. Further, studies at the Addiction Research Center have been largely responsible for the introduction of narcotic antagonists into treatment of drug addiction and played a significant role in demonstrating the properties of methadone and LAAM that are responsible for their clinical usefulness. These advances have been made without harm to our prisoner patients.

We personally feel that if these allegations by the prisoner patients and others are to be used critically as a basis for legislation and regulations concerning the use of prisoner patients in research, attempts should be made to determine their validity in accordance with ethical investigative and legal procedures.

Out of fairness, I hope that this letter will be published in the proceedings of your Subcommittee's hearings.

Sincerely yours,

William R. Martin, M.D.
Donald R. Jasinski, M.D.
John D. Griffith, M.D.

Department of Health, Education, and Welfare,
Rockville, Md., October 9, 1975.

Hon. Robert W. Kastenmeier,
House of Representatives,
Washington, D.C.

Dear Mr. Kastenmeier: Enclosed is an information sheet that is sent to the Bureau of Prisons facilities about the Addiction Research Center program. Also enclosed for your information is a copy of the Operations Manual of the Addiction Research Center regarding conduct of the research on prisoner subjects, as well as a booklet that is distributed to all prisoner patients when they are admitted which describes the program and regulations governing their behavior while they are at the Addiction Research Center.

Also enclosed is a complete bibliography by year of the papers that have emanated from the Addiction Research Center in its 40 years of existence. In this time 533 papers have been published. Virtually all of the work conducted at the Addiction Research Center of scientific merit has been published in the open literature which is freely available. The research has been published in the most reputable of scientific journals and has undergone rigorous criticism by fellow scientists.

The studies that the Addiction Research Center has conducted, as Dr. Dickson has pointed out, have been to fulfill statutory responsibilities of the Secretary of Health, Education, and Welfare in advising the Attorney General

concerning the scheduling of drugs. The legislative basis for these responsibilities is H.R. 11143 (the act creating the Bureau of Narcotics), the Narcotics Manufacturing Act of 1960, and the Comprehensive Drug Abuse Prevention and Control Act of 1970. The other studies that have been conducted have been related to understanding the disease processes that afflict narcotic addicts and efforts to develop treatment modalities. The statutory basis for these activities is the law that established the facilities at Lexington and Fort Worth (45 Stat. 1085, 1929) and the Public Health Service Act (58 Stat. 682).

Sincerely,

KARST J. BESTEMAN,
Deputy Director.

INFORMATION RE PROGRAM OF ADDICTION RESEARCH CENTER

Requests for transfer to a special unit of the Addiction Research Center at Lexington, Kentucky, for participation in research studies involving administration of drugs of abuse are being accepted by the Chief of Classification and Parole. To be eligible for transfer you must be 25 years of age or older, in good health, have a history of narcotic addiction, and have at least 18 months of sentence to serve at the time of volunteering. Volunteers who are transferred to the Addiction Research Center for research study participation will receive pay (meritorious compensation) and meritorious good time. They will reside in a special research unit. Dental and medical treatment will be provided. The Addiction Research Center program does not include psychiatric treatment or drug abuse therapy programs. In addition to participating in drug studies, patients will have vocational assignments for which they will also receive pay (meritorious compensation). Participation in research studies will be limited to no more than a two-year period except in special study cases.

Staff members of the Addiction Research Center will be at the institution the last week of June for interviewing and explaining the program to inmates who volunteer.

OPERATIONS MANUAL

Chapter I.—Regulation of Human Experimentation

I. INTRODUCTION

This chapter is concerned with the procedures that are employed in transferring prisoner research subjects from the Bureau of Prisons to the NIDA Addiction Research Center (ARC) and that regulate human experimentation at the Addiction Research Center. Among the responsibilities of the ARC is the assessment of the abuse potentiality of narcotic analgesics. This program has been ongoing since 1934, when it was established by Dr. C. K. Himmelsbach at Leavenworth Prison. The studies have continued at the ARC at Lexington, Kentucky. The Secretary of HEW had the statutory responsibilities under the Narcotics Manufacturing Act of 1960 for advising the Secretary of the Treasury concerning the abuse potentiality of strong analgesics. In 1970 the Narcotics Manufacturing Act was superseded by Public Law 91-513. The applicable sections of P.L. 91-513 that pertain to the Secretary of HEW's responsibility are:

"(b) The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

"(c) In making any findings under subsection (a) of this section or under subsection (b) of section 202, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this title.

"(d) If control is required by United States obligation under international treaties, conventions, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section.

"(e) The Attorney General may, without regard to the findings required by subsection (a) of this section or section 202(b) and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

"(f) If, at the time a new-drug application is submitted to the Secretary (of HEW) for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

"(g)(1) The Attorney General shall by regulation exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

"(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this title unless controlled after the date of such enactment pursuant to the foregoing provisions of this section."

The ARC has generated and supplied scientific data concerning the addictiveness of new analgesics in man to the Secretary of HEW.

II. PRISONER SUBJECTS

A. Selection of federal prisoner patients

Prisoners are informed by appropriate prison officials of the opportunity for voluntary transfer to the ARC as participants in research projects.

The prisoner volunteers by completing a written application (see Exhibit I).

The application is reviewed and mutually approved by the warden and medical officer of the prison where the prisoner is incarcerated, by the Assistant Director, Institutional Services, or his delegate in the regional office of the Bureau of Prisons, and by the Director, Addiction Research Center or his delegate.

The following standards must be met for approval of the application by the officials noted above:

The prisoner applicant must have a history of narcotic addiction. In this regard, a history of narcotic addiction shall mean either a statement by the prisoner that he has used narcotics, an admission to a federal, state or private hospital for the treatment of narcotic addiction, or having been arraigned and/or sentenced by a local, state or federal judge for violation of narcotic laws.

He must be in good physical health and have no major psychiatric disorders in and above a sociopathic or neurotic personality.

He must be at least 25 years of age and have at least 18 months remaining to serve on his sentence at the time he volunteers.

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B. Classification and approval of prisoners for research studies

Patients satisfying these criteria are classified into one of several categories of participation by mutual agreement among the warden of the prison or his medical officer, by the Assistant Director, Institutional Services, or his delegate in the regional office of the Bureau of Prisons, and by the Director of the ARC or his delegate:

1. *Unrestricted participation* means participation in any experiment involving narcotic analgesics, sedative-hypnotics, marihuana, cocaine, alcohol or psychotomimetic drugs, as well as other centrally acting drugs. For unrestricted participation the subject must have a minimum of five years documented history of narcotic addiction and must have at least three previous arraignments or treatments for addiction.

Treatment means admission to one of the PHS hospitals or another federal, state or local facility for treatment of narcotic addiction or incarceration for a sufficient length of time in either a federal, state or local correctional facility to assure withdrawal from narcotics.

Documentation means evidence of addiction to narcotics and treatment in the medical and administrative records of the Bureau of Prisons. The medical records, including the psychiatric, are reviewed for a history of addiction to narcotics and treatment for such addiction. Three items in the administrative records provide evidence. The FBI identification records are reports by contributors to fingerprint files of investigations, arrests, convictions and incarcerations. The presentence report, prepared by the U.S. Probation Officer, is primarily a social history which includes a review of criminal activity and previous incarcerations and rehabilitative efforts derived from interviews with inmates, interviews with family, friends, employers, etc., and perusal of official records. The Classification Report is primarily a review of past history and an evaluation directed towards planning rehabilitative goals and a prognosis for rehabilitation. This report is prepared from patient interviews and official records by the caseworker at the time of admission to prison and is updated yearly.

2. *Restricted participation* means no participation in studies involving opiates or the chronic administration of barbiturates, alcohol or the pharmacologic equivalents of these drugs. Criterion for restricted participation is no medical contraindication to participation in experiments.

Approval for research studies will be made for a period of one year or less. Approval can be renewed yearly with the approval of the Director of the ARC or his delegate and the Assistant Director, Institutional Services, Bureau of Prisons, or his delegate in the regional office. In special instances, subjects may continue to participate in studies in excess of two years.

C. Transfer

When approved for participation in research studies, the patient as well as his administrative and medical jackets will be transferred to the ARC. Transfers will be arranged by the Bureau of Prisons; however, the cost of transfer will be assumed by the ARC.

D. Admission to ARC

1. *Admission procedures.*—On admission a history and physical examination, blood count, chest x-ray and urinalysis will be obtained. The Administrative Officer or his delegate will take the responsibility for maintaining the administrative records on each inmate and determine the number of days that the inmate is earning and keeping accurate accounts of the length of sentence, eligibility for parole and other administrative details concerned with his sentence and release. The Administrative Officer or his delegate will also take responsibility for maintaining the medical records of inmates.

2. *Patient care.*—Following admission to the Center, patients will be assigned to ES or EN area where they will reside. Patient care, safety, custody and discipline in this area are the direct responsibility of the Director of the ARC. All inmates physically qualified will be given vocational assignments. Such assignments will be made on the basis of the patients' needs and desires and the need of the Center. They will be assigned to jobs such as food service or housekeeping positions within the unit, as well as to the Printing Trades Industry, or other units within the Addiction Research Center such as the stenographic pool, photography and library for vocational training.

3. *Medical care.*—The health of the inmate population is monitored by the ARC staff physicians who perform periodic examinations, maintain a regularly scheduled "sick call" and provide, on a rotating basis, 24-hour emergency coverage. The Federal Correctional Institution, Lexington, has assumed the responsibility to provide the inmate population at the ARC the same medical, surgical and dental care provided the residents at the Federal Correctional Institution, Lexington (BOP Policy Statement LEX–37600.1). The Federal Correctional Institution, Lexington, Kentucky provides a 100-bed general medical-surgical hospital, with supporting services, a dental clinic, contract consultants in medical and surgical subspecialties, as well as agreements for specialized hospital care with the Lexington Veterans Administration Hospital and the University of Kentucky Medical Center. Treatment of medical problems arising from research participation will be the responsibility of the ARC staff physicians. Procedures have been established with the FCI, Lexington, for hospitalization of ARC inmates on a routine or emergency basis.

4. *Recreation program.*—The recreation program for the inmates in the ARC is under the direction of the Correctional Administrative Assistant of the ARC. Arrangements have been made for their attendance at movies in the FCI auditorium, for use of their gymnasium, bowling alleys and tennis courts, and for other recreational facilities that are consistent with the program of the Federal Correctional Institution.

5. *Worship services.*—Inmates will be provided with the opportunity to attend religious services conducted by chaplains at the Federal Correctional Institution. They will be escorted to and from the chapel and will be separated from residents of the Federal Correctional Institution.

6. *Food services.*—All food services will be provided by the Federal Correctional Institution.

7. *Commissary.*—Inmates are provided the opportunity to purchase items from the commissary operated by the Federal Correctional Institution. The commissary will be open for a scheduled time two days each week. Further, patients will be permitted to purchase articles such as radios, phonographs, and recreation equipment.

8. *Clothing and laundry.*—All clothing facilities will be distributed by the Laundry and Clothing Section of the Federal Correctional Institution. Each inmate will be provided with suitable institutional clothing which will be laundered by the Laundry and Clothing Section of the Federal Correctional Institution.

9. *Mail.*—Incoming and outgoing mail including packages will be received at the mail room of the Federal Correctional Institution and after inspection for money or securities will be transferred to the staff of the ARC for final distribution. Money and securities will be removed from letters and scheduled by the mail supervisor of the Federal Correctional Institution for deposit with the Agent Cashier. The inmate will be given a receipt and it will be noted on the envelope the amount of money received.

10. *Visitors.*—Inmates will be allowed to have regular visits with approved visitors within the ARC under the supervision of the ARC staff. There will be no visitation between ARC inmates and the residents of the Federal Correctional Institution except in cases of legal wife, mother, father, son, daughter, brother or sister.

11. *Security.*—The ARC has the responsibility for the custody, security and discipline of patients. The ARC will have the responsibility of awarding meritorious good time through the ARC Awards and Classification Committee. Further, the ARC will have responsibility for withholding and forfeiture of all good time through appropriate committees appointed by the Director of the ARC, consistent with the good time withholding and forfeiture policy of the Bureau of Prisons.

E. Compensation

Prisoner patients are awarded meritorious good time and meritorious pay for research participation as well as for satisfactory behavior and job performance. Research participation at the ARC is regarded as meritorious service with awards in accord with regulations and policies of the Bureau of Prisons governing awards of meritorious good time and meritorious compensation (Bureau of Prisons Policy Statement No. 7600.50A: Feb. 23, 1971). In the Bureau of Prisons institutions, such awards are given for good behavior, for performance of routine job

assignments, for outstanding services and for successful completion of health research projects.

The schedule of awards of meritorious compensation and meritorious good time at the ARC are determined by the Director, ARC. The rate of earning or the total amount of awards at the ARC are less than or equal to potential awards available to the volunteer inmates at the Bureau of Prisons institutions from which they are recruited.

With respect to meritorious good time, the rate of earning and total amount that can be awarded is established by Federal Statutes. The total rate of good time awards at the ARC for both job assignments and research participation is similar on a monthly basis with that of an inmate performing satisfactorily in an industrial job assignment.

The current schedule of monetary compensation at the ARC is outlined in Exhibit II. For comparability, meritorious compensation for good behavior and routine job assignments is $15 monthly at the U.S. Penitentiary, Atlanta, and $12 monthly at the U.S. Penitentiary, Leavenworth. Monetary compensation for industrial job assignments averages $55–$60 monthly at the U.S. Penitentiary, Atlanta, and $75 monthly at the U.S. Penitentiary, Leavenworth. At the ARC subjects currently are awarded $11 per month for satisfactory behavior and job performance. Those prisoners assigned to Printing Trades earn an average of $17.12 per month (Fiscal 1975). The average monthly compensation for research compensation is $30.43 per month (Fiscal 1975).

Currently prisoner patients at the ARC receive a total compensation of $40–$50 per month which is less than the potential compensation available in an industrial assignment at the Bureau of Prisons institution from which they were recruited.

2. *Procedures for recommendation and payment of awards:*

(*a*) Work assignments—Recommendations for meritorious compensation for work assignments will be made by the work supervisor and will be reviewed and approved by the ARC Awards and Classification Committee.

(*b*) Research study participation—Recommendations for mertiorious compensation for participation in experimental studies will be made by the ward supervisor of the Clinical Pharmacology Section, ARC and must be reviewed and approved by the Senior Investigator of the research study and by the ARC Awards and Classification Committee. The amount of meritorious compensation for each study will be specifically stated in the study plan for each experiment.

(*c*) Payment—Following final approval by the Director, ARC, and official recording by the ARC Awards and Classification Committee, a monthly invoice for cash awards will be prepared by the ARC and transmitted to the Agent Cashier, F.C.I., for crediting all payment to the prisoner patient accounts, listing each participating prisoner patient by name and the amount to which he is entitled. This amount will reflect completed participation for each month given.

3. *ARC Awards and Classification Committee.*—The ARC Awards and Classification Committee consists of a chairman, a secretary and members appointed by the Director, ARC. The term of membership is indefinite. All are voting members.

(*a*) The Committee will review recommendations for all good time time awards, withholding, and forfeitures of good time and make recommendations to the Director, ARC.

(*b*) The Committee will review reports on persons receiving all monetary awards and make recommendation for amount of award as well as suspension or termination of award.

(*c*) Sends its recommendations to the Director, ARC, indicating its action along with the reports on which the action was based.

F. Termination of Participation

The research participation of prisoners at the ARC is terminated (1) at the prisoner's request, (2) at the expiration of the approved period, (3) six months prior to release from prison, (4) upon being granted parole, or (5) by administrative transfer for security reasons. In all events, prisoners will be transferred to a Bureau of Prisons institution. In the cases of parole or completion of sentence, prisoners are returned to a Bureau of Prisons institution with sufficient time remaining incarcerated to ensure a drug free period before discharge, and to allow the staff of the Bureau of Prisons to prepare and assist in discharge plans.

III. NON-PRISONER SUBJECTS

A. Selection

Non-prisoner subjects will be selected from the local area through cooperating organizations such as the University of Kentucky, Salvation Army, Volunteers of America, etc.

B. Standards for Selection

The type of study will determine the type of subject needed and will set the standards for selection, i.e., normal volunteers, alcoholics, sociopathic personality, etc.

C. Admission to Program

1. The study will be explained to the subject incuding the benefit expected from the study and he will then sign a consent form.
2. He will be given a physical examination and laboratory work before he begins his participation in any study.
3. He may withdraw from the study at any time without prejudice to himself.

D. Compensation

The sponsoring organization of the subject will be compensated for his participation in accordance with the conditions of the contract with the ARC.

IV. PROTECTION OF RIGHTS

The subject has a right to withdraw from the program at any time after his admission to the ARC. A prisoner subject may request transfer from the Center or may request to participate in limited research activities. The request will be promptly granted without prejudicing the patient in any way. This is a continuing right as long as he is at the ARC and is in addition to his right to not participate in specific research studies noted under Section VI. This right is specifically outlined in writing in patient's orientation information sheet (Exhibit III).

V. ORGANIZATION REVIEW COMMITTEE

A. Functioning of the Organizational Review Committee

The Organizational Review Committee of the ARC has essentially two major functions:

1. The Committee meets three to four times a year with the purpose of (a) discussing general problems concerning clinical experimentation, (b) to review special problems that have arisen concerning patient participation in research studies and technical problems related to particular experiments, and (c) to give advice to the Director, ARC, concerning the conduct and operation of clinical programs.
2. The Organizational Review Committee reviews all clinical study plans. The study plans for each experiment conducted on the wards of the ARC are circulated to all committee members. They review the study plan and either, (a) approve it, (b) approve it but make suggestions concerning the experimental design and conduct of the experiment, or (c) do not approve it, and indicate to the investigator in writing their reasons for not approving it. No study is initiated without the approval in writing of the entire Organizational Revew Committee of the ARC.

B. Method of selection

The Organizational Review Committee is selected by the Director of ARC. Several criteria are used in the selection of this Committee. (1) A substantive portion of the committee must have technical expertise such that they can assess the soundness of the experimental designs to be employed, the risks to the health of the patients, and the efficacy of procedures taken to avoid or treat toxic or adverse reactions. (2) Other members of the committee are selected because of their knowledge and background concerning the relevance of the particular experiments and general experimental program of the ARC to the common good. (3) Other members of the committee are selected on the basis of their knowledge and experience to provide guidance to the Director, ARC, on issues concerning the humane treatment of prisoner-patients and ethical questions concerning the conduct of experiments.

The committee will make determinations of whether subjects will be or not be at risk as defined in Part II, "Protection of Human Subjects" Regulations:

" 'Subject at risk' means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

The committee will also determine that the sum of benefits so outweigh the risk to the subject that allow the subject to accept these risks.

C. Organizational Review Committee composition

Members	*Qualifications*
Harris Isbell, M.D., 417 Foch St., Eastland, Tex.	Paid consultant; board certified internal medicine; clinical pharmacologist; professor of medicine, University of Kentucky; formerly director of ARC.
Abraham Wikler, M.D., professor of psychiatry, University of Kentucky Medical Center, Lexington, Ky.	Paid consultant; board certified in neurology; board certified in psychiatry; professor of psychiatry and pharmacology, University of Kentucky.
Robert Straus, Ph. D., professor and chairman, Department of Behavioral Sciences, University of Kentucky Medical Center, Lexington, Ky.	Paid consultant; fellow, American Public health Association; member, National Advisory Commission of Alcoholism.
T. Z. Csaky, M.D., professor and chairman, Department of Pharmacology, University of Kentucky Medical Center, Lexington, Ky.	Paid consultant; member, American Society for Pharmacology and Experimental Therapeutics; member, American Physiological Society.
Charles W. Gorodetzky, M.D., chief, section on drug metabolism and kinetics, NIDA Addiction Research Center, Lexington, Ky.	Full-time employee; clinical pharmacologist.
Donald R. Jasinki, M.D., chief, clinical pharmacology section, NIDA Addiction Research Center, Lexington, Ky.	Full-time employee; clinical pharmacologist.
David C. Kay, M.D., chief, section on experimental psychiatry, NIDA Addiction Research Center, Lexington, Ky.	Full-time employee; board certified psychiatrist; neuropsychopharmacologist.
John D. Griffith, M.D., chief, stimulant and hallucinogen unit, NIDA Addiction Research Center, Lexington, Ky.	Full-time employee; board certified psychiatrist; clinical pharmacologist.
William R. Martin, M.D., director, NIDA Addiction Research Center, Lexington, Ky.	Full-time employee; clinical pharmacologist; neuropsychopharmacologist.

VI. IMPLEMENTATION OF APPROVED STUDIES

A. Research protocol (study plan)

A research protocol for each study plan will be prepared in writing by the investigator, and must include the following information:

(1) Describe the requirements for a subject population and explain the rationale for using in this population special groups such as prisoners, children, the mentally disabled or groups whose ability to give voluntary informed consent may be in question.

(2) Describe and assess any potential risks—physical, psychological, social, legal and other—and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

(3) Describe consent procedures to be followed, including how and where informed consent will be obtained.

(4) Describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks and an assessment of their likely effectiveness.

(5) Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.

(6) Analyze the risk-benefit ratio.

The protocol will be submitted to the Organizational Review Committee. The Organizational Review Committee will review the study plan and:

1. Approve it, or
2. Approve it but make suggestions concerning experimental design and conduct of the study, or
3. Disapprove it.

If the plan is approved, the Committee will make a determination of whether or not the subjects will or will not be "at risk" as defined in Part II "Protection of human subjects" regulations and so inform the Director, ARC.

The Director, ARC, will review and approve the study and sign the certification in accordance with Section VII of this Operations Manual.

If the study plan involves an investigational new drug within the meaning of the Food, Drug and Cosmetic Act, the drug shall be so identified in the request to proceed, together with a statement that the 30-day delay required by 21 CFR 130.3(a)(2) has elapsed and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested the sponsor to withhold or to restrict use of the drug in human subjects; or the Food and Drug Administration has waived the 30-day delay requirement.

In those cases where the 30-day delay interval has neither expired nor been waived, a statement shall be forwarded to the Secretary of HEW upon such expiration or upon receipt of a waiver.

The study plan will then be submitted to the secretary of HEW for approval through appropriate channels.

B. Recruitment of approved patients

1. *Participation in studies.*—Prior to participation in each study, each subject will undergo a complete history and physical examination, as well as have appropriate laboratory tests.

2. *Informed consent:*

(*a*) The informed consent procedure of the ARC is complex. The first explanation of the study is usually by one of the senior biological technicians on the ward of the ARC, who explains the study to the patient to determine if he would have an interest in participating. If the patient exhibits an interest, the details of the study are discussed with the patients either in a group or sometimes individually by the principal investigator. If the patient still has an interest in participating in the study, the patient is given the consent form to read (Exhibit IV). Following this, the investigator reads the consent form to the patient, frequently paraphrasing statements in the consent form, if it seems appropriate, in the presence of a witness (usually a biological technician) and asks the patient whether he has any questions concerning the experiment.

If the patient at this time wishes to participate in the experiment, he signs the consent form in the presence of an investigator and the witness and the consent form is co-signed by the investigator and the witness.

b. *Compensation.*—Incentives will include both good time and cash awards and are explicitly stated in the research study plan (protocol) and the consent form (See Exhibit IV).

VII. CERTIFICATION, GENERAL ASSURANCES

All proposals involving human subjects must be reviewed and approved by the Director, ARC, before submission to HEW.

The approvals will be placed on the margin of the page of the proposal signed by the Director, ARC, so either (1) Human subjects: Reviewed at Risk, Approved, Date; or (2) Human subjects: Reviewed not at Risk, Date.

[Exhibit I]

AUTHORIZATION FOR RESEARCH STUDY AND EXPERIM. NTATION

1. Patient authorization:

I, _____, Register No. _____, a prisoner in the U.S. Penitentiary, _____, being of lawful age and sound mind do hereby offer myself of my own free will and without duress and persuasion, to be transferred to the NIDA Addiction Research Center, Lexington, Ky. to participate in experiments and studies of addicting drugs, drugs that may be helpful in the treatment of addiction and causes of drug addiction.

I certify that I have been addicted to _____, _____ and _____ from time to time since _____.

I understand that this program is entirely voluntary and that I can withdraw from the program for any reason and be transferred to a Bureau of Prisons institution at any time upon my request.

WITNESS:

_____ _____

_____ Signature

Name and Title

_____

Date

2. Information about patient:

Age ____ Date of birth _____ Physical Condition _____ Sentenced _____ Length _____ Exp. full term _____ Exp. Good-time _____ Parole Not Eligible ( ) Reg. Sent. ( ) A–2 ( )

3. Action by NIDA Addiction Research Center:

Approved ( ) Restricted ( ) Unrestricted ( ) Unrestricted single dose ( ) Disapproved ( )

Signed _____ Date _____

Name and Title

4. Action by U.S. Penitentiary:

(a) Approved ( ) Disapproved ( ) Signed _____

Date _____ Warden

(b) Approved ( ) Disapproved ( ) Signed _____

Date _____ Chief Medical Officer

5. Action by Bureau of Prisons:

Approved ( ) Disapproved ( ) Signed _____

Assistant Director, Division of Institutional Services

Date _____

6. General information:

Admitted to ARC _____ Approved to _____.

[Exhibit II]

SCHEDULE FOR MERITORIOUS COMPENSATION

A. RESEARCH PARTICIPATION

1. Single dose studies generally:

(*a*) $5 per study day not to exceed 6 study days per month

(*b*) In instances approved in advance by Chief, Clinical Pharmacology Section, $6 per study day not to exceed 5 study days in any one month.

2. Chronic Studies—$40 per month.

B. JOB ASSIGNMENT

1. Routine job and satisfactory behavior—$11 per month.

2. Printing trades[1]—schedule attached

[1] Prisoner patients cannot earn both meritorious compensation for job assignments and Printing trades pay.

C. CONCLUSION OF STAY AT ARC

At time of return to the Bureau of Prisons, patients may receive a bonus of $50 for each year of participation in program at the ARC with a maximum of $100.

SCHEDULE FOR COMPENSATION PRINTING TRADES ARC

[Following will be used as a step-rate method of payment to patients assigned to printing trades]

Classification	Hour rate, step 1 (new)	After 6 mo training, step 2 (new)	After 1 yr training, step 3 (new)
Janitor	0.27	0.32	0.37
Shipping clerk	.27	.32	.37
Clerk	.27	.32	.37
Stuffing envelopes	.27	.32	.37
ZIP coding	.27	.32	.37
Hand assembly	.27	.32	.37
Purchasing (clerk-stenographer)	.27	.32	.37
Binding	.27	.32	.37
Stapling	.27	.32	.37
Graph-O-Type operator	.27	.32	.37
Addressograph	.27	.32	.37
11×14 press	.28	.33	.38
11×17 and 15×18 press	.29	.34	.39
17×22 press	.30	.35	.40
Relief press operator	.30	.35	.40
Collator operator	.29	.34	.39
Paper cutter operator	.28	.33	.38
Photo-lithographer	.28	.33	.38

Note: Patients must have worked a minimum weekly average of 20 hours and performed in a satisfactory manner in order to be eligible for the next higher step. Patients will work a maximum of 4 days per week unless they have permission to work longer.

[Exhibit III]

ADMISSION ORIENTATION INFORMATION TO ALL INMATES ADMITTED TO THE NATIONAL INSTITUTE ON DRUG ABUSE, ADDICTION RESEARCH CENTER

Welcome to the National Institute on Drug Abuse, Addiction Research Center, Lexington, Kentucky.

As part of the research program, the Addiction Research Center conducts studies in prisoner volunteers to assess the abuse potential of drugs, to study the causes of addiction and to investigate new treatments for addiction. Prior to your transfer to this institution, in your initial interview with a member of the Addiction Research Center staff, he explained to you in some detail the program of the Addiction Research Center.

Your transfer to the Addiction Research Center is as a volunteer to participate in these research studies and not for treatment of your addiction problem. You have the right to withdraw from this program at any point in time during the course of your stay here. Also you may withdraw from any specific study at any time without prejudice to you in any way. Your entire participation in this program is voluntary on your part.

Prior to your participation in each research study you will undergo a complete physical examination as well as having appropriate laboratory tests to insure you have no medical contraindications to participating in the study. The investigator will explain the purpose of the study, the procedure to be used, a description of the effects expected, as well as possible harmful effects of the drugs or the procedures. You will be awarded compensation including both good time and cash awards for each study which will be detailed in the informed consent agreement you must read and sign prior to the start of the study. It is your right to ask any questions and to have satisfactory answers concerning the study. In signing the consent form, you certify that the study has been explained to you to your satisfaction and that all things considered you voluntarily agree to participate.

As a federal prisoner on your first admission to a Bureau of Prisons institution you were advised in writing of your rights and your responsibilities as well as the acts prohibited in the institution and the type of disciplinary action which may

be taken. These same Bureau of Prisons regulations cover you during your stay at the Addiction Research Center. You are encouraged to ask any questions you may have concerning your participation in the research program.

Through your cooperation, scientists are able to gain a better insight into the problems of addiction and the addictive process.

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APPENDIXES

APPENDIX 1

Statements submitted for the record

AMERICAN BAR ASSOCIATION,
Washington, D.C., January 7, 1976.

HON. ROBERT W. KASTENMEIER,
Committee on the Judiciary,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: Thank you for your letter of December 22, 1975, requesting my views on H.R. 3603, a bill to prohibit medical experimentation on prisoners. Although time does not permit me to undertake an extensive analysis, I would like to submit this brief statement of my position.

I have been involved in the general question of human experimentation for the past two years, first as an official of the Civil Rights Division in the Department of Justice (and as the Department's representative on a Federal interagency task force on experimentation) and presently as Associate Director of the ABA Commission on the Mentally Disabled. Although most of my work has been focused on the rights of the mentally disabled, I have come to the conclusion that there is, if anything, even less justification, in constitutional terms, for experimentation on prisoners than there is for research on the mentally ill or retarded or on other "special" subjects. It is my personal opinion that in the absence of such justification, nontherapeutic biomedical experimentation on prisoners is constitutionally impermissible.

Basic to any analysis of the propriety of human experimentation is the assumption that under the Fifth, Eighth, and Fourteenth Amendments, all citizens are entitled, vis-a-vis the State,[1] to be free from cruel and unusual punishments and from violations of their privacy, human dignity, and physical integrity. See, *e.g.*, *Roe* v. *Wade*, 410 U.S. 113 (1973); *Furman* v. *Georgia*, 408 U.S. 238 (1972); *Griswold* v. *Connecticut*, 381 U.S. 479 (1965); *Rochin* v. *California*, 342 U.S. 165 (1952). In the case of nontherapeutic research, which by definition involves a degree of risk to the subject's mental or physical well-being, these rights can arguably be waived where informed consent may be given to experimental procedures; but to expose subjects to such risks without consent is a violation of these rights and of due process of law. Moreover, to afford the protection of informed consent to "normal" subjects, while denying it to captive populations and other special groups, deprives these latter groups of the equal protection of the law.

According to the Nuremburg Code, the concept of informed consent requires that research subjects be "so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion." It is simply inconceivable that an inmate of such an inherently coercive and oppressive institution as a State or Federal prison or jail could exercise free choice as so defined. The Department of Health, Education, and Welfare, even while determining (at least tentatively) to permit experimentation on prisoners, has recognized the barriers to their giving informed consent:

"Many aspects of institutional life may influence a [prisoner's] decision to participate [in experimentation]; the extent of that influence might amount to coercion, whether it is intended or not. Where there are no opportunities for productive activity, research projects might offer relief from boredom. Where

[1] While there is some governmental involvement in most types of experimentation, the State's role is especially evident in the case of research on prison populations.

there are no opportunities for earning money, research projects offer a source of income. Where living conditions are unsatisfactory, research projects might offer a respite in the form of good food, comfortable bedding, and medical attention. While this is not necessarily wrong, the inducement (compared to the deprivation) might cause prisoners to offer to participate in research which would expose them to risks of pain or incapacity which, under normal circumstances, they would refuse. In addition, there is always the possibility that the prisoner will expect participation in research to be viewed favorably, and to his advantage, by prison authorities (on whom his other few privileges depend) and by the parole board (on whom his eventual release depends)."

HEW Draft Study Group Report, Protection of Human Subjects, Policies and Procedures, 38 F.R. 31738, 31743 (November 16, 1973). All these specific obstacles to informed consent must be viewed against a background of the inherently coercive nature of any closed institution, particularly the long-term, medium or maximum security prisons where experimentation is likely to be conducted, and the resulting phenomenon of "institutionalization." See *Kaimowitz* v. *Department of Mental Health*, No. 73-19434-AW (Circuit Court of Wayne County, Mich., July 10, 1973). I can conceive of no "consent" procedure, regardless of how many committees or lawyers of review are created,[2] which in any way diminishes the influence of these coercive factors.

In view of the potential for abuse in a prison situation (which has been well documented), the overwhelming and ineradicable compulsion flowing from penal incarceration, and the virtual impossibility of remunerating prisoner subjects at a rate which is both equitable in comparison to that paid outside subjects and not an undue inducement to participation or a distraction from rehabilitative programs, I think the impossibility of informed consent renders unconstitutional any nontherapeutic experimentation on prisoners which exposes them to any degree of risk, pain, or incapacity.

It is sometimes argued that under some sort of "balancing" or "compelling State interest" test, the rights of certain types of special subjects can constitutionally be overridden, to the extent of imposing a given level of risk without fully informed consent, because of society's interest in advancing medical knowledge and in the prevention and treatment of disease. This argument can be made, if at all, only where the information sought to be acquired relates to or arises from a unique characteristic of the subject group—*e.g.*, a particular stage of fetal or childhood development or a particular type of mental disease or defect. No such claim of scientific necessity can be made with respect to prisoners, who are not physiologically different from members of the general population.

Rather, the "interest" which is served by experimentation on prisoners is nothing more than simple administrative convenience,[3] or, to state it more realistically, the economic welfare of drug companies and other experimenters. This observation is impressively documented in *Medical Experimentation on Prisoners: Some Economic Considerations*, a monograph published by the Correctional Economics Center of the ABA Commission on Correctional Facilities and Services (Washington: June 1975), a copy of which is enclosed. Among the findings of this study were the following:

1. Prisoners, because of their incarceration, are five times as likely as free subjects to participate in experiments and incur risks—for rates of pay as low as one-tenth of what non-prisoners demand. In addition to being compensated at minimal rates, these prisoners are not insured or protected against long-term after-effects of experimentation.

2. The use of prison subjects results in a subsidy to pharmaceutical companies and other experimenters of $26.05 per subject-day, multiplied by hundreds of thousands or even millions of subject-days per year.

3. Many experiments conducted in prisons benefit the experimenters—in terms of profits on drugs and devices sold after testing, or professional kudos—but are

[1] See, *e.g.*, Proposed Rules, Protection of Human Subjects 39 F.R. 30648, 30651-30652, 30654-30655 (August 23, 1974).

[2] "Prisoner groups are particularly valuable in properly conducted clinical trials since they provide a stable subject population which can be followed over a period of weeks or months rather than days or hours." Proposed Rules, Protection of Human Subjects, 39 F.R. at 30648. Even this advantage may be highly overstated; of the 22,000 inmates of the Federal prison system, 14,000 come and go every year. *Proceedings of the Conference on Drug Research in Prisons* (Davis, California: Pharmaceutical Manufacturers Association and National Council on Crime and Delinquency, August 1973), at 191, cited in *Biomedical Experimentation on Prisoners*, Health Policy Program, University of California School of Medicine (San Francisco: September, 1975), at 3.

of little value for society as a whole. Reduction of the subsidy resulting from the use of prison subjects would eliminate much of this unnecessary experimentation.

Obviously, risking the life, health, or safety of prisoners cannot be justified in order to preserve a scheme which produces "benefits" of so little societal or medical significance.

Aside from constitutional considerations, of course, there are valid policy reasons for not permitting experimentation on prison subjects. Research programs are likley to dilute the already scarce staff and other resources of penal institutions, and to divert prisoners from whatever rehabilitative opportunities may exist. The overall and long-term effect of such programs will inevitably be to make it even more difficult for those once convicted of crimes to become functioning members of a free society.

As for the details of H.R. 3603, my primary concern is that it might be read to prohibit therapeutic experimental techniques which might be necessary as a last resort after established procedures have failed to ameliorate a particular prisoner's medical condition. Although there is a tendency on the part of experimenters to find therapeutic benefits where none in fact exist, I would not want the bill to bar the use of drastic medical procedures in appropriate cases, even if such procedures were experimental and even if the results were used to "determine the safety or effectiveness"[4] of the technique in question. Otherwise, I would most strongly urge enactment of the bill.

The above comments are my personal views and do not necessarily represent the views of the Department of Justice at the time I worked there or of the American Bar Association or the Commission on the Mentally Disabled. Nonetheless, I hope you will give them serious consideration.

Sincerely,

MICHAEL S. LOTTMAN,
Associate Director.

DEPARTMENT OF JUSTICE,
Washington, D.C., January 27, 1976.

Hon. PETER W. RODINO, Jr.,
Chairman, Committee on the Judiciary,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice on H.R. 3603, a bill to ban medical research on Federal prisoners, military prisoners, and prisoners in state correctional facilities receiving LEAA funds.

This bill would prohibit prisoners covered by the Act[1] from being "the subject upon whom any medical research is conducted." The term "medical research" is defined in the bill as:

> "Research, experimentation, or testing which (as determined under regulations which the Secretary of Health, Education and Welfare shall promulgate) is conducted to determine the safety or effectiveness of any drug,[2] medical device,[3] or medical practice.[4]"

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[4] Proposed 18 U.S.C. 4012(c)(2).

[1] The covered categories of prisoners are:
(1) persons confined in Federal penal and correctional facilities (Section 1(a));
(2) persons confined under the authority of any Act of Congress in any penal or correctional facility (Section 1(a));
(3) persons confined in any military correctional facility (Section 2(a));
(4) persons confined in any correctional facility having been charged with, or convicted of, an offense under the Uniform Code of Military Justice (Section 2(a));
(5) persons confined in correctional facilities of a state, or any political subdivision thereof, or confined under the authority of any state, or political subdivision thereof, receiving LEAA funds are covered by virtue of the requirement that the state, before receiving funds, must give LEAA assurances that no medical research will be conducted on such persons (Section 3);
(6) persons confined in any penal or correctional institution of the District of Columbia (Section 4(a)).
(7) persons confined under the authority of the District of Columbia (Section 4(a)).

[2] "Drug" means "any drug as defined by paragraph (1) of Section 201(g) of the Federal Food, Drug and Cosmetic Act".

[3] "Medical device" means "any device as defined by Section 201 of the Federal Food, Drug and Cosmetic Act".

[4] "Medical practice" means: "any practice, procedure or technique which is intended (A) for use in the diagnosis, cure, mitigation, treatment or prevention of any device or other health problem of man; or (B) to affect the structure or any function of the human body".

The constitutional foundation for this bill is the right of Congress to place reasonable restrictions on the expenditure of federal funds. See *Lau* v. *Nichols*, 414 U.S. 563, 569 (1974). Some constitutional questions may be raised because the bill proposes to limit the freedom of prisoners in a way which is related to the terms of the sentence imposed by the court or to the needs of security and order in the prison. Cf. *Coffin* v. *Reichard*, 443 F.2d 443 (6th Cir. 1944); Hollen, "Emerging Prisoners' Rights," 33 *Ohio State Law Journal* 1. We believe, however, that if Congress determines, and makes explicit findings, that it is necessary to eliminate the freedom of prisoners to volunteer for medical research in order to protect the prisoners from the harm that could result from such research, there would be little question of the constitutional authority of Congress to enact this legislation as a reasonable restriction on the expenditure of federal funds. Even so, severe constitutional problems would remain if therapeutic experiments were prohibited.

But even were a constitutionally acceptable bill to be offered, the Department would still question the wisdom of enacting a blanket prohibition at this time. In making this recommendation, we do not wish to appear unsympathetic to the ethical concerns which prompted the sponsors to introduce H.R. 3603. On the contrary, we share those concerns and believe they are consonant with the intention of Congress expressed as recently as 1974, when it created the National Commission For the Protection of Human Subjects of Biomedical and Behavioral Research.[5] Among the Commission's duties are: (1) to "conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects;"[6] and (2) to "develop guidelines which should be followed in such research . . ."[7] It is to complete its work by December, 1976. Inasmuch as the Commission is holding hearings on and will make recommendations with respect to the specific problems of experimentation on prisoners, we believe it would be wise to postpone consideration of legislation until the Commission has reported its findings.

Although closely linked to the universal problems encountered with the use of humans for medical experimentation, the conduct of medical research on persons incarcerated in federal institutions presents some peculiarly troublesome problems. First, medical experiments conducted within an institutional environment are far less likely to be exposed to public scrutiny. Second, the ethical requirement that a participant in such experimentation give voluntary and informed consent may be threatened by the existence of this environment. Supporters for legislation such as H.R. 3603 contend that the environment of prisons is such that informed consent is not possible. While we readily acknowledge the coercive nature of imprisonment, we are unwilling to accept a total denial of an inmate's ability to make decisions, particularly those which directly affect his own life.

As we pointed out earlier, this bill may be interpreted to prohibit an inmate from participating in therapeutic experiments as well as those which are nontherapeutic. Accordingly, we believe that it would be extremely unwise to deprive an inmate of the benefit which experimental medical testing may procure for him. A ban on such testing could be eliminated by an amendment to the bill, but it is in the area of nontherapeutic experimentation that we are faced with policy decisions of major proportions.

The argument of the proponents of H.R. 3603 is that prisoners cannot give informed consent and therefore are not appropriate subjects for medical research. Among the factors cited in support of this position are: (1) the prisoners believe that they may get an earlier release if they volunteer for medical experiments; (2) the economic status of prisoners is such that the prospect of receiving pay for participation is, per se, coercive; and (3) the barrenness of prison life compels prisoners to seek the more pleasant environment associated with the experiments. While we agree that these factors can be and often are coercive, we believe that it is possible to implement controls which do not irrevocably deprive prisoners of the ability to choose whether or not to participate in experiments. In fact it has been argued that "prisoners themselves would deeply resent a ban on, as they see it, their freedom to volunteer"[8] for medical

[5] Title II of the National Research Service Award Act of 1974, P.L. 93-348, 1974, U.S. *Code Cong. and Admin. News* 379.
[6] See 202(a)(1)(A)(i).
[7] See 202(a)(1)(A)(ii).
[8] "Prisoners as Laboratory Animals," Mills and Morris, *Society*, Vols. I and II, July/August 1974, pp. 60-63.

experiments. Ultimately, the relationship between the effects of captivity and the ethics of consent"[9] may have to be resolved by each person when faced with the problem. Nevertheless, we feel it is worthwhile to make the attempt to erect safeguards against abuse which would allow prisoners the choice of whether or not to participate in medical research. Though some prisoners may be influenced by the coercive atmosphere inherent in correctional or penal institutions, we believe that at least some prisoners have genuinely altruistic motives in volunteering for experimentation.

We are, therefore, opposed to a broad ban on medical research such as that suggested by H.R. 3603. We would suggest, however, that any legislation await the 1976 report of the National Commision for the Protection of Human Subjects of Biomedical and Behavioral Research. Perhaps then, after reviewing the recommendations of the Commission, more informed deliberation would permit an ethically acceptable and fully informed solution to what is unquestionably a difficult and delicate problem.

The Office of Management and Budget has advised this Department that it has no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

MICHAEL M. UHLMANN,
Assistant Attorney General.

COMMITTEE ON THE JUDICIARY,
HOUSE OF REPRESENTATIVES,
Washington, D.C., November 11, 1975.

HON. NORMAN A. CARLSON,
Director, Bureau of Prisons,
Washington, D.C.

DEAR MR. CARLSON: I am writing to discuss with you some of my observations following two days of Subcommittee hearings on H.R. 3603, a bill which would prohibit the use of federal prisoners as subjects in medical research and the granting of LEAA funds to states which permit such research.

Because the Subcommittee members have considerable respect for your judgment and experience we invited you to testify on the issues raised in the legislation. However, it is my understanding that the Justice Department has required more time to consider this legislation, and consequently neither your views nor those of the Civil Rights Division have as yet been forthcoming.

Regardless of the official position which the Justice Department eventually takes, I know that you recognize the seriousness of the ethical, medical and correctional concerns raised by this troubling issue. My primary concern centers around a firm conviction that a prison inmate is not in a position to grant truly informed consent in such a matter as the use of his body for medical research. In my experience, prisoner actions are frequently taken because of a strong hope for reward or a definite fear of reprisal. Truly uninfluenced, thoughtful personal decisions are difficult, if not impossible, in most prison settings.

Clearly, many state correctional authorities and medical professionals have come to recognize that the use of prisoners in medical research is both ethically questionable and of uncertain medical credibility. I am pleased to note that a number of states have chosen to phase out biomedical research in prison. Of the forty-one states which permit biomedical research, studies are presently conducted in only seven. However, only in the state of Oregon is medical research with prisoners specifically prohibited by statute, and the greatest portion of initial drug research is conducted with prisoners.

The situation with regard to Federal institutions is of particular concern to both of us. Some of the most troubling testimony which we received at our recent hearings was from former inmates who had recently been released from the Federal system. Each of them had at one time been incarcerated at the Addiction Research Center at Lexington, Kentucky. They testified about the de facto inducements they received to participate. They told the subcommittee of being imprisoned at Leavenworth Penitentiary with all of the resultant conditions with which we are both familiar.

[9] Id., at 74.

They told us of being offered a place at the Lexington facility in which physical safety, personal privacy and relative comfort are items generally available and not subject to favor, barter or violence. They told of relaxed postal restrictions and higher quality food. In effect they told us that they were offered a comfortable, safe and relatively privileged life to replace the dangerous, overcrowded, anxiety-ridden existence of Leavenworth Penitentiary. Additionally, they were each personally interested in the possibility of receiving drugs at Lexington. The prison "grapevine" had told them that "bonus shots" of heroin and other drugs were offered to cooperative subjects. Dr. Martin testified that such bonuses are no longer given. However, recent testimony before a Senate Subcommittee confirms that at one time bonuses were paid to prisoner-subjects at Lexington in the form of narcotics. I personally find this to be an appalling inducement to offer a prisoner with a history of drug abuse. Apparently, the prisoners still believe that such bonuses are available, and, you know, it is the subject's state of mind which determines the quality of his informed consent.

Further, the almost complete lack of aftercare afforded participants in the NIDA-HEW research is very troubling. Dr. Martin testified that prior to a prisoner's release to another Bureau facility he would be "detoxified" and a period of six weeks recuperation would be permitted. However, following the prisoners' release from Lexington there appears to have been no further medical attention, examination or follow-up by the ARC staff. Considering the seriousness of the research conducted at Lexington and the uncertainty about the effects of the various drugs used, it is amazing to me that HEW does not require substantive aftercare of those federal prisoners used in its research.

Unfortunately each of these dilemmas is duplicated throughout the sorry history of drug research with prisoners, and while I do not generally question the professional integrity of medical personnel working with prisoners as subjects, you and I both know that abuses have occurred at a level far higher than is tolerated in free world research.

The Subcommittee had the benefit of the testimony of the noted medical researcher Dr. John Arnold. Dr. Arnold, who conducted malaria research with prisoners as subjects for 27 years, is the author of proposed HEW regulations on the use of prisoners as subjects. He now advocates and uses free-world subjects as an alternative to prisoners as subjects. In 1974 he used 200 such subjects in both metabolic and drug studies. They are paid the local minimum wage and learn to negotiate their contracts with skill. Dr. Arnold testified that: "The prediction that alternate populations were not available has been wrong . . . We no longer need to propose that important programs be dismantled if we discontinue use of prison volunteers."

In addition, he suggested that the use of alternate populations would, in fact, be an improvement since their commitment to research is stronger, the quality of their consent is better, there are fewer problems with contraband drugs, the research staff is better, and the subjects are less dependent on the researcher which means that the option to withdraw is more realistic. He argued that it is easier to develop systems for followup and aftercare and compensation for these populations, and the research is more open to public scrutiny. Further, he estimated that changing to alternative populations will increase the cost of new drug development by only 1%, while improving the credibility of clinical research as well as its product.

My work as Chairman of the Subcommittee and my study of the testimony and literature of this issue firmly suggest to me that the public interest would be best served by termination of medical research with prisoners as subjects.

Certainly I cannot predict that Congress will support this persuasion, however, in a recent informal meeting the Subcommittee tentatively decided to move into markup on H.R. 3603, to consult with our colleagues who share jurisdiction on this issue, and to carefully follow the current work of the National Commission for the Protection of Human Subjects. I believe that the Subcommittee is disposed toward positive action on this legislation, at least in the form of a moratorium.

Pending such action by the Committee and Congress, I would like to suggest that the Bureau review its continuing commitment to the use of prisoners as subjects for medical research. Apparently you have begun this proceess, and I note that Mr. Kitchener, your research director, has commented publicly on the

informed consent problem, stating that he believes prisoners are not free agents and are subject to exploitation.

I would suggest that this re-examination process be expanded and include the possibility of withdrawal of federal prisoners from HEW research at Lexington. The issues of corrections are so fundamental and so perplexing I would hope that we could move swiftly in a progressive direction in those areas in which there is a clear positive option.

I look forward to receipt of the Department's official views on this legislation and would be happy to hear your thoughts on the future of Federal prisoner participation in the Lexington research.

Sincerely yours,

U.S. DEPARTMENT OF JUSTICE,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice.

U.S. DEPARTMENT OF JUSTICE,
BUREAU OF PRISONS,
Washington, D.C., March 1, 1976.

HON. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties and the Administration of Justice, Committee on the Judiciary, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: This is in further reference to my letter to you of November 21, 1975, wherein I indicated that I was asking some of my staff to fully evaluate the use of federal prisoners in the Health, Education and Welfare research at the Addiction Research Center in Lexington, Kentucky.

The research at the ARC is the only medical research program in existence utilizing federal prisoners. During the past five years we have gradually phased out of all other medical experimentation which utilized federal prisoners.

As was indicated in my November 21 letter, I appointed a task force to review the use of federal prisoners in the ARC program. It was the conclusion of that group and of the executive staff that reviewed their report, that continued use of federal prisoners in any medical experimentation should not be permitted. Based on that determination, I have contacted the responsible officials in the National Institute of Drug Abuse and advised that we would discontinue sending federal prisoners to the ARC as soon as replacement civilian volunteers could be recruited. They have indicated that the process of identifying and recruiting volunteers would begin immediately. It is our expectation that this process would be concluded no later than the end of 1976. I agreed to this phase-out schedule because of the significant research that has resulted in the past from this program and also to permit the researchers to continue with the programs they have already initiated at that facility.

If I can provide any further information, please do not hesitate to contact me.

Sincerely,

NORMAN A. CARLSON,
Director.

DEPARTMENT OF THE ARMY,
Washington, D.C., February 3, 1976.

HON. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties and the Administration of Justice, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your request to the Secretary of Defense for the views of the Department of Defense on H.R. 3603, 94th Congress, a bill "To Limit Use of Prison Inmates in Medical Research."

The basic purpose of H.R. 3603 is to limit use of prison inmates in medical research.

We are opposed to H.R. 3603 because we believe it would impede medical research to an extent greater than is necessary to safeguard the rights and physical well-being of potential subjects. The prohibitions established by this bill would apply regardless of the quality of free and truly voluntary in-

formed consent which might be involved, and regardless of whether or not the proposed medical practice was of immediate potential benefit to the prisoner. For example, it would apply where a particular drug, device, or other medical procedure had been proven safe and only its effectiveness remained to be established.

The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, established in Part A of Title II of Public Law 93–348, is specifically charged with the responsibility of identifying the requirements for informed consent to participation in biomedical and behavorial research by children, prisoners, and the institutionalized mentally infirm, and with developing and recommending to the Congress such additional legislation as might be necessary to insure the attainment of these objectives. This bill would pre-empt the assigned responsibility of this Commission, and prevent an orderly and meritorious evaluation of this problem. Accordingly, we recommend that no action be taken on H.R. 3603 or similar legislation until the Commission's work has been completed.

The fiscal implications of this bill are not known, but it is anticipated that it would result in some additional cost to the Department of Defense for duplication and/or replacement of some existing facilities.

The DOD is currently supporting medical research in prisoners as volunteer subjects at only one site, the Maryland House of Correction, Jessup, Maryland. This research is being performed by the University of Maryland with support from three contracts with the U.S. Army Medical Research and Development command. The contracts are as follows:

Contract No.	Title	Principal investigator
1. DA-49-193-MD-2740	Studies on human malaria (antimalarial drug testing)	David F. Clyde, M.D.
2. DADA 17-67-C-7057	Study of shigella vaccines in man	Richard B. Hornick, M.D.
3. DA-49-193-MD-2867	Pathogenesis detection, prevention, and treatment of infectious diseases of military importance.	Do.

The DOD is conducting no experimental medical research using military prisoners.

Sincerely,

MARTIN R. HOFFMANN,
Secretary of the Army.

UNIVERSITY OF MARYLAND, SCHOOL OF MEDICINE,
DIVISION OF INFECTIOUS DISEASES,
Baltimore, Md., October 17, 1975.

Chairman ROBERT N. KASTENMEIER,
Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Suite 2137, Rayburn House Office Building, Washington, D.C.

DEAR MR. KASTENMEIER: This letter is in reference to the bill (HR 3603) introduced by Mr. Parren Mitchell and others, hearings on which were recently begun by your subcommittee. This bill, as you know, would prohibit the use of prisoners as subjects in medical research.

I write to you in my capacity as assistant to the director of the medical research program at the Maryland House of Correction, Jessup, Maryland. This program, which has existed since 1958, has apparently been one of a number of items presented to your subcommittee in support of the contention that incarcerated individuals cannot grant truly informed consent.

Our knowledge of your hearings has been confined to that reported by various news media. We gather, however, that Mr. Gary Sabatini, an ex-inmate and volunteer, made several allegations against our program and in support of Mr. Mitchell's bill. As you may be aware, Mr. Sabatini is one of several named plaintiffs in a suit brought to end medical research at the House of Correction. From the very beginning, we have welcomed the institution of this suit, as we have every desire to protect the rights of prisoners. In particular, we are most anxious to have a legal precedent set concerning an inmate's right to volunteer and to give informed consent.

We are most reluctant, however, to see the issues be tried in the newspapers or to be presented to your subcommittee in a fashion that could be misleading or at least not representative of all sides concerned.

In this context, I am enclosing a letter recently written by a participant on our research program, and have taken the liberty of enclosing copies for the other members of your subcommittee. We know that it will receive your thoughtful consideration.

Sincerely yours,

WILLIAM E. WOODWARD, M.D.,
Assistant Professor of Medicine,
Assistant Director, Medical Research,
Division of Infectious Diseases.

Enclosure.

JESSUP, MD.

DEAR SIR: I take this opportunity to write in connection with the hearings that are being held concerning infectious disease studies in this country; I ask that you consider what I have to say prior to making any decision which might cause such research to be discontinued.

I am presently confined at the Maryland House of Correction at Jessup, Maryland and have, during the recent months, participated in several studies of this nature. Each time it was a totally voluntary action on my part; contrary to allegations made by several persons within this institution, no one, to my knowledge, has ever been in any way coerced into taking part in any study at this institution. The program here is administered by The University of Maryland and it is one of the few things at the institution that functions smoothly and efficiently. I suggest that to abolish it would be a mistake. I do not attempt to deal with that particular aspect of the program in this letter as I trust that the courts will have an opportunity to decide that issue. My only hope is that an effort will be made to ascertain *all* of the facts before any action is taken; and that "sensationalism" and politics not be allowed to destroy what I see as being a most beneficial program to my fellow human beings.

Are you gentlemen aware of any statistics in connection with this issue? Are you aware of the number of deaths that are caused each year by such things as malaria, cholera and typhoid? Are you also aware that it has been determined that the present so called "remedies" and preventive vaccines for these diseases are virtually useless? If any among you has had the misfortune of coming into contact with any of them under uncontrolled conditions, you may realize that there is a definite need for something better. The term *controlled conditions* may well be the important factor of this whole issue. I have never reached the point of being seriously ill during any study, nor have I ever been concerned that I might be allowed to become that way. As I have said already, those who are assigned to look after me are very thorough and efficient. Such is not always the case with the children in India, Africa and far too often in this country also. They don't always have someone readily available to check on them every hour or so, the proper medication is not always available at the right time and when it is, it is frequently ineffective! As a result, those children die. There are those of us who care about such things and speaking for myself and I am certain others here, the issue is more than a political football.

I gain little or nothing from this program. The majority of what is provided for payment to those who participate ends up in the pockets of our keepers here at this institution. I lose five (5) extra good days for each month that I am involved in a study due to the fact that I am not assigned to a regular institutional job. I eat the same as everyone else here and I must give up my yard and recreation privileges. Even my library privileges are restricted; yet I continue to participate and will do so as long as the program continues because I believe it will be worthwhile. If my being a little uncomfortable for two or three days will serve to prevent just one child from dying, I will gladly do just that on a regular basis for the rest of my life and ask nothing in return other than the knowledge that I have done so.

I feel a sense of worth in doing this and I ask that you not deny me that . . . but I ask too that you consider those who have in the past benefited from such research as well as those who will, without doubt, benefit from it in the future . . . unless it is destroyed by those who oppose it for reasons that are, at best, of very questionable merit.

If you require any additional information in connection with this program, I will be most willing to provide it if I am able to. In the event that I am not, I am most certain that there are those who can and will if given the opportunity to do so. I have discussed this matter with a number of persons here and feel that there is ample support for this program; we wish to have it continued. I realize that there are those who have levied certain charges against its administrators; these are self serving individuals who seek to better their own situations by distorting the facts and I ask that you consider the allegations made by those persons with an open mind and an objective eye. I gain nothing by writing this letter, nothing that is except the knowledge that I might be in some way instrumental in saving this program and, as a direct result of that, the world might be a little less painful for someone. I say again that to abolish this would be a senseless and totally unnecesary mistake, as well as a tragic one for those who might die from these diseases in the future.

Sincerely Yours,

RUSSELL E. TODD, Jr.

UNIVERSITY OF MARYLAND, SCHOOL OF MEDICINE,
DIVISION OF INFECTIOUS DISEASES,
Baltimore, Md., November 20, 1975.

Chairman ROBERT N. KASTENMEIER,
Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Suite 2137, Rayburn House Office Building, Washington, D.C.

DEAR MR. KASTENMEIER: This letter is a supplement to my last of October 17, 1975, regarding HR 3603, a bill designed to end medical research in U.S. prisons.

TodayI enclose a copy of a petition independently written and signed by 96 inmates at the Maryland House of Correction, Jessup, Maryland. As you will note, this petition takes the position recently endorsed by volunteer participants at Jackson State Prison, which was detailed in the Washington Post on November 16, 1975 (copy enclosed).

We concur strongly with the sentiments expressed in the petition and feel that such volunteers should be represented by us, or others, should your subcommittee conduct additional hearings on the matter.

Enclosure.

Sincerely,

WILLIAM E. WOODWARD, M.D.,
Assistant Professor of Medicine,
Division of Infectious Diseases.

Enclosures.

MARYLAND HOUSE OF CORRECTION,
Jessup, Md.

Re: Infectious Disease Area, Maryland House of Correction.

TO WHOM IT MAY CONCERN: At the present time there are approximately three hundred (300) men at this institution (Pop. over 1600) enrolled in the studies conducted by the University of Maryland. Up until now all of the publicity and even legal proceedings have been instituted by a very small minority. We believe that the rest of us, (the Majority) have the same right to be heard, as the eventual outcome will affect all of us. There are some people, who given the opportunity, will abuse anything for personal gain or advancement. The following are a few facts that those of us who have participated can attest to:

(1) No one has ever been coerced or pressured into participating in a study. Everything is strictly on a volunteer basis.
(2) A Staff Physician visits each and every day.
(3) A Nurse is on duty 24 hours daily.
(4) All studies are closely controlled.
(5) A Laboratory whose equipment cost nearly a half million dollars is located in the area. Blood and Urine samples can be analyzed in minutes.
(6) The quality of Medical Care is the best in the Institution.
(7) All studies are conducted by experienced, dedicated men, whose only aim is the upgrading of medical care and drugs available to our people.

Drugs are by far the most effective weapons in the Treatment of Patients. Imagine life today without polio vaccine, digitalis, insulin, anesthetics and all the other drugs that keep us alive and free of pain. Today, few valuable new drugs are being discovered in the U.S. mainly because few experiments are being done to discover them. There are two phases in drug discovery. One is

pre-clinical—Pharmacology, chemistry, toxicology and other types of non-human research. The other however, the clinical phase, is the critical one. Every hypothesis or observation made pre-clinically *must be tested in humans.* This involves some slight risk. However, everything we do in living our lives today involves some risk, and most of us add to that from time to time. The fact is that human experimentation under *controlled conditions* carries with it no greater risk than we take every day in our travels, our work, etc.

The amount of physical and mental suffering that exists today, despite all our modern therapy, is vast. In scientific, social, and moral terms, it is certainly acceptable and even desirable for some of us to take risks to diminish this vast amount of suffering and even death not only here but around the world.

Less than 8% of the men here participate in these studies. Those that do, believe that it is a vital contribution to society and we should be given the right to determine if we want these studies here or not. (No test could be run without participants).

WE BELIEVE that the few facilities left, who are engaged in this type of research are desperately needed and should be jealously safeguarded. Further we demand the right to participate in this type of research, the voices of a few malcontents not withstanding.

PAUL W. SPENCER, 110083.
(and 95 others)

UNIVERSITY OF MARYLAND, SCHOOL OF MEDICINE,
DIVISION OF INFECTIOUS DISEASES,
Baltimore, Md., November 21, 1975.

Chairman ROBERT W. KASTENMEIER,
Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Suite 2137, Rayburn House Office Building, Washington, D.C.

DEAR MR. KASTENMEIER: Enclosed is a statement that I would have presented if I would have had the opportunity to speak to your subcommittee dealing with HR 3603. I hope that this statement will adequately summarize my position regarding this bill.

I think this will be an unnecessarily restrictive law and should not be given favorable approval by your subcommittee. Thank you very much.

Sincerely yours,

RICHARD B. HORNICK, M.D.,
Professor and Director,
Division of Infectious Diseases.

Enclosures.

REMARKS OF RICHARD HORNICK, M.D.

My name is Dr. Richard Hornick and I am a Professor of Medicine at the University of Maryland School of Medicine. I have been the Director of the Division of Infectious Diseases in the Department of Medicine for the past 12 years. Since 1959 I have been in charge of a unique research unit at the Maryland House of Correction at Jessup. During this period it has been my privilege and that of my colleagues to have had the opportunity to work with inmate volunteers participating in our studies. In the course of the past seventeen years over 3500 men have freely elected to take part in our studies. What follows is an overview of this work which I hope will give you a perspective regarding medical experimentation in prisons.

Briefly, the research conducted at the Maryland House of Correction involves the evaluation of vaccines and certain drugs to prevent infectious diseases that represent international and nationwide medical problems. Thus, we have worked in three areas of infectious disease research: first—upper respiratory viral infections. It is not necessary to relate to you the vast sums of money spent in this country solely for medications for the symptomatic relief of the "common cold" and flu. When the money lost due to time spent away from work as a result of these illnesses is added on, the total financial burden is about five billion dollars. A preventive vaccine or curative drug is needed to reduce the morbidity associated with these viral infections. In the last few years significant advances have been achieved towards an effective vaccine for influenza and some of the viruses that cause the common cold. Such a vaccine will be administered as nose drops. The final phases of testing of one such flu vaccine are now underway. It

is important to point out that willing volunteers at the House of Correction were some of the first humans to receive this new and novel effective vaccine. The volunteers at Jessup were important for the evaluation of this vaccine because they could be kept under close supervision for a period of many weeks to learn from them the biological activities of the vaccine: did it produce immunity to influenza, how long did the virus persist in the nose, did the vaccine cause any illness, did the vaccine virus spread to other non-vaccinated volunteers. etc.

The second type of investigation conducted in his program involves diarrheal diseases. The World Health Organizaton estimates that as many as 70 million people on any day suffer from diarrhea and this disease is the leading cause of infant death in the late developing countries. Much still needs to be learned about the multiple agents causing this type of disease. These data would allow for means of control to be developed. In the volunteer unit several forms of infections that cause disease in the intestine have been studied. Information gained from these studies has had far reaching public health importance; for instance, they demonstrated the lack of effectiveness of currently available typhoid and cholera vaccines in use since the turn of the century. This information plus new knowledge gained from the volunteer studies on the means by which these diseases are acquired has been responsible in part for changes in federal quarantine laws and for the elimination of required cholera vaccine for travelers to many parts of the world. Furthermore, these results have led to the development of vaccines to be given by mouth to prevent the causative bacteria from penetrating the lining of the gut. This means of protection would effectively prevent disease. In the past few years such oral vaccines have been evaluated in willing volunteers at Jessup and these new vaccines have produced exciting results: protection has been achieved that is superior to any former vaccine. Thus, for both cholera and typhoid, for the first time, new oral vaccines will be soon available for world wide use. The role of inmate volunteers in these studies has been paramount. To conduct these studies requires many weeks of daily observations and close followup that is readily obtained in a prison population. As with the respiratory viral vaccines, careful followup of the volunteers is needed to determine that the vaccine is harmless for the recipient. An interval of at least six weeks is needed following vaccine administration before the second phase of evaluation occurs, that is to test whether the vaccine will in fact prevent the disease. This evaluation will consume at least six additional weeks. Thus, from start to finish at least 4 months are needed to evaluate such a vaccine. A stable population is needed for this type of study. Each of the diarrheal diseases that are studied are caused by bacteria that can be effectively treated with antibiotics, a necessary control to allow these studies to be conducted. This insures the health of the volunteer. There have been no permanent adverse effects as a result of these studies.

The third major area of infectious disease research also involves a disease of major world wide significance—malaria. This infection, after the common cold, is the most common infectious disease in the world. It has played a very important role in the history of many areas of the world because it has impeded development of the country. There has never been a vaccine for malaria. Those who have served in the Armed Forces in malarial regions recall the various drugs that were given to prevent or to treat malaria. In the late fifties and early sixties, it became evident that malarial parasites had become resistant to many of these drugs. A search was begun to find new, more effective drugs and to attempt to create a vaccine. Both of these aims have been partially fulfilled, thanks again to willing inmate volunteers at Jessup and elsewhere in this country. For the first time a vaccine has been shown to be effective in the prevention of malaria; this work having been performed at Jessup. Further development is now going on. To study vaccines or drugs for malaria requires prolonged blocks of time, similar to the commitment described above, and including time for careful medical followup. These type of studies thus can be best carried out in an institution such as the House Correction.

One other area of investigation has been a small part of o r program at Jessup. This involves the evaluation of drugs for the FDA. As you know, there has been considerable controversy in recent years regarding the prescribing of generic versus brand name drugs. The use of generic drugs does involve monetary savings to the purchaser of the product. However, it has been claimed by certain pharmaceutical manufacturers that generic drugs are not as reliable as the brand name drugs. The FDA has the expanding responsibility to ascertain that generic drugs indeed are equivalent to the brand drugs. In order for the FDA to make such a certification, these drugs (each is a common one prescribed by physicians) must be given to volunteers and tested to determine that equivalent blood

levels and drug excretion occur as are obtained with the standard brand name drug. The U.S. Congress has stated that generic drugs will be used for federally supported medical programs. Much work remains to certify that generic drugs are equivalent and this type of bioavailability study has to be expanded to obtain the necessary human data. Willing prison volunteers are a valuable part of the population needed to conduct such studies.

Our experience with over 3500 inmate volunteers in the past seventeen years has been enlightening. These men have taught us a great deal about social consciousness and awareness. Prisoner volunteers also gain a great deal from participating in medical experimentation. One carefully controlled study demonstrated that inmates gained an increase in self esteem and self concept and of great interest, diminished aggression. (1) These benefits are not apparent to a casual observer but are the type of factual data needed to assess whether prisoners should have a right to participate in medical studies. The motivation on the part of inmates to volunteer involves many factors many of which are identical to those that motivate nonprisoners to volunteer. It is abundantly clear to us that inmates have a choice, they can or cannot volunteer. Obviously, only a fraction of the men at Jessup over the years have decided to be in our program. Those that have, have demonstrated their confidence in the program by participating in more than one study; the average number of studies the 3500 men have taken part in has been about three. There have been a few men that have volunteered for more than 30 studies during the seventeen year period of this program. Inmates who may wish to participate will initiate a request form which is forwarded to the Warden's office for security clearance and proof of legal age. These forms are then forwarded to our personnel who will then notify the men with completed forms when a study is in the first phases of organization. The potential volunteer is informed of the study and asked if he is interested in participating. A medical history and physical exam are performed and depending upon the nature of the study, various blood tests, an electrocardiogram and certain x-ray studies are carried out. Those individuals who are medically acceptable are certified for the studies. It is important to point out that many men are rejected because of abnormalities in their blood tests and occasionally for more serious medical problems not recognized previously. Such persons are referred directly to the prison hospital when indicated. Those volunteers who are medically fit are again informed of the nature of the study. Before any inmate participates in a study he signs a consent form attesting to the fact he has been instructed about the investigation and has voluntarily agreed to participate. All efforts have been made to provide adequate medical facilities to support the research program. At Jessup we have a 33 bed hospital unit staffed by our own male nurses and medical students. At least one physician visits the patients every day. No prisoner has ever been informed nor has it been implied that his participation will assist in obtaining parole, in fact, no record is made in his personnel file that he participated as a volunteer. They are advised that they will be paid two dollars a day, a fee established in 1959 and continued since then.

Research involving humans, whether these be children, the mentally retarded, prisoners or patients in hospitals, has come under increasing controls since World War II. Many important advances in medical knowledge had been gained prior to World War II employing volunteers but no formal guidelines were followed in the conduct of these studies. The atrocities perpetrated in German prisoner of war camps in the war period are the ultimate in desecration of the concept of voluntary consent for medical experimentation. As a result of these crimes against humanity, the jurists at the Nuremberg post war trials established a code of ethics to cover human experimentation. We have scrupulously and consistently followed these guideline. This code stipulates that the voluntary consent of the human subject is absolutely essential.

Additional guidelines for human experimentation were promulgated in the sixties by the World Health Organization. Since their publication we have carefully followed these guidelines. Subsequently, the NIH required all universities to establish peer groups which are charged with the responsibility of examining and approving or disapproving research protocols involving humans. This committee will totally prohibit a study or make modifications in the proposed study to insure the safety of the participants as well as approve studies that are well designed. None of our research is undertaken without the advance approval of a peer review committee. We take pride in the knowledge that our group was utilizing a similar review mechanism prior to the federal requirement and that input from our Department Chairman, Dr. Theodore E. Woodward, was partially responsible for the establishment of national peer review committees.

These guidelines and controls have been effective and workable. Newer modifications are under consideration by the federal government and they contain provisos for prisoner participation. The NIH recognizes that prisoner populations are important parts of the research effort in this country. It is for that purpose that the new guidelines have been proposed. We welcome these and think they would contribute to the continued fine record of medical advancements obtained from prison research. The one significant proposed control involves a review committee consisting of inmates and prison personnel. In addition, it has been suggested that there be a small group, the consent committee, that insures that prisoners are informed of the nature of the planned medical experiment. These proposed regulations are positive steps, designed to protect prisoners but yet maintain their rights as individuals to contribute to medical science. They should not be deprived of this right, just as any other concerned person should not be similarly denied.

The requirement that voluntary consent be given before a human subject participates in medical experimentation has been interpreted by some to mean that prisoners are not in such a state of mind as to give a free consent. In our experience, the prisoner is most certainly able to make a free choice. There is no coercion. In addition, he is well aware that he is free to withdraw from any study at any time without recriminations. Recent psychological and sociological studies have indicated that as a group inmates are quite representative of the population at large in terms of the results of psychological and intelligence tests.[1] When one works with them on a daily basis during a medical research investigation, he becomes impressed with the sophistication of many of the men. They are wise to the ways of the world and are constantly looking out for ways to help themselves. They are able to decide whether they will volunteer again for additional studies; as stated, the majority of them do so.

The issue of whether any person in any institution can freely volunteer for a medical study needs to be resolved. We would prefer to have this decision based on the summation of solid facts relating to the positive and negative physical, psychological and sociological aspects of prisoner participation. To date the published studies bearing on this important issue have demonstrated only the positive benefits. Hearsay and emotional uninformed arguments do not substitute for factual data. Until valid studies demonstrate adverse effects on prisoners participating in medical research and it appears that these will not be forthcoming, we would urge this subcommittee to weigh the accumulated evidence supportive of such research and vote an unfavorable report on bill HR 3603.

CENTER FOR BIOETHICS, CENTER FOR POPULATION RESEARCH, LABORATORIES FOR REPRODUCTIVE BIOLOGY

THE JOSEPH AND ROSE KENNEDY INSTITUTE
FOR THE STUDY OF HUMAN REPRODUCTION AND BIOETHICS,
Washington, D.C., October 9, 1975.

Representative ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, House of Representatives, Washington, D.C.

DEAR REPRESENTATIVE KASTENMEIER: Enclosed please find my written comments on H.R. 3603. Should there be any questions, please contact either me or my secretary, Adela Betancourt, at (202) 625-2371.

Sincerely yours,

ANDRÉ E. HELLEGERS, M.D., *Director.*

Enclosure.

STATEMENT BY ANDRÉ E. HELLEGERS, M.D., DIRECTOR OF THE JOSEPH AND ROSE KENNEDY INSTITUTE FOR THE STUDY OF HUMAN REPRODUCTION AND BIOETHICS, GEORGETOWN UNIVERSITY, WASHINGTON, D.C.

In Re: H.R. 3603

Mr. Chairman and Members of the Committee: In response to your request I am delighted to present testimony on H.R. 3603. My name is André E. Hellegers, and I am Professor of Obstetrics-Gynecology and of Physiology-Biophysics at Georgetown University, where I am the Director of the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics. For purposes of this testimony, I suppose I ought to add that I have never been a prisoner, nor have I ever owned any interest in the drug industry or permitted any procedure or test on any prisoner.

[1] Pharmacological Testing in a Correctional Institution: Volunteer Characteristics and Motivations Social, Psychological and Attitudinal Implications. S. H. Wells, P. M. Kennedy, J. Kenny, M. Reznikoff, and M. H. Sheard. Charles C. Thomas, publishers, 1975.

My own interest in the bill is twofold: it is in the medical and in the ethical. It is in the medical because I think it is indisputable that prison populations are a majority of the research subjects on whom primary drug testing is done in the U.S. Since drugs developed in the United States constitute the greatest pharmacological technology used to combat disease, the subject is of obvious importance to the world of medicine as a whole. In brief, on the one hand, one should not lightly or arbitrarily abolish medical research in prisons. On the other hand, the importance of the ends does not confer a blanket toleration of the use of any and all means, and obviously research on prisoners should be stopped if no ethical method of obtaining their free and informed consent can be devised.

Let me then briefly sketch some of the issues and questions which arise in this context.

Obviously, from the *technical* point of view, drug testing in prisons is ideal. The population tested remains intact; one minimizes the scientific complications arising if part of a tested group does not turn up for a scheduled visit. Close medical supervision is possible, allowing greater safety of testing. One's clinical trial population will not include pregnant women with all dangers attached to fetal damage by drugs. One can establish a semi-permanent testing facility of high technical quality in one location, instead of working with "roving laboratories." And, obviously also, with such absence of transportation problems, research costs are reduced. In view of the importance of American drug testing for world health, these advantages should not be taken lightly.

The opposition to clinical trials, and medical research in prisons, holds that the situation of prisoners is inherently so unfree that either individually, or corporately, prisoners cannot be considered able to provide free and informed consent to incorporation in a medical study. Really, the issue is *free* consent, rather than *informed* consent, since prisoners are clearly capable of being informed. If they were not so, they could not have been held accountable for the crimes which landed them in prison. They were obviously held legally accountable for their acts. The issue, then, is *free* consent.

Major arguments against the ability of prisoners to give free consent are several. They include the inherently unfree situation of prisons, the possibility that not joining in the trial may affect parole eligibility, higher earning ability by joining the program than is otherwise available in prisons, greater comfort, less boredom—in sum, a series of inducements which approximate a systematized form of bribery. I believe most or all of these problems can, at least in theory, be corrected. Scales of compensation can be altered. Methods can be devised to remove the occurrence of volunteering from parole records.

Testing facilities can even be made less comfortable. In the final analysis, these are but practical details which can be corrected by regulation. The only key question, as I see it, is whether free consent is *inherently* impossible in prisons.

Those not, *a priori*, opposed to incorporating prisoners in clinical trials use other arguments. They would assert that it is not part of our penal system to remove the ability to do good from individuals. Those of more religious bent would even hold that prisoners might properly wish to be offered the opportunity to make repairs to society for the harm they may have caused it. They would point to the life story of Nathan Leopold to show that consent can, indeed, be free in prisons.

It is not my purpose in this testimony to join the ranks of either group of protagonists in the debate. Rather, it is to assert that this bill comes before the House in the absence of empirical data to show which of the positions held *a priori* is ethically correct. Given the importance of the subject to medicine, to industry, and to the ethical treatment of prisoners, one can only wonder why the ethics of this activity has never been empirically tested. Yet I believe this can be done.

It *can* be scientifically tested whether parole boards have been influenced by prisoners volunteering for drug testing, and similar activities. It *can* be tested among *former* prisoners, now *free*, whether their consent to become subjects for testing was truly *free* when they were *prisoners*. Such studies can be performed

with *former* prisoners and *former* parole board members, so that no fear need exist that their *present* opinions are held unfreely. I am quite certain that proponents, and opponents, of medical research in prisons can both bring witnesses before the Committee to give individual opinions on the matter.

It does not resolve the old question of whether such individual testimony is representative of the experience of all, of a majority, or of a single individual. What should have been done long ago, given the magnitude and importance of these activities in prisons, is to do the studies which would have given this committee the empirical data on which to base a judgment. That this was not done shows, in my opinion, a lack of ethical sensitivity or a lack of common sense on the part of organized medicine, of drug industries and of the prison systems. I enclose a copy of a column I wrote for a Physicians' News Service in *Ob.-Gyn. News* on this subject.

The issue of free and informed consent in medical research is so obviously central to the ethics of that research that one can only stand perplexed at the paucity of empirical and theoretical studies in this field. In fact, however, one should not be perlexed. Neither government, nor medicine, has in the past, or even clearly in the present, determined where the locus for such responsibility lies in this country. Such negligence leads to what will now obviously become an emotional debate for this committee. Had all parties concerned done their homework, the debate would have been unnecessary and the facts clear. My testimony, therefore, Mr. Chairman, is a plea for common sense rather than emotion. It is a plea for the gathering of empirical data in this and other bioethical fields.

Dispute Over Prisoner Testing

Dr. Hellegers is with the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics and the department of obstetrics and gynecology, Georgetown University.

Recently a group of lawyers, students, and other self-proclaimed protectors of prisoners, took the University of Maryland's School of Medicine to task for using prisoners in clinical trials of vaccines.

Of course, the University of Maryland is not the only institution engaged in such research.

Why the fuss? It is generally agreed that informed and free consent is a prerequisite for involving another person in a clinical trial. So the first question is whether prisoners can give informed consent. I see little reason to question this. After all, if the prisoner were insane or a minor, he would not be in prison in the first place.

So the issue is rather, whether he can give free consent. Therein lies the rub. Before attempting to answer that question, we should perhaps ask why one would use prisoners in clinical trials at all. The answer is fairly simple and comprises four good reasons:

1. There is ready access to prisoners. One knows where to find them, and they are usually bored and have little else to do. They are therefore easier to enroll in a clinical trial than people who are busy with all sorts of other things.

2. In any clinical trial, one likes to keep one's experimental and control groups intact and prison inmates are more likely to be traceable and to stay put than are highly mobile nonincarcerated persons.

3. Clinical trials can be quite costly if one has to recompense individuals for the transportation to the site of the trial, or baby-sitters to take care of their children, and for loss of income while participating in the trial.

Prisoners are not likely to make much more than a dollar a day and are therefore easily compensated (not to say bribed, and we shall return to that topic).

4. Last but by no means least, clinical trials are probably more safely done on prisoners than on any other group. One can bring the clinical facility to the trial anticipant, rather than vice versa. Therefore, much closer medical supervision is possible in prison than outside.

For these reasons, I think it is safe to say that perhaps a greater technical medical sense is made by the use of prisoners than of outsiders. However, that is obviously not the sole issue in the debates on the problem. The question is raised: Can the prisoner give *free* consent?

Here opinions differ, but data on which to base an intelligent opinion are pitifully few. Those doing the trials insist the prisoners are glad to join in. Opponents imply that prisoners are tacitly coerced.

Some general considerations must be brought forward before we attempt a conclusion. By international agreement, no prisoner of war may be incorporated in clinical trials or experiments. An international attempt was made to exclude civilian prisoners. It failed—largely, it is said, because of American opposition.

The allegation is made that the prisoner's situation is inherently so unfree that he cannot possibly give free consent. He may be too easily bribed since his earnings are abnormally meager.

Similar arguments could be made about those on welfare, or the use of ward rather than private and semiprivate patients.

Parole Incentive?

Since the major concern of prisoners is to get out, it is also alleged that they will "volunteer" so the parole board may release them earlier.

Of course, in theory and perhaps even in practice, such potential abuses (if that's what they are) could be obviated by committees of overview, by restricting payment to ensure true humanitarian volunteering, or by omitting all information from parole board records.

However, other people would argue quite differently. They would hold that restricting an individual in prison should not include depriving him of his rights to contribute to the welfare of mankind. Indeed, more religiously oriented commentators may hold that prisoners may wish to make reparation to mankind for the crimes they committed against it. Whether consent based on guilt feelings is free can also be debated, of course—in prisoners and others.

What bothers me is the paucity of empirical data with which sense could be made of the entire subject. All information tends to be anecdotal—a TV interview with inmates or with physicians conducting the trial, or with the prisoner protection groups.

Studies Needed

Surely, well-designed studies could be done to determine whether consent-givers acted freely. Ex-prisoners who took part could be interviewed.

Perhaps "volunteers" in prisons could be tested with polygraphs, if the data procured this way even came close to providing accurate information.

Perhaps parole boards could be studied to see if they take volunteering into account at all—and, if so, why.

Perhaps omission of payment could be tried, to see if volunteering would continue, and the same could be done if parole boards were not to be given information on participation or nonparticipation.

To argue the ethical issues in a void makes for an interesting cocktail conversation. It does little to resolve a medically and humanly very important issue.

Perhaps a drug company engaged in such trials would put its funds where its convictions lie and give us the answers.

Until then, emotion is likely to be the master over common sense.

Children's Defense Fund
of the Washington Research Project, Inc.,
Washington, D.C., October 9, 1975.

Representative Robert W. Kastenmeier,
Chairman, Subcommittee on Courts, Civil Liberties, and to the Administration of Justice, Committee on the Judiciary, House of Representatives, Washington, D.C.

Dear Mr. Chairman: Thank you very much for your letter of September 23 asking me to submit written comments on H.R. 3603, a bill to prohibit medical experimentation on prisoners.

The bill would end one of the primary sources of unethical, if not illegal medical research by prohibiting the use of federal prisoners as human subjects. Its inclusion of juvenile offenders is particularly important since incarcerated children are doubly vulnerable. As with all prisoners, they can not be recruited as research subjects except under inherently coercive circumstances. At the same time, as minors they can not legally give informed consent.

I am concerned, however, that H.R. 3603 as introduced on February 24, 1975 fails to distinguish between medical experimentation and medical treatment in that "medical research" is defined so broadly as to deny medical treatment

which, while experimental, is undertaken primarily for the benefit of an individual, ill prisoner. Thus, H.R. 3603 defines medical research as:

"Research, experimentation or testing which . . . is conducted to determine the safety or effectiveness of any drug, medical device, or medical practice."

"Medical practice" is defined as

"Any practice, procedure or technique which is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any disease or other health problem . . ."

This definition would, as drafted, prohibit any medical procedure which, while experimental, is designed solely to diagnose or treat an individual, sick prisoner. To take an obvious example, the above language would prohibit the use of experimental chemotherapy by an individual physician to save the life of a prisoner dying of cancer.

I would therefore suggest that the definition of "medical research" be redrafted so that it does not include medical procedures which are performed for the specific purpose of diagnosing or treating an illness or disease in an individual patient, which, if successful, would be reasonably expected to result in a diagnosis or substantially alleviate that patient's condition.

I appreciate the opportunity to comment on this legislation. Please let me know if I can be of any further help.

Sincerely,

WILLIAM C. SMITH,
Project Director,
Medical Experimentation Study.

JOHN O. NESTOR, M.D.,
Arlington, Va., October 29, 1975.

Chairman ROBERT KASTENMEIER:
U.S. House of Representatives,
Washington, D.C.

DEAR CHAIRMAN KASTENMEIER: As a pediatric cardiologist and a medical officer at the FDA for more than 14 years, I am taking the liberty of commenting on the enclosed copy of an article from U.S. Medicine reporting on testimony before your Subcommittee concerning the use of prisoners as subjects for research with new drugs.

Our State prisons have become factories for testing new drugs. It has been estimated that ¾ of Phase I testing is currently being conducted in prisons. It is also public knowledge that the general level of medical care and supervision in prisons is appallingly low. One example is furnished by the testimony of a prisoner from McAlester, Oklahoma before Senator Kennedy's Subcommittee in July 1975. This human subject became ill on a Friday but no medical care was available to him until the following Monday from any source.

Incidentally, the drug was Benurestat and there were several prisoners who suffered severe liver damage and one death. Certainly Mr. Joseph Stetler knows about this. He must also know of the activities of Doctors Stough and Long in Alabama and other southern States as exposed in the New York Times in July 1969. These men were responsible for a large number of cases of hepatitis including several deaths. For an intelligent man, Mr. Stetler displays an amazing ignorance of current affairs. Doctors Long and Stough cut a swath through five southern states. In fact, I believe Stough started at the infamous McAlester Prison and then moved south passing through several State prisons.

I agree that (or with) Norman Carlson that investigation of new drugs should not be performed in prisons because it is simply impossible to obtain fully informed voluntary consent in the prison atmosphere. I would *not* agree to allow the National Institutes of Health to conduct research in prisons. In my experience reviewing new drug applications the investigators at NIH have been the worst violators of procedures and protocols. They—and the FDA—seem to take the attitude that anything done by people at NIH is alright simply because they are at the NIH. They have been permitted to do things that outsiders are not permitted to do.

You have made a good start. Please don't let up.

Sincerely,

JOHN O. NESTOR, M.D.

INSTITUTE OF SOCIETY, ETHICS AND THE LIFE SCIENCES,
Hastings-on-Hudson, N.Y., October 23, 1975.

Hon. ROBERT W. KASTENMEIER,
U.S. House of Representatives,
Washington, D.C.

DEAR MR. KASTENMEIER: In response to your request for comments on the bill HR 3603 dealing with the limitation of the use of prison inmates in medical research, I have the following comments to offer.

I am deeply concerned and disturbed about reported abuses of prisoners in the name of medical research. Even if we concede that incarceration is a legitimate social option to deal with deviant behavior in a modern society, incarceration cannot carry with it the deprivation of all civil and human rights. A prisoner must both maintain the right to medical treatment and the right to freedom from abuse in the name of medical research. Thus, some action is duly called for at this point in history to stem the danger of such abuses.

I am not convinced, however, that HR 3603 is an adequate vehicle for that action, at least in its present form. First, the bill as I understand it will forbid research on any subject confined in any federal penal or correctional institution or confined under the authority of any act of congress. This apparently excludes not only research for the benefit of society, but potentially therapeutic research as well—that is research which might offer therapeutic advantage to the individual prisoner. Since I hold that the prisoner retains the same right to medical treatment as any other citizen, I must oppose any legislation that would forbid even experimental medical treatments which may plausibly be of therapeutic benefit to the individual. Thus, the bill ought to be amended so as clearly to permit potentially therapeutic research, of course with the safeguards of reasonably informed consent and review to which all medical research must be subject.

Second, I am concerned about the relationship of this bill with the ongoing work of the National Commission on the Protection of Human Subjects of biomedical and behavioral research. Since they are charged currently by Congress for the development of an overall policy involving protection of human subjects, it would appear wise for research on prisoners to be coordinated with that general investigation.

Third, I am not sure that the definitions contained in the bill are inclusive enough to eliminate some of the most dangerous and abusive medical research. For instance, research designed to observe the medical behavior of prisoners rather than to determine the safety or effectiveness of any drug, medical device or medical practice apparently would not be excluded. I have in mind studies which have taken place in the past, which have in my judgment been abusive, where institutionalized individuals are screened without consent for the clandestine use of drugs or other medically related issues. I think the bill must be reworded to conclude all research of a medical and behavioral nature not simply that outlined in Section (c)(II) of paragraph 4012, that is line 3 of page 3 of the draft of the bill as I have received it.

Fourth, I am concerned about the rights of prisoners to participate in research as well as to refrain from such participation. If we are really commited to the autonomy and dignity of the prisoner, it seems to me we cannot unilaterally decide that he is incapable of giving his consent to a behavior which he may find justifiable. Of course, protection of this right must be done in such a way that any attempt at coercive recruitment of prisoners will be eliminated. Thus I would favor the exclusion of any record of such participation in the prisoners' files which are sent to a parole board. I would not at this time favor a general prohibition on research in prisons on the grounds that it deprives the prisoner of dignity and rights which ought to be his. I would, however, think it appropriate that there be a temporary moratorium on prison research in any jurisdiction that does not have ample evidence of adequate safeguards to protect the prisoners' rights. This would seem to me to be a constructive incentive to develop systematic safeguards while at the same time it would not classify prisoners as a group of individuals who are not capable of being responsible for their own affairs.

Finally, I would like to endorse the new paragraph 955 which is an amendment to title 10 of the United States Code dealing with the use of military prisoners in medical research. I see no possible justification for non-therapeutic research on any military prisoner, although again there may have to be qualification pertaining to research potentially therapeutic to the individual military prisoner.

I thus think that the issue here is an extremely important one—one which deserves the attention of the United States Congress, but think that significant amendments would be necessary to make HR 3603 a workable bill.

Sincerely yours,

ROBERT M. VEATCH, Ph. D.

INSTITUTE OF SOCIETY, ETHICS AND THE LIFE SCIENCES

(Brief comment on H.R. 3603 by Peter Steinfels, Associate for the Humanities and co-editor, "Hastings Center Report")

I am in sympathy with the apparent intent of H.R. 3603—to protect the human rights and dignity of prisoners. There is little doubt in my mind that the safeguards meant to assure that medical research is conducted only upon informed and consenting subjects, and only when the risks have been scrupulously considered and justified, frequently do not operate in the prison setting.

However, the apparently sweeping prohibition of medical research on prisoners by H.R. 3603 raises several problems. All these problems also center on the rights of prisoners.

First, there is the problem that participation in medical research (*if* such participation could be regulated by a measure less sweeping than this) may indeed be the genuine desire of at least some prisoners, a means of acting altruistically, making reparation, or simply earning money. If total prohibition is the only way of preventing widespread abuses—and it is my opinion that currently there are widespread abuses—then I believe we must regretfully refuse these interested and willing prisoners this opportunity. But we should first satisfy ourselves that less broad measures will not be equally or nearly equally effective in preventing abuses.

The second problem is perhaps more serious. Medical research may be appropriate for certain disabilities peculiar to prisoners and prison settings. Without any mechanism for making exceptions to the general prohibition in H.R. 3603, such research could not be carried out on the logical subjects, thus hindering improvements in the lot of prisoners, the very class this bill is intended to protect. A similar problem exists, of course, in the cases of experimentation on children and the mentally disabled.

The third problem is one of definition, and could possibly be the most serious of all. It is not clear—as it should be—that this prohibition would not touch upon experimental procedures of therapeutic value to the subject himself or herself. The bill seems to be aimed solely at testing of drugs, devises, or practices of no therapeutic benefit to the subjects but rather of possible benefit to *others*. The definition of "medical research" in the bill could be tightened, or regulations carefully drafted by DHEW, to cover this problem; but since the basic conditions which make, for example, commercial drug testing in prisons a questionable enterprise also create difficulties for *therapeutic* experiments, I am afraid that a complete ban aimed at one type of experimentation might easily extend to the other. The effect, in that case, would be to deny prisoners therapeutic benefits which, however experimental, may be their best chance to overcome physical or psychological disabilities. Obviously a step like that, running counter to the general intent of this bill, should not be taken unless all other measures for preventing abuses had been exhausted, and even then only if it were unmistakably established that possible abuses outweighed the possible benefits which might be denied.

Finally, as a general observation, it seems to me that this bill short-circuits some of the work being done by the National Commission for the Protection of Human Subjects, and that the bill's sponsors or the Subcommittee on Courts, Civil Liberties, and the Administration of Justice might, on further reflection, prefer to await the outcome of the National Commission's deliberations.

I would not want any of the points I raise to lead to the conclusion that the issue addressed by H.R. 3603 is not a serious one. At the proper moment and in the most precise way possible, definite action must be taken to protect prisoners from unjustified, dangerous, and coercive medical research.

PETER STEINFELS.

WASHINGTON, D.C., *October 17, 1975.*

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil, Liberties and the Administration of Justice, Committee on the Judiciary, House of Representatives, Washington, D.C.

DEAR REPRESENTATIVE KASTENMEIER: Only recently did I become aware of H.R. 3603, a bill to limit the use of prisoners in research which is under consideration by your Committee. Having conducted and directed such researches from 1933–1944 I feel qualified to express a view on the subject—and perhaps one which has not been brought to your attention.

The prisoner with a longer history of addiction to narcotic drugs, who has a history of recidivism, and whose chances of relapse following release are 98%, constitutes an ideal subject for participation in studies designed to detect the presence (or absence) of addiction (dependence) liability in new analgesics under consideration for therapeutic use. In such studies, the prisoner is really a co-investigator since his views and reactions represent a level of expertise developed by years of personal experience, illicit though it may have been. Thus, as an expert collaborator he has served a most useful role in assessing the likelihood of addiction resulting from the bonafide use of pharmacologic agents under study.

His consent to participate in such research is enthusiastic and unequivocal. No coercion or duress is required. As a matter of fact, one doesn't need to seek volunteers, they seek you. And so far as informed consent is concerned, no research subject could be better informed on the subject of drug effects.

The importance of prerelease studies of the addiction liability of new analgesic drugs becomes obvious when one recalls the devastating and tragic consequences of the following errors:

Morphine was introduced as a non-addictive substitute for opium.

The hypodermic syringe was touted as a way to prevent addiction to morphine.

Heroin was claimed to be a non-addictive substitute for morphine.

The testing program started in 1933 prevented similar consequences from the introduction of Dilaudid and Demerol.

It also prevented the introduction of numerous agents which had been under serious consideration.

The need for such research will continue and in my opinion can be done ethically with safety only by using recidivist addict prisoners as voluntary research subjects.

Sincerely yours,

CLIFTON K. HIMMELSBACH, M.D.

THE UNIVERSITY OF TEXAS,
HEALTH SCIENCE CENTER AT HOUSTON,
MEDICAL SCHOOL,
November 17, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties and the Administration of Justice, House of Representatives, Washington, D.C.

Re: Bill HR3603

DEAR HONORABLE KASTENMEIER: Pursuant to the upcoming bill concerning suitability of research among prison populations, I would like to state my views. In my opinion, prisons do represent appropriate places to conduct medical research. The population, while a captive one, does have the right to participate or not to participate. While any form of medical research can be done in an unethical manner, this is no more likely to occur in a prison setting. Also, as with other issues there will always be exceptions which can be looked upon to cast doubt on the appropriateness of prison research. However, in my experience in prison research which was done at the University of Maryland for approximately six years, I found most inmates who participated in the study to be more aware of the risks

and potential benefits of the research than the average patient in a hospital setting who is subjecting himself to a research protocol. Also, in certain situations they seemed more ready to withdraw from the study during its course when they felt the pain and suffering was of more consequence than the minimal remuneration received. Seldom does a hospitalized patient withdraw from such a protocol. Volunteer programs conducted among populations outside of prisons, tend to attract former inmates who do not have the same security (food, shelter, etc.) than when they were incarcerated. In a sense, they are less able to truly volunteer.

All prison research is not good and I have noted a great disparity among investigators working in prison populations. It is my feeling that we should attempt to formulate legislation that would standardize medical research both in and out of the prison so that the rights of the human subjects can be protected. In my opinion, a blanket bill which would prevent any medical research in a prison population is not looking appropriately at the real issues. Some of the most striking benefits which our society has achieved have resulted from trials among prison populations. These studies have shown various vaccines to be not only safe, but efficacious.

No longer am I engaged in prison research studies. One cannot do such studies casually for there is a great deal of thought and work which must be done to protect the rights of the prisoner. However, I recognize the need for other groups to concentrate in such a population. These groups which should be supported are looking for help from persons knowledgeable in legal and moral issues. A prison research unit can be organized where the rights of humans are protected and where research in nonfatal illnesses can be continued in the quest for prevention or control of disease.

Sincerely,

HERBERT L. DUPONT, M.D.,
Professor and Director,
Program in Infectious Diseases and Clinical Microbiology.

SALT LAKE CITY, UTAH, *November 5, 1975.*

Hon. ROBERT KASTENMEIER,
U.S. House of Representatives,
Washington, D.C.

MY DEAR MR. KASTENMEIER: Some recent reports on the hearings you have been holding on the advisability of prohibiting medical research on prisoners have come to my attention.

The reason for considering such legislation is, no doubt, a genuine concern for the civil rights of prisoners, as they are in a position to be more easily coerced than many others in our society.

I would suggest that the situation be viewed from a different aspect: from the standpoint of our society as a whole. First, I think that we should consider the needs of our society for human beings as test subjects for new drugs, new medical procedures, etc. I will not attempt to document the need for this testing here, but it can be readily documented. There are no other animals that can replace man for much of the testing that must be done.

Second, we should consider the availability of suitable subjects for testing. Generally, the persons undergoing the tests must be watched or controlled in some way to be sure that they do not voluntarily do something which may interfere with the test (such as drinking a bottle of beer). Many of the tests must be done on healthy individuals. Self selection of subjects (through volunteering in response to a promise of money) will sometimes influence the results of the test. For instance, sometimes the only ones who will respond to calls for volunteers are prostitutes (who are accustomed to selling rights to their bodies for money), or asthmatics who hope to be benefited directly by the testing. Prisons are a ready source of suitable healthy subjects, who are much less subject to the vagaries of the usual population of volunteers.

Third, what does society expect of the prisoners? Generally, it expects them to expiate or atone for their crimes. They are expected to simply spend a specified time in confinement. However, many are placed on probation so that they can atone in other ways. Why not include being a subject for drug or medical procedures as an alternate method of paying society for their crimes? Many prisons, in fact, already consider it in this light by shortening sentences or hastening parole.

Fourth, prisoners have usually committed some crime which violated someone else's civil rights. Our society has generally considered that an important part of punishment is the deprivation of the offender's civil rights, either temporarily or permanently. Confinement in prison is a loss of civil rights, loss of the voting privilege is another, inability to hold civil service positions and many other jobs after release is another. In fact, even after they have served their sentence, our society often continues to punish them by discrimination in social and work situations. I suspect that our society would not only approve the permitting of prisoners to volunteer for medical testing, but would even go further and approve compulsory participation in tests, if there were enough control over the tests to insure that prisoners were not subjected to health risks much greater than non-prisoner volunteers would accept. I am not advocating compulsory submission to tests, but I think it should be seriously considered by our courts and penologists as an alternative to confinement in prison.

Fifth, the matter should also be viewed from the standpoint of prisoners. For many of them, the experiments are a relief from the tedium of confinement. For some of them, (what fraction, I have no idea) it gives a sense of repaying society for their sins—a much better payment than staying behind bars, because it is actually contributing something to that society. For others, it gives them an opportunity to "earn" a shortened sentence, more privileges, etc. I suspect that if prisoners themselves were given a vote in the matter, that they would vote overwhelmingly to have the tests continued, so long as they were done on a voluntary basis, and some type of reward was offered for participation.

I would agree with those who fear that drug companies and other researchers might take advantage of prisoners unless there are safeguards. I am not sure that there are sufficient safeguards at the present time. The warden of every prison should have a panel consisting of toxicologists, physicians and biological researchers to whom he could submit proposals for use of prisoners. This panel would then evaluate the proposal to see that the objective warranted the use of human subjects, to see that the risk to participants was not excessive, and to see that an appropriate explanation was given to prospective volunteers.

In summary, I think this problem of prison research should be viewed with a much broader perspective than the narrow one of "informed consent without coercion".

Yours truly,

VICTOR E. ARCHER, M.D.

NATIONAL COUNCIL ON PRISON REFORM AND OFFENDER WELFARE, INC.,
October 22, 1975.

Hon. ROBERT W. KASTENMEIER,
Congress of the United States, Committee on the Judiciary, Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: I was just informed by our legislative committee, that your subcommittee is considering a bill submitted by Representative Parren Mitchell, H.R. 3603, a proposed ban on the use of federal, state, military and District of Columbia prisoners in any medical research hearings.

We feel that those with an interest in the balances of justice all feel that the relief for prisoners which will be granted by this legislation, must be granted.

I have met many men who were victims of behavior modification and medical experimentation. I know of the work of the National Prison Project of the American Civil Liberties Union where they are investigating instances of behavior modification right here in Virginia at the Beaumont Training School (for juveniles), and at Somers, the maximum custody state prison in Connecticut, where they have a major suit pending against the system.

The elements of coercion for parole are numerous now, and I can imagine the effects upon a man given an "opportunity" to enter a program which will "help" him to become rehabilitated, with a certain knowledge that the parole board will view any man who does not want to be rehabilitated as a "risk to society."

The entire thing smacks of something out of "Clockwork Orange." If we open the doors to the kind of shock therapy and behavior modification going on in this country, where are we going to stop? The "Clockwork Orange" type of institutional torture is right around the corner.

Last year, I'm sure you know, the LEAA, yielding to pressure from civil libertarian groups, stopped funding behavior programs at state prisons. And the U.S. Bureau of Prisons announced it would discontinue such programs at Federal institutions. What happened to this or was it another of Norman Carlson's blank promises?

I was pleased to note the name of Representative Mitchell as a sponsor of the bill. Representative Mitchell serves as a Sponsor for the National Council on Prison Reform and Offender Welfare, Inc. and his sponsorship of this important legislation is indicative of why we solicited his support for the COUNCIL in meeting our goals.

I hope you act favorably when this legislation comes before your subcommittee, and as always, I would appreciate your forwarding copies of the hearings conducted when printed as well as any legislation proposed and voted out of your subcommittee.

I'm certain your subcommittee will give this Bill the favorable action it so urgently calls out for.

Respectfully yours,

ROBERT M. LEVY,
Special Assistant to the Executive Director.

AMERICAN MEDICAL ASSOCIATION,
Chicago, Ill., November 3, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee on the Judiciary, House of Representatives, Washington, D.C.

DEAR MR. KASTENMEIER: This letter is in response to your recent invitation to the American Medical Association to offer its views on H.R. 3603 which we understand was the subject of hearings before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary. We welcome this opportunity and hope that our views will be helpful to the Subcommittee in considering this legislation. We request that this letter be included in the record of the hearing of the Subcommittee on H.R. 3603.

H.R. 3603 would specifically prohibit the use in medical research of Federal prisoners incarcerated at the federal, state, or local level as well as of prisoners in military facilities and of anyone incarcerated in any Federal penal facility. In effect, all Federal prisoners and all prisoners in Federal penal institutions would be, categorically, unable to be considered for participation in medical research. In addition, any state applying for penal facility construction grants would have to assure that similar provisions were required under state law for state purposes.

The AMA has a long history of active concern for the development of the potential benefits of biomedical research without violation of human ethical and moral values. This concern was expressed formally in 1947 when the Association's House of Delegates enumerated ethical standards for medical research with human subjects. The Association proceeded thereafter to adopt internationally acknowledged standards when it endorsed the 1964 Declaration of Helsinki, the World Medical Association's Guidelines for Clinical Investigations. In 1966, the AMA House of Delegates augmented these guidelines when it adopted ethical guidelines for clinical investigation, a copy of which is attached for your information.

However, it must be kept in mind that notwithstanding all the precautions which must be taken prior, during, and following medical research using human subjects, all such research still entails a certain amount of risk to the research participant and carries the potential of producing unforseeable and undesirable side-effects. This unpredicatability is inherent in research and will never be totally removed from human experimentation. The research community has long labored, and continues to strive, to carry on research while minimizing the risk to the research subject.

While these risks must not be brushed aside as an inevitable price of scientific progress, neither should the benefits which have accrued to society through such research be permitted to fall from view. If scientific techniques are to continue to improve, and if the physician's knowledge to help his patients to return to good health and productivity is to increase, then medical research must not be unnecessarily restricted. When the risks are balanced against the benefits, the choice is clear that well structured medical research projects utilizing human subjects must continue.

We recognize that involving prisoners in medical research presents special concerns. The prisoner is already severely restricted in the choices which he is permitted to make in his daily life, and he is particularly susceptible to covert pressures. It is essential that no coercion, in any form, be permitted to distort the free exercise of choice by the prisoner as to whether he will volunteer to participate in the medical research project. The medical researcher must be particularly vigilant that the rights of the human subject are recognized and respected when a prison population is being utilized for medical experimentation.

However, as a corollary to the concerns over "humane" aspects of involving prisoners in medical research, a second facet should be considered. An institutionalized population is a particularly valuable group for certain types of medical research, particularly in the area of drugs. Such a group enables the researcher to supervise more closely the undertaking of the research, to monitor its effects, to note and to ameliorate undesirable side-effects at the earliest possible time, and to report his findings and to document his conclusions. The institutionalized individual is generally at much less risk than is his non-institutional counterpart because he can be so closely monitored.

There currently exists within HEW safeguards as to research supported by Federal funds which provide appropriate protection to medical research subjects. These guidelines are the culmination of extensive study by HEW and have had the benefit of public review and comment. In addition, the private sector has been active in exercising its responsibility to medical research subjects in order to provide maximum assurance that the individual's rights are fully recognized and protected.

We believe that the rights of research subjects, be they prisoners or individuals recruited from the general public, must be fully protected. To this end, the present activities being carried on by HEW, as well as those of researchers in the private sector reflect that adequate authority presently exists to protect all medical research subjects.

We would, therefore, urge the Subcommittee to reject H.R. 3603 and to permit present authority to continue to offer necessary protection for rights of all medical research subjects.

Sincerely,

JAMES H. SAMMONS, M.D.

Declaration of Helsinki

RECOMMENDATIONS
GUIDING DOCTORS
IN CLINICAL RESEARCH
ADOPTED BY THE
WORLD MEDICAL ASSOCIATION
IN 1964

and AMA Ethical Guidelines for Clinical Investigation

AMERICAN MEDICAL ASSOCIATION
535 North Dearborn Street
Chicago, Illinois 60610

Declaration of Helsinki

RECOMMENDATIONS GUIDING DOCTORS IN CLINICAL RESEARCH

INTRODUCTION

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of The World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration" and the International Code of Medical Ethics which declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. BASIC PRINCIPLES

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to forseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. CLINICAL RESEARCH COMBINED WITH PROFESSIONAL CARE

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. NON-THERAPEUTIC CLINICAL RESEARCH

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgment, it may, if continued, be harmful to the individual.

We, the undersigned medical organizations, endorse the ethical principles set forth in the Declaration of Helsinki by the World Medical Association concerning human experimentation. These principles supplement the principles of medical ethics to which American physicians already subscribe.

American Federation for Clinical Research
American Society for Clinical Investigation
Central Society for Clinical Research
American College of Physicians
American College of Surgeons
Society for Pediatric Research
American Academy of Pediatrics
American Medical Association

ETHICAL GUIDELINES FOR CLINICAL INVESTIGATION

(Adopted by House of Delegates, American Medical Association, Nov. 30, 1966)

At the 1966 Annual Convention of its House of Delegates, the American Medical Association endorsed the ethical principles set forth in the 1964 *Declaration of Helsinki* of the World Medical Association concerning human experimentation. These principles conform to and express fundamental concepts already embodied in the *Principles of Medical Ethics* of the American Medical Association.

The following guidelines, enlarging on these fundamental concepts, are intended to aid physicians in fulfilling their ethical responsibilities when they engage in the clinical investigation of new drugs and procedures.

1. A physician may participate in clinical investigation only to the extent that his activities are a part of a systematic program competently designed, under accepted standards of scientific research, to produce data which is scientifically valid and significant.
2. In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.
3. In clinical investigation *primarily for treatment* —
   - A. The physician must recognize that the physician-patient relationship exists and that he is expected to exercise his professional judgment and skill in the best interest of the patient.
   - B. Voluntary consent must be obtained from the patient, or from his legally authorized representative if the patient lacks the capacity to consent, following: (a) disclosure that the physician intends to use an investigational drug or experimental procedure, (b) a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits, (c) an offer to answer any inquiries concerning the drug or procedure, and (d) a disclosure of alternative drugs or procedures that may be available.

   - i. In exceptional circumstances and to the extent that disclosure of information concerning the nature of the drug or experimental procedure or risks would be expected to materially affect the health of the patient and would be detrimental to his best interests, such information may be withheld from the patient. In such circumstances such information shall be disclosed to a responsible relative or friend of the patient where possible.
   - ii. Ordinarily, consent should be in writing, except where the physician deems it necessary to rely upon consent in other than written form because of the physical or emotional state of the patient.
   - iii. Where emergency treatment is necessary and the patient is incapable of giving consent and no one is available who has authority to act on his behalf, consent is assumed.
4. In clinical investigation *primarily for the accumulation of scientific knowledge* —
   - A. Adequate safeguards must be provided for the welfare, safety and comfort of the subject.
   - B. Consent, in writing, should be obtained from the subject, or from his legally authorized representative if the subject lacks the capacity to consent, following: (a) a disclosure of the fact that an investigational drug or procedure is to be used, (b) a reasonable explanation of the nature of the procedure to be used and risks to be expected, and (c) an offer to answer any inquiries concerning the drug or procedure.
   - C. Minors or mentally incompetent persons may be used as subjects only if:
     - i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.
     - ii. Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.
   - D. No person may be used as a subject against his will.

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THE UNIVERSITY OF SANTA CLARA,
SCHOOL OF LAW,
Santa Clara, Calif., October 29, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Committee on the Judiciary, House of Representatives,
Congress of the United States,
Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: I appreciate your invitation to comment on H.R. 3603. As you will see from my enclosed statement, I support your efforts to end medical experimentation in prisons. I have addressed my remarks, however, to the special problem of the prison inmate who may be suffering from a disease with no known cure where there is an experimental drug or medical procedure. In such a rare case I believe the interest of the inmate is better served by allowing the utilization of the experimental drug or procedure, but only after established procedural safeguards have been met.

The rest of my remarks are directed to the problem of the use of a drug or procedure for behavior control purposes and not for research. This usage might escape attack under H.R. 3603 as it is presently worded.

I support your efforts, and I will follow the progress of H.R. 3603 with great interest. Please call on me again for commentary on bio-medical issues and the law.

Sincerely yours,

ALAN W. SCHEFLIN,
Associate Professor of Law.

Enclosure.

STATEMENT OF ALAN W. SCHEFLIN, ASSOCIATE PROFESSOR OF LAW, UNIVERSITY OF SANTA CLARA LAW SCHOOL

Human experimentation is an integral part of the advancement of medical technology. The delicate question of who shall serve as fit subjects for such experimentation has been a subject of much discussion and dispute, especially in the last several years. H.R. 3603 reflects a policy judgment that prisoners in the correctional setting are not appropriate subjects for medical experimentation. This is a value judgment with which I agree. The Subcommittee has heard extensive testimony on this issue, and I do not wish to duplicate the thoughtful comments of others. For numerous reasons, medical experimentation on prisoners has had a long history of abuse. Recent sensitivity to the area of prisoners' rights, to the use of medicine for behavior control purposes, and to the doctrine of informed consent as a reflection of the right of the person to control his or her destiny and to be treated with respect and dignity, all lead to the conclusion that the coercive setting of a total institution is an inappropriate place to conduct medical research.

At the same time, H.R. 3603 will not unduly restrict valid medical experimentation necessary for the advancement of the healing arts. The extra financial outlay which testers may be required to spend will be more than balanced by the increase in our sensitivity to the moral and legal rights of test subjects.

The gain in concern for human dignity, almost totally lacking in prison testing, more than outweighs the small increment in cost that may result from the passage of H.R. 3603. Also, in my judgment, a by-product of this Bill will be an increase in the quality of experimental procedures, not only indirectly through more thorough animal testing before human experimentation is conducted, but directly through a more rigorous construction of testing procedures and search for optional test subjects and situations.

Rather than discuss the central issue of whether or not medical experimentation should be conducted upon prisoners, I prefer to accept the judgment of the Subcommittee that it should not. I would like to address myself, however, to two major issues raised by H.R. 3603: therapeutic experimentation and non-research experimentation (including behavior control).

THERAPEUTIC EXPERIMENTATION

Let us assume that a prisoner in a Federal Correctional facility is suffering from a disease for which there is no known cure. However, recently a drug has been synthesized which promises to afford some relief. The drug, however, has not been completely tested, although testing is presently underway. The question

is whether or not H.R. 3603 would forbid the administration of that drug to the prisoner. The dilemma here is that if we give the drug to the prisoner and do not study its effects, some valuable research information may be needlessly lost. On the other hand, if we do not give the drug to the prisoner, we may be denying a form of relief contrary to the prisoner's best interests. In order to address ourselves to this dilemma, one distinction needs to be made at the outset. That distinction is between therapeutic and non-therapeutic experimentation. Therapeutic experimentation is a research plan which is designed to aid the subject of the research, as well as other people. Non-therapeutic experimentation is research upon an experimental subject which is conducted, not for the benefit of the subject, but rather only for the benefit of others. An example of the latter would be research done on malaria where healthy prisoners were injected with the malaria disease in order to study effects and possible cures. There is no therapeutic value in taking healthy people and making them ill. The difference between therapeutic experimentation and nontherapeutic experimentation is often expressed in terms of the question "Is this experimentation for the benefit of the subject or for the benefit of others?" If the former, then the experimentation is therapeutic, if the latter, then it is not. (20 Stan. Law Rev. 99).

I believe that for cases of non-therapeutic experimentation H.R. 3603 states a sound policy. For cases of therapeutic experimentation, however, H.R. 3603 may have a very unfortunate adverse consequence. This consequence is the denial of treatment to a prisoner when such treatment would be obtainable by a "free" person in society. If this is a correct interpretation of H.R. 3603, then it raises serious constitutional questions of equal protection and the right to treatment. My problem with H.R. 3603 at this juncture is that because it does not articulate the basis for the policy judgment that experimentation upon prisoners should be forbidden, it may raise the inference that prisoners cannot give informed consent in such a total institutional setting. I think that this would be an unfortunate reading of the intention of H.R. 3603.

The Subcommittee is undoubtedly aware of the recent celebrated case of *Kaimowitz* v. *Department of Mental Health*, Civil No. 73-19434-AW (Cir. Ct., Wayne County, Mich., July 10, 1973). In that case, a patient institutionalized for over 15 years in a hospital for the criminally insane was offered the opportunity to participate in an experimental program involving psychosurgery. A three judge court determined that the coercive atmosphere of the total institution negatived the ability of the inmate to give a truly voluntary and informed consent. The court's opinion was buttressed by the fact it determined that psychosurgery was an experimental procedure. To the extent that the *Kaimowitz* opinion can be read as articulating the rule that an inmate of a total institution does not have the capacity to give informed consent, then this ruling would be most unfortunate indeed because there are many decisions which require an inmate's judgment and it would be the epitome of paternalism to disallow him or her to make any of them. In actual fact, in the *Kaimowitz* situation, the inmate was told by the doctor in charge of the experiment that he would never get out of the institution unless he consented. Unfortunately this fact does not appear in the court's opinion. Also, in that case, a very strong attack was made upon the contemporary practice of psychosurgery. The *Kaimowitz* court was most likely responding more to the adverse proof in reference to psychosurgery than it was to the ability to give informed consent. In other words, the court was probably more motivated to disallow psychosurgery than it was to disallow informed consent. Although this is conjecture on my part, it is based upon my reading of the transcript and my consulting with most of the attorneys and parties in the case. *Kaimowitz* has almost uniformly been condemned in the legal literature for its failure to recognize that while it is true that total institutions are indeed coercive, and that the problem of informed consent within them is much more complex than the problem of informed consent in the free society, nevertheless it is an untenable position to maintain that informed consent is impossible even within such a highly coercive environment (See 54 Boston Univ. Law Review 301).

H.R. 3603 may make the same mistake that the *Kaimowitz* court made. In other words, the impact of H.R. 3603 may be to deny the inmate the ability to give informed consent to an experimental procedure where that inmate may himself benefit from that experimental drug or procedure. I am in no way suggesting that the defendant in *Kaimowitz* would have benefitted from the psychosurgery. Indeed, a careful study of the record of that case clearly shows

that the operation was sought to be performed as an inducement for other inmates to consent to it even though the defendant was not the optimal candidate for this neurosurgery. He happened to be the only inmate who consented. In addition, the procedure to be used was condemned on the facts of the case by the surgeon who pioneered the operation. My remarks are addressed to the *Kaimowitz* court's conclusion that informed consent to an experimental procedure is impossible in a total institution, even where the procedure might be therapeutic. Thus, in a situation of therapeutic experimentation, where there is no doubt that a non-incarcerated citizen would be able to give consent, to deny the prisoner the same opportunity to receive that treatment would be another way of saying that the prisoner does not have the capacity to consent. In the very desire to protect the prisoner, H.R. 3603 may be doing him or her the most harm. But it may be asked "if you believe that the prisoner has the capacity to give informed consent to a medical experimentation, then don't you have to take the position that H.R. 3603 is wrong in denying to medical experimenters prison populations?" I think that this can be answered quite simply. The values sought to be protected are the dignity and autonomy of the individual and the integrity of the medical profession. A perfectly reasonable value judgment can be made that a prison setting is an improper place for medical experimentation. This value judgment may be based on some of the following observations, which reflect the inappropriateness of the prison setting as a valid experimentation proving-ground:

(1) Prison experiments tend to be shoddily designed and poorly conducted by low level researchers. (2) The controlled environment of the prison makes it difficult to translate the effects of research to a heterogeneous population. (3) The coercive nature of the institution makes consent readily obtainable even though involuntary. (4) There are strong inducements for the prisoner to keep silent about adverse side-effects—fear of being bumped from the experiment thereby losing pay and further good time. Also, the prisoner may fear that he or she will not be allowed to participate in other experiments. (5) The insensitivity to the prisoner as a human being accounts for inadequate protection of his or her legal and moral rights.

The very strong possibilities of abuse of medical procedures makes some protection of prison inmates absolutely necessary. H.R. 3603 does not cut off medical experimentation *in toto* but simply recognizes that there is less legal difficulty and more medical appropriateness in the use of populations other than prison inmates. It is a far different thing, however, to say that an inmate in need of medical attention is incapable of receiving that attention. This judgment cannot be based upon the medical inappropriateness of giving the relief, nor can it be based upon the inappropriateness of the setting in which the relief is received. So the denial of medication to a prisoner can only be predicated on the inability to give consent to the experimental nature of the medication. There is thus no inconsistency in saying that for non-therapeutic experimentation, the prison setting is inappropriate, whereas for therapeutic experimentation, the prisoner has a right to receive treatment, even though it is experimental treatment, provided the conditions of informed consent can be met. These conditions include the competence of the inmate to give consent, the voluntariness with which consent is given, and the fullness and adequacy of the knowledge which forms the basis of consent. Especially where there is no reward attached to the giving of consent (as in a promise, either expressed or implied, of a parole date or early release or good time), to extend the policy judgment to these cases of therapeutic experimentation would simply be to say that the prisoner has no ability to give informed consent to help himself or herself. This would certainly destroy the initial attempt to protect the values of private autonomy and human dignity.

I am not unmindful of the possibility of abuse by prison officials of this "loophole". Because the possibility for abuse of any type of experimentation is always present in a prison setting, it is with genuine hesitancy that I suggest a procedure which might create a further avenue for violation of prisoners' rights. And so I believe that some safeguards may be necessary. In the first place, the prisoner should have a medically recognized disease or illness confirmed by an outside physician. Secondly, the prisoner should be given the right to consult with outside physicians and attorneys before deciding on whether or not to undergo experimental treatment. Third, the law on informed consent must be met both as to the information conveyed to the prisoner, and the documentary form in which the

consent is preserved. Fourth, in the case of new drugs, the Federal Drug Administration should be notified. Fifth, some peer review procedure should be adopted to alleviate the possibility of abuse.

The above enumerated safeguards should protect the prisoner without hampering his or her ability to consent to experimental treatment. I am mindful that many of my colleagues feel that the possibility for abuse is so strong that no experimentation, even if therapeutic, should be permitted on prisoners. I appreciate the genuineness of this concern, but in my mind the greater evil lies in foreclosing experimental treatment by denying the capacity to give informed consent. The consequences of removing free will in this special case are, to me, far more serious in implication than is establishing a set of safeguards to protect the prisoners when therapeutic experimentation may seem warranted.

NONRESEARCH EXPERIMENTATION

H.R. 3603 defines medical research in the following manner: "Research, experimentation, or testing, which . . . is conducted to determine the safety or effectiveness of any drug, medical device, or medical practice." This definition appears to define research in terms of the attempt to discover the consequences of the administration of a drug or device or practice. This definition may leave available to prison authorities the opportunity to engage in a form of "non-research experimentation." California's experience with Anectine may illustrate the way in which prison officials might abuse the intention of H.R. 3603. (The most accessible description of the "Anectine therapy" may be found in Volume 45 of the *Southern California Law Review* beginning at page 633.) Anectine is a drug used as a muscle relaxant which has the effect of causing a loss of muscular control. It is normally injected before the application of another therapy, such as electroconvulsive therapy or anesthesia before surgical operations. The manufacturer's recommended usage suggests that the drug should take effect when the patient is in an unconscious state and it should be used in conjunction with another therapy. In select California prisons, however, another use was found for Anectine. It was injected to full conscious patients in the absence of other therapies. The effect was to produce a death-like state in which all muscle control was lost, including control of respiration. Prison inmates described the experience as feeling like they were "drowning" or "dying." Losing the ability to breathe, they were under the direct control of prison officials who administered oxygen while at same time instructing them that they would not receive such a "treatment" if they would behave themselves.

Although this use of Anectine was in violation of the manufacturer's suggested usage, prison officials justified it on the grounds that this was not a *research* but rather a *clinical* trial of a procedure in common use elsewhere. In other words, they took the position that they were using the drug in the same way that it was always used, but were simply suspending the other therapy that would normally accompany it. I have been informed by F.D.A. officials that once a drug is cleared for one usage, it may be used by doctors for other nonprescribed uses without violating F.D.A. rules. If this is true, then it may be possible for prison officials to do what was done in California—use a drug in a non-prescribed way yet legitimate that usage by claiming that it is not research. In particular, it is worth noting that the language of H.R. 3603 would not appear to prohibit the Anectine "therapy". Prison officials would claim that the drug was not used "to determine the safety or effectiveness" of its usage. At a conference of the California Assembly Criminal Justice Committee on October 23, 1973, Dr. Clanon, the official in charge of the Anectine experiments, justified this use of the drug on the grounds that aversion therapy (punishment) had been in practice for over fifty years and "the purpose of Anectine is to produce a very unpleasant sensation which is what it does." In other words, Dr. Clanon would say we do not need to determine the safety or effectiveness of the drug, because we know that already, and even though we are making a non-prescribed use of the drug, we are not doing it for research purposes. Nevertheless, it is clear, at least to me, that this is an illegitimate procedure.

And so I see an important gap in H.R. 3603 which will allow prison officials to engage in a form of behavior control and experimentation without running afoul of the literal language of this Bill. In addition, my suggested differentiation between therapeutic and non-therapeutic experimentation may serve to widen this loophole even more. Yet I feel, on the one hand, that the prison inmate

should not be denied access to a treatment, even though experimental, which may actually medically benefit her or him, yet I feel as strongly on the other hand that the Anectine torture, and its progeny, should not be allowed to continue. Prison officials should not be allowed to engage in behavior control techniques while calling it treatment. Yet how can one make that distinction and protect the rights of prisoners? I believe this would be an appropriate place for regulations which I know the Secretary of Health, Education and Welfare is asked to promulgate. In those regulations, I would suggest that a distinction be made between drugs administered for their medical benefit to a prisoner, and drugs administered for their benefit to the institution. Certainly a crucial difference between the therapeutic experimentation I spoke about earlier and the administration of Anectine is that the therapeutic experimentation would be to alleviate or lessen a diagnosible and recognizable medical condition of the prisoner, whereas the administrating of Anectine was designed to curb behavior problems and increase the efficiency and orderly administration of the institution. Because Anectine was not given for a diagnosible medical condition, it seems to me that the Secretary could easily draft regulations which would condemn its use as well as the use of other drugs or procedures for similar behavior control purposes, without interfering with the private autonomy of an inmate to consent to a therapeutic experimental regimen.

I sincerely appreciate the opportunity to submit these comments on H.R. 3603.

STATEMENT OF ROY BRANSON, PH. D., SENIOR RESEARCH SCHOLAR, THE JOSEPH AND ROSE KENNEDY INSTITUTE FOR THE STUDY OF HUMAN REPRODUCTION AND BIOETHICS, GEORGETOWN UNIVERSITY, WASHINGTON, D.C.

Mr. Chairman and Members of the Committee: In response to your request, I am happy to testify concerning H.R. 3603. My name is Roy Branson, and I am Senior Research Scholar at the Joseph & Rose Kennedy Institute for the Study of Human Reproduction and Bioethics. I am by training and experience an ethicist, and have written on topics in bioethics, including the question of experimentation with prisoners.

I support H.R. 3603, subject to two provisos, which I do not think alter the intent of the bill: First, that medical research in the wording of the bill be more carefully defined. Second, that within five years of the enactment of H.R. 3603, some body such as the National Commission for the Protection of Human Subjects review the bill and its impact. Unless Congress acted to revoke H.R. 3603, it would remain the governing legislation.

DEFINITIONS

I wish to analyze the ethical arguments implicit or explicit in the debate concerning experimentation with prisoners, and mention factors that lead me to support a ban of the sort called for in H.R. 3603. At the outset I shall define two ethical terms that I will use to sort out arguments concerning the use of prisoners in experimentation. First, I will describe some arguments as consequentialist. Consequentialist arguments decide what is right by calculating whether an act, policy or rule will result in consequences producing a greater balance of good over evil than any available alternative. Second, I will describe other arguments as fairness arguments. These assert that in addition to whatever good an act or rule produces, there are certain features of the act or rule itself that make it right, such as the fact that it is inherently fair, or just. I will note the consequentialist arguments first.

CONSEQUENTIALIST ARGUMENTS

The consequentialist argument for using prisoners states that experimentation using prisoners is right because it results in increased scientific knowledge, which contributes to society's good. Before this committee, Mr. Stetler, president of the Pharmaceutical Manufacturers' Association, representing 131 drug companies, whose research develops most of the prescription drugs in the United States, testified on October 1 regarding the use of prisoners. He insisted that "given the kinds and amounts of biomedical data required by current standards of research as reflected in FDA new drug regulations, there are actually few practical

alternatives." Prohibitions on the use of prisoners, he said, "may also delay development of new drugs which will benefit all people, including the prisoners themselves." [1]

The Department of Health, Education and Welfare 1974 guidelines concerning use of prisoners in clinical experimentation summarized the scientific utility of using prisoners:

"Clinical research often requires the participation of normal volunteers; for example, in the early stages of drug or vaccine evaluation. Sometimes the need for standardization of certain variables, or for monitoring responses over an extended period of time, requires that the subjects of research remain in a controlled environment for the duration of the project. Prisoners may be especially suitable subjects for such studies, since unlike most adults they can contribute their time to research at virtually no cost to themselves." [2]

Assuming the importance and value of scientific research for the human community, assuming the necessity of using prisoners to carry on at least certain kinds of scientific research, and assuming as consequentialists do, that the right act or policy is one that produces a greater balance of good over evil than any available alternative, one arrives at the conclusion that using prisoners in experimentation is right.

However, reliance on the consequentialist form of argument has not settled the question. Robert Burt, a University of Michigan professor of law, who helped argue the *Kaimowitz* (Michigan) psychosurgery case, has given an eloquent statement of a consequentialist argument against use of prisoners. His remarks focus particularly on psychosurgery, but could be extended to include other experimentation using prisoners.

Burt believes that the physical and psychological separation of imprisonment already defines some humans into a different order, what Erik Erickson calls a "pseudo-species." Adding to imprisonment the performance of experimental psychosurgery would be another step in the process of dividing "us" from "them." So far, Burt is not a consequentialist, because he can be understood to be objecting to psychosurgery as treating a prisoner unfairly, as though he did not share a basic humanity with us. He could say that if treating the prisoner as a pseudo-species contributed markedly to scientific knowledge and human good, it would still be inherently unfair.

However, Burt proceeds:

"The central danger, of course, is not simply the fact that we choose to define some people as different species of mankind from others. But such definition provides justification for, and impulse toward, increasing and mutually destructive action by one "pseudo-species" against another." [3]

Burt refers to the suspicion and fear of not only those being separated, but those in charge of the separation. "When we do that to him, what will we think of ourselves? What will others think of us? . . . This is the cycle of violence, punitive repression, and increased violence. These are the dark, atavistic fears that afflict us all whenever we treat one group of men as radically different, radically inferior, less human than the rest of us." [4]

Burt explicitly acknowledges that he is proposing a quantitative balancing of a prisoner's rights with that of society. "I am content to say that the risks I have described affect so many people so far in the future that prisoners' current interests in obtaining the surgery are outweighed." [5]

Burt may, or may not, extend his ban on therapeutic psychosurgery to all experimentation using prisoners. But if others believed that any experimentation utilizing prisoners created antagonistic groups in society, they could make the same argument for all experimentation. Such conclusions are the opposite of those who approve of using prisoners in experimentation, but the form of ethical argumentation is the same: what is right is what produces the greatest balance of good over evil. And there are those who would conclude that the evil to society of using prisoners outweighs the good.

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[1] C. Joseph Stetler, Statement on H.R. 3603, October 1, 1975.
[2] D.H.E.W., N.I.H., "Protection of Human Subjects, Policies and Procedures," 1973, p. 677.
[3] Robert Burt, "Why We Should Keep Prisoners From the Doctors," *Hastings Center Report*, Vol. V, No. 1 (February 1975), p. 33.
[4] *Ibid.*, p. 34.
[5] *Ibid.*, p. 34.

FAIRNESS ARGUMENTS

There are some who would argue that whatever good or evil is produced by experimentation with prisoners, there is, in addition, another consideration that is determinative: it would be unfair to prevent prisoners from volunteering for biomedical experimentation.

Both the Pharmaceutical Manufacturers' Association and the Department of Health, Education and Welfare Guidelines invoke this reasoning in addition to their consequentialist argument. Mr. C. Joseph Stetler, President of the Pharmaceutical Manufacturers' Association, in his testimony before this committee declared that "if we eliminate the prisoner as someone eligible to take part in these carefully controlled trials, we remove another right of choice from his or her already restricted life." [6] The 1974 D.H.E.W. Guidelines say that "many prisoners are strongly motivated to participate in research, and view as unfair suggestions that they be denied that opportunity." [7]

Many concerned with fair treatment of the individual emphasize the importance of the principle of informed consent as a minimal safeguard to a person's being treated with equal fairness. Paul Ramsey has movingly explained why informed consent in medical and experimental relationships is necessary if we are to be truly faithful in treating our fellow human beings fairly.

"The principle of informed consent is a statement of the fidelity between the man who performs medical procedures and the man on whom they are performed . . . the fidelity is the bond between consenting man and consenting man in these procedures. The principle of informed consent is the cardinal canon of loyalty joining men together in medical practice and investigation. In this requirement faithfulness among men—the faithfulness that is normative for all the covenant or moral bonds of life with life—gains specification for the primary relations peculiar to medical practice." [8]

In settling the suit of *Gabe Kaimovitz* vs. *The Mental Health Department of the State of Michigan*, the court decided that a "criminal sexual psychopath" confined to a maximum security hospital could not freely consent to an experiment even if it was therapeutic. The court cited the invasive and irreversible nature of the experiment, but also the powerful effect incarceration has on a person who otherwise has the capacity to give voluntary consent.

"Although an involuntarily detained mental patient may have a sufficient I.Q. to intellectually comprehend his circumstances . . . the very nature of his incarceration diminishes the capacity to consent to psychosurgery . . . The fact of institutional confinement has special force in undermining the capacity of the mental patient to make a competent decision on this issue, even though he be intellectually competent to do so . . . involuntarily confined mental patients live in an inherently coercive institutional environment . . . They are not able to voluntarily give informed consent because of the inherent inequality in their position."

The American Civil Liberties Union—National Prison Project makes the same argument regarding non-therapeutic experimentation. In its complaint to the U.S. District Court for the District of Maryland on behalf of seven prisoners involved in viral diarrhea, malaria, shigella and typhoid experiments conducted at the Infectious Disease Area of the Maryland House of Corrections in Jessup, the National Prison Project does argue that the Court should decide that use of prisoners in such experiments is unconstitutional because of the "specific conditions" found in the Maryland House of Corrections and its Infectious Disease Area. However, the National Prison Project also asks the court to declare that "the use of prisoners in non-therapeutic biomedical experimentation of this type is unconstitutional *per se* because of the impossibility of truly voluntary consent."

In both the Kaimowitz and the National Prison Project cases, the argument against using prisoners is based on considerations of fairness—the impossibility of gaining informed consent in a prison setting to protect the possibility of fair dealing between free and prison populations. The debate among those using consequentialist arguments to approve or disapprove of experimentation with prisoners becomes an analysis of whether such experimentation produces more good or

[6] Stetler, Statement on H.R. 3603, October 1, 1975.
[7] D.H.E.W., *op. cit.*, p. 50.
[8] Paul Ramsey, *The Patient as Person*, Yale University Press, New Haven, 1970, p. 69.

evil for society. The debate among those using fairness arguments has become an analysis of whether or not inmates in a prison can give a sufficiently free and informed consent to medical experiments.

EMPIRICAL ANALYSIS

In the end it comes down to an assessment of the empirical conditions within which prisoners are asked to give consent to experiments that put them at risk. While it is possible for me to admit that, theoretically, it might be possible for an inmate of some ideal prison to give a sufficiently free consent to participation in an experiment, the evidence about both administration and structure of prisons in America is sufficient, I think, to raise serious and reasonable doubt that prison inmates can actually give sufficiently free and informed consent. There is the insufficiency of options comparable to medical experimentation for prisoners to choose among. No other prison activity pays comparably.[9]

A number of studies indicate that activities open to prisoners other than biomedical experimentation are not conducted in comparably comfortable and secure surroundings. Very importantly, there appears to be a paucity of alternative means for prisoners meaningfully to express their altruism.[10]

Even more important than the absence of options for those citing the *de facto* impossibility of prisoners giving a sufficiently free and informed consent is the attitude which volunteers within prison have in approaching experimentation. The dependent role of the layman in the doctor-patient relationship appears to some observers to be heightened in the prison setting. Dr. Arnold and his associates reported that a "factor that plays a major role in volunteerism is the factor of the substitute parent . . . there developed by the volunteer an almost parental view of the research physician. In part the research team has replaced the real family. Many prisoners would say "I would do anything the doctor tells me to." This sometimes continued after prison.[11]

In other words, whatever paternalism there is in the medical relationship is intensified by the even stronger paternalism built into the very structure of the prison system itself.

The impossibility in fact of obtaining a sufficiently free consent within the American prison draws heavily on two kinds of persuasive analyses of the structure of the prison. First, the studies of sociologists synthesized by Erving Goffman and Gresham Sykes. Erving Goffman describes a prison as a total institution, place of residence and work where a large number of like-situated individuals, cut off from the wider society for an appreciable period of time, together lead an enclosed, formally administered round of life." [12]

All activities are designed to make the prisoner subservient and dependent on authority.

"First, all aspects of life are conducted in the same place and under the same single authority. Second, each phase of the member's daily activity is carried on in the immediate company of a large batch of others, all of whom are treated alike and required to do the same thing together. Third, all phases of the day's activities are tightly scheduled." [13]

Goffman describes a variety of procedures by which the inmate of a total institution "begins a series of abasements, degradations, humiliations, and profanations of self." Goffman notes forms by which the inmate adapts to the total institution, including conversion or conformity to the environment: "The inmate appears to take over the official or staff view of himself and tries to act out the role of the perfect inmate." [14]

It is argued that medical experiments conducted in such an environment cannot be treated as if they were being carried out in the free society. They are conducted within "a social system in which an attempt is made to create and main-

[9] "Alvin Bronstein Discussion" in *Experiments and Research with Humans: Values in Conflict, National Academy of Sciences*, Washington, 1975, pp. 130–135.
[10] John D. Arnold, Daniel C. Martin and Saray E. Bayer, "A Study of One Prison Population and Its Response to Medical Research," 1969 Annals of the New York Academy of Sciences, 1970, pp. 463–469. Stephen H. Wells, et al., "Pharmaceutical Testing in a Correctional Institution," Charles C. Thomas, New York, 1974, pp. 35–37.
[11] S. Katz, *Experimentation with Human Beings*, Russell Sage Foundation, New York, 1972, p. 1025.
[12] *Asylums*, Aldine Publishing Co., Chicago, 1962, Introduction.
[13] *Ibid.*, p. 6.
[14] *Ibid.*, p. 63.

tain total or almost total social control." It is argued that in such a context precisely the attractive and beneficial features of experimentation can overcome the inmate's ability to give sufficiently free consent. Gresham Sykes, after studying in depth the New Jersey Maximum Security Prison, observed that "it may be that when men are chronically deprived of liberty, material goods and services, recreational opportunities and so on, the few pleasures that are granted take on a new importance and the threat of their withdrawal is a more powerful motive for conformity than those of us in the free community can realize." [15]

The second kind of analysis indicating strongly that the very structure of American prisons makes it *de facto* impossible for prisoners to give a sufficiently free and informed consent to experimentation is historical analysis. David Rothman, especially, with coinciding studies by Gerald Grob and others, argues that the coercive structure of the American prison society and its powerful impact on the attitudes of prisoners is not accidental. One hundred and fifty years of attempting to rehabilitate or alter the consciousness of prisoners undergirds the structure of those total institutions we call prisons.

The new institutions established in Auburn (1819–1823) and Sing Sing (1825), and Philadelphia (1829), were large buildings with massive gates and thick walls designed to isolate the prisoner from his corrupting environment. The reformers responsible for the erection of these prisons or penitentiaries consciously organized the life of the prisoner so as to change his character. They relied on isolating him from evil influences in the outside world and forcing him to acknowledge authority, down to and including wearing uniforms and moving in a shuffling version of a military march. During the 1830's official observers from England, Prussia and France came to New York and Pennsylvania to learn from America's experiment in altering the behaviour and personalities of prisoners. It is not simply the present administration of prisons, limiting options to experimentation, which cast doubt on the possibility of prisoners giving sufficiently free and informed consent, but the fundamental structure and historic purpose of American prisons.

SUMMARY

The consequentialist argument in favor of using prisoners for experimentation would be immensely strengthened if it could be shown that using prisoners in experimentation is not only convenient, but necessary for producing scientific knowledge beneficial to society. But that simply has not been proven. Most importantly, prisoners are not biologically unique. Furthermore, the experimentation that absorbs the greatest number of prisoners is initial testing of the safety of new drugs. Drug companies who conduct much of this experimentation have themselves said that such experimental uses small groups of prisoners for relatively brief periods of time (for example one month).[16] Those details indicate that alternatives to experimenting within prisons could be organized. Indeed, such arrangements have already been tried, using free subjects who volunteer to remain in a hospital ward for twenty or thirty days. The fact that free subjects are paid ten times what prisoners are paid, raises the cost of experimentation, but the drug companies have alraedy testified that financial considerations are not at issue in the debate concerning prison experimentation.[17]

While prisoners are not necessary to obtain scientific knowledge for the good of man, (and using prisoners in medical experiments might lead to evil consequences for society) there is serious and reasonable doubt that in fact a prisoner in the American prison system can give a sufficiently free and informed consent to an invitation to participate in medical experiments. I conclude that a ban on medical experimentation using prisoners is not obviously against the good of society, and is fair for the prisoners.

I suggest certan changes in H.R. 3603 as presently worded. First, that language be included that makes it clear that a physician may use a medical procedure for the purpose of providing for a particular patient, even if that procedure is innovative and not yet a part of standard medical practice. Such an interpretation may be implicit in the bill's definition of medical research, but physicians and prisoners should be assured that they can receive this kind of therapy.

Second, I suggest that the bill state that within two years the bill and its impact be reviewed by the National Commission for the Protection of Human Subjects.

[15] See next page.
[16] Stetler statement on H.R. 3603, Oct. 1, 1975.
[17] Ibid.

Such a review could include the relevance to H.R. 3603 of certain definitions the commission comes to agree upon or finds to be standard; definitions of such terms as biomedical research, behavioral research, therapeutic research and nontherapeutic research. More precise definitions might lead Congress to decide that prisoners could be allowed to put themselves at risk in some kinds of research, since that research could be specified with greater precision. The Commission could also survey whether medical research using free volunteers has produced scientific knowledge comparable to the kind, quality and quantity produced by experiments relying on prison populations, or whether there has been a drastic loss of scientific knowledge. Of course, even if the Congress concluded that the H.R. 3603 had led to harmful consequences to society it could refuse to revoke legislation because fairness demanded that prisoners receive the protection provided by the legislation.

With these provisos, I support H.R. 3603.

RUTGERS UNIVERSITY, THE STATE UNIVERSITY OF NEW JERSEY,
SCHOOL OF LAW, NEWARK,
Newark, N.J., October 20, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee on the Judiciary, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: I have your recent letter inviting me to comment on H.R. 3603, and am flattered to have been so requested. The area is one in which I am extremely interested, and presently doing research. Nevertheless, I do not believe that, in the short time left before the deadline for comments, I could compose a thorough consideration of all the issues involved. I will note, however, that I basically support the bill, although, in my own view, it should be much broader, prohibiting FDA and other agencies from allowing the use of *any* prisoner, whether federal or state, from participating in such experimentation. Although I personally believe that it is *legally* possible for prisoners to consent to such programs, the ethical considerations are so strongly in favor of a ban, or at least a moratorium, that I believe that is the better and more rational approach to the issue. At the very least, a two-year moratorium on *all* such testing would allow time for detailed and complete investigation of the issues.

I regret that I cannot, at the moment, more fully explicate my own views on the subject. This is a critical question in penology, and a momentous decision in terms of our social fabric, for a society which allows prisoners to "buy" their freedom, or increased comforts, while establishing the abnormal conditions in which such comforts may only be luxuries, must certainly reevaluate its own priorities. If there is an opportunity, in the future, for further comment on this bill, or on similar topics, I would greatly appreciate an invitation to present comment and/or testimony.

In short, I commend H.R. 3603, and hope that its scope may be extended. I am sure that I am one among thousands who applaud the committee for its recent hearings on this subject, and its aim to act on this question. If these hearings are printed, or if there is other information which might be available, I would greatly appreciate a copy.

Cordially,

RICHARD SINGER, *Associate Dean.*

UNIVERSITY OF PENNSYLVANIA,
Philadelphia, Pa., September 30, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties and the Administration of Justice, House of Representatives, Congress of the United States, Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter of September 22, 1975, inviting me to testify on October 1 at the hearings you have scheduled on H.R. 3603. I very much regret that a number of prior commitments here at the University preclude my coming to Washington that day. Instead, I have followed your alternative suggestion and set forth on the attached pages a few comments on the proposed legislation for your printed record.

As is explained more fully in my statement, I believe that a legislatively-mandated cessation in prison testing is justified. Nevertheless, I am not one who believes that it is impossible to conceive of a legitimate place for a properly supervised program of experimentation within a prison. The idea that prisoners are presently not in a position to give free and knowledgeable consent is one of the aspects of the current situation which support the conclusion of H.R. 3603 that research in penal institutions should cease. But it does not follow, at least as a logical matter, that the problems of consent (like the other problems with current testing) could not be overcome.

Thus, it seems to me that the ban on experiments in prisons contained in the proposed statute should be treated as the provocation for a reassessment of such experimentation and the adequacy of present means of oversight and protection. Any "reevaluation" conducted while testing is still going on would be much less effective because it would be undertaken against a backdrop of practices assumed to be acceptable and because it would probably not engage the full and urgent attention of the proponents of prison research.

H.R. 3603 needs to be amended to include an explicit mechanism for this process of rethinking. The "moratorium" on experiments in penal institutions thus mandated could either be specified to terminate on a certain date (say, two years hence), or preferably, upon the promulgation by a designated body of adequate regulations for the proper conduct of such experiments in the future. The body charged with examining the situation, evaluating the need for and alternatives to prison testing, and devising the safest way to conduct it might be either your Subcommittee, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Department of Justice, the Department of Health, Education and Welfare, the Food and Drug Administration, or some combination of these specially constituted for the task.

Finally, as minor questions about H.R. 3603, I wonder whether the act should not be clearer on whether research into penological questions is precluded if it involves a "drug" or "medical practice" and similarly research intended to treat the medical condition of an individual prisoner. There is certainly a strong argument that research in these categories ought not to be barred, since the captive subject is also the potential beneficiary of the tests. On the other hand, some of the most serious objections to research in prisons has been raised about studies (usually in the "behavior modification" category) which would fall into this exception.

I hope these comments will be of help to your Subcommittee in its consideration of H.R. 3603.

Sincerely,

ALEXANDER MORGAN CAPRON,
Associate Professor of Law.

Enclosure.

STATEMENT ON H.R. 3603, SUBMITTED BY PROF. ALEXANDER MORGAN CAPRON, UNIVERSITY OF PENNSYLVANIA LAW SCHOOL, PHILADELPHIA, PA.

H.R. 3603 would prohibit medical research on inmates in Federal penal institutions, military prisons, and the correctional institutions of the District of Columbia and those of any state receiving Federal support under the Omnibus Crime Control and Safe Streets Act of 1968. This bill is designed to remedy a serious set of problems. Subject to one important amendment, and a number of minor ones, it ought to be adopted.

1. A BAN ON THE USE OF PRISONERS FOR MEDICAL RESEARCH IS JUSTIFIED

On the present record, the need for Federal regulation of prison testing is clear. Nothing has happened since the hearings held by the Senate Subcommittee on Health in 1973 that suggests that the problems raised by research in prisons have been brought under control. No mechanism yet exists to prevent abuses (including deaths and serious illness) revealed specifically in the testimony of March 7, 1973. Indeed, there is as yet no means of oversight by a responsible agency with full knowledge of what is going on. I am, unhappily, certain that the current hearings will only uncover further examples of questionable experiments which harmed their subjects.

The only change since March 1973 is the issuance in the *Federal Register* of August 23, 1974, of a revised set of proposed regulations by the Department of Health, Education and Welfare applicable in part to prison research. While these draft regulations provide better guidance than anything else yet in existence, they would apply only to research sponsored by the Department and, in any case, are not yet officially promulgated. Since most research in prisons is privately sponsored, largely by drug, medical supply, and cosmetic companies, the crying need, as was made apparent at the 1973 hearings, is for knowledge in the Food and Drug Administration of the location, type and extent of such testing.

The opponents of a ban on prison testing argue that federal supervision is unnecessary because of the drug industry's self-regulation, as was asserted by Joseph Stetler of the Pharmaceutical Manufacturers Association at the 1973 hearings. It would be interesting to know whether the PMA ever exercised "self-regulation" to rule that a particular prison was "off-limits" or that a particular researcher was not acceptable to conduct drug studies because of abuses or improper work? The FDA has suspended a handful of investigators because of the poor quality of their work. It would not be surprising to discover that the drug industry had *not* taken similar prior action against these people, however. The slipshod methods of such investigators may permit them to operate at a lower cost, which the companies would appreciate. Moreover, an individual company may be unaware of the heavy volume of research which an investigator is carrying out for many drug companies at a single prison; it is the large volume which often creates the greatest scientific and ethical problems.

Since neither government nor private regulation seems to be working to prevent harm at the present, a ban on prison research seems justified.

2. THE SUGGESTION THAT PRISON TESTING IS NECESSARY FOR MEDICAL PROGRESS IS UNCONVINCING

Opponents of a ban must face three facts about the current situation. First, a great deal of present testing in prisons (no one has the information which would be needed to supply a precise percentage) is of no scientific importance. This would include such procedures as testing over-the-counter preparations (including face creams, adhesive bandages and the like) on which consumer complaints have been received of "sensitivity reactions." Rather than advancing medical knowledge, participants in such "research" are merely working for the manufacturer, just as if the prison system permitted them to be employed (for perhaps $4 per day) assembling General Motors cars or RCA television sets.

Second, the argument that prisons are "ideal" environments for testing because of their controlled nature simply winks at the reality of most prisons. The actual diets—to say nothing of illicit drugs—consumed by prisoners are often far different than that supposed by the researchers. Moreover, the money earned by prisoner-subjects can be the very means used to obtain these unauthorized items—as well as generally disrupting prison life, leading to sexual abuses and so forth.

Third, the assumption that there are no other alternative means of conducting legitimate and important research is largely untested or, to the extent it has been tested, is demonstrably untrue. In such settings as universities or medical research institutions (such as NIH), and even among the general public, willing volunteers can be found. If a "controlled environment" is necessary for the period of the test, this may increase the cost of the study, because the subjects will have to be properly housed and fed and remunerated for the time. But it is nonsense to say that there is any inherent barrier to conducting such studies outside of prisons.

3. EXPERIMENTATION IN PRISONS IS OBJECTIONAL ON THE PUBLIC POLICY GROUND THAT PRESENT CONDITIONS TEND TO EXPLOIT SOCIETY'S CAPTIVES AND NOT ON THE ETHICOLEGAL GROUND THAT NO PRISONER CAN EVER GIVE VOLUNTARY, INFORMED CONSENT

The moral justification for all human experimentation is that the benefits attainable for all human beings (or, more narrowly, for the members of one's society) are so great as to justify the risking of human lives. The limitation placed on this utilitarian calculus under our moral and political system is that the human instruments (that is, the experimental subjects) must be drawn into the enterprise knowingly and voluntarily.

Some people have gone beyond this and have asserted a general "right" *to be* a subject in medical experiments. (See, for example, Benjamin Freedman's "A

Moral Theory of Informed Consent," in Vol. 5, *Hastings Center Report*, August 1975, at pp. 32–39.) Although I would not deny a right of an individual to engage in experiments upon himself, as a part of his general power of self-determination and autonomy, I see no basis for an unlimited right when one is speaking of the social practice of experimentation by one person or another. This activity is, and ought properly to be, subject to regulation to the extent it (a) deviates from collective norms or (b) involves collective resources.

Prison research is thus subject to state control on both these grounds. Prisoners are the captives of the state. If they are abused, it is an abuse for which we all, as their keepers, are responsible. Moreover, anything that is done with prisoners ought to be aimed at benefiting society, since the justification for their incarceration is that through their confinement society will be improved, by the deterrence of crime, the incapacitation of past wrongdoers and their future reformation.

This is an argument based on public policy, not on any premises about the *inevitable* effect of prisons in depriving their inmates of the capacity freely to give their "informed consent" to participate in research. In the article cited previously, Professor Freedman points (with some irony) to the fact that when my testimony from the Senate hearings was published in the June 1973 *Hastings Center Report* ("Medical Research in Prisons," pp. 4–6), the editors also reprinted as a "box" a brief news report from the *New York Times* stating that prisoners at the Lancaster County prison had petitioned to overturn Pennsylvania's halting of prison research. The fact that some, or even all, prisoners might *want to participate* in research is not sufficient to overcome the conclusion that it should not be permitted. Prisoners are, for reasons of public policy, deprived of a great many choices. If we believe that, in order to prevent the exploitation of these social "captives" by a particular segment of American (or foreign?) industry, it is necessary to exclude certain activities from correctional institutions, this is no more a contradiction of any "moral theory" than any other regulation of prison life.

4. THE BAN ON PRISON RESEARCH SHOULD BE SUBJECT TO RECONSIDERATION AND CONDITIONS FOR ITS TERMINATION SHOULD BE SPECIFIED

Halting prison experimentation, as specified by H.R. 3603, is a necessary step if there is to be a *serious* and *diligent* rethinking of the practice. But the ban should be conceived of as a "moratorium"—to promote cooperation by all parties in the process of reassessment and not to lead to angry resistance (and even violation of the law) by those who are unconvinced of its merit. (The advantages of a "moratorium" were set forth in my 1973 testimony, a copy of which is attached.)

H.R. 3603 should thus be amended to incorporate either a specified end point for the ban on medical studies in prisons or, preferably, a set of objectives for a study, including eventually the promulgation of appropriate laws and regulations. The concern of such rules would be to specify such points as: (1) what are the attributes of a proposed research project that would justify using a captive population, and what are the alternatives (at what cost?) to such use? (2) what are the characteristics of a prison which would make it an appropriate setting for such research, such as the availability of alternative, comparable types of employment to prisoners, and so forth? and (3) how will prison research be reviewed in advance and then actually supervised, recognizing that the danger of intentional and unintentional abuse of the subjects is increased by the isolated nature of prisons?

The process of thinking this matter through could be undertaken by a Congressional committee, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Department of Justice, the Department of Health, Education, and Welfare, the Food and Drug Administration, or some combination of these bodies specially constituted for this task. The premise would be the open and unbiased one that it may be possible for *some* research project to be justifiably conducted in *some* correctional institution under *some* conceivable set of controls. It would be open for the group conducting the study, however, to conclude that this is *not* the case and that prison research ought to continue to be banned.

5. CERTAIN OTHER MINOR REVISIONS OF H.R. 3603 APPEAR TO BE NEEDED

H.R. 3603 as presently drafted would ban the testing of "any drug, medical device or medical practice." This would appear to forbid an *experimental* therapy on a prisoner for whom it is considered the best medical treatment. Do the drafters really mean to inject federal law into the doctor-patient relationship in this way when the patient is a prisoner who is not being used simply as a subject for research but may also be an immediate beneficiary of it?

This raises the more difficult question of research being conducted by persons concerned with criminology or penology, but employing drugs or medical practices. An example would be research on techniques of "rehabilitation" or "reform" of prisoners which employs behavior control methods developed by psychiatrists. Here, too, the prisoners are the immediate objects of a hoped-to-be beneficial "therapy." But such research has also raised some of the strongest cries of "abuse" of prisoners. Should any amendment of H.R. 3603 include—or exclude—such studies from the ban on experiments in prisons?

Finally, it might be advisable for H.R. 3603, or a companion bill, to address the problems raised by experiments in the military—and not simply those conducted on military *prisoners*. From the relevant perspective, all soldiers are like prisoners in being "captives" of a "total institution." Not only may there be serious freedom-limiting constraints on their choices but the other reasons for abuse in prison research (such as the isolated, secretive nature of the institution) also exist in the military.

PHILLIP SHAPIRO, M.D.,
San Francisco, Calif., September 17, 1975.

Hon. R. W. KASTENMEIER,
Chairman, Subcommittee on Courts, etc., Committee on the Judiciary, House of Representatives, Washington, D.C.

DEAR MR. KASTENMEIER: I think the enclosed statements on the subject of human experimentation in prisons may be of interest to your Committee.

In the matter of the use of neuroleptic drugs in prisons: such drugs with their attendant serious hazard of producing permanent brain damage resulting in tardive dyskinesia, are, to my knowledge, being given in excessive dosages[1] to inmates in the California prison system.

Sincerely yours,

PHILLIP SHAPIRO, M.D.

MEDICAL COMMITTEE FOR HUMAN RIGHTS,
BAY AREA CHAPTER,
San Francisco, Calif., October 23, 1973.

STATEMENT ON THE SUBJECT OF "HUMAN EXPERIMENTATION IN PRISONS" BEFORE THE CALIFORNIA STATE ASSEMBLY COMMITTEE ON CRIMINAL JUSTICE

Thank you, Chairman Sieroty and members of the Assembly Committee on Criminal Justice, for inviting me to this hearing on "Human Experimentation in Prisons." I appear here as a member of the Bay Area Chapter of the Medical Committee for Human Rights and as Co-Chairperson of its Prison Health Committee. I am a psychiatrist in private practice in California since 1941 and a Life Fellow of the American Psychiatric Association. I am also a member of the American and of the International Psychoanalytic Associations.

I wish to begin my remarks with a general statement of principle which is not unrelated to the matter at hand and which I present to you with the utmost seriousness and deliberation: For a very long time there has been overwhelming evidence that the prison system does much more harm than good, to the prisoner, his keepers and the public at large. That the prison system cannot be made to work and is beyond reform has been attested to by outstanding authorities, including the participants in the annual conference in honor of Chief Justice Earl Warren held last year. The Medical Committee for Human Rights holds that the California prisons should be phased out and the system abolished at

[1] As established by George Crane, M.D., Director of Research, Spring Grove Hospital Center, Catonsville, Maryland.

the earliest possible moment. Drastic reduction in the prison population could begin with the immediate release of all those held for non-victim crimes and by the abolition of bail for those awaiting trial. Coupled with such a development it would be appropriate to make available to all released prisoners, without coercion, educational, vocational, medical and psychiatric services and suitable opportunities for employment. Hospitalization would be provided for those requiring further in-patient care.

That substantial steps can be taken in this direction is demonstrated by the example of the Commonwealth of Massachusetts which has already succeeded in reducing the population of its juvenile prisons by 94% in three years.

Were the prisons to be closed down and this festering wound on the body politic be healed, the issue which has brought us here today would of course become moot, as it should be, for I can think of no less appropriate subjects for such investigations than those held in involuntary detention.

So long as California prisons continue to remain open it is our position to give unqualified support to the demand of the Prisoners' Union that those incarcerated be provided with worthwhile jobs at prevailing union wages. I can think of no step on the road to our ultimate goal which would be more constructive than this. It would also, incidentally, make a ban on human experimentation in prisons quite feasible.

Pending such a development, and in order to protect the prisoner from further exploitation and potential harm, we propose that the experimental programs be dropped now and that this move be coupled with an arrangement whereby the former prisoner/subject would suffer no loss of current income. To a man who might now earn from $2 to $10 per month by working a full shift in a prison shop (when and where such an assignment is available) the $30 or more per month which he can make by participating in a drug testing experiment is of tremendous importance. Therefore alternative work assignments requiring a comparable expenditure of time and effort should be made available for which the prisoner would be compensated at the rate he previously earned in the drug testing program.

A principal reason for our opposition to human experimentation in prisons (though not the only one) is that it violates the basic canons of medical research and the civil and human rights of the prisoner. I refer to the fact that the fundamental requirement of "free and informed consent" is inevitably compromised in the prison setting. It is a requirement which I have never felt can be adequately met by one incarcerated within a closed and inescapably coercive system. Such "consent" by a prisoner is not truly "free" nor adequately "informed," nor is it "consent" in the sense of an agreement between equals under conditions of trust.

In 1947, after the Nuremberg Tribunal condemned a number of Nazi physicians to death by hanging for having subjected concentration camp victims to involuntary and unconscionable experimentation, a code was enunciated which forbade the use of prisoners for medical experiments. In 1961 the World Medical Association, meeting in Helsinki, proposed a similar resolution which failed of adoption essentially because of the opposition of some American physicians. Later, the National Institutes of Health at Bethesda, Maryland, in stating its guidelines on human experimentation, said, "the inalienable rights of human beings supersede all other considerations that may be raised in the name either of science or of the general welfare." In May 1973 the Northern California Phychiatric Society officially declared its belief that "prisoners are unable to give fully free and truly informed consent for experimental procedures . . ." Finally, we have the decision rendered by the three-judge panel of the Wayne County (Michigan) Circuit Court in July affirming the same position.

Of course, the pharmaceutical companies would be most unhappy to lose their convenient and cheap reservoir of human material which the prisons now afford them. It has been estimated that in the last eight years they have profited to the tune of about ten million dollars by exploiting prisoners at Vacaville who have been receiving $\frac{1}{10}$ to $\frac{1}{100}$ of the pay their services would have earned had they been contracted for outside the prison walls. I hope your committee will explore this matter with Mr. Urbino of the Solano Institute of Medical and Psychiatric Research when he appears here later today.

The researchers and investigators won't like it either. Medical schools and university hospitals are in a mad scramble for funds. Any staff member who hopes for advancement, tenure and status is under tremendous pressure to "publish or perish" and the prison population has provided them and their patrons with a veritable field day.

The author of "Kind and Usual Punishment," Jessica Mitford,[1] has made a most apt suggestion for dealing with any dearth of human subjects for experimental purpose which might result from the withdrawal of prisoners from the market: let those who are stockholders in one of the most lucrative businesses in America, i.e., the drug industry, volunteer their own bodies in the service of mankind and of greater profits! Gentlemen, I heartily second that motion. Thank you.

PHILLIP SHAPIRO, M.D.,
Prison Health Committee, MCHR.

MEDICAL COMMITTEE FOR HUMAN RIGHTS,
BAY AREA CHAPTER,
San Francisco, October 30, 1974.

Re protection of human subject.

CHIEF, INSTITUTIONAL RELATIONS BRANCH,
Division of Research Grants,
National Institutes of Health,
Bethesda, Md.

DEAR SIR: In response to the invitation of the Secretary, DHEW, we hereby submit the following statement of our position regarding the subpart of 39FR30648 relating to prisoners:

We hold that prisoners cannot be considered "normal volunteers" as referred to in 38FR31743 V, A for the following reasons:

(a) Prisoners cannot be considered "volunteers" in the usual sense because the fundamental requirement of "free and informed consent" is inevitably compromised within the prison's closed and coercive system. Such "consent" by a prisoner is not truly of an agreement freely entered into by equals under conditions of trust. These considerations cannot properly be set aside simply because his status as a member of a captive population has made the prisoner a convenient and inexpensive experimental subject.

(b) The major considerations motivating prisoners to "volunteer" are (1) significant (to them) material inducements which promise to make their incarceration more tolerable and (2) the hope (or promise) that participation will bring an earlier release. An unequivocal elimination of such factors, as proposed in part by § 46.404a (1) and (4) (cf. 39FR30654–5), would sharply reduce this reservoir of human subjects.

(c) Prisoners cannot be considered "normal" subjects because their response to experimental activities is susceptible to being skewed to a greater or lesser degree by the fact that (1) the prison is not a "normal" environment and inescapably has a distorting effect on the prisoner, (2) covert drug abuse is rampant in prisons and (3) prisoners may consciously distort experimental results if this will, in their view, aid in their release or ameliorate the conditions of their confinement.

(d) Efforts to protect subjects of experimentation by the establishment of "Protection Committees," etc., with minority representation by fellow prisoners (or parolees) is no solution, for such prisoner representatives are more or less subject to the same constraints as their fellows and cannot therefore serve them as free agents. Furthermore, it is now clear from § 46.405(b), (4), (cf 39FR30655), that prisoner representation (even subject to the limitations noted above) on the "Consent Committee" would not be mandated by this latest version of the proposed rules.

In view of the foregoing considerations, concern for the human rights of the subject and for the scientific validity of experimental results compel us to oppose *in toto* the use of prisoners as experimental subjects and to insist that the Nuremberg Code prohibiting such use must be stringently applied. Other countries have demonstrated that they are able to carry out necessary research involving human subjects without resort to the prison population. We can and must do likewise.

Respectfully submitted.

PHILLIP SHAPIRO, M.D.,
RICHARD FINE, M.D.,
Co-chairpersons, Prison Health Committee.

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[1] I wish to acknowledge my debt to Miss Mitford in the preparation of this statement.

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STATEMENT OF THE AMERICAN PHARMACEUTICAL ASSOCIATION, ACADEMY OF PHARMACEUTICAL SCIENCES

This statement prepared by Dr. Gilbert S. Banker, Chairman of the Public Policy Committee of the APhA Academy of Pharmaceutical Sciences and Head of the Industrial and Physical Pharmacy Department of the School of Pharmacy at Purdue University and by Dr. William F. McGhan, Executive Secretary of the APhA Academy of Pharmaceutical Sciences.

We are responding to the Subcommittee's invitation to the American Pharmaceutical Association (APhA) to present comments on H.R. 3603, a bill to limit the use of prison inmates in medical research.

The American Pharmaceutical Association is the national professional society of pharmacists. Its approximate 50,000 members are composed of practicing pharmacists, pharmaceutical educators, pharmaceutical scientists and pharmacy students.

Organizationally, the APhA includes three subdivisions. One of these, the Academy of Pharmaceutical Sciences, provides an organization within the APhA for more than 2,000 pharmaceutical scientist members. These scientists are associated with colleges of pharmacy, pharmaceutical manufacturers, government agencies and private research laboratories. The purpose of the Academy is to elevate and promote scientific, technical and academic accomplishments in all the disciplines related to the discovery, testing, production and control of drugs for the benefit of the public health.

PRACTICING PHARMACISTS

For many years the APhA has realized that as drug experts, pharmacists know that from the investigational drugs of today come the life-saving drugs of the future. The proper control, labeling, reporting and recording of investigational drugs is an increased responsibility that is readily accepted by pharmacists involved in various research efforts. Pharmacists practicing in community, institutional or prison environments are continually alert for adverse drug reactions and proper enforcement of research protocols for the investigational drugs they dispense to patients or to research subjects.

As drug experts on the health care team, pharmacists are continuing to increase their involvement in patient therapy. Pharmacists are eager to inform physicians about the virtues of new or improved modes of drug therapy. Many pharmacists continually appraise the plethora of new drug information since physicians sometimes have insufficient time to review and evaluate this data on their own.

In the June 1975 issue of *Drug Intelligence and Clinical Pharmacy*, Dr. John A. Romankiewicz, Assistant Director of Clinical Pharmaceutical Services at Cornell Medical Center, has emphasized that pharmacists must become involved in human drug research. Many pharmacy schools have educated their pharmacist graduates in the proper design and methodology of drug trials, and more and more pharmacists are becoming directly involved in the research of new drugs and new drug therapy.

PHARMACEUTICAL SCIENTISTS

Since the Academy of Pharmaceutical Sciences was founded in 1965, we have been very concerned about the issue of drug testing and evaluation. In November 1967, the Academy held a national meeting in Washington, D.C. with the theme—"Safer and More Effective Drugs."

At this important meeting, Irwin C. Winter emphasized that "If humanity and medicine are to progress, the human trial of new drugs must continue effectively. It is difficult to find patients who will allow themselves to be subjected to the controls and manipulations which modern drug research requires," . . . and "the expense of drug development has very markedly increased."

"It is necessary that the public have a better understanding of some of the facts of drug investigation. We must somehow achieve public acceptance of the need and individual willingness to serve if needed."

Pharmaceutical scientists, in academia and industry, do much research which depends upon testing in human subjects. These areas of involvement include:

Pharmacognosists are concerned about isolation of new drugs from plants;

Medicinal chemists are concerned about the synthesis of new medically useful chemical compounds;

Pharmacologists and toxicologists are concerned with human subjects when studying the safety and efficacy of compounds;

Scientists specializing in pharmaceutics or industrial technology are concerned with absorption, distribution and excretion of various product formulations and these factors are studied during research in humans.

One pharmaceutical scientist, who worked on an evaluation of prisoner experimentation in his state, concluded that prisoner experimentation could be considered moral and ethical if four basic conditions are guaranteed:

1. that the prisoner is fully informed and there is true voluntary consent after knowing what, how, and why the experiment is being conducted along with fully understanding the risks involved;
2. that there is no chance for the experiment to cause death, threat to life, or serious injury;
3. that the experiment will result in definite benefit to mankind which could not be obtained by any other means;
4. that the welfare of the individual subject is the primary concern in the study.

POLICY STATEMENT

Due to the considerable attention focused on the use of prisoners in human experimentation, the Academy developed background materials so that the House of Delegates of the American Pharmaceutical Association could consider this subject at the recent 1975 APhA Annual Meeting. The APhA House of Delegates adopted the following policy:

"The American Pharmaceutical Association fully supports all reasonable procedures, including use of institutional review committees, informed consent and other procedures as described in HEW's 1971 guide and the May 30, 1974 regulations on this subject, for the protection of all classes and groups of human subjects who are to be used for any form of experimentation.

"Future regulations which are promulgated should permit the continued effective use of prisoners in experimentation in a manner which is not substantially different from non-institutionalized human subjects."

The Academy recognizes the important and unique role of prisoners as experimental subjects, particularly in the development of new and improved drugs and drug products. We recognize that special problems and potential abuses regarding free consent may exist with prisoner populations, which warrant careful protection of these subjects in this regard.

The Academy supports the principles delineated in the "Institutional Guide to DHEW Policy on Protection of Human Subjects," DHEW Publication No. (NIH) 72-102, December 1, 1971, which has now been updated with the May 30, 1974, HEW regulations entitled "Protection of Human Subjects" (39 FR 18914).

However, provisions of the August 23, 1974, Federal Register proposal (39 FR 30648), and in particular section 46.404 (Additional Duties of the Organizational Review Committee where Prisoners are Involved) could be counterproductive in protecting the subjects as well as excessively limiting in permitting subject use in appropriately controlled studies. Part (a) (1) of section 46.404 stipulates that, "there will be no undue inducements to participation by prisoners as subects in the activity, taking into account such factors as whether the earnings, living conditions, medical care, quality of food and amenities offered to participants in the activity would be better than those generally available to prisoners."

If, for example, this regulation were to be interpreted in such a way that a comprehensive medical examination before and/or after a study or close medical surveillance during a study constituted better medical treatment than that available to the general prisoner population at that institution, his rule and such an interpretation would be counterproductive in the matter of subject selection, monitoring, and protection.

Likewise, if this regulation were interpreted to require that a prisoner not be separated from his normal prison rountine, prison location, or prison diet or diet schedule, many controlled studies involving drugs would be rendered impossible or useless.

The Academy of Pharmaceutical Sciences fully agrees that all aspects of a subject's activity must be appropriate when studies are performed whether using prison volunteers or nonprisoners. There must be adequate procedures for prisoner subject selection, securing of consents, monitoring and subject protection in

general, equal to those for non-institutionalized subjects. While the Academy of Pharmaceutical Sciences realizes that problems associated with assuring informed consent without coercion can exist among prisoner populations, it feels that suitable regulations can be developed to deal with these problems, without creating a climate in which studies involving prisoners would be virtually impossible.

CONCERNS ABOUT PRISONER VOLUNTEERS

Over 20 states have policies which highly regulate or preclude prisoner experimentation. Prisoners in Illinois and Connecticut asked that experimentation continue when the states considered banning these activities. In Pennsylvania's Lancaster County prison system, 60% of the prisoners signed a petition to continue their right to participate when an experimentation ban was proposed.

There have also been negative reactions from prisoners about experimentation. Alvin Bronstein, Director of the National Prisoner Project of the American Civil Liberties Union Foundation, does have letters from prisoners expressing great distress about experiments conducted in their prisons. On the other side of the story, the President of a prisoners society (called Fortune, in New York) has said that he has never received a letter from a prisoner objecting to prisoner experimentation.

The Academy of Pharmaceutical Sciences has followed the criticisms of drug testing in prisoners from such individuals as Alvin Bronstein. Mr. Bronstein feels that prisons are inherently coercive which he says makes informed consent without coercion impossible.

We certainly do not feel that Mr. Bronstein's views are frivolous, but we feel that HEW has taken positive steps in formulating new regulations which will overcome many of the criticisms of prisoner experimentation.

As APhA policy states, we feel that any government rules or legislation that are developed should permit the continued utilization of prison populations in a fashion not substantially different from non-institutionalized human subjects.

We feel that prisoners should have the right to volunteer for projects just as easily as the general population under the supervision of appropriate review committees (to remove coercive factors).

We agree with former HEW Secretary Weinberger when he spoke on the issue of prisoner experimentation at a National Academy of Sciences Forum. He stated: "Scientists have long viewed prisoners as an ideal population for certain controlled studies, because their diets and their life-styles are easily observed and easily controlled. As you know, many very beneficial discoveries, particularly in the fields of immunization and microbiological processes, have come from research on prisoner subjects. I think it is clear that prisoners are needed in many kinds of research."

At this same National Academy of Sciences Forum, Dr. Albert Sabin, developer of the polio vaccine, passionately supported the use of prison volunteers which were a critical factor in his own research which has saved thousands of lives.

In support of his position, Dr. Sabin states that many prisoners have written to him that they have obtained a great sense of worth and personal reward from participating in research projects. Dr. Sabin believes that prisoners should not be deprived of the right to volunteer.

In a report in the *Journal of Pharmacology and Therapeutics* Dr. Frank Ayd of Baltimore, Maryland reported that prisoners participating in a research project experience an increase in self-esteem that usually triggers favorable changes in life style and behavior. These changes usually are long-lasting and possibly permanent.

In the same journal Dr. Paul Calabresi of Brown University commented on Dr. Ayd's results by agreeing "that the motives among noncaptive populations to accept risks or adventures are not 'qualitatively' different from those of a captive population. We must always assure ourselves, however, that they are not made so different 'quantitatively' that an unreasonable or unfair benefit/risk equation is created."

From his experiences at the Harry Truman Research Laboratory in Kansas, Dr. John Arnold has concluded that one of the major justifications from allowing prisoners to participate in Phase I studies is—*safety*. In Phase I testing, when drugs are being tested in human subjects, close medical surveillance is important. In non-prisoner populations the monitoring in these tests requires confinement,

and the preferred long range follow-up, a few weeks after the drug administration to the subject is discontinued, is very difficult.

As for the institutions which sponsor the experiments, pharmaceutical manufacturers have reported no known episodes of death or serious injury since the 1962 Kefauver-Harris Amendments. Admittedly, prior to 1962, a prison population in Vacaville, California was being used to test Varidase which did cause serious side effects.

The exclusion of prisoners from medical experimentation is not the answer to solving the concerns about human testing. Some of the problems and trouble that occurred in various studies have clearly demonstrated the need for properly enforced controls and protocols even in human testing involving non-prisoner populations. The nation's newspapers and press have made it well known to this country that the government (namely the Department of Defense and Central Intelligence Agency) has had serious problems in its experiments with non-prisoner subjects. Recent disclosures of experimentation with the hallucinogens, LSD and "BZ" (which lasts 3 days), and the lack of follow-up on non-prisoner populations, leaves many questions about the controls and protocols of these government tests. Other examples are the well publicized Public Health Service experiments which utilized non-treated syphilis patients in Tuskegee, Alabama. The solution to this overall problem lies in developing and enforcing adequate research guidelines; the solution will not come about by preventing some or all human populations from participating in human testing programs.

THE NEED FOR CONTINUED HUMAN DRUG TESTING

Safe and effective drugs are extremely important to all Americans including those in the prisons. It has been reported that drugs are the number one, and usually preferred method of treatment for a majority of diseases, as opposed to other treatments such as surgery, radiation, or other forms of therapy.

Over the last 30 years, drugs have played the major role in extending the average life expectancy an additional 10 to 20 years, so that the average life span in this country today is nearly 70 years.

Since the 1962 drug amendments, Investigational New Drug Applications (IND) are required before drug experimentation can begin in human subjects. The first critical part of these studies (Phase I) are generally conducted on a small number of patients to determine such things as effective dose and potential toxicity.

It has been reported that 90% of the Phase I tests are currently conducted with prisoner populations: the other 10% of the subjects are generally students along with other volunteers from the general public.

Of the 400,000 prisoners in the United States only 20% volunteer for medical research, 50% of these drop out after being informed of the rigors of the experiments and another 20–30% are eliminated during physical examination and screening. Considering other factors this extrapolates to about 20,000 prisoners involved in medical experiments.

PAST AND PRESENT CONTRIBUTIONS OF PRISONERS

Prisoners who have consented to participate in medical experiments have made monumental contributions toward the betterment of health in the American public. Prisoner experimentation has led to perfection of blood transfusion techniques, and the development of drug treatments for yellow fever, typhus and polio.

If the 20,000 prisoners in the country, who are participating in medical research, are excluded from participating in drug testing, other human subjects will have to be found.

The long term studies easily performed with prisoners will be difficult to duplicate in non-prison populations. There are many areas where more drug research and testing is needed to better the health of society, and prisoners do provide an ideal and stable study group.

Another special area in the pharmaceutical sciences that is requiring an increasing number of human subjects is that area called bioavailability. The term bioavailability is defined as: the rate and extent to which a therapeutic moiety is absorbed from a drug product and becomes available to the site of drug action in the body.

To work toward guaranteeing drug quality in the U.S. the Food and Drug Administration has recently proposed regulations to require human testing for 47 different drugs. These new regulations will require a number of human subjects as a test population to be used to verify and sustain the high quality of drug products in the United States.

In the APS publication—"Guidelines for Biopharmaceutical Studies in Man"—and APhA's—"The Bioavailability of Drug Products"—procedures are recommended for the equivalency testing of drugs in human subjects. Many of these tests require cross-over testing of different drug products in the same subjects. In some of these tests the patient diets must be controlled while blood levels of the drug, as produced by the respective products, are being measured. To scientifically compare the bioavailability of two different brands of the same drug product, a patient must sometimes be tested with one brand of the drug product on one week and the other brand of the same drug a week or more later. This separation of time is necessary so that no trace or metabolic effect of the first brand would interfere with the second brand tested in the same patients.

Because of the length of time that human subjects are required for these types of tests, prison populations are ideal for controlling diets and monitoring of drug blood levels as well as monitoring to prevent any possible adverse drug reactions in the subjects.

THE FUTURE IMPACT ON NEW DRUG RESEARCH

With enactment of the 1962 Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act, many more requirements were implemented with regard to testing in human subjects. Some people have suggested that this has led to a decrease in the development of new drugs in this country thus causing a drug lag in the U.S. compared to new chemical entities in foreign countries which have less stringent regulations. Physicians Lasagna and Wardell of the University of Rochester have reported that the U.S. is not now suffering from a drug lag, but they warn that over-regulation of new drug testing may lead to a decrease in the innovation of new drugs. If prisoners are excluded from participating, we hope that this will not lead to a decrease in the rate of development of new drugs for the betterment of the public health.

We understand that the drug research facilities which were initially planned for construction in the United States by one or two pharmaceutical manufacturers are now being considered for relocation in other countries such as England and Japan. One of the reported reasons for these considerations is related to the potential problems in obtaining human volunteers and the high cost of drug research in this country. The foreign location of these facilities could have a detrimental impact on the creation of new drugs and new drug therapy for the American people. Once these drugs are tested and approved under the less stringent foreign requirements, we may lack the facilities and resources to rapidly complete the additional or different drug studies required for approving these "foreign developed" drugs for use in this country.

RECOMMENDATIONS ON H.R. 3603

We recommend that this bill be drafted so that all prisoners (federal, state and local) would be protected by the proposed HEW regulations. There have been some stories of less-than-reputable research facilities operating on an intrastate basis which excludes these facilities from FDA and HEW regulations. A statute which requires the enforcement of the proposed HEW regulations at all levels (federal and local) would be a positive move for the protection of the prisoner's rights.

Under H.R. 3603 as presently drafted, there are some individuals who are quite concerned that prisoners will be denied the right to be treated with drug therapy sometimes used in treating the general public, because such drug therapy may still be considered as investigational use of a drug.

We certainly do not generally advocate therapy through use of unapproved drugs, but for life threatening diseases in prisoners, such as cancer or exotic foreign disease (possibly transported by military prisoners which could threaten civilian populations), investigational therapy may be the only alternative for the afflicted individuals. If H.R. 3603 is strictly interpreted, prisoners would be denied the right to this type of experimental emergency therapy which is available to the general public with their informed consent.

CONCLUSION

The APhA and its Academy of Pharmaceutical Sciences recognize the unique and substantial contribution that prisoner subjects have made to drug and drug product development. We fully support the intent of the proposed HEW regulations which would permit prisoners to continue to have freedom of choice to make this important contribution, and we urge laws and regulations which will allow the continued voluntary use of prisoners in controlled, meaningful studies.

It would be better, in our view, to fully enforce HEW's proposed regulations (with suggested modifications) on this issue without enacting H.R. 3603, as presently drafted. H.R. 3603 could deny the right of prisoners to volunteer for innovative drug research that benefits all mankind.

STATEMENT OF ROBERT B. COUCH, M.D., AND J. VERNON KNIGHT, M.D.[1]

We have been informed that the House Judiciary Subcommittee for Courts, Civil Liberties, and Administration of Justice is considering a bill that will prohibit biomedical research involving prisoners. We appreciate and share the concern of the subcommittee in this matter. As investigators participating in investigations involving prisoners, we would like to present a view on their participation in medical research. Our group of investigators have for the past 14 years performed studies involving prisoner volunteers. We have personally been involved in supervising and conducting studies on common colds and influenza which are entirely oriented toward developing new vaccines, improved vaccines and other methods for the control of these illnesses. Programs originally initiated at the National Institutes of Health with the cooperation of the Federal Correctional System have continued in Houston, Texas, with the cooperation of the Texas Department of Corrections.

Certain types of biomedical research, e.g., investigations leading to the development of new vaccines and medicines, require the availability of healthy adults. For these studies medical researchers have most frequently used prisoners, medical students, medical center employees, college students, and military servicemen. Each of these groups contains relatively large numbers of healthy persons who will be available for repeated and close observations.

Prisoners have been recently identified as a group of individuals requiring special consideration. They are required by "society" to be confined in an institution. Since this group is considered to be consent prone, it is therefore necessary that their involvement be a situation in which they clearly have the option *not to volunteer*. In our case, a maximal effort is always made to insure availability of this option to prisoner volunteers. For example, potential participants are not identified until after they have volunteered and thereafter may withdraw at any time without prejudice. The second major concern is that reward incentives, particularly financial remuneration for participation, an established practice in virtually all volunteer research, not be excessive. If these prerequisites and those which are essential for all research involving volunteers are met, we believe studies involving prisoner volunteers are ethical. Positive values to society include new vaccines, new medicines, and new knowledge that leads to improved health care. The contribution of prisoners to the present status of health care has been significant and should be clearly acknowledged. In addition, there are positive benefits to the prisoner and these include gratification for having volunteered to help mankind, the opportunity to be associated on a personal basis with people from the outside world, the opportunity to break the monotony, and the opportunity to obtain money for small luxuries such as candy, extra food, toiletries, etc. On the basis of these considerations and our experience, we believe that prisoners should be allowed the right to participate as volunteers in medical research.

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[1] For identification purposes, Robert B. Couch, M.D., is professor, Department of Microbiology and Immunology and Department of Medicine, and Director, Influenza Research Center, at Baylor College of Medicine in Houston, Texas. J. Vernon Knight, M.D., is Professor and Chairman, Department of Microbiology and Immunology, and professor, Department of Medicine, at Baylor College of Medicine, Houston, Texas; Dr. Knight is also former Clinical Director of the National Institute of Allergy and Infectious Diseases, Bethesda, Maryland.

The situation is indeed complex, but we believe the issue will receive a fair hearing by the congressional and executive committees currently concerned with the matter.

AMERICAN CORRECTIONAL ASSOCIATION,
College Park, Md., October 1, 1975.

HON. ROBERT W. KASTENMEIER,
Member of Congress, Congress of the United States, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: In response to your request for information regarding the position of the American Correctional Association on medical research, we would like to offer the following for your committee records.

In 1972 the American Correctional Association accepted the position that medical and/or pharmaceutical experimentation was acceptable within a correctional institution only under very strict guidelines.

A very well qualified committee of the American Correctional Association, whose members names are attached to the enclosed Protocol, worked diligently over several months and prepared the document. The Board of Directors accepted the document and in February, 1972 it became policy and is in effect today.

Because medical experimentation and particularly pharmaceutical experimentation is extremely controversial at best, a survey was taken in 1974 to determine what was being done in this area. As the survey indicated at that time, twenty states did not involve themselves in experimentation. Eighteen states did allow some type of experimentation and fifteen states chose not to respond.

In February, 1975, the American Correctional Association's Executive Committee, very conscious of the concern of its members and agencies regarding this area, asked a select committee to review our current position on this vital issue.

The committee reported back in August of 1975 with a draft proposal of a new policy. The committee asked that they be allowed to continue working until February, 1976. The recommendation was accepted and the committee will continue to seek a position which will be acceptable to the membership of the American Correctional Association.

The American Correctional Association shares the concern of Congress as well as that of the professional community that human research and experimentation is and continues to be a controversial area. Many members of our Association honestly feel that such experimentation is in the best interest of society and can truly be voluntary on the part of inmates, and make a major contribution to improve the health of all people. Others feel that no inmate can really volunteer while he is confined against his will.

We have attached the draft copy of a new position statement which will be discussed in February, 1976. This draft would severely limit experimentation and is a step toward elimination of it entirely.

Our Association, therefore, is moving in the direction of a policy that would suggest the elimination of medical and/or pharmaceutical experimentation in correctional settings and would probably support Bill H.R. 3603, if we were ready to bring it to a vote. The bill is a good bill and I believe will be supported by the great majority of correctional professionals.

In summary, we wish to convey to your committee that the issue is extremely complicated and our Association has grave concern regarding the entire subject. However, the current policy of the American Correctional Association is that experimentation is acceptable under the guidelines of the Protocol as presented.

Peace,

ANTHONY P. TRAVISONO,
Executive Director.

Enclosures.

AMERICAN CORRECTIONAL ASSOCIATION,
College Park, Md., March 3, 1972.

PROTOCOL FOR MEDICAL EXPERIMENTATION AND PHARMACEUTICAL TESTING

Attached will be found a report entitled Protocol for Medical Experimentation and Pharmaceutical Testing. This report was prepared by an outstanding committee. The chairman was Robert Brutsche, M.D., Chief Medical Officer, U.S. Bureau of Prisons, Joseph Satten, M.D. formerly of the Menniger Clinic, now Director, Division of Law and Psychiatry, San Francisco, Mr. John Gavin recently retired Commissioner of Corrections, Commonwealth of Massachusetts, Ralph Gray, M.D., Director of Medical Services, Texas Department of Corrections, and Mr. Eugene Barkin, General Counsel, U.S. Bureau of Prisons.

This material was presented at the Mid-Winter Board meeting held in Omaha, Nebraska, February 17–18, 1972. It was approved by the Board with an expression of appreciation to Dr. Brutsche and his Committee for their fine contribution.

Because regulation changes by federal departments and court decisions affect the areas covered by this Protocol an attempt will be made to make revisions when the need is indicated.

I trust this material will be of help to you and if you have any comments, please share them with us.

E. PRESTON SHARP, Ph. D.,
General Secretary.

PROTOCOL FOR MEDICAL EXPERIMENTATION AND PHARMACEUTICAL TESTING

1. The Administration[1] shall utilize a committee as described in Title 21, USC, required by the Food and Drug Administration for experimentation with all investigational drugs.[2]

2. It shall be the responsibility of the administration to insure proper and complete review from both the technical and the broad ethical and moral standpoint. If appropriate personnel are not available from staff or consultants, another committee should be utilized. Such a committee most often would be a standing committee at a university or other medical center.

If an outside committee is utilized, an inside committee shall also be available to finalize recommendations to the Administrator.[3]

3. The Administrator shall retain authority to veto any experimental project (either prior to initiation or during progress) even though approved by all committees. The Administration shall take particular cognizance of features of the experimentation that are inappropriate in the correctional setting.[4]

4. Each volunteer shall be given a full verbal and written explanation compatible with the principle of medical "informed consent." This shall be documented and each volunteer shall execute a signed consent.[5]

5. The Administration shall insure that each volunteer is screended for both physical and emotional preparedness for participation in the experiment.[6]

6. The Administration shall carefully evaluate the nature and degree of compensation provided to any and all volunteers and satisfy themselves that the compensation is compatible with the general welfare of the institution.[7]

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[1] The term "Administration" is used throughout to mean institution, correctional system or other jurisdiction, whichever is applicable.

[2] The Institutional Review Committee, required by the FDA, must be multidisciplined to adequately review both the scientific and the ethical and moral aspects of a proposed study. In addition to scientific representatives, committee membership shall include one to several of the following: lawyers, clergymen, sociologists, social workers, psychologists, and other mental health professionals, and when possible, representatives of the consumer population (the prisoners).

The Committee shall have responsibility not only for the initial approval of a project, but also for ongoing monitoring and periodic evaluation of progress, with the option of stopping the project at any time.

[3] This inside committee should also be multi-disciplined and may be required to perform the sole review of those experiments not covered under FDA regulations.

[4] There are clearly many projects which constitute no problem in other settings but because of the nature, risk, or ramifications are unwise in the correctional setting; for example, any significant risk of fatality. A project involving such a risk is unfair to the volunteers and potentially damaging to the image of corrections.

[5] Preferably the signed consent shall include a reasonable review of the project in the text of the consent with a copy given to the volunteer. Documentation should also enumerate and clarify the full consent procedure that was followed.

[6] Particular attention should be paid to emotional factors including reasons for volunteering. Professional assistance should be sought in the evaluation of borderline volunteers who are being favorably considered.

[7] The Ad Hoc Committee discussed at length the entire question of authenticity of *volunteering*, particularly when compensation is offered. For example, minority view held that any offer of additional "good time" constitutes unfair inducement; or even the act of volunteering carries with it the expectation of latent benefits and conversely failure to volunteer may create the expectation of adverse action. It was the majority and final view of the committee that the usual benefits offered are too small to be considered unfair inducement. The unofficial legal opinion held that a prisoner may be considered a bonafide volunteer despite small inducements. The matter of compensation is therefore left with the administration.

7. The Administration shall insure that any infringement upon inmate schedules does not compromise ongoing programs and/or other related correctional activities.[8]

8. Even though in many situations a prison population may constitute an unusually satisfactory group for a particular experimental study (there may be a specific need for a population existing under these controlled conditions) the Administration should not be unduly influenced by this need.[9]

9. The Nuremberg principles (enumerated at the Nuremberg War Crimes Trial—attached) and the Declaration of Helsinki should be followed though with appropriate expansion and other modification by the Administration to avoid unreasonable risks.[10]

"PERMISSABLE MEDICAL EXPERIMENTS ON VOLUNTEERS"

(Prepared by the War Crimes Trial Prosecution at Nuremberg)

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury may occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

[8] Adequate time is necessary for education, vocational training, recreation, work detail, counseling, and related programs. In most instances, experimental projects requiring significant amounts of inmate time would, in fact, compromise these basic programs.

[9] The prison population constitutes a readily available group of individuals whose environment can be well identified, described and controlled. Prisoners are usually willing volunteers and accept minimal compensation. Consequently they are frequently sought for experimental studies.

[10] The Nuremberg principles are quite broad and require more critical definition with respect to institutional problems.

AMERICAN CORRECTIONAL ASSOCIATION,
College Park, Md., January 8, 1975.

To: All State Directors (adult programs).
From: Anthony P. Travisono, executive director.
Subject: Survey on medical/pharmaceutical testing.

During the spring of 1974 a survey was made of all State Corrections Departments regarding policy and implementation of medical/pharmaceutical experimentation in correctional institutions.

The results of the survey were not published because of internal problems in our office, and we do not wish to publish information now which was gathered one year ago as some of it is probably outdated. However, the attached list indicates the states which responded and whether or not they had an ongoing program of experimentation in the spring of 1974.

If you would like details or current information, it would be advisable to correspond directly with the individual State Corrections Department.

Should you be interested in having ACA conduct another survey on this issue, or on any other, please let us know.

Enclosure.

SURVEY—MEDICAL AND/OR PHARMACEUTICAL EXPERIMENTATIONS IN CORRECTIONAL INSTITUTIONS

State	Do you have a policy regarding medical/pharmaceutical experimentation?	Have you conducted recent research?	Is inmate compensation a part of program?
Alabama	Not reporting		
Alaska	Yes	No	No.
Arizona	Yes	Yes	Yes.
Arkansas	Not reporting		
California	Yes	Yes	Yes.
Colorado	No	Yes	Yes.
Denver	No	No	No.
Connecticut	Yes	Yes	Yes.
Delaware	No	No	Yes.
Florida	Not reporting		
Georgia	Not reporting		
Hawaii	Yes	No	No.
Idaho	No	No	No.
Illinois	Yes	Yes	Yes.
Iowa	No	No	
Kansas	Not reporting		
Kentucky	Yes	No	No.
Louisiana	Not reporting		
Maine	No	No	No.
Maryland	Yes	Yes	Yes.
Massachusetts	Not reporting		
Michigan	Yes	Yes	Yes.
Minnesota	No	No	
Mississippi	No	No	
Missouri	Not reporting		
Montana	Yes	Yes	Yes.
Nebraska	No	No	
Nevada	Yes	No	No.
New Hampshire	Yes	No	No.
New Jersey	Yes	No	No.
New Mexico	Not reporting		
New York	Not reporting		
Westchester Co	Yes	No	
North Carolina	Not reporting		
North Dakota	Yes	No	
Ohio	Not reporting		
Oklahoma	Yes	Yes	Yes.
Oregon	No	No	No.
Pennsylvania	Not reporting		
Rhode Island	No	No	
South Carolina	Yes	No	No.
South Dakota	Yes	No	No.
Tennessee	Not reporting		
Texas	Yes	Yes	Yes.
Utah	Yes	No	No.
Vermont	Yes	No	No.
Virginia	No	No	
Washington	Yes	No	
West Virginia	No	No	
Wisconsin	Yes	Yes	No.
Wyoming	Not reporting		
District of Columbia	Yes	Yes	No.

Summary: Number of States which allow experimentation, 18; number of States which do not allow experimentation 20; number of States not reporting, 15.

American Correctional Association, Position Statement, Medical & Psychological Research on Prisoners and Detainees

BACKGROUND

"Medical experimentation on human subjects has been the object of concern and controversy in recent years. In no area has the debate been more intense than with reference to experimentation using incarcerated offenders and detainees. The convenience and the economy of using prison inmates as experimental subjects, the peculiar nature and conditions of prison life, an emerging focus on the retained rights of persons in confinement, and the fact that remuneration for participation in experiments, however meager, is often among the highest that convicted offenders can earn within institutional walls, are among the factors which have fired interest and complicated analysis of this problem." [1]

The climate of concern regarding human experimentation is evidenced by the following recent developments:

1. The adoption, in 1963, by the American Psychological Association in the statement of Ethical Standards of Psychologists of Principle 16, Research Precautions, which specifies and limits conditions under which human subjects should be exposed to "physical or emotional stress" and provides that: "Investigations of human subjects using experimental drugs should be conducted only in such settings as clinics, hospitals or research facilities maintaining appropriate safeguards for the subjects."
2. The adoption, in 1964, by the World Medical Association of the Declaration of Helsinki which incorporates "recommendations as a guide to each doctor in clinical research."
3. The publication by the Department of Health Education and Welfare of a proposed policy on the *Protection of Human Subjects* which appears in the *Federal Register*, Vol. 38, No. 221 and Vol. 39, No. 165.
4. The preparation by the Pharmaceutical Manufacturers Association of a "Statement of Principles on the Conduct of Pharmaceutical Research in Prison Environment" which was developed in response to hearings on the subject of use of prisoners in clinical research conducted by the Sub-Committee on Health of the U.S. Senate Committee on Labor and Public Welfare on March 7 & 8, 1973.
5. The publication by the Correctional Economics Center of the American Bar Association of *Medical Experimentation on Prisoners: Some Economic Considerations*, Washington, D.C., June, 1975.

That it is important that the American Correctional Association address itself to issues related to the use of prisoners as subjects in medical and psychological experimentation is evidenced by the numbers of prisoners and detainees who are currently participants in such projects. In the ABA report, the researchers estimate "that the annual subject days of experimentation totalled 2.1 million and the estimated number of inmates who would annually come into contact with experimental programs of pharmaceutical manufacturers would be 16,380."

The findings of the ABA study have significant implications for the development of a position statement by the American Correctional Association and for the formulation of administration policies by those responsible for the administration both of state correctional programs and local detention facilities as well. The major findings of the study are directed toward the use of prisoner or detainee subjects in pharmaceutical research and are summarized as follows:

1. "Prisoners, by virtue of their incarceration, are willing to participate in experiments and incur risks at rates in excess of five times the voluntarism exhibited by free persons. Moreover, they will submit to such risks at rates of pay as low as one-tenth of what non-prisoners demand.
2. The constraints under which prisoners exist, as well as the correctional institution's execution of its obligations to feed, clothe and house its inmates, combine to provide a subsidy in lowered costs of experimentation to pharmaceutical companies and other outside experimenters which is estimated to be a minimum of $26.05 per subject-day at current costs. This subsidy is provided at no real cost to the institutions and so constitutes an "efficiency gain" or "savings" which derives from experimenters' access to prisons.

[1] Meyer, Peter B., *Medical Experimentation on Prisoners: Some Economic Considerations*. American Bar Association, 1975, pg. i.

3. Experimentation, by medical practitioners, social and psychological experts, and the pharmaceutical manufacturers, is pursued at a rate of hundreds of thousands if not millions of subject-days per year, so the "efficiency gains" are large indeed, running to millions of dollars annually.
4. Experiments in prisons are an activity which inevitably produces a profit for the outside companies and personnel granted access to the institution: pharmaceutical manufacturers sell the drugs and medical devices tested in prisons at a profit, while the other experimenters gain at the least professional kudos for published research, if not direct financial remuneration. Moreover, the *entire* savings derived from such access to inmates accrues to the experimenters under current policy.
5. Participation in experiments, especially those involving tests of new drugs, involves risks of long-term after effects. The subjects, however, are not provided with insurance or any other coverage to protect them against such post-experiment costs. The cost of complete medical and disability coverage for a "typical" inmate experiment subject for the lifetime that s/he will spend outside the walls of correctional institutions after release is estimated to be close to $10,000 at current rates.
6. Extensive evidence of unnecessary experimentation has been uncovered in all types of experiments. That is, the purpose of the experiments were such that little value for the society as a whole was to be expected from the work; the efforts, however, benefited the experimenters. It appears that this imbalance between the social and individual benefits from experimentation exists largely because of the exceptionally low cost of subjects to experimenters granted access to prisons. Reduction of the subsidy provided, i.e., having the experimenters bear more of the normal costs of their endeavor, can be seen to reduce this phenomenon." [2]

The ABA report suggests that there are three major directions which further research should pursue.

"*Issue 1.*—Does the presence of experiments within the prisons contribute to or detract from the effectiveness of the corrections process?

Issue 2.—Does the presence of experiments in institutions, and the dependence of experimenters on the inmates of large institutions, introduce a societal bias favoring the "big house" over correctional alternatives for reasons having little to do with corrections?

Issue 3.—Could the funds produced as "savings" or efficiency gains from allowing prisoners to be used as experiment subjects be employed for purposes other than reducing costs or outlays of experimenters and so as to produce greater value to (a) the corrections process, and (b) society as a whole?" [3]

While the issues posed are related to the conduct of pharmaceutical research conducted by or under the auspices of drug manufacturers, they appear to have applicability to physical or mental disease studies which are conducted under the auspices of public health agencies or psychological experimental studies conducted using human subjects confined or detained against their will.

RECOMMENDATIONS

A careful review of the ABA report and other available literature suggests that a final and completely definitive position statement of the American Correctional Association must await further study and research.

It is, therefore, the recommendation of the Excutive Committee that the Association's Research Council be requested to adopt as an important area of its responsibility the collection and the assessment of emerging research data concerning experimentation and research on human subjects and make appropriate recommedations to the Policy Statements Committee of the Association prior to the annual Congress of Corrections in 1976.

It is clear, however, the Association should proceed promptly toward the adoption of a policy position which takes into account the standards which have been established to date by national and international governmental and professional organizations. It is therefore the recommendation of the Executive Committee that the position statement which follows be submitted to the Board of Directors for adoption by that body.

[2] *Ibid.*, pp. ii–iii.
[3] *Ibid.*, pg. iii.

Position Statement of the American Correctional Association

Subject: Medical and Psychological Research on Prisoners and Detainees

PURPOSE

The American Correctional Association shares the concern of society as well as that of the professional community that human research and experimentation be conducted within Federal, State and Local correctional institutions in accordance with the highest professional standards and with minimal risks to the goals of corrections as well as to prisoner subjects and correctional staff. The Association, therefore, adopts the following guidelines with respect to such activities:

POLICY

A. It is the policy of the ACA to encourage and assist in only those research projects involving human subjects confined in correctional facilities which meet the following conditions:

1. The highest priority will be assigned to those projects which contribute to the accepted objectives and goals of the correctional process.
2. Prior to the authorization of a human research project of any description, the responsible correctional administrator seeks and obtains the competent professional advice to assure himself that:
   a. The conduct of the research project within an institution is necessary because a controlled setting is essential to the research activity.
   b. The research activity will contribute to knowledge which will serve the interests and the needs of the correctional community or contribute substantially to knowledge which promotes the well-being of society.
   c. The physical and psychological risks assumed by prisoner participants and by the personnel of the institution is minimal.
   d. The personnel to be involved in the conduct of the activity are competent and responsible and possess the requisite knowledge and skill to conduct the project.
   e. The conduct of the project will be totally consistent with the published standards of ethical conduct recognized by international and national professional organizations and agencies—especially those which relate to the professional discipline which will have primary responsibility for the conduct of experimentation and research.
3. With respect to the human subjects who are to participate in experimentation and research within correctional institutions, the administrator accepts the responsibility to assure himself that:
   a. The primary incentive offered to the potential participant will be the promise of contributing to human knowledge and capacity.
   b. Other incentives offered to inmate participants will not be greater than those available to inmates involved in other institutional programs or activities and that amenities available to research participants are no greater or more substantial than are required for the conduct of the research activity.
   c. All participants will become involved in the research program voluntarily and that they enter the program on the basis of informed consent. The policies and procedures of the Department of Health Education and Welfare on the Protection of Human Subjects should be employed by the correctional administrator as guidelines.
   d. All participants shall have an unconditional right to withdraw from the project.
   e. Each participant will be provided necessary medical and psychiatric care and treatment for adverse physical or emotional consequences which may result from involvement in the activity.
   f. Each participant will be insured adequate compensation for permanent injuries or disabilities which arise as the consequence of his or her involvement in the research or experimentation.
4. The correctional administrator will develop policies and guidelines which will fully advise staff and personnel regarding agency expectation both with respect to the implementation of human experimentation projects generally and with respect to each individual project which is given agency approval.
5. The correctional administrator will consistently with his long-standing common-law responsibility to protect the health of persons for whose custody he is accountable, seek to inform himself of the policies and standards which have been adopted regarding the protection of human research subjects and develop methods for obtaining current information on the changes in policies and procedures which have implications for correctional practice and be guided accordingly.

Bibliography

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Pharmaceutical Manufacturers Association, "Statement of Principles on the Conduct of Pharmaceutical Research in the Prison Environment", Washington, D.C., February, 1975.

U.S. Bureau of Prisons, "Policy Statement 6110.1, Research", Washington, D.C., October, 1967.

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Draft Position Statement of the American Correctional Association

SUBJECT: MEDICAL AND PSYCHOLOGICAL RESEARCH ON PRISONERS ANE DETAINEES

PREAMBLE

The American Correctional Association has grave concern about the involvement of persons detained or imprisoned as subjects of human research and experimentation under public or private auspice.

It recognizes its responsibility to continue in collaboration with other professional organizations to use its resources to determine under what circumstances, if any, the conduct of human research in correctional facilities is justified.

Pending the completion of such an investigation, the Association adopts the following guidelines with respect to such activities:

POLICY

A. It is the policy of the ACA to encourage and assist in only those research projects involving human subjects confined in correctional facilities which meet the following conditions:

1. The highest priority will be assigned to those projects which contribute to the accepted objectives and goals of the correctional process.
2. Prior to the authorization of a human research project of any description, the responsible correctional administrator seeks and obtains the competent professional advice to assure himself that:
   (*a*) The conduct of the research project within an institution is necessary because a controlled setting is essential to the research activity.
   (*b*) The research activity will contribute to knowledge which will serve the interests and needs of the correctional community or contribute substantially to knowledge which promotes the well-being of society.
   (*c*) The physical and psychological risks assumed by prisoner participants and by the personnel of the institution is minimal.
   (*d*) The personnel to be involved in the conduct of the activity are competent and responsible and possess the requisite knowledge and skill to conduct the project.
   (*e*) The conduct of the project will be totally consistent with the published standards of ethical conduct recognized by international and national professional organizations and agencies—especially those which relate to the professional discipline which will have primary responsibility for the conduct of experimentation and research.
   (*f*) No correctional official or correctional worker will receive compensation or other benefits as the result of his/her authorizing or otherwise participating in projects which involve prisoners as subjects in human research or experimentation.
3. With respect to the human subjects who are to participate in experimentation and research within correctional institutions, the administrator accepts the responsibility to assure himself that:
   (*a*) The primary incentive offered to the potential participant will be the promise of contributing to human knowledge and capacity.

(*b*) Other incentives offered to inmate participants will not be greater than those available to inmates involved in other institutional programs or activities and that amenities available to research participants are no greater or more substantial than are required for the conduct of the research activity.

(*c*) All participants will become involved in the research program voluntarily and that they enter the program on the basis of informed consent. The policies and procedures of the Department of Health, Education, and Welfare on the Protection of Human Subjects should be employed by the correctional administrator as guidelines.'

(*d*) All participants shall have an unconditional right to withdraw from the project.

(*e*) Each participant will be provided necessary medical and psychiatric care and treatment for adverse physical or emotional consequences which may result from involvement in the activity.

(*f*) Each participant will be insured adequate compensation for permanent injuries or disabilities which arise as the consequence of his or her involvement in the research or experimentation.

4. The correctional administrator will develop policies and guidelines which will fully advise staff and personnel regarding agency expectation both with respect to the implementation of human experimentation projects generally and with respect to each individual project which is given agency approval.

5. The correctional administrator will consistently with his long-standing common-law responsibility to protect the health of persons for whose custody he is accountable, seek to inform himself of the policies and standards which have been adopted regarding the protection of human research subjects and develop methods for obtaining current information on the changes in policies and procedures which have implications for correctional practice and be guided accordingly.

APPENDIX 2

On October 17, Chairman Kastenmeier wrote the following letter to each of the 50 State attorneys general:

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE,
October 17, 1975.

The Honorable——— ———.

DEAR———: As Chairman of the House Judiciary Subcommittee on Courts, Civil Liberties, and the Administration of Justice, I have the legislative and oversight responsibilities with regard to the Federal Bureau of Prisons and corrections issues in general.

The subcommittee is currently considering legislation which would prohibit the use of prisoners as subjects in medical research. The bill, H.R. 3603, applies this prohibition to Federal and military prison systems, as well as to those states which utilize federal LEAA funds.

As part of our review of the effect of this legislation, I would like to ask that your office kindly respond to the following questions:

1. Is medical research currently being conducted in your state?
2. If so, at which institutions and under whose auspices?
3. If so, and if this legislation becomes law would your state continue to conduct medical research?
4. Would you please review the legislation and provide the subcommittee with your views?

I greatly appreciate your assistance in this matter. In order that your response be included in the official Committee record, I request that it be sent to us no later than November 15, 1975.

Sincerely yours,

ROBERT W. KASTENMEIER, *Chairman.*

The responses to this letter collaborate the survey conducted by the staff of the National Commission for the Protection of Human Subjects, which is included at page 389.

The following letters are selected views and information provided by various State officials:

OFFICE OF THE ATTORNEY GENERAL,
Phoenix, Ariz., December 5, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee on the Judiciary, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: Attorney General Bruce E. Babbitt has asked that I respond to your recent inquiry regarding the use of prisoners as subjects in medical research.

I am attaching copies of a response of Mr. Thomas W. Korff, Assistant to the Director of the Arizona Department of Corrections, with attachments which indicate that the only medical research being conducted within the corrections system is a plasma collection program at the prison.

I have appended the attachments to the Mr. Korff letter which address your additional questions and appears to be no current interest in using prisoners as medical research subjects.

Sincerely,

MICHAEL M. SOPHY,
Special Assistant Attorney General.

Enclosure.

ARIZONA DEPARTMENT OF CORRECTIONS,
Phoenix, Ariz., November 21, 1975.

Re request for information for Congressman Kastenmeier.

Mr. MICHAEL M. SOPHY,
Special Assistant, Office of the Attorney General,
State Capitol, Phoenix, Ariz.

DEAR MR. SOPHY: Attached please find copies of some earlier correspondence relating to medical research conducted with prisoners along with a copy of the pertinent statutes covering this area. The situation has not changed since these letters were written and rather than "rehashing" all this material, I am providing you with these copies.

Basically, our only involvement in this area is a plasma collection program at the Mens' Division of the Arizona State Prison. We are not now, nor do we plan to get involved in any medical research programs and we would even like to phase out the plasma collection program if we are able to improve the inmate pay situation.

If you need further information, feel free to contact me.

Sincerely,

THOMAS W. KORFF,
Assistant to the Director.

Attachments.

ARTICLE 10. PRISONER PARTICIPATION IN MEDICAL RESEARCH AND PLASMAPHERESIS AND WHOLE BLOOD PROGRAMS

§ 31-321. Prisoner participation in approved programs

A. Any prisoner with the written consent of the superintendent and the prison physician may volunteer to participate in an approved program of medical research or plasmapheresis and whole blood program.

B. Each prisoner prior to consenting to participate in such program shall be advised by the prison physician and a representative of the person, firm or corporation conducting such program of the nature of the program and the dangers, if any, which may result by reason of such participation.

C. The consent of any prisoner to participate in such program shall be evidenced in writing and as a condition precedent to a prisoner's participation he shall release the state, the superintendent and the prison physician from any and all liability for claims arising out of his participation in such program. Added Laws 1966, Ch. 30, § 2.

Effective March 28, 1966.

§ 31-322. Approval of programs

A. Any person, firm or corporation desiring to conduct a program of medical research or plasmapheresis and whole blood program employing prisoners shall submit to the superintendent a written proposal containing a detailed statement of the purpose and nature of the proposed program.

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B. The superintendent shall submit any proposal received pursuant to subsection A to the prison physician for his review and recommendation

C. Upon a favorable recommendation from the prison physician, the superintendent may approve the proposed program subject to such conditions as may be prescribed by the superintendent or the prison physician.

D. The superintendent may grant to the person, firm or corporation conducting an approved program of medical research or plasmapheresis and whole blood program a revocable license to enter upon the state prison and conduct the approved program. Added Laws 1966, Ch. 30, § 2.

Effective March 28, 1966.

§ 31-323. Compensation for prisoner participation in approved programs

A. An approved program of medical research or plasmapheresis and whole blood program may provide for the payment of compensation to participating prisoners.

B. Proceeds from prisoner participation in approved programs shall be paid into the trust fund or escrow fund account established by the superintendent pursuant to section 31-261, subsection B.

(1973 legislation, effective date August 8, 1973)

APRIL 17, 1974.

Messrs. ALBERT R. JONSEN, S.J., Ph.D. and Philip R. LEE, M.D.
University of California, San Francisco, Health Policy Program,
San Francisco, Calif.

DEAR MESSRS. JONSEN AND LEE: In response to your letter of inquiry of April 3, 1974. I am enclosing a copy of a letter written by this office to our Legislative Council concerning the issue of experimentation.

This letter outlines our involvement in this area. We are involved in a plasma collection program only, and are not involved in medical experimentation. We would also like to phase out this program when funds for inmate pay have been improved.

I have enclosed a copy of our authorizing legislation and a copy of a bill introduced in our current legislature by Senator John Roeder of Scottsdale. This bill has generated much controversy and discussion, and seems to be a first by way of attempting to control experimentation at this level.

We would appreciate receiving a copy of your findings upon completion of this survey.

If you have further questions, feel free to contact me.

Sincerely,

THOMAS W. KORFF,
Assistant to the Director.

Enclosures.

FEBRUARY 1, 1974.

MR. HARRY GUTTERMAN,
Executive Director, Arizona Legislative Council,
Phoenix, Ariz.

(Attention Mark Heinen, research analyst).

DEAR MR. GUTTERMAN: Mr. Moran has asked me to respond to your letter of January 10, 1974.

The Arizona State Department of Corrections has not, nor does it intend to use aversion therapy, shock treatments, sensory deprivation nor psychosurgery as treatment methods with its committed population. Tranquilizing drugs have been, and are, used when prescribed by a licensed physician as a medical treatment in an individual case. They are not used as a general means of behavior control, but simply as part of a prescribed medical treatment for an individual.

The Department of Corrections has a contract with Cutter Laboratories for plasma collection at the Arizona State Prison. Whole blood is removed, the serum plasma and cells separated, the plasma is kept for processing and the cells are returned to the individual. The individual inmate receives six dollars for each donation. This program is strictly voluntary and is carried out under close medical scrutiny. Authorization for this program is provided by ARS 31-321—31-323.

Corollary to the plasmapheresis program are two programs for manufacturing rabies vaccine and tetanus vaccine. In this program, an inmate is immunized with a standard rabies or tetanus vaccine to build up his immunity, the extracted

plasma from his blood is used in the manufacturing process for the vaccine. The inmate is not exposed to actual tetanus or rabies, but simply given the vaccine to raise his level of immunity.

In the past, arrangements had been made through the Prison and the Harvard Medical School to test sun-screen type lotions using inmate volunteers. The individual inmate was paid a stipend and the program involved testing various externally applied sun-screen preparations.

In the history of these programs, no serious reactions or injuries have occurred. If you have further questions, feel free to contact me.

Sincerely,

THOMAS W. KORFF,
Assistant to the Director.

STATE OF ARKANSAS,
OFFICE OF THE ATTORNEY GENERAL,
Little Rock, Ark., October 28, 1975.

Re H.R. 3603.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee on the Judiciary, U.S. House of Representatives, Washington, D.C.

DEAR CHAIRMAN KASTENMEIER: This is in response to your letter of October 16, 1975, to Attorney General Tucker who has asked me to respond.

At the present time no medical research is being conducted in the Arkansas Department of Correction.

At present, the policy of the Arkansas Board of Correction is that "any request from drug companies or others for the testing or experimentation of drugs in the Department of Correction must first have the approval of the Medical Experimentation Protocol Committee of the University of Arkansas Medical Center, the staff of the Department of Correction and finally the Board of Correction. No drug testing or experimentation will take place within the Department of Correction without the specific authorization of the Board of Correction."

There has been no recent medical testing done in the Arkansas Department of Correction. You can contact Mr. Terrell Don Hutto, Commissioner, Arkansas Department of Correction, P.O. Box 8707, Pine Bluff, Arkansas 71601, to find out when the last medical experimentation was done.

The Office of the Attorney General of Arkansas agrees that inmates in our prison systems should not be used for medical experiments and in principal supports H.R. 3603. The only word of caution that I would make is that H.R. 3603 should not prevent the giving of blood plasma by inmates. The Arkansas Department of Correction presently maintains a blood plasma program and has found it to be beneficial to the inmates.

Sincerely yours,

ROBERT A. NEWCOMB,
Assistant Attorney General.

STATE OF CALIFORNIA,
DEPARTMENT OF JUSTICE,
OFFICE OF THE ATTORNEY GENERAL,
Sacramento, Calif., December 9, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: As Chairman of the House Judiciary Subcommittee on Courts, Civil Liberties, and the Administration of Justice, you have asked for my response to the following questions:

1. Is medical research currently being conducted on state prisoners in California?
2. If so, at which institutions and under whose auspices?
3. If H.R. 3603, currently before your subcommittee, were to become law would California continue to permit medical research to be conducted on state prisoners?
4. Would I review H.R. 3603 and provide the subcommittee with my views?

Firstly, some medical research and pharmaceutical testing with state prison inmate volunteers is being conducted in California according to the Department of Corrections of the State of California.

Secondly, the California Medical Facility at Vacaville, California, is the only institution where such research and testing is performed. The majority of this research and testing is under the auspices of the Solano Institute of Medical and Phychiatric Research which operates at the California Medical Facility through a Research Review Committee consisting of three licensed M.D.'s, one licensed pharmacist, one licensed veterinarian, one businessman, and one ex-inmate. None of these individuals are connected with the California Department of Corrections.

We are advised that the Department of Corrections permits outside research scientists, the majority of whom are associated with California universities, to conduct research, provided that there is strict compliance with the established procedures assuring close scrutiny and continuous evaluation of both the safety and the welfare of prisoners including extensive measures to insure that their rights and their freedom of choice are protected. No promises of special favors or early release by the California Adult Authority are involved according to statements made by the Department of Corrections. Specific details on the operations of these programs may be obtained from the Department of Corrections, Sacramento, California.

Thirdly, we are unable to predict at this time the effect upon continued medical research at the California Medical Facility if H.R. 3603 were enacted.

Fourthly, there can be no question but that no medical research of any kind should be conducted unless the persons who are the subject of that research freely volunteer. Some testing on human beings of drugs which appear to be safe for human use seems to be acceptable prior to the release of such drugs for general public consumption. The major problem would appear to be to insure that prisoner volunteers are truly volunteers. Institution of controls to insure that subject consent is truly voluntary may be a more appropriate solution than a blanket prohibition.

An additional safety requirement where prisoners are involved should be that no research or new drug can be utilized in a prison setting unless the procedure or drug has been previously studied with human subjects elsewhere without significant adverse consequence. That is a precaution utilized by the California Medical Institutional Research Review Committee.

Very truly yours,

EVELLE J. YOUNGER,
Attorney General.

STATE OF CONNECTICUT,
DEPARTMENT OF CORRECTION,
Hartford, Conn., November 13, 1975.

Hon. ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: Your correspondence addressed to Attorney General Ajello has been referred to this office for reply.

I will reply to your questions in order:

1. Yes.

2. Connecticut Correctional Institution, Somers; Connecticut Correctional Institution, Enfield. Please find attached Connecticut Department of Correction Administrative Directive No. 6.7.

3. Our agency is the recipient of LEAA funds, none of which has any relationship to our bio-medical testing program. We would not continue to conduct medical research if it would jeopardize our LEAA funding.

4. Although I do not have the bill available, I feel strongly that medical research can be conducted in correctional institutions with proper safeguards. I would not be in favor of any legislation which prohibits research.

If I can be of further assistance please feel free to contact my office.

Very truly yours,

RAYMOND M. LOPES,
Deputy Commissioner of Institution Services.

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UCONN HEALTH CENTER
PRIMARY REVIEW SUBCOMMITTEE
(BIO MEDICAL STUDIES)

1. The RAC shall carefully evaluate the nature and degree of compensation provided to any and all volunteers and satisfy itself that the compensation is compatible with the general welfare of the institution. Fees shall be as prescribed in attachment; Bio-Medical - 7.

   Ten percent (10%) of any earnings creditable to an inmate's account shall be posted to his savings account and held there for him until his release.

   The Business Manager shall, at the time of posting payments recieved from drug test sources, issue a written notification to each participating inmate, of the amounts posted to his institutional savings accounts. The notice shall specify the payor and the study for which payment is made.

   Any offer of additional "good time" constitutes an unfair inducement. The act of volunteering should not carry with it the expectation of latent benefits and conversely failure to volunteer should not create the expectation of adverse action.

2. Compensation of any kind or amount by a member of the Research Advisory Committee which is related to reviews made by or studies approved by the RAC, constitutes an irreconcilable conflict of interest. On becoming aware of such a conflict, the Chairman should ask the member to resolve the conflict whether by his refusal to be eligible for payment in any form (rejecting any such payment, if tendered) or his resignation from the RAC.

   It is incumbent on Committee members to report any payments, in conjunction with the business of the RAC, which payments are received from or tendered by an Investigator or a sponsoring company. Such an offer or payment shall be grounds for the elimination of any future testing under Department sanctions.

3. The Connecticut Department of Correction, its Commissioner, Research Advisory Committee and employees of the Department of Correction, the UConn Health Center and other groups represented on the RAC or its Subcommittees do not singly or in any combination, assume any of the responsibilities of sponsorship normally associated with an "Investigator" by the FDA. The intended function of the RAC is that it review Investigator applications to use Departmental facilities and to regulate the manner of their use and by so doing, looks to the Investigator to provide all necessary safegaurds to study participants and the proper handling of projects and equipment necessary to or used in the study.

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"PERMISSABLE MEDICAL EXPERIMENTS ON VOLUNTEERS"

Prepared by the War Crimes Trial Prosecution at Nuremberg

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury may occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

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8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgement require of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

FORMAT OUTLINE FOR BIO-MEDICAL RESEARCH PROPOSALS

The following procedure will be followed in connection with protocols for Bio-Medical research within the facilities operated by the Department of Correction

1. Applicants, after they have been assigned a protocol number and a study location, shall furnish the RAC Chairman with copies of their protocol or proposal. Protocols not available at least three weeks prior to a subcommittee meeting will not be considered at that meeting. Each protocol, as it is recieved by the RAC Chairman, will be acknowledged by form letter. The date, time and place of the protocol airing will be specified in the letter. If materials submitted are incomplete, the RAC Chairman will so notify the applicant.

   In addition, copies of any animal toxicology reports will be provided to the RAC Chairman. The cover page shall indicate in lay terms the nature of the product, its purpose and the objective of the test program. It should indicate the RAC protocol number, planned test location, number of total study participants, test duration for a normal participant, and the names of the Institutional Protection Committee members with chairman and secretary indicated.

   If a Bio-Medical protocol has been approved by the Primary Review Subcommittee, the Investigator shall be notified to submit copies of the application plus modifying or clarifying remarks by the Subcommittee to the Organizational Review Subcommittee which will review adminsitrative safegaurds, fees ethical and other considerations. The ORS meeting will normally be within three weeks after approval by the Primary Review Subcommittee, providing the Investigator mailing occurs within one week of action by the PRS.

2. The determination of research projects to be accepted shall be the responsibility of the Research Advisory Committee. Its decision shall be final, subject to a veto by the Commissioner of Correction in exceptional cases.

3. In the event that the study is Phase I, then the Investigator will submit copies of the toxicological report as submitted to the FDA in the number of copies as designated by the RAC Chairman.

   If the study is Phase II and has previously been tested in Phase I or Phase II, not in an environment for which the Connecticut Commissioner of Correction is responsibile, then three weeks prior to the Primary Review Subcommittee meeting (1, above) the applicant will submit a written report which fairly states the previous study final results to date, if tests are in progress. Copies of this report shall also be submitted to the Institutional Protection Committee via the RAC Chairman.

   If a Phase II study is applied for and Phase I or Phase II testing was previously conducted within a facility under control of the Commissioner on the product or essentially the same product, then a written report of the test final results, or results to date for a study in progress, shall be made to the RAC Chairman for distribution to the Primary Review Subcommittee and the Institutional Protection Committee three weeks before a scheduled meeting.

4. Bio-Medical research projects accepted by the Committee shall be subject to final confirmation contigent upon submission of the following:

   a) Written acceptance of the fee schedule for Bio-Medical studies, as published by the Department and with conditions and adjustments as may be agreed on with the Department Business Manager and filed with the RAC Chairman.

   b) A statement of financial responsibility, acceptable by the State's Attorney, for all claims which may arise from the research.

   c) A statement listing membership of the company's board of governance and chief administrative officers.

   d) The vita of the research project director and principle investigator(s).

   e) A clear statement of risks and risk acceptance, for signature by inmate participants or their guardians, in the case of minors.

      The inmate consent statement shall also contain: A release on access of his medical records for the study to review by a proper agent of the FDA in the event a request for review is made by FDA.

   f) A payment budget for a typical volunteer participant will be included as a part of the informed consent statement or if the information is considered proprietary by the Investigator it may be submitted to the subcommittees separately.

      The applicant must provide the RAC with a one-time conflict of interest statement including:

      I) "The investigator has not participated in the selection of Research Advisory Committee members."

      II) "The investigator's role with the Committee does not go beyond providing the Committee with information. No payment or other items of value have been offered or paid to any member of the RAC."

   g) Submit copy of form OMB No. 57-R0031 Statement of Investigator (Clinical Pharmacology) as submitted to Supplier of Drug.

   h) Investigator should submit to the RAC a copy of the report of clinical pharmacology as required in paragraph 6d. of form OMB No. 57-R0031.

   i) Sponsor to notify RAC Chairman and Institutional Protection Committee by copy of its notification to FDA in the event an investigation in process is discontinued.

   j) A copy of any report of medical problem as observed results of the study should be submitted directly to the Chairman of the RAC

5. No later than 30 days subsequent to the completion of the project, the project director or Investigator shall submit to the Chairman, in the format provided, a financial statement detailing all expenditures made during the life of the project and including names and amounts paid to inmates, State employees, the inmate welfare fund, direct and indirect overhead charges.

6. Copies of the final research report shall be submitted to the Chairman with the financial statement and final payments as set forth in the schedule of fees.

7. The letter should be addressed to Chairman, copy to the warden and department medical officer at the institution(s) where testing took place, giving notice of completion, the number of subjects tested, and a paragraph, in lay terms, of project results including statement of any known lingering effects on any one or more testees.

8. The RAC Chairman subject to veto by the Commissioner will be the sole judge of whether materials submitted are adequate for deliberations. If deemed inadequate, the Chairman will advise the applicant and re-schedule discussion for a later regular meeting.

9. In the event that any company which has previously been authorized to conduct a Bio-Medical test, has not filed the final financial and completed study reports (items 5 and 6, above) the Chairman shall give notification to the company that he will not place future protocols on its agenda until such reports have been received.

Procedure for Financial Arrangement and Fee Schedule for Bio-Medical

Research Conducted in Facilities of the Department of Correction

In submitting a Bio-Medical protocol for consideration by the Primary Review Subcommittee of the Research Advisory Committee and the Institutional Protection Committee, a statement will be made to the effect that "subject to special fees as may be prescribed by the RAC and approved by the Commissioner of Correction, the (name of company) agrees to the Department of Correction fee schedule dated _____".

The following fee schedule will be followed for listed procedures. Items not listed will be negotiated on an individual basis and established by the Organizational Review Subcommittee, subject to approval by the Commissioner.

1. General Fees & Participant Budget Format

   a. The minimum fee per participant in studies of less than one week duration shall usually be $25.00.

   b. For studies in excess of 7 days duration, a "Participant Fee" varying from a minimum of $25.00 to a maximum of $75.00 will be paid to each inmate who is successfully selected for a given research program following the screening procedures. This applies to all studies which continuously last a week or longer, but not to one or several two-or-three-day studies done intermittently. A medically disqualified volunteer will receive $10.00 for the screening process.

      Subjects who are required to appear from time to time for interview or examination of test reactions where no drugs or medications or blood drawings are administered, shall receive no less than $1 for each such event of less than 15 minutes portal to portal duration or $2 for events in excess of 15 minutes but not more than one hour.

   c. The following procedure charges (set in the format that they should show in the volunteer consent statement) will be paid to the inmate to the extent that they exceed $25.00 in a study which last longer than a week.

      The participant budget statement required to be included as part of the consent statement should resemble the following:

	PROCEDURE	AMT	NO. REQUIRED	EXT
1.	Initial blood drawing for laboratory screen or profile	$10.00		$
2.	All blood specimens after initial screen	2.50		
3.	Urine and fecal specimens	1.00 ea.		
4.	24-hour urine and/or	5.00		
5.	B.S.P. (Bromsulphalein Test) 2-3 bloods	7.50		
6.	Glucose Tolerance test (5 bloods)	12.50		
7.	Spinal puncture	15.00		
8.	EKG	3.00		
9.	Inmates performing clerical duties with minimum of $10.00 per study	10.00 per wk		
10.	Blood donations for research			
	1/2 unit (250 cc)	10.00		
	1 unit (500 cc)	20.00		

Itemized Individual Participant Budget Subtotal: $_____

The Participant Fee (Set at the time of RAC approval). $_____

Total Participant Budget: $_____

d. On completion of the study, make check payable: Inmate Fund, (Somers) Correctional Institution (or Center, as applicable) and mail directly to the Business Manager of the facility.

2. An additional payment equal to 50% of the total paid to inmates for each protocol, is to be paid to the inmate welfare fund of the institution providing participants. Make check payable to: Inmate Welfare Fund (for the Institution or Center involved) and mail to facility Business Manager.

3. If payment is to be made by the Department of Correction to employees, a fringe benefit direct cost of 30% shall be added to personal services costs payable by the company. Make check payable: State of Connecticut.

4. A direct charge of 12% based on payments to inmates exclusive of the amount paid to the general inmate welfare under (2) above. Make check payable: State of Connecticut.

5. An indirect charge of 6% based on the total of (3) and (4) above shall be paid to the State of Connecticut. This represents the value of services furnished by other State agencies such as Auditors, Personnel, Comptroller, Treasurer, Purchasing Division, and Central Office of the Department of Correction. The indirect cost rate will be adjusted yearly.

CONTINUED

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charity cases from Cincinnati General Hospital. Most had I.Q.'s below 90 (100 is average), and their average length of schooling was six years.

Even some of the most important (and ultimately life-saving) tests conducted in public hospitals involve significant risks. Though never fully studied for use in infants, the antibiotic Chloramphenicol for several years was widely used as a prophylatic to counteract the high infection rate in premature newborns—until two studies by Dr. Joan Hodgman revealed that the drug appeared to be killing a significant number of infants to whom it was administered. Both studies were conducted in the Premature Center of Los Angeles County Hospital, where virtually all of the infant participants were from poor families, most of them black or Chicano.

The first study demonstrated that at some dosage levels Chloramphenicol is extremely toxic for premature infants. The study also found that antibiotics did not lower the mortality level when given as a prophylactic to certain healthy prematures. Consequently the Premature Center, concluding that the potential risk outweighed the possible benefits, discontinued the use of the drug for helping prematures.

Believing that "Chloramphenicol would still be useful for the treatment of infected prematures if a safe dosage schedule were established," Dr. Hodgman and her colleagues then conducted a second test. This time they gave varying dosages of Chloramphenicol to 126 prematures, most of whom were "in good condition," but who had been exposed to staphylococcal infection. Six of the infants developed symptoms associated with Chloramphenicol toxicity—such as refusing to nurse, regurgitating a formula, abdomens becoming distended, loose green stools, and, within twenty-four hours after the appearance of toxic symptoms, becoming ashen gray and lethargic. Three of the infants who developed these symptoms survived; three died. Although the deaths may have been due to other causes, the study concluded that "it is possible that these three infants represent a toxic reaction [to Chloramphenicol] at relatively low blood levels." Partly as a result of Dr. Hodgman's test, Chloramphenicol now is seldom given to premature infants, and then only in very small dosages.

Public hospital patients are rarely in a position to evaluate the merits of an experiment that they are asked to join. In her office at New Orleans Charity Hospital, Dr. Margaret Smith, who is a member of the Public Health Service's Committee on Immunology Practices, described the parents from whom she had received "informed consent" for their children to participate in a meningitis study: "Most of the parents are uneducated blacks. Some of them can't read—they're not very sophisticated people."

In defense of public-hospital tests, Dr. Smith contends that according to nurses at the hospital, "public patients get much better care when they are part of a drug study." While undoubtedly true, this explanation raises as many questions as it answers. Because treatment at public hospitals and prisons is often substandard, physicians may justifiably believe that the medical benefits of testing outweigh the risks. But is it just to ask the poor to accept the risks of medical experimentation in order to obtain adequate health care?

A similar problem arises with the legal requirement to obtain a patient's "informed consent" before beginning the test. Technically, the researcher must clearly explain the drug's potential risks and the available alternative, non-experimental forms of medication. Researchers often find it easiest to obtain the consent of poor or institutionalized populations. More than one drug investigator told us that their poor patients would cut a finger or an arm off without asking questions if they recommended it. For people living under such circumstances, one wonders whether the phrase "informed consent" has meaning.

Yet even such heretofore acquiescent groups are beginning to resist medical experimentation. During the summer of 1969, 398 women in San Antonio, Texas, participated in a test designed to evaluate the side effects produced by various kinds of oral contraceptives. Most of the women were Mexican-Americans who had been referred to the test by Planned Parenthood. Activists in the Chicano community later became outraged when it was revealed that seventy-six of the participants had been given a placebo, or sugar pill, instead of an oral contraceptive, and that seven of those women had become pregnant. Although executives at Syntex Laboratories, sponsor of the test, admitted to us that they had anticipated that as many as nine of the women given the placebos would become pregnant, apparently none of the women were apprised of this possibility. As a result of an investigation by the Chicano-dominated local Community Action Board of the OEO, which provides the city's Planned Parenthood program with

most of its funds, Planned Parenthood's executive director resigned, and new, tougher guidelines on human experimentation were adopted. Finally, this spring, after a prolonged investigation, the FDA officially found that in several crucial respects the test had been improperly conducted. Two years ago a proposed test of the amphetamine-like drug Nitalin on preschool children of Florida migrant workers was abandoned after an emotion-packed newspaper article on it generated a series of local protests. And in 1968, in response to parents' complaints, the D.C. Children's Clinic in Laurel, Maryland, stopped testing all drugs on mentally-retarded children after participants in its test of TriA were hospitalized with serious liver dysfunctions.

These are not isolated examples. Several trends in American society are combining to complicate the task of finding suitable and willing test populations. Ethnic groups have become increasingly suspicious of those who wish to perform experiments—medical or social—on members of their communities. Increased interest in prison reform has begun to focus attention on medical problems in state and local prisons, and the current trend in mental retardation is to confine only hard-core cases, leaving institutions with fewer good subjects for tests that require a modicum of intelligence.

Nevertheless, there is still a clear need to test some new drugs and vaccines on human subjects. Few would contest the importance of the development in recent years of drugs and vaccines to treat matters ranging from birth control to polio. Before such products are put on the market, they must be carefully tested to find effective dosages and to make certain that they don't produce intolerable side effects. Indeed, many leading physicians and government officials have said that drugs, particularly those used on children and the elderly, may require a great deal *more* testing than they presently receive. Dr. Harry Shirkey, chairman of the Department of Pediatrics at Tulane University, believes that prior to receiving FDA approval, all drugs that may be used by children should be specifically tested on children.

Dr. Shirkey notes that many if not most drugs on the market today have not been tested for use on children; such tests are expensive and present enormous ethical problems. Although these drugs must contain a warning that they are not approved for use on children, parents who have successfully used the medication sometimes give it to a sick child, and it is not uncommon for doctors who have heard that it works on children to prescribe it. Due to the impact of a few "pediatric catastrophes" like Chloramphenicol and the efforts of pediatricians like Dr. Shirkey, several high-ranking FDA officials advocated the adoption of a regulation stating that no new drug which may be given to children can be approved for marketing until adequate studies have been conducted in a series of tests in various age groups up to fourteen years. This proposal was rejected, however, after the pharmaceutical industry explained that it would be far less expensive to agree not to let the drug be used on children than to conduct the needed experiments. FDA officials say they are making every effort to persuade drug manufacturers to perform such tests voluntarily.

As with many areas in which scientific development has created significant ethical and political dilemmas, there is no single simple solution to the problem of testing new drugs. But here are some possible reforms:

Drug companies should use greater restraint before testing new drugs that duplicate, with minor variations, the functions of drugs now on the market.

Medical schools and the scientific community should encourage greater professional responsibility. Though strict codes of research ethics have been adopted by the American Medical Association, a recent study found that most physicians engaged in clinical research never studied the ethics of testing while in medical school, and that a "significant minority" place personal and scientific achievement ahead of their responsibility to the test population.

Institutions where new drugs are tested should establish effective, broadly based review committees in accordance with rules adopted by the Food and Drug Administration and the Public Health Service. Though such committees are now required by law, the Food and Drug Administration makes no systematic effort to ensure that they are established and function effectively. These committees would examine the scientific merits of proposed tests and protect the rights of test subjects. They should be composed of clergymen, lawyers, and community representatives as well as scientists. The Florida

prison system's new citizens' committee plans to visit state intitutions regularly and ask inmates for their comments on the tests.

Congress could adopt legislation proposed by Sen. Gaylord Nelson of Wisconsin that would increase the government's role in the selection of clinical investigators. Senator Nelson notes that at present, since drug firms select their own researchers and pay them to accumulate data demonstrating that a new drug is safe and effective enough to be allowed on the market, researchers have a vested interest in highlighting the drug's good points, not its potential dangers.

Another possible legislative reform would provide insurance for the subjects of medical experimentation. When the details of the Public Health Service's syphilis test were revealed last summer, Alabama senators James B. Allen and John J. Sparkman introduced legislation to provide financial compensation for test participants who had needlessly suffered from syphilis.

None of these reforms, however, will remove the special risks of drug experimentation from the powerless segments of our society. That can only be done by having each citizen, rich or poor, undertake an ethical, and perhaps legal, responsibility to share the risks as well as the benefits of the experimentation. Even if Senator Nelson's bill is passed, questionable research is likely to be conducted on poor and institutionalized subjects. Some of the most troubling tests, including the Alabama syphilis experiment and the Cincinnati cancer test, are financed by the federal government. Despite the FDA's finding that the San Antonio test cited above was improper, the physician who directed it is now conducting a disturbingly similar study under a $2 million contract from the Agency for International Development.

Furthermore, funds from the federal government, like funds from private companies, will continue to seduce the administrators of institutions such as hospitals, prisons, and homes for mentally retarded children. In the absence of decent public financing, they will be persuaded that it is humane to fund an institution by allowing inmates to serve as test subjects. And the poor and institutionalized, needing money themselves and having little power to resist, will often succumb.

[From the Hastings Center Report, vol. 5, No. 4, August 1975]

Reassessing the Meaning of Valid Consent—A Moral Theory of Informed Consent*

(By Benjamin Freedman**)

Most medical codes of ethics, and most physicians, agree that the physician ought to obtain the "free and informed consent" of his subject or patient before attempting any serious medical procedure, experimental or therapeutic in nature. They agree, moreover, that a proxy consent ought to be obtained on behalf of the incompetent subject. And informed consent is seen not merely as a legal requirement, and not merely a formality: it is a substantial requirement of morality.

Acceptance of this doctrine, however, requires the solution of a number of problems. How much information need be imparted? At what age is a person mature enough to consent on his own behalf? Can prisoners give a "free and informed consent" to be experimented upon? Lurking behind these and similar questions there are more fundamental difficulties. What are the functions of consent for the competent and the incompetent? What is the sense in which the patient/subject must be "free," "informed," and "competent?" It is by way of an approach to these latter questions that I shall attempt to respond to the more specific questions.[1]

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*The research for this paper was begun during an internship at the Institute of Society, Ethics and the Life Sciences in the month of June, 1973. I gratefully acknowledge the help of Dr. Daniel Callahan, Marc Lappé, Peter Steinfels, and Robert Veatch, of the Institute, who helped make my internship profitable and enjoyable. My wife Barbara read the manuscript and suggested a number of needed changes.

**Benjamin Freedman teaches ethics and law at Tel Aviv University in Israel, and was an intern at The Hastings Center.

[1] For examples of a similar method applied to different problems, see Thomas I. Emerson, "Toward a General Theory of the First Amendment" (New York: Vintage Books, 1967).

I. Consent and the Competent

The negative aspects of the doctrine of informed consent have ordinarily been the focus of attention: difficulties in obtaining the informed consent of the subject/patient render the ethics of experimentation and therapeutic measures questionable. Our common view of informed consent is that, when at all relevant, it represents a minimum condition which ethics imposes upon the physician. It is seen as a necessary condition for medical manipulation, but hardly as a sufficient condition.

The reasons why this is so—why it is not sufficient that an experiment, for instance, have received informed consent from his subject before proceeding—are quite obvious. The scarcity of medical resources (which includes a scarcity of qualified physician-investigators) forbids us from wasting time upon poorly-designed experiments, or upon experiments which merely replicate well-established conclusions. There seems to be, as well, a limit to the dangers which we (ordinarly) allow subjects to face. We do not, as a matter of policy, think it wise to allow would-be suicides to accomplish their end with the aid of a scientific investigator. Many other reasons could be given for the proposition that a person does not have a right to be experimented upon, even when he has given valid consent to the procedure.

The Right to Consent

But there does seem to exist a positive right of informed consent, which exists in both therapeutic and experimental settings. A person who has the capacity to give valid consent, and who has in fact consented to the procedure in question, has a right to have that recognized by us. We all have a duty to recognize a valid consent when confronted with it.

From whence derives this right? It arises from the right which each of us possesses to be treated as a person, and in the duty which all of us have, to have respect for persons, to treat a person as such, and not as an object. For this entails that our capacities for personhood ought to be recognized by all—these capacities including the capacity for rational decision, and for action consequent upon rational decision. Perhaps the worst which we may do to a man is to deny him his humanity, for example, by classifying him as mentally incompetent when he is, in fact, sane. It is a terrible thing to be hated or persecuted; it is far worse to be ignored, to be notified that you "don't count."

If an individual is capable of and has given valid consent, I would argue that he has a right, as against the world but more particularly as against his physician, to have it recognized that valid consent has been given. (The same applies, of course, with still greater force, with regard to *refusals* to consent to medical procedures.) The limited force of this claim must be emphasized: it does not entail a right to be treated, or to be experimented upon. It is a most innocuous right, one which most of us would have little hesitation about granting.

It is, therefore, curious that the literature on informed consent has failed to recognize this right—has, in fact, tacitly denied this right, at least as regards experimentation. In writings on informed consent it seems to have been assumed that if, under certain conditions, it is *doubtful* that valid consent to an experiment has been granted, it is best to "play it safe" ethically. In cases of doubt, we prefer not to take chances: in this case, we will not take a chance upon violating the canons of ethics by experimenting without being certain that the subject has validly consented to the experiment. Since we do not at present know whether a prisoner can give a valid consent, let us not take chances: we call for a moratorium on prison experimentation. Since we do not know at what age a person has the capacity to give a valid consent, we avoid the problem by setting the age of majority at a point where it is beyond doubt that maturity has been attained. If we must err, we shall ensure that we err in being overly ethical.

The establishment of the innocuous right to have valid consent recognized as such eliminates this expedient. Other writers have conceptualized the conflict as one between a right and, at best, a mere liberty. From the patient's point of view, he has a right to have his health protected by the physician, and a mere liberty to be experimented upon. From the physician-investigator's point of view, he has a duty to protect the subject's health, and a mere liberty to experiment upon the subject (contingent, of course, upon obtaining the subject's consent). A recognition of the claims of personhood and autonomy, however, reveals this to be a conflict between rights and duties. The physician-investigator

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has a duty to recognize consent when validly offered. When the consent is of doubtful validity, therefore, the physician experiences a conflict between two duties. He wil not be ethically well-protected by choosing not to experiment, for there exists the possibility—which, as cases are multiplied, becomes a probability—that he is violating a duty in so choosing. Problems in informed consent present us with a dilemma. It is no longer the case that the burden of proof devolves upon the would-be experimenter. The would-be abstainer-from-experiments may have to prove his case as well.

These considerations give us a new point of departure in investigating problems of informed consent. They shows us that there is no "fail-safe" procedure which we can fall back upon in cases of doubt. Rather, what is required is an exhaustive examination of each case and issue, to see whether or not a valid consent has in fact been obtained.

When we fail to recognize a valid consent, of course, more is involved than a denial of personhood. Other benefits may be denied as well. Dr. Vernon Mark, for example, maintains that psychosurgery should not be done on prisoners with epilepsy because of the problem in obtaining a voluntary consent from prisoners.[2] But a resolution of this problem has not been shown to be impossible. Surely, the proper thing to do here would be to see whether prisoners can or cannot give valid consent to such a procedure. To remain satisfied with doubts, to fail to investigate this question, complex though it be, results in a denial of medical treatment for the prisoner, as well as representing a negation of the prisoner's human capacities. In depriving prisoners of the opportunity to serve as subjects in medical experiments, there are losses other than those of human respect.[3] Not the least of these is the loss of an opportunity to be of altruistic service to mankind.[4] Even a child feels at times a need to be useful; in promoting a moratorium on prison experimentation we deny prisoners the satisfaction of this psychic need. We should not need a reminder from John Stuart Mill that there are "higher" as well as "lower" pleasures and needs.

The right to have valid consent recognized as such does not indicate that we must experiment on prisoners. What it does indicate is that we have a moral responsibility to investigate in detail the question of whether prisoners can, under certain conditions, validly consent to experimentation. It also requires that we not prevent a researcher from experimenting on the basis of overscrupulousness. If prisoners *can* give valid consent, we wrong not only the researcher but the prisoner as well by forbidding prison experimentation.

The Requirement of Information

The most common locution for the requirement which I am discussing is "informed consent"—we require "informed consent" to protect a doctor from legal liability resultant from his therapeutic endeavors, or to ensure the "ethicacy" of an experiment. But I believe "informed consent" to be a serious misnomer for what we do, in fact, want medical practice to conform to.

No lengthy rehearsal of the absurdities consequent upon taking the term "informed consent" at face value is necessary. The claim has been made, and repeated with approval, that "fully informed consent" is a goal which we can never achieve, but toward which we must strive in order to ensure that fully informed consent has been given, it has seriously been suggested that only medical students or graduate students in the life sciences ought to be accepted as subjects for experimentation. *Reductio ad absurdum* examples of "fully informed consent" have been elaborated, in forms which list all the minutiae of the proposed medical procedure, together with all of its conceivable sequelae. With such a view of "informed consent" and its requirements, it is not surprising to find doctors who claim that since they cannot fully inform patients, they will tell them nothing,

[2] "Brain Surgery in Aggressive Epileptics," in Hastings Center Report, February 1973.

[3] See the insert to Alexander M. Capron's call for a moratorium on prison experimentation, "Medical Research in Prisons," Hastings Center Report, June 1973. The insert is a report from the New York Times, April 15, 1973, and reads in part: "Ninety-six of the 175 inmates at Lancaster County prison have written to a newspaper here protesting a recent decision by the state to halt all medical experiments on state prisoners. In their letter to the Lancaster New Era, they urged that state to allow the research [which] did not harm them and enabled them to pay off their fines and court costs."

[4] See Henry K. Beecher, Research and the Individual: Human Studies (Boston: Little, Brown, 1970), p. 56. Professor Beecher notes a study of prison inmates, who, for participation in an experiment involving malaria, received pay but no reduction of sentence. Half of the volunteers cited "altruism" rather than money as their motive for volunteering. Those inmates who did not volunteer "expressed or implied respect for those who did volunteer".

but instead will personally assume the responsibility for assuring the subject's safety.

In truth, a *reductio ad absurdum* of this view of "informed consent" need not be constructed; it serves as its own *reductio ad absurdum*. For there is no end to "fully informing" patients. When the doctor wishes to insert a catheter, must he commend to the subject's attention a textbook of anatomy? Although this, of course, would not suffice; he must ensure that the patient understand the text as well. Must he tell the patient the story of Dr. X, that bogey of first-year medical students, who, in a state of inebriation, inserted ("by mistake") his pen-refill instead of the catheter? With, of course, the assurance that *this* physician never gets drunk ("Well, rarely, anyway.") Must the patient be informed of the chemical formula of the catheter? Its melting point?

The basic mistake which is committed by those who harp upon the difficulties in obtaining informed consent (and by critics of the doctrine) is in believing that we can talk about information in the abstract, without reference to any human purpose. It is very likely impossible to talk about "information" in this way; but impossible or not, when we do in fact talk about, or request, information, we do not mean "information in the abstract." If I ask someone to "tell me about those clouds" he will, ordinarily, know what I mean; and he will answer me, in the spirit in which he was asked, by virtue of his professional expertise as an artist, meteorologist, astronomer, soothsayer, or what-have-you. The meteorologist will not object that he cannot tell you the optical refraction index of the clouds, and therefore that he cannot "fully answer" your question. He knows that you are asking him with a given end in mind, and that much information about the cloud is irrelevant *relative to that purpose.*

That this "abstract information" requirement is not in question in obtaining valid consent is hardly an original point, but it is worth repeating. One of the leading court opinions on human experimentation puts it like this: "* * * the patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required. * * *"[5]

The proper question to ask, then, is not "What information must be given?" That would be premature: we must first know for what purpose information is needed. *Why* must the patient be informed? Put that way, the answer is immediately forthcoming. The patient must be informed so that he will know what he is getting into, what he may expect from the procedure, what his likely alternatives are—in short, what the procedure (and forbearance from it) will mean, so that a responsible decision on the matter may be made. This is the legal stance, as well as, I think, a "common sensical" stance; as Alexander Capron writes, the information component in valid consent derives in law from the recognition that information is "necessary to make meaningful the power to decide."[6] The proper test of whether a given piece of information needs to be given is, then, whether the physician, knowing what he does about the patient/subject would want to know this before making up his mind. Outré, improbable consequences would not ordinarily, therefore, be relevant information. Exceptionally, they will be: for example, when there is a small risk of impotence consequent upon the procedure which the physician proposes to perform upon a man with a great stake in his sexual prowess. This is only sensible.

Our main conclusion, then is that valid consent entails only the imparting of that information which the patient/subject requires in order to make a responsible decision. This entails, I think, the possibility of a valid yet ignorant consent.

Consider, first, the therapeutic context. It is, I believe, not unusual for a patient to give his doctor *carte blanche* to perform any medical procedure which the physician deems proper in order to effect a cure. He is telling the doctor to act as his agent in choosing which procedure to follow. This decision is neither unwise nor (in any serious sense) an abdication of responsibility and an unwarranted burden upon the physician. We each of us choose to delegate our power of choice in this way in dealing with our auto mechanic or stockbroker.

It may be harder to accept an ignorant consent as valid in the purely experimental context. I think, however, that much of this difficulty is due to our paucity of imagination, our failure to imagine circumstances in which a person might choose to proceed in this way. We might approach such a case, for example, by

[5] *Cobbs v. Grant*, 502 P. 2d 1, 11.

[6] Alexander M. Capron, "Legal Rights and Moral Rights," in Hilton, et al., Ethical Issues in Human Genetics (Plenum Press, 1973), 228.

imagining a Quaker who chooses to serve society by acting as a research subject, but who has a morbid fear of knives and pointed instruments. The Quaker might say to the physician-investigator that he wants to serve science but is afraid that his phobia would overcome his better judgment. He might consequently request that any experiment which would involve use of scalpels, hypodermic needles, and such, be performed without informing him; while, say, he is asleep or unconscious. He might further ask the doctor not to proceed should the experiment involve considerable risk. In such a case, or one similar, we would find an instance of a valid yet ignorant consent to experimentation.

The ostensible differences between the therapeutic and experimental contexts may be resolved into two components: in the therapeutic context it is supposed that the physician knows what the sequelae to treatment will be, which information, by definition, is not available in the experimental situation; and in the therapeutic context the doctor may be said to be seeking his patient's good, in contrast to the experimental context where some other good is being sought. On the basis of these differences it may be claimed that a valid yet ignorant consent is enough permission for therapy, but not for experimentation.

Closer examination, however, reveals that these differences do not necessarily obtain. First, because I believe it would be granted that a valid yet ignorant consent can be given in the "therapeutic-experimental" situation, where a new drug or procedure is being attempted to aid the patient (in the absence of any traditional available therapy). In the therapeutic-experimental situation, as in the purely experimental situation, the sequelae are not known (although of course in both cases some definite result is expected or anticipated). If a valid yet ignorant consent is acceptable in the one, therefore, it must be acceptable in the other.

Secondly, because it is patently not the case that we can expect there to be no good accruing to the subject of an experiment by reason of his participation. There are, commonly, financial and other "tangible" benefits forthcoming (laboratory training, and so on). And it must once again be said that the pleasures of altruism are not negligible. The proposed differences between experimentation and therapy do not stand up, and so we must say that if a valid yet ignorant consent is acceptable in the one it must be acceptable in the other. It must be remembered that this statement only concerns itself with one part of the consent doctrine, which is, itself, only one of the requirements which the ethical experiment must satisfy.

To mention—without claiming totally to resolve—two problems which may be raised at this point: First, it is said that a doctor often does not know what will happen as a consequence of a recommended procedure, and so cannot tell the patient what the patient wants to know. The obvious response to this seems to be right: the physician should, in that case, tell the patient/subject that he does not know what will happen (which does not exclude an explanation of what the doctor expects to happen, and on what he bases this expectation).

Second, it will be objected that the adoption of a requirement such as I propose would forbid the use of placebos and blind experiments. I am not sure that this is so; sometimes it must be the case that the subjects in an experiment may be asked (without introducing artifacts into the results) to consent to an experiment knowing that some will, and some will not, be receiving placebos. Another alternative would be to inform the subjects that the experiment may or may not involve some subjects receiving placebos.[7] I am aware, however, that these remarks are less than adequate responses to these problems.

Our conclusion, then, is that the informing of the patient/subject is not a fundamental requirement of valid consent. It is, rather, derivative from the requirement that the consent be the expression of a responsible choice. The two requirements which I do see as fundamental in this doctrine are that the choice be responsible and that it be voluntary.

The Requirement of Responsibility

What is meant by saying that the choice must be "responsible?" Does this entail that the physician may at any time override a patient's judgment on the basis that, in the physician's view, the patient has not chosen responsibly?

[7] If this sort of explanation were given as a matter of course in *all* experiments, this might still further reduce the problem of artifacts. The remarks, it should be noted, are directed towards medical experiments. By and large, they are inapplicable to, say, experiments in social psychology.

Surely not; to adopt such a criterion would defeat the purpose embodied in the doctrine of consent. It would mean that a person's exercise of autonomy is always subject to review.

Still, some such requirement would appear to be necessary. A small child can certainly make choices.[8] Small children can also be intelligent enough to understand the necessary information. Yet surely we would not want to say that a small child can give valid consent to a serious medical procedure.[9] The reason for this is that the child cannot choose *responsibly*.

We are faced with a dilemma. On the one hand, it appears that we must require that the choice be responsible. To require only that the choice be free would yield counter-intuitive results. On the other hand, if we do require that the choice made be a responsible one, we seem to presuppose some body which shall judge the reasonableness of choices; this represents a paternalism which is antithetical to the doctrine of consent. An elderly patient chooses to forgo further life-saving measures. How are we to judge whether or not this choice is a responsible one?

The path between the horns of this dilemma involves saying that the "responsibility" which we require is to be predicated not on the nature of the particular choice, but on the nature of the patient/subject. What we need to know is whether *he* is a responsible man ("in general," so to speak), not whether the choice which has been made is responsible. In this way, we avoid the danger of upholding as "responsible" only those choices which we ourselves feel are good choices. We can and do admit into the community of responsible persons individuals who make choices with which we do not agree.

In this sense, responsibility is a dispositional characteristic. To say that someone is a responsible individual means that he makes choices, typically, on the basis of reasons, arguments, or beliefs—and that he remains open to the claims of reason, so that further rational argument might lead him to change his mind. It is to say that a person is capable of making and carrying through a life-plan—that he is prepared to act on the basis of his choices. It is to say that a person is capable of living with his life-plan; he can live with the consequences of his choices, he *takes responsibility* for his choices.[10] Of course, none of these are absolutes; all responsible people are at times pigheaded, at times short-sighted, at times flighty. That is to say, all responsible men at times act irresponsibly. Should the lack of responsibility persist, of course, to an extreme degree, we may say that the person has left the community of responsible folk.

Voluntarism and Reward

The other requirement of valid consent is that it be given voluntarily. The choice which the consent expresses must be freely made.

We all know some conditions which, if satisfied, make us say that a consent has been given involuntarily. The case which immediately springs to mind occurs when an individual succumbs under a threat: we call this duress or coercion. But the threat need not be overt: and perhaps there need not be a threat at all to render consent involuntary.

Hence, the major problem currently engendered by the requirement of voluntariness. It is typified by the prisoner who "volunteers" for an experiment in the hope or expectation of a reward: significantly higher wages, an opportunity for job training, better health care while involved in the experiment, a favorable report to his parole board. Is the consent which the prisoner offers a voluntary consent? The problem may be stated more generally thus: At what point does reward render consent involuntary?

The problem of reward is particularly difficult, since it involves questions of degree. Is a prisoner's consent involuntary if the reward for his participation in the experiment is a three-month reduction of sentence? Is it relevant here that the prisoner is serving a twenty-year sentence, rather than a one-to-five-year sentence? Does a possible increase in wages from twenty-five cents per hour to one dollar per hour constitute duress? Should we consider the percentage increase, or the increase in absolute value, or the increase in actual value which the seventy-five cent disparity represents in the prison environment?

[8] The counter-suggestion may be made that children cannot *really* make choices. This would, I think, put too great a weight upon the requirement of voluntarism. We would be recruiting the concepts of choice and volition to do a job which they have not been designed for.

[9] I am speaking of course in the moral, not the legal, context. It may be that in an emergency a child may, in the absence of his parents, give legally valid consent.

[10] This gives us the link between "responsible" in the dispositional sense explained here, and "responsible" in the blame-sense of the word ("I'll hold you responsible for that.").

To some, of course, questions like these have little meaning. They have little meaning to those who are indifferent to the demands of justice and autonomy which the consent doctrine represents, to those who are willing to buy guinea pigs, rather than to reward human beings. And they have little meaning for those who are convinced that prisoners are inherently unfree, and who thus would call for a total cessation of prison experimentation. Each of these positions denies, in an *a priori* fashion, freedom to prisoners; each must be rejected. A recognition of the fact that decisions about consent may be over as well as underprotective forces us to deal with this sort of question, complex though it may be.

As is so often the case, posing the question in a different way may facilitate response. We have been considering the question of how much reward nullifies the validity of consent, how much reward renders the subject unfree. But is it in fact the case that *reward* is the disruptive factor here?

This problem may be clarified by the following examples. Imagine an upper-middle-class individual, who can provide for his family all of their needs and most of the amenities of civilized life. Let us say that this person is offered one hundred dollars to cross the street—if you like, make it one thousand or ten thousand dollars? He chooses to cross the street. Is his choice *involuntary*? Despite the substantial reward, I think most of us would agree that the consent was freely offered (and would that we should have such problems!).

Consider a person who deeply wants to be an astronaut. He is told that as part of the program he must participate in experiments to determine resistance to high-G conditions. Is his consent to this invalid, involuntary? I think not. We would say, this is part of his job; he should have expected it; and if he can't stand the heat, he should get out of the kitchen. In this vein, consider Evel Knievel, a financially prosperous man, who is offered millions of dollars to perform daredevil stunts. His choice may be bizarre, even crazy; but has his reward rendered it unfree?

Finally, consider a man who is informed by his doctor that he will most likely die unless he has open heart surgery. His "reward" for consenting is his life; the penalty for not consenting is death. Does this mean this man cannot give the doctor valid consent—morally valid consent—to proceed?

There are two distinctions which, I think, go a long way towards dispelling these problems. First, I think it must be granted that natural contingencies ("acts of God," things which come to pass naturally, those contingencies which we cannot hold anyone responsible for) do not render a person unfree, nor do they render unfree the choices which a person makes in light of those contingencies.[11]

That natural contingencies do not render a man unfree is a point which is apt to be forgotten in the present context. I am not—in the morally relevant sense—lacking in freedom because I cannot, unaided, fly through the air, or live on grass. Nor am I unfree because my heart is about to give out. Nor am I unfree when, recognizing that my heart may give out, I choose to undergo surgery. I may, of course, be so crazed by knowing that I am near death's door that I am in a state of general impotence, and hence must have the choice made for me; but general incompetence is not in question here. The distinction between choices forced by man, and choices forced by nature, is, then, of importance.

The second distinction is between those pressures which are, and those which are not, in Daube's words, "consonant with the dignity and responsibility of free life."[12] I would explain this as follows: there are certain basic freedoms and rights which we possess which *entitle* us (morally) to certain things (or states of affairs). We would all, no doubt, draw up different lists of these rights and freedoms; but included in them, would be safety of person, freedom of conscience and religion, a right to a certain level of education, and, for some of us, a right to some level of health care. When the "reward" is such as only to give us the necessary conditions of these rights and freedoms—when all that the reward does is to bring us up to a level of living to which we are entitled, and of which we have been deprived by man—then the "reward," I think, constitutes duress. A reward which accrues to one who has achieved this level, or who can easily achieve it (other than by taking the reward-option), and which hence serves only

[11] The *caveat* must be added: natural contingencies do not have, as their *sole* result, the rendering of a person unfree, in the sense which vitiates consent: a man's brain tumor can make the man an idiot, schizophrenia can make a man insane, but these do not so much affect a person's volition as they do disturb his entire psychic structure.

[12] David Daube, quoted in Beecher, p. 146.

to grant us "luxury" items, does not constitute duress, and hence does not render choice unfree, no matter how great this reward may be.

The rewards above the moral subsistence level are true rewards. In contrast, we may say (with some touch of metaphor) that the "rewards" which only bring us up to the level to which we were in any event entitled are properly viewed as functioning as *threats:* "Do this, or stay where you are:"—when you should not have been "where you are" in the first place.

The astronaut, Evel Knievel, and the upper-middle-class street-crosser are being granted "luxury" items, and hence are capable of giving free consent. But consider a man who will not be admitted to the hospital for treatment unless he agrees to be a subject in an experiment (unrelated to his treatment). Those who feel, as I do, that we are, here and now, morally entitled to medical treatment would agree, I trust, that this illegitimate option coerces the man into agreeing. Or consider a man who has religious scruples against donating blood, who takes his daughter to a hospital for treatment. He is told that the doctors will not treat her unless the family donate a certain amount of blood. His freedom has been nullified; his "consent" to donating blood is morally invalid. Similarly, the college student whose grade is contingent upon his participation in the instructor's psychological experiments is not validly consenting to serve. He is entitled to have his grade based upon his classroom work.

It yet remains to apply this distinction to our original problem, prison experimentation. The application will not be attempted here, for we would first need to be clear in our minds what rights and freedoms a prisoner is entitled to. I would not hesitate to say, though, that when a situation is created whereby a prisoner can only receive decent health care by participating in an experiment, he is being coerced into that experiment. I would have little hesitation in claiming that if subjecting himself to experimentation is the only way in which a prisoner could learn a trade which may be used "outside," then that prisoner is being coerced, his consent is not free. When we take into account the condition of our society, these would seem to be reasonable entitlements for the prisoner. Other rewards—for example, higher pay—may or may not constitute rewards above the moral subsistence level; if they are, then consent in light of these rewards could be freely offered. Perhaps too much has been said already; judgments like these must be made in an individualized fashion, one which is sensitive to the realities of prison life.

II. CONSENT AND THE INCOMPETENT

In this section will be discussed, first, the question of how the age of majority and minority with reference to valid consent ought to be set; and secondly, the problems associated with the concept of proxy consent.

The Age of Consent

It has been argued that the requirements for obtaining valid consent are that the patient/subject must have consented freely and that he must be a responsible individual. The requirement of voluntariness does not raise any novel problems when applied to minors. Rather, what we usually have in mind when restricting the power of the minor to consent is that he is not, in the sense required, a responsible individual.

I have claimed that to be a responsible individual one must be capable of rationally adopting, following through, and accepting the consequences of a life-plan. The age, therefore, at which society indicates a presumption that individuals can satisfy these conditions can be said to be the age at which society ought to grant the right to give valid consent to serious medical procedures. The examples which spring to mind are the age of conscription and the age of marriageability. At these ages society has indicated that one is capable of acting, in a complex society, as an individual.

This is not an argument like that which says "If you are old enough to fight, then you are old enough to vote." The requirements necessary for being a soldier may be wholly unrelated to the requirements necessary before the franchise may be properly exercised. In contrast, the responsibility which we assume to be possessed by those capable of soldiering and contracting marriage is the same responsibility which is required to make consent valid: the ability to work through and with a life-plan.

The first thing which needs to be said, then, is that the age of consent should be lowered from 21 to 18. In those jurisdictions which have not yet done so. This

should not entail merely that an 18-year-old may consent in the absence of parental disapproval; it should be a full power to consent, irrespective of what others might say.

But the setting of an age of consent indicates only a presumption and nothing more. The fact that someone has passed the age of consent is not conclusive proof that he is responsible (in the sense required); the fact that someone is below the age of consent is not conclusive proof of irresponsibility. The presumption may be defeated in either direction.

It is clear, for example, that an adult is not, *ipso facto*, responsible. The adult may be insane.

It is equally clear that a minor need not be irresponsible. People mature at different rates. If evidence of responsibility may be supplied on behalf of one below the age of consent, the presumption of irresponsibility should be defeated. The sort of evidence which would be necessary is that which indicates that the person can work through a life-plan. It may be said that this notion is being approached by the law in the special provisions sometimes made for the "emancipated minor." Marriage or economic self-sufficiency are among the common requirements for being considered an emancipated minor. One of the special prerogatives of the emancipated minor is that he may consent on his own behalf to medical care. I would argue that this should be extended to cover participation in experimentation as well.

Proxy Consent

Proxy consent is consent given on behalf of an individual who is himself incapable of granting consent. The major category of those who require proxy consent are minors, but proxy consent may need to be obtained for the insane or the unconscious as well. My comments will nevertheless be restricted to the case of minors, leaving the other cases to be detalt with by implication. In minors, proxy consent is ordinarily granted by the child's parent or guardian: exceptionally, it may be given by another close relative or by an individual appointed by the court for the specific purpose of granting consent to some procedure.

I have argued that the function of informed consent is to respect the autonomy and dignity of the individual. This cannot be the function of proxy consent. The minor patient/subject cannot fully express autonomy and dignity through choices. It may be said that the function of proxy consent is to protect the right of the parents to raise their child as they see fit, to do with the child as they like. But the child is not the property of the parents; parents do not have an absolute right of disposal over the child. In law we recognize constraints upon the parental power, and common morality affirms the justice in this. What then is the function of proxy consent?

I think it would be best to turn this question on its head. By virtue of what right which the child possesses do we require the granting of proxy consent before a medical procedure may be intiated? What *could* be the source of such an obligation? We ordinarily recognize that there is only one fundamental right possessed by minors, a right to be protected and aided in development. "* * * A child, unlike an adult, has a right 'not to liberty but to custody.'"[13] All other rights which a child possesses, all other duties which we have towards children, are derivative from this single right, and are void when inconsistent with it. Broadly speaking, in consequence of this right, we must do what we may to promote the welfare of the child; we must abstain from doing what will injure the child, physically or otherwise; and, as far as this right goes, we are at liberty to deal with the child in ways which neither help nor hurt.

That proxy consent is ordinarily to be obtained from the parent or guardian of the child is understandable. We feel that the parent has the best interests of the child at heart, and knows how best to seek the child's welfare. It also follows from this right, however, that, when the parent does not have the best interests of the child in mind, the power of proxy consent should be transferred to another. It is on such a basis that society feels justified in removing a child from his parent's custody, and in appointing another to act *in parens patriae*. If this system is to be effective, society must, by and large, act on the basis of shared common views about what the welfare of the child consists of. We cannot allow anything which a parent considers to be a benefit to the child—being boiled in oil to save his eternal soul—to count as action in the child's best interests. This does not preclude a certain amount of leeway in a liberal society as to permitted

[13] *In re Gault*, 387 U.S. 1 (1967).

views of welfare: if most feel that it is better, when the money is available, to send the child to a private school, we yet will not fault an affluent parent who decides to send his child to a public school.

The consequences of these propositions for cases when proxy consent is being sought for the purpose of giving therapy to a child accord well with the way the law handles this subject. The problem situation which arises concerns parents who, because of religious scruples, refuse to consent to needed medical treatment for their child. Jehovah's Witnesses, for example, who believe that blood transfusions are forbidden by the law of God, will not consent on behalf of their child to blood transfusions. Society feels that the benefit of the child is to be found in allowing the procedure. Because of this, the hospital will often turn to a judge, who appoints someone to act *in parens patriae* for the purpose of consenting to the specific procedure. I suggest that if it were clearly the view of society that it is to the mongoloid infant's benefit to survive, should a parent refuse to consent to a life-saving procedure for that infant, a similar course would be followed: the consent of a court-appointed guardian would be substituted.

Proxy consent to experimentation on children is a more complicated matter. In law, there are two kinds of intervention in the person of another which are actionable in the absence of consent: those interventions where harm does, and where harm does not, result. The latter are termed "wrongful" or "harmful touchings" (though no harm has occurred). In other words, the mere *doing* of something to a person without his consent is, in itself, an actionable wrong.

We may say that, corresponding to this division, there are two sorts of experiments: those which do, and those which do not, injure the subject appreciably. Beecher has noted, for example, that "Many thousands of psychomotor tests and sociological studies have been carried out in children during the child's development and have revealed much information of value. . . . Sound nutritional studies without risk have been carried out. So have certain blood studies."[14] It must be added that many studies of value cannot, due to metabolic and other differences, be carried out in adults with results which will be valid for children.

It is clear, on the basis of the principal of benefit, that proxy consent to dangerous or harmful experiments on children cannot be valid. What about those experiments which carry no appreciable risk—the "wrongful touchings" sort? In an adult, it would seem, the right to autonomy, the right "to be let alone," is sufficient basis for the action of wrongful touching. But the child does not have a right to autonomy, except insofar as some measure of autonomy is necessary to promote the child's development and well-being.

Harmless experiments on children, therefore, which satisfy the other canons of medical ethics—good design, well-trained experimenters, and so forth—could be performed. Parents would not be derelict in their duty should they consent, on behalf of their child, to experiments of this sort. Participation in these experiments do not infringe the child's right to welfare, unless they would result in a *harmful* (and not just any) restriction of autonomy.

As I see it, the fundamental problem with those who would forbid *all* experimentation upon children[15] is that they confuse consent in adults with proxy consent for children. These two are fundamentally different requirements. Children are not small adults; our relations with children must not be made to approach as nearly as possible to our relations with adults. There are things which you ought to grant to children which need not be granted to adults: if a child is thirsty you provide him with drink. And there are things which may licitly be done to children which could not be done with adults: if my parents annoy me I may not send them to their room. A child is (morally) a different sort of thing than is an adult; we must adjust our relations with them according to their claims upon us.

CONCLUSION

This paper represents an attempt to formulate what I call a "moral theory" of the requirement of consent to serious medical procedures. The method used involves an interplay between cases and principles, such that each influences the other. Well-established moral intuitions about cases suggested some principles and called for the rejection of others. These principles in turn, once established, enabled the clarification of a proper approach to other, borderline cases.

[14] Beecher, p. 67.

[15] See, for example, Paul Ramsey, "Consent as a Canon of Loyalty With Special Reference to Children in Medical Investigations," in "The Patient as a Person" (New Haven: Yale University Press, 1970).

Under the influence of situation ethics, much of the work on medical ethics has stressed the respects in which cases differ. This has resulted in the development of an *ad hoc* literature on cases which pose difficulty for the doctrine of informed consent. As the cases accumulated, the doctrine began to seem more and more amorphous.

In contrast, this paper has sought to unify the doctrine of consent. Principles which are developed through considering the problems raised by prison experimentation in turn suggested solutions to other situations; rather than stressing the differences between the experimental and the therapeutic contexts, their similarities were emphasized. There is, I think, a need for such efforts at unification, as there is a need for a literature which is committed to the unique aspects of different cases.

[From JAMA, vol. 202, No. 6, p. 511, Nov. 6, 1967]

Special Communications—Why Prisoners Volunteer To Be Experimental Subjects

(By John C. McDonald, M.D.) [1]

Recently, while engaged in a clinical experiment involving inmates of a nearby state prison, I became rather perplexed by the reaction of colleagues to the program.[2] There was considerable interest in why inmates subjected themselves to such experimentation. The question most frequently raised concerned what rewards were given to such volunteers, and the prevailing attitude seems to be that this was a group of men who were simply being exploited, albeit for a good cause. This attitude is understandable coming from one whose viewpoint stems from a rather comfortable position in society, but the view is entirely different when it comes from within the walls of prison.

In the flurry of current concern over the proper ethical guidelines of human experimentation, the rights of the subject to be protected have received attention as has the right of society for progress. I have not seen any discussion of the right of the volunteer (particularly the inmate volunteer) to volunteer.

The inmate does not volunteer because he expects his sentence to be shortened, nor does he volunteer for financial reward. Actually, he does so for much more immediate reasons, which are quite apparent to him and which seem quite sound.

The fact that the inmate does recognize advantages in these programs is attested to by his eagerness to participate in them as well as by his willingness to persevere unto the end, in spite of morbidity.

For the experiment which occasioned these reflections, 2,000 men were given a prepared circular calling for participants. In three days there were approximately 350 petitions submitted. Since no more petitions were accepted thereafter, the number of volunteers who eventually would have applied remains unknown. Further, of the 50 men eventually accepted for an experiment which required three successive skin allografts over a period of 12 weeks, there was only one man who dropped out of the program of his own accord.

To understand this phenomenon some consideration from the prisoners' view is required.

The image of the medical profession still stands largely unblemished to the inmate, and as a result he accepts as an article of faith the axiom that a physician would not ask him to subject himself to risks that were not justified. This faith places enormous responsibility upon the investigator and is the principal reason that some protective procedures are necessary. Nevertheless, while this faith burdens the investigator, it frees the inmate to volunteer for more personal advantages.

Volunteering is an opportunity to break the monotony of his life. Prison life, as it exists today, is quite stereotyped. Life is regimented. One arises at a specified time, performs specified tasks in specified clothes under specified conditions, eats specified foods, sees visitors at specified times, and even writes letters under specified conditions.

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[1] From the State University of New York at Buffalo and Edward J. Meyer Memorial Hospital, Buffalo.

[2] The experiments referred to were performed at Attica (NY) State Prison, with the consent of the Commissioner of Correction of the State of New York, Paul D. McGinnis. Advice was provided by Warden Vincent R. Mancusi and assistance by Senior Prison Physician, S. T. Williams, Jr., MD.

It would be unfair to the Department of Correction of the State of New York to imply that many opportunities are not available to inmates to occupy their time and to provide for their self-improvement. Every effort is made to interest the inmate in such programs. Nevertheless, many do not respond. To these inmates, life is basically a bore, and one day is quite like another. The experiment breaks this boredom and as such is refreshing. It also introduces a note of excitement into prison life. Man in general needs some stimulation. The state of total security in which these men find themselves becomes, after a while, both unhealthy and unpleasant. The experiment, in the sense that it includes an element of the unknown and an element of personal risk, temporarily relieves this condition. Many of the men verbalize these motives with their expression: "It [the experiment] breaks the time."

The inmates enjoy being involved in positive action. They are "doing something" and, just as important, they have something to talk about. Conversation turns rather stale in prison, and subjects of genuine interest are scarce. Each day an inmate sees the same people he saw yesterday, and they haven't done anything that he hasn't done. Consequently, conversation eventually degenerates into what the inmate calls "prison gossip." The men in the experiment, however, had an item of conversation. Not only did they have an item of conversation, they *were* an item of conversation. The volunteers were subjects of interest to the entire prison, not only to the other inmates, but also to employees of the prison at all levels. People inquired of the experiment's progress, what was being required of the inmates as volunteers, and what was being learned. As they conversed, the volunteers found that they were no longer nonentities. Suddenly, they were important! They became, at least for a while, the elite of their own society.

Consequently, the experiment also serves to strengthen the ego. The inmate has been singularly unsuccessful and has ultimately found himself in society's lowest estate. Being a prisoner undoubtedly is one of the most severe tests of ego structure yet devised. It is extraordinarily difficult to maintain a sense of one's own personal value under such conditions. The experiment offers an opportunity for the inmate to prove to himself or to his friends and relations that he can do something worthwhile. Participating in the experiment requires risk; it requires sacrifice, perseverance, and altruistic ideals. Such behavior improves his own self-esteem and elevates his status in the eyes of those who are important to him.

The inmate has a real desire to be a part of society at large, and the experiment provides this opportunity since it originates from the "outside." The inmate also wishes to have the opportunity to relate to people from the outside. Once he becomes acquainted with the investigative personnel, he frequently seeks advice from them on many subjects. Apparently, this is due to his deep-seated distrust of anyone associated with the correction system. The investigators, having no such connection, are not automatically suspect and, therefore, their opinions are held in higher esteem.

The following excerpt is from a letter written by an extremely intelligent, 27-year-old man serving a life sentence. I quote with his permission:

"A former warden once said, 'The strongest desire of most men in prison is to be able to take part in outside activities.' I agree with this, adding however, that this goes double when there is a possibility of being of benefit to humanity.

I'd like to say further that it was a very interesting twelve weeks. If you ever have any complaints about your bedside manner, just remember your boys here, with whom your corn-pone humor made the sca[l]pel and needle work something to look forward to.

If these motives are discussed with inmates, they readily accept them as being valid. The inmates maintain, however, that in addition they volunteer simply because it is a good thing to do. In a spontaneous discussion with some ten of the group, they pointed out rather articulately that circumstances make them the logical persons to perform such tasks. They do not have the responsibilities of a job, nor do they support a family. No one is dependent upon them who has not already adjusted to doing without them. They, therefore, feel justified in accepting risks for the common good which they themselves would not accept if they were outside.

Finally, the group of men became a group. As a genuine esprit de corps developed, they became interested not only in themselves but also in each other. Their attentions were diverted from their own problems to those of the group and of experiment. The volunteers became interested in the entire subject of trans-

plantation and began to read and to suggest ideas. They helped to make the mechanics of the experiment run more smoothly. If a light faltered, it was quickly repaired. If a man faltered, he was encouraged (not always, I'm afraid, by unadorned rhetoric). The volunteers even selected a name for the group. Transplant experiment Attica was considered (to be called TEA), but the contraction was not agreeable. They finally settled upon Skingraft, Attica Group, Experiment (to be referred to as the SAGE group, or the SAGE sera).

Certainly they enjoyed the entire process. Most expressed regret when it was completed, and, to a man, they wished to be kept informed of the progress of the laboratory studies.

This report has been written with considerable misgiving caused by the fear of being misunderstood. The benefits to the inmate discussed here are not being proposed as justification for experiments. Obviously, this is absurd. Rather, the report has been written to point out that the inmate is not a neutral quantity, nor is he exploited by proper experiments. He volunteers for certain advantages that are clear to him, and he continues because these desires are largely fulfilled.

As the guidelines of human experimentation evolve, it is to be hoped that the inmates' point of view will not be ignored.

[From JAMA, vol. 202, No. 6, p. 513, Nov. 6, 1967]

Special Communication—The Use of Prisoners for Medical Research

(By Robert E. Hodges, MD, and William B. Bean, M.D.[1])

The moral and ethical implications and the practical operating code we have developed in Iowa were described by one of us in a University of London lecture on July 14, 1967. The basic principles do not differ from those set forth in an address to the Central Society for Clinical Research in Chicago in 1951. Since this aspect of our interest has been dealt with elsewhere, we will confine our comments to the practical aspects of using prisoners from custodial institutions in Iowa in our clinical research.

In the last analysis, the introduction of any new form of diagnosis or treatment, any new drug or medicine, is an experiment. There must be a first. Our problem, therefore, is to determine to what degree experimentation on human subjects is permissible and what should be the strict lines of control and consent. In recent months and years, books have been written, symposia have been held, and hardly a journal of clinical investigation has not had some comments and ideas on the matter. Before the present scientific explosion, clinical research was done by physicians who were not specially trained for it. Their experience was that of general medicine or surgery. Their orientation was practice; their concern was basically that of the patient. Problems arising in the context of a sickbed (in the form of disease and its exceptional behavior in a puzzling patient) provided incentive enough to seek solutions by whatever methods were at hand. Oliver Wendell Holmes and Semmelweis epitomized the utility of careful empiricism before Koch and Pasteur provided the exact science that put mechanisms on a high level of comprehension. Lind knew how to prevent scurvy nearly 200 years before vitamin C was discovered, a curious lag which is small tribute to skill in human communication of ideas. Walter Reed had found out the manner of yellow fever's spread before the causative virus was understood or identified. As one of us (W.B.B.) said previously:

Never forget that the difference between an experiment on human beings without a clear understanding and freely granted permission and the determination of the minimum lethal dose in man is one of degree, not of thing. The patient however humble and however ill, in whatever degree derelict or forlorn, has sacred rights which the physician must always put ahead of his burning curiosity.[2]

Experiments on human beings fall roughly into three categories: (1) experiments done to test physiological states and environmental manipulation, both internal and external, in "normal" subjects; (2) the trial of new methods, procedures, or drugs on persons who are ill; and (3) the use of doomed patients with a fatal illness to test potentially dangerous drugs or procedures. These

[1] From the Department of Internal Medicine, University Hospitals, University of Iowa, Iowa City.

[2] Bean, W. B.: A Testament of Duty. *J. Lab. Clin. Med.* 39: 9 (Jan.) 1952.

experiments may be either potentially helpful or of no help to the patient but possibly may advance scientific knowledge and benefit others.

It is unlikely that the legal aspects of permission to experiment and a codified statement exactly defining "informed consent" will be settled either by courts of law or by philosophers. It may be very difficult, though certainly not impossible, for the clinical investigator who is working on healthy subjects, as we have been doing with men from the prisons in the state of Iowa, to avoid at least a small element of observer bias or parallax. Even in giving the clearest possible description of the nature of the proposed experiment, there are difficulties. We think the nature of the program and procedures should be made as explicit as language and thoughful communication can produce. It is proper to use a written consent form. Certainly the preexperiment discussion should be free and open. The option to get out of the experiment should be available to volunteers at any time.

As will be pointed out later, we have had a number of subjects depart from the hospital without permission, but with the great majority of inmates there was no trouble. The very large number wishing to volunteer for subsequent studies is strong evidence that the experiments and the experiences have been satisfactory to the subjects. We feel justified in using our continuing efforts and increasing skills in these difficult and time-consuming studies. Only in such ways can we gain a larger grasp of health-giving and sometimes lifesaving knowledge, an achievement impossible without bold and cooperative subject, our companions in medical science and adventure.

EXPERIENCES IN IOWA

In 1949, after a series of frustrating experiences, one of us (W.B.B.) came to recognize the need for a supply of normal volunteers who would be willing to stay in the hospital for a prolonged period of time while undergoing medical studies. At that time, a patient in one of our medical wards had a chronic skin disorder which did not impair his health. He was an inmate of one of the prisons in Iowa, serving a life sentence for murder, and was in no hurry to return to the prison. We were attempting to study the effects of certain antivitamins upon pantothenic acid metabolism, so we seized the opportunity to admit him to our newly established metabolic ward. There he remained for almost one year. Both he and we were content with these arrangements, but when his prolonged hospital stay came to the attention of prison officials, they requested that in the future we not retain their men for research purposes without the knowledge and approval of the prison. Because we needed this type of volunteer urgently, we held a conference with officials of both prisons, members of the Board of Control which governs these institutions, and physicians from several departments of the College of Medicine and the University Hospitals. As a result of this conference, a working arrangement was agreed upon verbally. The physician who wished volunteers was to send a written request to the warden who would then ask for those inmates who wished to participate in a particular project. We knew that this procedure was not specifically permited by law but neither was it specifically prohibited. But the law did permit the hospitalization of prisoners at the University Hospitals for treatment of medical illness.

For a time things went well. As a result of this arrangement, we were able to conduct and complete many useful investigations. As time went by, new state officials were puzzled about this arrangement. On one occasion, the state attorney general was asked to rule upon the legality of our operation. In his judgment, it was not legal for us to accept prison volunteers for medical research. Accordingly, we discontinued use of prisoners for research purposes for two years. During this time, we sought and obtained enactment of a specific law permitting the use of prisoners for medical research at the University Hospitals. This law states:

"The board of control may send to the hospital of the medical college of the state university inmates of the Iowa state penitentiary and the men's reformatory for medical research at the hospital. Before any inmate is sent to the medical college, he must volunteer his services in writing. An inmate may withdraw his consent at any time."

Since enactment of this law,[3] we have availed ourselves of this valuable

[3] Iowa Code, 1964, chapter 246, Penitentiary and Men's Reformatory, section 246:47, Patients for Medical Research. Acts, 1963, chapter 158, section 1.

opportunity to conduct clinical investigation in healthy volunteers under ideal investigative conditions.

One of the chief advantages of this arrangement is that it permits selection of men of any given age, height, and weight. By screening, the investigator can select persons who have a specific disorder, such as diabetes mellitus or hypertension. He can select subjects with any characteristic that might commonly be found within a prison population. These subjects can then be hospitalized in the metabolic ward under combined prison and research discipline or in the clinical research center under similar supervision for the time necessary to complete an experiment.

We have often wondered what incentives and motives induce prisoners to volunteer for research studies which are usually somewhat unpleasant and in a few instances involve distinct risks. For some, it probably represents a new experience which takes them away from the monotony and oppressiveness of prison routine. For others, monetary gain may be the incentive, though inmates are paid only one dollar daily, and, under favorable conditions, they earn nearly as much in prison activities. Prison volunteers are less reluctant to be visited by their children in the hospital environment. We like to think that for some a feeling of altruism motivates them to try to repay their debt to society. For a few, perhaps, volunteering represents an opportunity to escape, and indeed some have done this. For others, there is undoubtedly the hope for more favorable treatment in the future. Perhaps for all there is a longing for feminine proximity even though they realize that careful supervision would prevent any unacceptable behavior.

Once a faculty member has decided upon a project, he presents his proposal to a research committee of the College of Medicine. Following the committee's evaluation and approval, the dean sends a note of approval to the investigator who establishes liaison with the prison authorities by calling or writing the director of penal institutions in the Board of Control and sends a copy of the message to the warden of the prison. (There are two prisons, the Men's Reformatory at Anamosa, which houses approximately 600 men and the Iowa State Penitentiary at Fort Madison, which houses approximately 1,000 men.) After the proposal has been approved by the Board of Control, the warden is authorized to present to the men a simple explanation of the type of study to be conducted and to provide an opportunity for volunteers to make themselves known. From these volunteers, the prison authorities select a suitable group of men who are not emotionally ill, nor habitually unreliable, nor otherwise unsuited for the project. Usually the authorities provide a select group of volunteers which is about double the number requested by the investigator. The investigators, along with the head nurse of the metabolic ward and other authorized personnel, then visit the prison for the purpose of explaining in detailed yet simple language the nature of the investigation, the risks involved, and the manner in which the study will be conducted. The volunteers are then given an opportunity to withdraw or to ask additional questions before accepting. After the final selection is made, the men are transported by prison authorities to the University Hospitals where they are hospitalized either on the metabolic ward or on the clinical research ward. In no instance are prison research subjects housed on the open wards. After they arrive at the hospital, they are given an additional detailed briefing and an opportunity to ask additional questions. Then they sign a consent form and undergo the customary detailed history and physical examination followed by appropriate laboratory tests.

The metabolic ward and the clinical research center have similar rules of patient conduct, which include the wearing of hospital garb, confinement to a given area, and regulation of hours of arising and going to bed, use of television and radio, etc. In addition, the prison volunteers must observe certain rules that prevail at the prison. These include control of their correspondence with friends and relatives and restriction of visitors to an approved list who may return only at specified intervals. The men are encouraged to engage in hobbies and crafts, and they are required to participate in certain forms of exercise, such as supervised walks, for a designated length of time each day. For their participation in research activities, they receive no reduction of their sentences nor any favoritism regarding paroles. We do, however, send a letter to the warden at the termination of each experiment expressing our appreciation for the inmate's participation in the study. It is possible that this letter in the prisoner's file may favorably influence the parole boards.

Since our first patient, who was an unofficial volunteer, we have accepted a total of 224 prisoners for medical research at University Hospitals. Only a few of these represent "repeaters" since we try to avoid selecting a man more than once. Most of the men have been housed on the metabolic ward, but a substantial number have been studied in the clinical research center. Of the total, ten have escaped. Most of the escapees were subjects for the medical experiment who had been selected rather hastily at the insistence of an investigator; hence prison officials had not been given ample opportunity to make their usual careful selection.

The level of compliance by prisoners with research rules and regulations has been surprisingly high. They have eaten strange diets, swallowed tubes, submitted to repeated venipunctures, and participated in a wide variety of physiological tests with a commendable degree of good humor and cheerfulness. Although any man may leave the study to return to the prison if he so desires, this has happened in very few instances. There have been some personal problems and some instances of disappointment on the part of the prisoners, but most of the men seem to feel they have performed a useful service by participating. The research studies conducted on prison volunteers have yielded important results. Vitamin deficiencies have been characterized, antibody responses studied, and important aspects of fat and cholesterol metabolism clarified. More than 80 scientific publications have resulted from these studies. We feel that the use of prison volunteers for medical research is justified and highly desirable for the investigator, for the subjects, and for society. It not only permits the conduct of human investigation under ideal circumstances, but it enables the participants to feel that they are serving a useful function as indeed they are.

SUMMARY

A system of voluntary participation firmly based on legal and ethical standards has provided a rich opportunity for clinical investigators who wish to study metabolic, physiologic, pharmacologic, and medical problems. This has been a rewarding experience both for the physicians and for the subjects.

[From Atlantic Monthly, January 1973]

Experiments Behind Bars—Doctors, Drug Companies, and Prisoners

(By Jessica Mitford)

"Criminals in our penitentiaries are fine experimental material—
and much cheaper than chimpanzees."

Before a new drug can be marketed in the United States, it must, according to Food and Drug Administration rules, be tested on human beings. In recent years, most of the early testing of our increasingly exotic drugs has been done in prisons. And prisoners have been the subjects of other medical experiments as well.

For some time, international medical societies have attempted to prohibit the use of prisoners as subjects, but these efforts have been effectively frustrated by American medical experimenters. The World Medical Association proposed in 1961 that prisoners "being captive groups should not be used as the subject of experiments." The recommendation was never formally adopted, largely because of the opposition of American doctors. "Pertinax" writes in the *British Medical Journal* for January, 1963: "I am disturbed that the World Medical Association is now hedging on its clause about using criminals as experimental material. The American influence has been at work on its suspension." He adds wistfully, "One of the nicest American scientists I know was heard to say, 'Criminals in our penitentiaries are fine experimental material—and much cheaper than chimpanzees.' I hope the chimpanzees don't come to hear of this." [1]

Although few involved in prison experiments like to talk openly about them, alarming stories crop up in the press with sufficient regularity to give some indication of the scope and nature of the experiments. In 1963, *Time* magazine reported that the federal government was using prisoner "volunteers" for large-

[1] See M. H. Pappworth, M.D., *Human Guinea Pigs*, Beacon Press, 1967.

scale research, dispensing rewards ranging from a package of cigarettes to $25 in cash plus reduction of sentence; that prisoners in Ohio and Illinois were injected with live cancer cells and with blood from leukemia patients to determine whether these diseases could be transmitted; that doctors in Oklahoma were grossing an estimated $300,000 a year from deals with pharmaceutical companies to test out new drugs on prisoners; that the same doctors were paying prisoners $5 a quart for blood which they retailed at $15.

In July, 1969, Walter Rugaber of the New York *Times* reported that "the Federal Government has watched without interference while many people sickened and some died in an extended series of drug tests and blood plasma operations . . . the immediate damage has been done in the penitentiary systems of three states. Hundreds of inmates in voluntary programs have been stricken with serious disease. An undetermined number of the victims have died."

The stakes in prison research are high. The drug companies, usually operating through private physicians with access to the prisons, can obtain healthy human subjects living in controlled conditions that are difficult, if not impossible, to duplicate elsewhere. In addition, the companies can buy these for a fraction—less than one-tenth, according to many medical authorities—of what they would have to pay medical students or other "free-world" volunteers. They can conduct experiments on prisoners that would not be sanctioned for student-subjects at any price because of the degree of risk and pain involved. Guidelines for human experimentation established by HEW and other agencies are easily disregarded behind prison walls.

When the studies are carried out in the privacy of prison, if a volunteer becomes seriously ill, or dies, as a result of the procedures to which he is subjected, the repercussion will likely be smaller than they would be on the outside. As Rugaber discovered when trying to trace deaths resulting from the "voluntary programs," prison medical records that might prove embarrassing to the authorities have a habit of conveniently disappearing. There is minimal risk that subjects disabled by the experiments will bring lawsuits against the drug companies. Prisoners are often required to sign a waiver releasing those responsible from damage claims that may result. Such waivers have been held legally invalid as contrary to public policy and are specifically prohibited by PFA regulations, but the prisoner is unlikely to know this. The psychological effect of signing the waiver, along with the general helplessness of prisoners, make lawsuits a rarity.

For the prisoner, the pittance he gets from the drug company—generally around $1 a day for the more onerous experiments—represents riches when viewed in terms of prison pay scales: $30 a month compared with the $2 to $10 a month he might make in an ordinary prison job.

Dr. Robert Batterman, a clinical pharmacologist, told me, "The prisoner-subject gets virtually nil." He cited an estimate given him for experimenting on prisoners in Vacaville, California: $15 a month for three months to be *lowered* to $12.50 a month should the experiment run for six months. "We would normally do it the other way around with free-world volunteers. We'd give them more money if the experiment ran longer." Dr. Batterman makes considerable use of student-subjects from a nearby Baptist divinity school. For a comparatively undemanding experiment—one requiring a weekly withdrawal of blood—he would pay a student at least $100 a month, he said.

However, the problem as seen by some leaders of the American medical profession is not that the prisoner-subjects are paid too little, but rather that they may be paid too much. That a dollar-a-day stipend to a healthy adult can be so overwhelmingly attractive as to invalidate the results of medical research is a possibility only in the topsy-turvy world of prisons. Yet the fear that this will happen is precisely what is expressed by some spokesmen for the profession. Thus Dr. Herbert L. Ley, Jr., then commissioner of the Food and Drug Administration, testified in 1969 before the Senate Select Committee on Small Business:

"The basic problem here, Mr. Chairman, is that the remuneration to the prisoner was too much. This meant that the prisoner had a very strong pressure not to report and not to withdraw from the study. Therefore he would decline to say that he felt any adverse reactions. This is bad for the prisoner in that it exposes him to unnecessary risk, it is bad for our records in that it does not provide us full information."

Prisoners do indeed view the small sums paid as largesse. In a series of interviews conducted in 1969 at Vacaville prison, California, by Martin Miller, a graduate student at the University of California Department of Criminology, some of the prisoners commented: "Yeah, I was on research but I couldn't keep my chow down. Like I lost about thirty-five pounds my first year in the joint, so I started getting scared. I hated to give it up because it was a good pay test." . . . "Hey, man, I'm making $30 a month on the DMSO thing [Chronic Topical Application of Dimethylsulfoxide]. I know a couple of guys had to go to the hospital who were on it—and the burns were so bad they had to take *everyone* off it for a while. But who gives a shit about that, man? Thirty is a full canteen draw and I wish the thing would go on for years—I'd be lost without it." . . . "I was on DMSO last year. It paid real good and it was better than that plague thing [Bubonic Plague Vaccine Immunization Study] that fucked with guys last year. There was a lot of bad reactions to DMSO but I guess that's why it paid so good." Of DMSO Morton Mintz, staff writer for the Washington *Post*, had written three years earlier: "Human testing has now been severely curbed by FDA because of reports of serious adverse effects" (Washington *Post*, July 24, 1966).

The participating physician cashes in on the programs in various ways. He may make a direct deal with the drug company for financial backing, out of which he pays the expense of research and pockets the rest as his fee. An individual research grant might run from $5000 to more than $50,000, enabling a doctor with good prison contacts to double or triple his regular income. Or if he is, as many are, a faculty member in a medical school, he can route the grant through his university, to the acclaim of his colleagues. His prestige will be enhanced when the results of his research appear in a profesional journal.

Some of the vicissitudes that the medical researcher may expect to encounter in his quest for prisoner-subjects are described by Dr. Robert E. Hodges in the November 6, 1971, issue of the *Journal of the American Medical Association*. In the late forties, Dr. Hodges and his colleagues reached a "verbal working arrangement" with Iowa prison officials enabling them to canvass the prison population for volunteers who would submit to prolonged hospitalization in university hospitals as research subjects. "We knew this procedure was not specifically permitted by law," writes Dr. Hodges. "But neither was it specifically prohibited." Eventually the experiments came to the attention of Iowa's Attorney General: "In his judgment, it was not legal for us to accept prison volunteers for medical research." There followed two fallow years in which the experiments were halted, but Dr. Hodges during this time "sought and obtained enactment of a specific law permitting the use of prisoners for medical research at university hospitals." The path thus cleared, a total of 224 convicts were in the course of time delivered over to Dr. Hodges and his colleagues at the university hospitals.

Speculating on the "incentives and motives" that induce prisoners to volunteer for research studies "which are usually somewhat unpleasant and in a few instances involve distinct risks," Dr. Hodges surmises that "for some, it probably represents a new experience which takes them away from the monotony and oppressiveness of prison routine." The relief from monotony: "They have eaten strange diets, swallowed tubes, submitted to a repeated venipunctures, and participated in a wide variety of physiological tests. . . ."

For some prisoners, "monetary gain may be the incentive, though inmates are paid only one dollar daily." Iowa prisoners are not supposed to receive reduction of sentence in return for volunteering, but Dr. Hodges routinely sent a thank-you letter to the warden for each subject: "It is possible that this letter in the prisoner's file may favorably influence the parole board." As for the incentives and motives of researchers, Dr. Hodges reports that more than eighty scientific publications resulted from the Iowa studies on prisoners.

Dr. Hodges becomes almost lyrical in his discussion of the moral and ethical aspects of such experimentation. The prison-volunteers, he says, are "our companions in medical science and adventure"; the subject "in whatever degree derelict or forlorn has sacred rights which the physician must always put ahead of his burning curiosity." Dr. Hodges, without elaborating on these sacred rights, concludes: "A system of voluntary participation firmly based on legal and ethical standards has provided a rich opportunity for clinical investigators who wish to study metabolic, physiologic, pharmacologic, and medical problems. This has been a rewarding experience both for the physicians and for the subjects."

One such experience is described by Dr. Hodges in one of his papers: "Clinical Manifestations of Ascorbic Acid Deficiency in Man," in the *American Journal of*

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Clinical Nutrition of April, 1971. The object: "to define the metabolism of this vitamin in the fact of severe dietary deficiency." For the study, which consisted of experimentally induced scurvy, five companions in medical science and adventure were recruited from the Iowa State Penitentiary "and their informed consent was obtained." For periods ranging from 84 to 97 days they were fed by stomach tube a liquid formula free of ascorbic acid: "Because of the unpalatability of this formula, the men took it thrice daily via polyethylene gastric tube." They were exposed in a cold-climate "control room" to a temperaure of fifty degrees for four hours each day. The volume of blood drawn "for laboratory purposes" was large enough to "cause mild anemia in all the men." In a throw-away line, Dr. Hodges observes that "the mineral supplement [recommended by the National Research Council] was inadvertently omitted from the diets during the first 34 days of the depletion period."

The experiment was a great success. It was the second of its kind, Dr. Hodges having tried it once before with far less favorable results: "Despite a somewhat shorter period of deprivation in the second scurvy study, the subjects in the second study developed a more severe degree of scurvy . . . although none of the subjects in the first scurvy study developed arthralgia, this was a complaint in four out of five men who participated in the second scurvy study. Joint swelling and pain made themselves evident in Scurvy II, but had not been observed in the subjects participating in Scurvy I."

The gradual onset of scurvy in the five prisoners is traced by Dr. Hodges with some enthusiasm. "The first sign of scurvy to appear in both studies was petechial hemorrhage [hemorrhages in the skin]. Coiled hairs were observed in two of the men and first appeared on the 42nd and 74th days, respectively. The first definite abnormalities of the gums appeared between the 43rd and 84th days of depletion and progressed after the plasma ascorbic acid levels fell. . . . The onset of joint pains began between the 67th and 96th days. . . . Beginning on the 88th day of deprivation there was a rapid increase in weight followed by swelling of the legs in the third man, who had the most severe degree of scurvy."

By the time it was all over, Dr. Hodges was able to chalk up these significant accomplishments: all five subjects suffered joint pains, swelling of the legs, dental cavities, recurrent loss of new dental filings, excessive loss of hair, hemorrhages in the skin and whites of the eyes, excess fluid in the joint spaces, shortness of breath, scaly skin, mental depression, and abnormalities in emotional responses. The youngest, a twenty-six-year-old, "became almost unable to walk as a result of the rapid onset of arthropathy [painful joints] superimposed on bilateral femoral neuropathy [disease in both large nerves to the thighs and legs plus hemorrhage into nerve sheaths]. The onset of scurvy signaled a period of potentially rapid deterioration." Dr. Hodges' anticlimactic conclusion: "Once again our observations are in accord with those of the British Medical Research Council."

To other doctors, the "Ascorbic Acid Deficiency" study appears as a senseless piece of cruelty visited on the five volunteers. "This study was totally pointless," Dr. Ephraim Kahn of the California Department of Public Health said of Dr. Hodges' publication. "The cause and cure of scurvy have been well known in the medical profession for generations. Some of the side effects he lists may well be irreversible—the young man who had the most severe case of scurvy may never have recovered. There's a clue here to the degree of competence of these so-called 'researchers'—they 'inadvertently' omitted a mineral supplement from the diets. This no doubt weakened the men and exacerbated the other side effects. It might cause them to go into shock, and to suffer severe cardiac abnormalities." Among effects of the experiment recorded in the publication that could be permanent, Dr. Kahn cited heart damage, loss of hair, damage to teeth, hemorrhage into femoral nerve sheaths—the latter is "terribly painful and could lead to permanent nerve damage."

I asked Dr. Hodges, now a professor of internal medicine at the University of California medical school at Davis, how much he had paid the scurvy test volunteers. "I think it was one dollar or maybe two dollars a day," he replied. "Over the years, when I was in Iowa, as the cost of cigarettes and razor blades went up, we increased priosoners' pay somewhat. It's unethical to pay an amount of money that is too attractive. Oh, we had the money, we could have paid much more, of course—but we weren't just being cheap, we were considering the ethics of the situation. The prisoners got a bit extra for really unpleasant things—if we had to put a tube down their throats for several hours, or take a biopsy of the skin the size of a pencil eraser, we'd give them a few dollars more."

Doctors with whom I have discussed the matter agree unanimously that FDA regulations requiring drugs to be tested on humans before being marketed are sound and necessary. But human experimentation, they say, must be conducted within a framework of stringent rules for the protection of the human subject.

Since World War II a number of "guiding principles" and "codes of ethics" have been developed by the medical profession to govern the conduct of experiments. An American Medical Association resolution of 1946 on human research was in turn followed by FDA regulations of 1962 and the Helsinki Declaration of 1966.

These are largely repetitive. All affirm that human experiments must be based on prior laboratory work and research on animals, emphasize the grave responsibility of investigator to subject, and exhort him to avoid experiments that are of no scientific value or that subject humans to unnecessary pain and risk. Above all, the "informed consent" of the subject must be obtained.

In 1972 the U.S. Department of Health, Education and Welfare issued a set of comprehensive and detailed regulations, incorporating principles of the previous codes, entitled "The Institutional Guide to DHEW Policy on Protection of Human Subjects."

The Guide expresses a "particular concern" for "subjects in groups with limited civil freedom. These include prisoners * * *" Having uttered this praiseworthy sentiment, HEW has apparently let the matter drop. Dr. D. T. Chalkley, chief of the Institutional Relations Branch, Division of Research Grants, and signer of the Guide, tells me that HEW does not even maintain a list of prisons in which HEW-financed research programs are in progress and has "no central source of information" on the scope of medical experiments on prisoners by drug companies—in any event, the regulations set forth in the Guide apply only to HEW studies, and not to those sponsored by private industry. "The FDA has some data on prisoner usage by drug houses, but I doubt if this is collated."

What efforts have been made by HEW to enforce its guidelines in HEW-financed medical research behind prison walls? "We do give some grants that involve prisoners. But there's no convenient way of recovering the information as to whether our guidelines are being followed," said Dr. Chalkley. "That responsibility lies with the principal investigator." I asked him about a letter I had received from Dr. Richard B. Hornick, director of the Division of Infectious Diseases, University of Maryland School of Medicine, who is currently conducting cholera, typhoid fever, viral respiratory, and viral diarrhea studies at the Maryland House of Correction under a grant from the National Institutes of Health, a division of HEW. "We can predict how many people will get sick following a particular dose of bacteria," Dr. Hornick wrote. "With cholera or with typhoid we will use a dose of organisms that will produce disease in 25 to 30 percent of the control [unvaccinated] population." He had furnished me with a copy of the consent form prisoner-subjects in these studies are required to sign, in which the prisoner agrees to "release and forever discharge" the principal investigator and everybody else involved in the experiment "from liability for any injury which may result directly or indirectly from the performance of these investigations." "Oh *damn!*" said Dr. Chalkley. "I was aware of this form two years ago—I thought they said they were going to quit using it. I don't know. Give us hell; I guess we deserve it." Has HEW ever brought any action to enforce its regulations in any prisons anywhere? "None, to date."

Dr. Alan Lisook, of FDA's Office of Scientific Evaluation, said: "We've no list of prisons where drug research is going on. We know it does go on in certain prisons. The way we learn of it is through the IND [Investigational New Drug] submissions by the pharmaceutical companies. It's a touchy area, probably confidential information under the Trade Secrets Act. I suggest you make a written request—say the magic words 'Freedom of Information Act'—and I will get an opinion from counsel as to whether we can compile the information for you." I did so, and in the course of time I obtained a list of prisons. "It is without doubt imperfect since this information is not routinely abstracted in a retrievable form," wrote Dr. Lisook. He was unable to furnish the names of drug companies experimenting in these prisons, or numbers of inmates involved.

A forthright explanation of the secrecy surrounding prison research was furnished by a vice president of Wyeth Laboratories, who asked me not to use his name. "Almost all our Phase I testing is done in prisons," he said. "The locations

of the prisons in which we do research—that's fundamentally confidential information. *Where* we get our clinical work done is just as much a trade secret as *what* we're doing. There are industrial spies everywhere. If we let the names of the prisons out, our competitors could easily get a pipeline to what we're doing, and the secret would be out." Mr. Paul Stessel, public relations man for Lederle Laboratories, advanced a further reason for keeping mum. I asked him whether his company has a policy against disclosing names of prisons where it does research: "Yes, as a matter of fact." Why is that? "The prison administrators might get upset if there was publicity about it." [2]

Drug testing on human beings occurs in three stages: In Phase I, the new compound is tried out for effectiveness and possible toxic properties on a small group of normal, healthy individuals. If these survive without serious side effects and the drug appears promising, it is passed into Phase II, in which several hundred normal subjects are given the compound and the dosage is gradually increased until the experimenter decides the limit of safety has been reached. Once this is established, the drug is ready for Phase III, in which it is given as medication to patients to test its efficacy as a remedy for illness.

From my conversations with drug company executives and physicians involved in research, I learned that prisons today furnish virtually the entire pool of subjects for Phase I testing. "If the prisons closed down tomorrow, the pharmaceutical companies would be in one hell of a bind," said one medical researcher. (The drug houses, are, however, casting eyes in the direction of the "underdeveloped" nations as potential reservoirs of human experimental material.) Most pharmaceutical concerns have to queue up for available prison populations on which to experiment, but two of the biggest—Upjohn and Parke, Davis—are in the enviable position of having acquired exclusive rights to Michigan's Jackson State Prison. In what Charles Mangee, public relations spokesman for Upjohn, calls "a beautiful operation run in a highly ethical fashion," the two companies maintain fully equipped laboratories built at a cost of half a million dollars, complete with hospital bed space within the prison for forty inmate subjects. Upjohn says that these facilities incorporate greater safeguards against injuries to prisoners than is common in experiments conducted through private researchers. A group of three physicians, for example, reports directly to the Department of Corrections and any one of them may order an experiment stopped at any moment. Pay scales, however, are much the same as elsewhere.

Until recently, inmates have also served as laboratory workers in the Upjohn-Parke, Davis clinics. In 1968, some of them brought suit against the companies and the Department of Corrections, alleging that "the drug companies are obtaining or have obtained hundreds of thousands of dollars' worth of labor free * * *." The inmates, who frequently put in a sixteen-hour day, were paid a wage ranging from thirty-five cents a day for a nurse to $1.25 a day for a chief technician. (Although the allegations with respect to wage levels were not in dispute, the case was decided in favor of the defendants on other grounds.)

Over the past ten years a brisk traffic in human subjects for drug company experimentation has grown up in the California Medical Facility at Vacaville, a prison specifically designated for men deemed by the authorities to be in need of psychiatric treatment. Vacaville has a population of some 1500, of whom from 300 to more than 1000 may be in the volunteer medical research program at any given time.

The medical experiments are organized under the aegis of an organization called the Solano Institute for Medical Psychiatric Research (SIMPR), with headquarters in the prison. I discovered that even such prison knowledgeables as faculty members at the School of Criminology in Berkeley, and California legislators who have devoted years to studying prison conditions, were but dimly aware of the existence of SIMPR and had no idea of the extent and the nature of its activities.

Unlike the Upjohn-Parke, Davis operation, which is financed directly by the two drug companies, SIMPR is set up as a nonprofit corporation under California's charitable trust law. According to its financial statements filed with the Registry of Charitable Trusts, SIMPR's income from "various researchers" rose from $47,000 in 1963, its first year of business, to $266,000 in 1971. I asked Mr. Ralph Urbino, SIMPR administrator, which drug companies had paid over this money. He seemed quite shocked at the question: "We couldn't receive funds from drug companies," he said. "As a nonprofit organization we are barred from receiving money from private business concerns. Our income is derived from the physicians who have been given research grants for the purpose."

The "various researchers," then, for the most part faculty members from neighboring University of California medical schools, are a conduit for tax-exempt payments from giant pharmaceutical concerns, including Lederle, Wyeth, Dow Chemical, Roche, Abbott, and Smith, Kline & French. According to a 1972 SIMPR publication addressed to potential customers, "One research team from the University of California has been continuously active since the inception of our program here. * * * There have been no deaths or serious sequelae resulting from drug research at this institution * * * the reservoir of volunteer subjects offers investigational possibilities not found elsewhere."

Checking on SIMPR's claim that there have been no deaths or "serious sequelae" is not easy, since SIMPR maintains it is not required, under the California Public Records Act, to disclose medical data. But something of the modus operandi of the prison experimenters can be gleaned from records subpoenaed and depositions taken in a lawsuit, eventually settled out of court for $6000, that arose out of a 1962 experiment. The two principal defendants in that suit are prime operatives in SIMPR today. Dr. William C. Keating, Jr., then superintendent of Vacaville prison, was a founder of SIMPR and serves on its board of directors; Dr. William L. Epstein, chairman of the dermatology department at the University of California, conducted the experiment in question together with a colleague, Dr. Howard I. Maibach. Drs. Epstein and Maibach are the self-same "continuously active" research team featured in the 1972 SIMPR publication.

The plaintiff, who according to Dr. Keating had been classified as psychotic and sent to Vacaville for "psychiatric programming and treatment," was one of twenty subjects selected to undergo what Dr. Epstein calls "pain tolerance studies" consisting of intramuscular injections of Varidase (fibrinolytic enzymes used as an anti-inflammatory agent), a Lederle Laboratories product. Evidence given by independent physicians disclosed that after the drug was administered, the plaintiff suffered an agonizing, near fatal disease of the muscles, in the course of which his weight dropped from 140 to 75 pounds. He subsequently developed chronic stomach ulcers as a result of being treated for his condition with steroids.

From the depositions of the doctors in charge, it appears that nobody involved knew much about Varidase except that it can make people very ill. The purpose of the experiment, as explained by Dr. Epstein, was to find out just how ill and to learn more about adverse side effects caused by the drug: "The reason we did the experiment was the pain and the fever * * * what we were looking for was pain, discomfort, aching in the arm. We were told [by Lederle] they might also have fever, malaise, and chills." Dr. Keating recalled that the only information available to him on the drug was "a little brochure that comes with the preparation" containing "a list of medical cautions, but at the time I read them * * * this was not a significant concern." Could the Varidase injections have caused the plaintiff's condition? "There was the possibility that this could have been due to the drug," said Dr. Epstein. "I think that looking back on it now it is a possibility, a better possibility than I thought initially because I never heard of this thing. * * *"

As to his role as principal investigator in overseeing the experiment, Dr. Epstein could not remember if he had been present when the subjects were chosen or when the injections were given—they were given by inmate nurses, he said. His visits to Vacaville were infrequent, once a week or once every two weeks. * * * No signed consent was required of the prisoner-subjects, said Dr. Keating. Asked in his deposition whether "the dangers of any of those possible medical problems were mentioned or explained to any of the potential volunteers for this

[2] Missing from Dr. Lisook's imperfect list is Patuxent Institution, Maryland. Phil Stanford, writing in the New York Times Magazine (September 17, 1972), reports that Johns Hopkins, the University of Maryland, and the National Institute of Mental Health are conducting a number of experimental "behavioral control" drug programs in the institution. "It's no sweat getting volunteers because all of these programs pay volunteers," a staff member told him. Stanford cites a Johns Hopkins experiment in which an inmate is getting dosages of a female hormone, 'presumably to counteract his 'supermasculinity,'" and quotes the following exchange between Edward Tomlinson, a law professor, and members of Patuxent's professional treatment staff:

Tomlinson: Does he understand the effects of the drug?

Dr. Harold M. Boslow, director of Patuxent: Yes, we explained the whole thing to him. We don't want any misunderstanding.

Tomlinson: Well, what are the effects?

Dr. Arthur Kandel, associate director: We don't know. That's what they're trying to find out.

project," he answered: "I don't know. I would think not." A "large fund" was granted by Lederle for the research, said Dr. Epstein. Compensation to the plaintiff for taking part: "He received four dollars, three spendable and one to retention funds."

If pain, discomfort, fever, and chills were what Dr. Epstein was looking for, he was not disappointed. In a letter to his sponsors at Lederle he wrote: "I am enclosing a rough copy of the comments from one of the subjects. I thought you might enjoy his description of the symptomatology; it's fairly representative of what all the men experienced." Among the descriptions that Lederle might have enjoyed, given by the nineteen subjects who did not sue, and subpoenaed by the plantiff as part of the record: "Cold chills, sweated, nauseated throughout the night." "Sharp abdominal pains." "I have a headache and my stomach feels terrible." "My body feels weak all over, right arm hurts worse than ever." "My head feels as if it will fall off." "Chilled, feverish, weak and exhausted." "Lost 4 lbs. in three days—Dr. Epstein said it was a natural reaction except it was more severe in my case for some reason but not to worry." (What eventually became of the nineteen—whether they made full recovery—history does not relate. That nobody bothers to follow up the subsequent medical history of research subjects in prison can be inferred from Dr. Epstein's deposition to plaintiff's counsel Malcolm Burnstein: "Since [the plaintiff] cleared the initial experiment, it was forgotten, because like all the other people they were just let go. . . . And he came back, I couldnt' tell you how soon complaining of aching. . . .")

Thorough researcher that he is, Dr. Epstein was soon at it again. He writes to Lederle a month after the plaintiff was stricken: "We are planning this week to try four more men and I am prepared to give them some steroids when the severe symptomatology starts."

From my discussion with Mr. Urbino, a genial, retired Air Force man who is SIMPR's only full-time "free-world" employee, I concluded that SIMPR evolved in a somewhat haphazard fashion and is run on highly informal lines. For the first four years of its existence, SIMPR lived off the bounty of the prison (and hence the taxpayers), paying no rent or prison personnel wages. "It was a potential time bomb for the Department of Corrections," said Mr. Urbino. "Besides, they saw SIMPR as a very prosperous operation; they wanted to get their hands on some of that money." In 1966 SIMPR entered into a permit agreement with the Department. The corporation now pays an annual rent of $1000 plus "custodial coverage" (guards' wages) of about $14,000 a year, and provides moonlighting jobs for other state employees to the tune of some $17,000.

SIMPR also hires convict labor—technicians, nurses, para-medical and clerical personnel—for wages in the range of five to eight dollars a month, about one-hundredth of what free personnel would command in these positions. (As Ken E. Haden pointed out in a 1963 report on the Vacaville operation to the U.S. National Institute of Mental Health: "Without this reservoir of skilled technicians, laboratory aides, clerical help, medical research could not be more than a token activity in a prison setting.") In SIMPR's first four financial reports, this item, between $700 and $800 a year for work worth $70,000 to $80,000 outside the walls, shows up as "Inmate Salaries," Thereafter it is no longer itemized but is merged along with most other cost items into a general category labeled "cost of goods sold." Could these inmate salaries be another potential time bomb for the Department of Corrections? The California constitution specifically prohibits the contracting out of convict labor "to any person, copartnership, company, or corporation," which would seem to cover the SIMPR operation. Mr. Urbino, who is not a lawyer, was unaware of the constitutional prohibition.

Payment to the prisoner-subjects of the experiments is variously recorded in SIMPR's financial statements as "honoraria," "donations," "benefits to recipients under charitable trust." Spiraling upward with the fortunes of SIMPR, these honoraria, donations, or charitable benefits rose from $34,000 in 1963 to $150,000 in 1970. The nine-year total is $787,000. Thus, assuming the drug companies would have had to compensate free-world volunteers at ten times what they pay convicts, they obtained some $7.8 million worth of research for their $787,000.

Who establishes the amount of pay for each experiment? "I do," said Mr. Urbino. "Several factors go into it: number of times we bleed the man, number of times he has to report to the lab on any given day." Sample payments range from $15 a month for a two-month study of inflammatory dermatophytosis (fungi described in the protocol as "one of the most prevalent health hazards to military personnel stationed in Southeast Asia") to $30 for one day for Cleocin HFC

levels, an experiment run by Dr. Epstein in which a gram of muscle tissue is removed. If unusually adverse side effects are anticipated, the pay goes up accordingly. "We're in the middle of one now, conducted by Dr. Howard I. Maibach, a Wyeth safety study, WY–21,743. It pays sixty dollars a month." What side effects might be expected? Mr. Urbino, who is not a medical man, did not know. (I subsequently asked the Wyeth vice president what mysterious WY–21,743 consists of. His reply: "That's confidential information in the Investigational New Drug file. I wouldn't tell my own mother about it!" Nor would FDA reveal the formula. Dr. Lisook told me, "The Freedom of Information Act specifically prohibits such disclosure. Our new regulation says 'the very existence of an IND is confidential.'")

Why does the Department of Corrections tolerate the SIMPR presence—it is because the rent money and payment to guards (who would have to be paid anyway) is a nice financial cushion for the institution? "That's part of it," said Mr. Urbino. "But the main benefit to the Department is that the research programs cut down on disciplinary problems. A man has to have a relatively infraction-free record to qualify as a volunteer subject. And the Department figures if he has thirty dollars a month to spend on canteen, he'll be a lot cooler." Systematically impoverished by his keepers, denied a decent wage, the prisoner is reduced to bartering his body for cigarette and candy money.

Presumably to insure against any repetition of the 1962 lawsuit, SIMPR now requires each convict-subject to sign a consent form and waiver, stating, "I hereby fully and forever release, acquit and discharge" all state agencies involved, plus SIMPR, "from any and all liability which may accrue" from participation in the research project.

To my question whether the waiver is not in clear violation of HEW guidelines, I got the following answers. Dr. Alan Lisook, who had twice inspected the SIMPR operation on behalf of FDA, said he was not aware that such a waiver was being used. "Although we require a consent form in all drug experimentation, we do not require that the wording be cleared with us, nor that copies be submitted. It would be very difficult to enforce the prohibition against exculpatory clauses." The Wyeth vice president: "The medical monitor of Wyeth is in charge of that." (The name of the medical monitor is, however, confidential, he said.) Mr. Paul Stessel, public relations spokesman for Lederle: "It's the responsibility of the investigator to follow the guidelines and obtain a proper consent form. We don't dictate to the clinician how he runs these things. I'm sure you're aware that the more prestigious the clinician is, the more convinced he is that he knows what he's doing. If you use him, you have little choice but to trust what he says he does." Dr. Howard I. Maibach, principal investigator for many SIMPR experiments: "Yes, I'm familiar with the consent form used at Vacaville. It's in a period of change, a state of flux. * * *"

Theoretically, the University of California medical schools exercise considerable control over faculty member researchers through committees on human experimentation, consisting of medical professors and laymen, established by the president of the university in 1966. These are supposed to review and pass on the protocol for each proposed study under University of California sponsorship—"regardless of funding source"—in the light of HEW and FDA standards.

At a meeting of the University of California Medical Center Committee on Human Experimentation, I was told that few SIMPR protocols had ever been submitted to the committee. "Prison research that comes before this committee is extremely rare," said one member. "The minute a Vacaville study comes in, the red flag goes up!" Although both Dr. Epstein and Dr. Maibach are on the Medical Center faculty, the committee had never heard of most of the experiments they are currently conducting at Vacaville. Of another team of doctors, listed in SIMPR's 1971 report as faculty members of the Medical Center and principal investigators in current research studies, I was told that one had been "severed" by the university in 1966 and the other had died in 1968.

The California Department of Corrections publishes an annual research review, in one section of which some thirty experiments conducted under the auspices of SIMPR are set forth in précis form. Since these are couched in the language of pharmacology and medicine, the nature of the experiments is for the most part obscure to the layman. (An exception is the Aedes Mosquito Study, in which "freshly grown, unfed female mosquitoes in carefully prepared biting cages are applied to the forearms of volunteers for a period of ten minutes," which seems explicit enough.)

Seeking clarification, I showed a copy of the 1971 research review to Dr. Sheldon Margen, a physician with wide experience in human research, who, as chairman of the Department of Nutritional Sciences at the University of California uses students and other free-world volunteers as experimental subjects. Dr. Margen read with fascination and mounting indignation the experiments described in the review. He translated the procedures for me, interjecting a frequent "Wow!" or "Brother!" or "God, that kills me!" Some of the studies, he said, are innocuous; others, extremely painful and potentially dangerous.

He mentioned, as an example, Dr. Epstein's study of Cleocin HFC levels, for which "ten healthy normal volunteers" were selected: its purpose, "to determine antibiotic levels in various tissues and/or fluids." Each subject gets "150 mg of Cleocin q.i.d. for a single day," following which he will be relieved of "sebum, 2–4 ml; sweat, 4–5 ml; semen, amount of normal ejaculation; and muscle tissue, 1 gm. In addition, a 15 cc blood sample will be drawn. * * *" "Here's what happens to these ten guys," said Dr. Margen. "First they make them masturbate to collect the semen. Then they cut into the arm or go through the flesh to get the gram of muscle tissue. That's the horrific part. The experiment itself may be totally justified—the drug presents virtually no risk—but this procedure is cockeyed. It would never be approved for student-subjects." Nor had it ever been approved by the University of California Medical Center Committee on Human Experimentation. Dr. Leslie Bennett, chairman of the University of California committee, told me "there's no evidence this was ever submitted for review."

The Organic Phosphates Toxicity Study, the purpose of which is "to determine the threshold of incipient toxicity in human subjects of organic phosphates currently in wide use as insecticides," involves the use of the most dangerous and poisonous of all pesticides, said Dr. Margen. Would this be approved for experimentation on students? "Are you kidding?" Possible hazards of other experiments described in the research review include, he said, cardiac failure, total loss of blood flow resulting in neurological damage and loss of fingers, fungus infection, allergic reactions . . .

In 1947 fifteen German doctors, all distinguished leaders of their profession, were tried and convicted at Nuremberg for their cruel and frequently murderous "medical experiments" performed on concentration camp inmates. The barbarity of these crimes is of course unparalled, but the Nuremberg tribunal established standards for medical experimentation on humans, which, if observed, would end altogether the practice of using prisoners as subjects: "The voluntary consent of the human subject is absolutely essential. This means the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding, enlightened decision." Are prisoners, stripped of their civil rights when they enter the gates, subjected to years or decades of confinement, free agents capable of exercising freedom of choice? Can we trust that they are furnished by the experimenters with "knowledge and comprehension" to enable them to make "understanding and enlightened" decisions? To ask these questions is, I believe, to answer them.

[From Society, July/August 1974]

Crime and Punishment—Prisoners as Laboratory Animals

(By Michael Mills and Norval Morris)

Stateville Prison in Illinois might have been created by a Hollywood set designer. George Raft and his fellows in the romantic prison movies of the 1940s would recognize its massive walls looming over the empty countryside, the armed guard towers that prickle the horizon and the regimented flower beds at the front gate. Inside, the cells, exercise yards and vast steel-tabled dining halls would look familiar, too, although the occupants now are very much of the 1970s: young, mostly black, urban, violent and prone to riot.

Not a part of anyone's casual picture of prison life, then or now, is the Malaria Project located in a small research hospital in which Stateville prisoners serve as test subjects for new antimalarial drugs. Although Americans have largely forgotten the disease, save for a brief fever of interest in Vietnam, malaria remains the largest public health problem in the world: 200 million persons suffer each year and 2 million die. At Stateville, no one has died of malaria since the project began during World War II in a search for drugs to protect allied soldiers, but hundreds of prisoners have endured the fevers, chills and aches of the disease and many more have been dosed, measured, probed, punctured, wired and watched in other phases of the work.

Stateville is not alone in nurturing medical and other research. Prisoners make splendid laboratory animals. Healthy, relatively free of alcohol and drugs, with regulated diets, they are captives, unlikely to wander off and be lost to both treatment and control groups, and they are under sufficient pressure of adversity to "volunteer." No one knows precisely how many prisoners are sampling drugs, ingesting food additives or swabbing themselves with cosmetics. Reflecting a widespread lack of any but punitive interest in our prison systems, we do not know who or how many or where our guinea pigs are, the risks to which they are exposed, the rewards they receive or the conditions of their consent.

Nevertheless our investigations—and those of Walter Rugaber and Jessica Mitford before us—have marked out the range and character of research in prisons. Somewhat unfashionably in disagreement with Mitford and other liberal reformers of the prisons, we are persuaded that research in prisons can with appropriate safeguards make a useful contribution to the prisoner's welfare, to reform of the correctional system and, not least, to medical progress. We found research of four kinds:

testing methods of treating prisoners to "cure" their criminality,
testing new drugs for pharmaceutical manufacturers,
engaging in medical research not related to drugs,
testing cosmetics, hand lotions, band-aids and the like.

We do not in this study mark out the moral limits on coercively curing criminals. B. F. Skinner and A Clockwork Orange, aversive conditioning and The Terminal Man demand a complex inquiry into the foundations of criminal punishment, a task beyond our ambitions here. We do believe, however, that examining the use of prisoners in medical and quasi-medical research, for public health as distinct from crime-control purposes, will provide first approximations of the answers to the broader inquiry. First, therefore, we address the prisoner's role in drug testing.

Human Guinea Pigs

Drugs for humans are tested in three stages after animal studies are complete. In Phase I, the new compound is given to fewer than 100 normal, healthy persons in order to measure absorption, bioavailability, toxicity and side effects. Anyone can be a Phase I test subject; he need not have or risk the condition to be treated. As one researcher put it to us, "I've never tested in prisons, but I'm always looking for good subjects. Hell, I tested a contraceptive on a flock of nuns." He meant Phase I testing, to be sure, since in Phase II the drug's *effectiveness* is tested for the first time on a small group of patients. Prisoners excel in Phase I tests and, according to Dr. Marion Finkel, deputy director of the FDA's Bureau of Drugs, do "virtually all" such work for the drug industry.

Prisoners may also be Phase II subjects. At Stateville, for example, testing antimalarial drugs requires that disease-carrying mosquitoes be given an occasional free lunch upon a dozen or so healthy prisoners. That feeding ensures a supply of "patients" in a nation to which malaria is now virtually unknown.

If the drug appears safe and effective, testing moves into Phase III or controlled field trials involving as many as 5,000 patients. Antimalarial compounds are shipped to doctors in Southeast Asia, Latin America and other areas of the world where malaria is endemic. There, the new drugs are given to patients in the course of regular—but carefully observed—medical treatment. These stages are suggested by their apparent scientific logic and mandated by the Food and Drug Administration since 1962 when the European thalidomide tragedies moved Congress to require more extensive proof of new drug safety as well as efficacy.

Darvon, a product of Eli Lilly and Company, is one of the most common drugs for, as the package insert states, "the relief of mild to moderate pain." One of its forms, Darvon-N, was extensively tested in Phase I by prisoners of the Indiana State Reformatory, a part of the Indiana prison system with which Lilly has a close and symbiotic relationship. At the Lilly Laboratory for Clinical Research in the Marion County General Hospital in Indianapolis, a special ward has been established for Phase I testing. As many as 16 inmates at a time, selected from a long waiting list that has been screened by the prison staff, will be transferred

from the reformatory to the hospital for three to six weeks of research participation.

Last year 77 men came from the reformatory to the Lilly laboratory as research subjects. What did they get? They got a ward without guards as well as cigarettes, books, barbering, craft and hobby materials, color television, exercise rooms, daily rather than biweekly visiting privileges and $2 per day. (In the prison, regular wages are 20 cents per day, and there are no color televisions.) They also got the chance to make at least a small choice about their own lives in an otherwise wholly regimented setting. In turn the prison got a dishwasher, a remodeled hospital, high school supplies, an improved library and athletic equipment. And, of course, Lilly got its Phase I test results.

Lilly also conducts research with prisoners in the reformatory hospital and at the Marion County Jail, using nearly 1,000 men at the reformatory and 42 at the jail last year. In another mutually beneficial arrangement the Upjohn and Parke-Davis companies do their testing at the Southern Michigan State Prison at Jackson. Well over $1 million has been invested in sophisticated research clinics through which nearly half of the prison's 5,000 population pass each year. In addition to paying the prisoners on an elaborate schedule that ranges from 25 cents for a fingertip blood sample to $12 for a spinal tap, Upjohn provides pharmacy services and some emergency equipment to the prison's hospital. Moreover, the process of screening the volunteers often reveals medical problems that are referred to prison physicians for treatment.

Not all prison testing of new drugs is done with the scientific rigor and medical sophistication that Lilly, Upjohn and Parke-Davis plainly apply to their work in Indiana and Michigan. Many drug companies contract for research with individual physicians, university hospitals, clnics and profit-makng firms. The nature and extent of this farmed-out work is known only to the FDA, and only dimly to that agency. Dr. Alan Lisook, of the FDA's Office of Scientific Evaluation, told us that records of test sites are not routinely kept and could be obtained only by laboriously searching through each of the approximately 1,000 new drug applications filed every year.

One man whose work for drug manufacturers became well known is Dr. Austin Stough, an Oklahoma physician who left a trail of hepatitis and corruption through the prison systems of several states. His firm, Southern Food and Drug Research, virtually bought control of the Alabama prisons, reaping profits by testing drugs and selling blood plasma. Walter Rugaber's 1969 stories in the *New York Times* revealed that many of Stough's tests were scientifically worthless and medically irresponsible, but evidently not enough so to trouble either the sponsoring manufacturers (among them Wyeth Laboratories and Merck, Sharp & Dohme) or the FDA. A committee of the Alabama Medical Association reported that the manufacturers had "demonstrated some lack of discretion" in failing to supervise adequately the work upon which their claims of safety and efficacy for new drugs were to be based. Prisoners were not given proper examinations, many failed to take prescribed doses of the drugs and at Kilby Prison near Montgomery the hospital director was "a man with very little previous medical training whose experience . . . had been that of a venereal disease inspector."

Although the drug-testing programs were unsound and dangerous to potential consumers of new drugs, the prisoners suffered most from Stough's plasmapheresis project. In a variation of usual blood donation, a unit of blood is extracted, the plasma separated and the rest is reinjected into the donor—as often as 16 times a month. This procedure is not experimental, but was conducted with such gross indifference to infection of the donors from contaminated apparatus and unsterile procedures as only possible in the protective confines of prison. There, an epidemic of more than 500 cases of serum hepatitis, three of them fatal, went unnoticed.

In his busiest years, the mid-1960s, Dr. Stough was responsible for between 25 and 50 percent of all Phase I testing in the country and supplied 25 percent of the blood plasma. Now that he is dead, the FDA has issued regulations requiring that all drug testing be reviewed by independent committees of scientists, but in the absence of effective FDA supervision we have little assurance that another such grotesquerie will not soon be uncovered in another prison.

We also found medical research in prisons not related either to curing criminals or to testing drugs. Infectious hepatitis is a mild disease (unlike the dangerous serum hepatitis associated with addicts' needles and commercial blood banks) but so common that 9 out of 10 children will have it by the time they are 10 years old. The nature of the transmitting agent and the pattern of infectiousness are not understood. Awkwardly for researchers, rats and cats and other usual laboratory animals refuse to become infected. Even marmosets have been tried but only humans will do—and they must be in isolation to avoid uncontrolled exposure to infection.

Dr. Joseph Boggs of Northwestern University Medical School told us that he would be more afraid of measles than infectious hepatitis, but has suspended his studies on prisoners because recent political attention has made the research climate tense. The *New York Times* report of the abuses of Tuskegee, where hundreds of syphilis victims were left untreated in the name of science, and the revelations by Jessica Mitford in an *Atlantic* article have led all researchers to rethink questions of human rights. In the words of Gerald Houlihan of the New York State Department of Corrections, "Tuskegee scared the hell out of prison people." But, Dr. Boggs said, a ban on work in prisons "will absolutely stop research on hepatitis."

At the Oregon State Penitentiary, eight men some years ago subjected themselves to bilateral testicular biopsies as part of an investigation in reproductive health. The doctors wanted to know whether certain drugs would affect the rate of sperm production. Under local anesthesia, small incisions were made through which tissue was removed for examination, both before and after administration of steroids and sex hormones. To what result? As the doctors put it, "the rate of spermatogenesis in man therefore appears to be a biological constant in confirmation of Ortavant's conclusion derived from . . . studies on the ram."

The fourth kind of research in which prisoners are involved flows from America's insistent demand for shiny hair, processed food and sure cosmetic happiness. The shampoo that won't make baby cry was tested on a group of healthy and not particularly lachrymose adult prisoners. Sweeteners, expanders, smoothers, fresheners, brighteners, preservatives and other chemicals of the food industry must also be checked for safety : prisoners gulp them in massive doses. Miracle ingredients for face creams and wrinkle removers must pass a mundane test to be sure they are harmless (their efficacy being left for consumers to judge), and that too occurs in prison.

Hill Top Research, a private laboratory, uses prisoners from the Indiana State Prison in a variety of tests. Some are Phase I tests done under contract to drug manufacturers, but most are less exotic. For example, 210 men last year used new deodorant soaps for 10 days, allowing the investigators to make olfactory tests of the soaps' effectiveness. Another 200 men spent 15 days buttering themselves with a palette of cosmetics, soaps, perfumes and antiperspirants—to test for irritation and sensitivity. Similarly, a surgical scrub soap was checked for its ability to remove skin bacteria.

Jack Wild, Hill Top's vice-president, enthusiastically informed us that his firm does more testing outside prisons than in, often working with church and other volunteer groups that want to raise money. For nondrug tests, in which precise control and minute observation are less critical, free subjects are as good as prisoners.

A QUESTION OF FREEDOM

Prisoners are, it is clear, extensively used as the objects of drug and medical research, ranging from the vital to the frivolous. Should they be? Are they appropriate laboratory animals? Can a prisoner volunteer? Can he consent? Is not *free* consent by a prisoner a contradiction in terms?

The Declaration of Helsinki was the postwar medical world's formal reaction to the revelations at Nuremberg of Nazi abuse of prisoners in monstrous medical experiments. The declaration, when first drafted, contained a ban on the use of all prisoners in medical research. In its present form it forbids the use only of "administrative and political prisoners." The ethical basis of this distinction is at least elusive.

English, European and some American correctional administrators adhere to the earlier Helsinki position that prison life is inherently coercive and for this reason prohibit research using prisoners. The Oregon State Penitentiary, site of the testicular biopsy study described earlier, no longer permits medical research on its inmates. Administrator Hoyt Cupp told us that he had made the decision to ban research because "We're not running a Greek democracy here; no man is a free agent in prison."

Such a ban no doubt impedes medical progress important to the patient and the professional. More Asians and Africans would die from malaria without continued research, and England's strict control of animal vivisection and human subject research has, in the words of one medical commentator, made her "a second-rate biomedical power." America demands premarket testing, but that requires healthy, willing subjects, usually prisoners. Other nations are less demanding, but patients who get new drugs bear greater risks. The balance between medical progress and respect for human integrity is uneasy.

Asked about the consequences of a ban on research in prisons, Alan Lisook of the FDA said to us, "It would probably be disastrous. Our criteria for the approval of drugs, the amount of testing we require, are very strict. The British get along without prisoners, but they do not have such tough standards." He cautioned, however, that "it is obvious they're not dropping like flies in Britain."

Carrying our search for alternative test subjects to doctors running these experiments in prison, our inquiry "How many prison staff have volunteered?" was not well received. We hesitated to mention Jessica Mitford's trenchant suggestion that stockholders of drug companies would be the ideal voluntary subjects. Before being swept along by radical enthusiasm, however, it is well to recognize that prisoners themselves would deeply resent a ban on, as they see it, their freedom to volunteer. They need the money and they want to be of use to the community. Indeed, in April of last year 96 of the 175 inmates of the Lancaster County Pennsylvania Prison wrote to the local newspaper protesting the state's decision to stop all medical experiments on state prisoners, including the antibiotic research at Lancaster. The disgruntled prisoners made the points that they were unharmed and that the project allowed them to pay off their fines and court costs.

Absolutist positions are seductive but have at least two defects: they are unlikely to be accepted and, granting the need for human experimental subjects, it would seem a pity to exclude prisoners from participation if their involvement can be made advantageous both to them and to the community. So the contour lines of an *unfree*, informed, ethically justified consent must be sketched. The problem is one of coercion, the relationship between the effects of captivity and the ethics of consent.

Coercion diffuses along a troublesome continuum. Ivan Denisovitch would eagerly volunteer for a drug test merely to escape the Siberian cold for a day; add a crust of bread and the inducement would be overpowering. By contrast, in a small, open prison, decently run and containing short-term prisoners, there will be no stampede to participate.

At the Texas State Penitentiary in Huntsville, researchers from the Baylor College of Medicine and from the University of Texas carry on studies of respiratory diseases and cholera vaccines involving several hundred men per year. The inmates are paid $5 for each day's research participation, but nothing at all for work in the prison. The studies get many more volunteers than they can use; nonetheless, Carl Jeffries, director of support services for the Texas Department of Corrections, did not appear disturbed. He told us that, "We do not coerce these men in any way, shape, or form."

In Vermont, the state prison is now called the State Correctional Facility and holds only 140 men, half its 1969 population. The others have been transferred to small community correctional centers and have so reduced the volunteer pool that a long-term study of the relationship between obesity and diabetes had to be terminated for lack of subjects. Warden J. V. Moeykens, whose voice carries little of the tension heard in the voices of America's megaprison wardens, said when we asked about future research possibilities, "I would discourage them. Our first job here is corrections, and I just don't have the space to give up to outside projects." Warden Moeykens may be right, but there are clear advantages to the prison system in the presence of the medical researcher. He tends to inhibit otherwise hidden brutalities and to reduce the social isolation of the prison. In the sense that the prison institution tries to keep responsible community influences out, the medical research team breaks down the walls.

REWARDS OF RESEARCH

Why do prisoners volunteer? Freud is right, human behavior is overdetermined; here as elsewhere is a multiplicity of motives. Machismo, which leads prisoners to exaggerate the risks they take, is one. The altruism of community service is another, carrying with it for the prisoner the assurance that he is as

virtuous as those outside who have banished and rejected him. And if he sees himself as having wronged others by his crimes, here is a chance for expiation, of making restitution. Psychopathology apart, prisoners seem to be persistent risk takers—as their presence in prison suggests.

Other motives are obvious and less noble: the hope of earlier release, the reward of payment. These two merit closer consideration. But there is also one strong complex of pressures on the prisoner that is less well known. Participation in experiments provides an immediate temporary escape from the pervasive fear, endemic brutality and total anonymity of the typical American megaprison. When we visited Stateville, nearly 40 men were in solitary because they had asked to be—for their own safety.

These pressures are, if anything, even stronger in overcrowded city jails, many of which are also involved in drug tests. Jail life is unstable, no other jobs are available and the need for money in the jail and as a stake upon release is even more compelling. Most prisoners are locked up in a jail, after all, solely because they lack money for a bail bond.

Inmates of state and federal prisons know that the fact of their volunteering for medical experiments is noted on the records seen by the parole board. But they do not deceive themselves that volunteering has more than marginal influence on their chances for parole. Prisoners tend to see parole decisions as so capricious and unprincipled that participation in medical experiments cannot be a reliable key to unlock the prison gates. A temporary escape to a less brutal imprisonment, yes—but a sure path to an early freedom, certainly not.

Nathan Leopold, of the Loeb and Leopold case, an early volunteer for the Stateville Malaria Project, put it well: "There was no assurance whatever that volunteers would be rewarded by having their time cut. Of that fact each group was solemnly and emphatically reminded before they were allowed to sign their contracts. But the possibility did exist that there would be time cuts. And that was a chance I could not afford to miss."

What of the economic incentive? The usual payments is toward the top of the prison wage scale, say $1 or $1.50 a day. Those of us on the outside may not find $1.50 either sufficient reward or compelling incentive, but our economic choices are not so restricted, nor are our markets so deflated. One prisoner reminded us that the state's grant to him upon discharge will be $50, "enough to buy a gun and a few bullets." A longtime participant in the Stateville Malaria Project, he will instead take with him about $300 in accumulated research pay, enough, he says, "to make a fair stake for a new start."

There is a dilemma here. If we offer the prisoner what would be necessary to attract the next less vulnerable group, say the free unemployed, then the effect of this payment in the prison marketplace will be unacceptably coercive. But if we do not, it is plain that the prisoner is being used to subsidize the drug company and the medical researcher. Although for some researchers subject costs may be important, the large pharmaceutical companies are not troubled by paying substantially more than they now do. We should perhaps note, as did Dr. James Goddard, former chief of the FDA, that the pharmaceutical industry has a higher rate of return on its capital investment than any other industry in America. Dr. Alan Varley, medical director of Upjohn, informed us that, "The development cost of a new drug may be $7 million; what we pay prisoner subjects is an insignificant part of that total. We would like to pay more, but prison administrators won't let us."

In searching for alternatives it may help to consider the practice of using prisoners in a less emotionally charged but analogous setting. Occasionally in country districts near a prison there will be a shortage of labor to harvest a crop. Prisoners will volunteer to help; promises not to try to escape will be extracted and cautiously evaluated; and teams of prisoners will bring in the crop. The proper economic arrangements have evolved in many parts of the world to meet this common contingency. The farmer pays the cost of an ordinary farm laborer and the prisoners receive the top of the prison wage scale. The substantial difference is held in trust by the prison administrator for prisoner welfare. Larger stakes on release for all prisoners might be one socially sensible use for these funds.

But prison is a potently corruptive institution and even this arrangement has resonances of corruption. Stories of brutal jailers selling prison labor and pocketing the proceeds, of the economic serfdom achieved in the early English jails under private franchise, of southern chain gangs at work on private farms come to mind. Most state prison systems are rife with rumor, and perhaps fact, about

misappropriation of prisoner funds by staff. Any unsupervised system can be abused.

At the present stage of penal development in this country, the surplus value of the prisoner's labor as a volunteer for medical research, the product of the apparent arbitrage between the captive and free labor markets should be held to the benefit of prisoners generally. The prisoner subsidization of drug companies and medical research is inequitable and unprincipled, encouraging the manipulation of economically vulnerable people.

If, as seems desirable, we dramatically change the character of our prisons, arrangements different and beter than the welfare fund we have proposed could be made. A presidential task force recommended the establishment of a full wages prison on an experimental basis. The prisoner would be compensated at the ordinary market rates for his labor and would meet the costs of his board and keep (not of his imprisonment—that is what we and he pay taxes for). Similarly, the National Council on Crime and Delinquency is urging that private enterprise take over prison production, establishing rates of remuneration and standards of safety applicable to free industry and manufacture. Under such practices, the prisoner's involvement in medical research would present no economic problem—he would receive the free market rate.

It is clearly improper to require, as some projects do, that volunteers sign waivers of their right to sue for damages for injuries or illness flowing from negligence in the conduct of the experiment. It is doubtful that such waivers are binding; in any event they are unethical. But that is not enough. The prison volunteer must be compensated for any medical expenses or loss of earning capacity by the experiment. We need, in effect, "no fault" liability here, too. The prisoner may properly volunteer to bear the physical risk, but he should not be expected to volunteer to bear the economic risk.

There is no great cost in this. Such lasting illnesses are rare indeed—in the 25 years of the malaria project at Stateville Prison, Illinois, not one has occurred. The dangers are much less than those in other prison trades and industries. The entrepreneurs of research should ensure against such costs or perhaps special funds like workmen's compensation might be established. The Illinois General Assembly is now considering legislation drafted by one of the authors that would assure compensation for all human subjects, captive and free alike.

We are, of course, assuming that any research done in prisons has been subject to the professional peer review required of virtually all research. Senator Edward M. Kennedy has proposed a National Commission for the Protection of Human Subjects, with wide authority to regulate research. One part of that proposal replaces existing peer review committees with an institutional human investigation committee (IHIC). IHIC would serve as liaison between the research institution and the National Commission and would have two subcommittees: a protocol review group (PRG) made up of research professionals and a subject advisory group (SAG) to control and review procedures for obtaining informed consent.

Whether or not SAGs would be useful generally is problematic. It is hard to see any commonality among, for example, patients in a general hospital that would make them effective and critical members of a subject advisory group. But the idea is excellent for prisons and prisoners. In each prison or jail the SAG should include prisoners as a majority of its members, preferably other than those who are participating, have participated or hope to participate as subjects of medical research. Professional peer group review can assure an appropriate benefit/risk ratio, examine research protocols and certain aspects of informing potential volunteers. Prisoner advisory group review will help to achieve decency in the difficult issues of informed and free consent in captivity and the economic aspects of volunteering when destitute.

The Department of Health, Education and Welfare, which funds much research and regulates all drug testing, early in 1974 proposed new regulations governing the use of prisoners in activities within the agency's jurisdiction. If they are adopted, they will have nearly universal application, because most institutions and firms conducting non-HEW activities are also engaged in HEW work and have a single set of procedures for both.

The regulations provide that no federally funded research or testing of drugs for FDA approval be conducted unless the prison meets federal standards for medical care, living conditions, alternative work opportunities and wage levels. A review committee, one of whose members shall be a prisoner or "a representative of an organization having as a primary concern protection of the interests of prisoners," will review procedures for selection of participants and monitor the conduct of research.

HEW intends to accredit prisons for research if they comply with the regulations and have adequate facilities. We are not certain what the effect of these new regulations will be, though the intention and the policy statement are laudable. If prisons shut out researchers because of unwillingness to improve their facilities, then inmates will have lost the benefits we think come from this work. If HEW accredits institutions without serious investigation because manpower is as insufficient for this task as it already is for inspection of drug-testing programs generally, then unacceptable programs will have acquired a protective imprimatur. Finally, we do not think the proposals go far enough: the pay differential problem is not addressed.

Discussion about the use of prisoners in research usually turns into a conflict between the dignity and integrity of the individual on one hand and the freedom of scientific inquiry on the other. That argument is too easily lost in rhetorical foliage. What we must face is that prisoners want to participate, that flat bans may drive more testing overeas to countries less scrupulous (presumably because less wealthy) about the use of human subjects and that the free consent of the unfree can be protected. We do not say that existing protections are adequate; obviously, they are not. Rather, we have asserted that no insurmountable barrier to participation lies either in the ethics of consent or in the quality of prison life.

In our view, three things must be done if prisoners are to continue to be used as laboratory animals:

1. Prisoners must be paid what would be required to attract a free volunteer to the same reesarch project. So long as internal prison wages are low, the difference between the low prison wage and a free volunteer's reward must be paid into a fund for the general welfare of prisoners.
2. Any prison permitting research must establish, in addition to a scientific review group, a subject advisory group, a majority of whose members are prisoners.
3. Prisoners must be compensated for all lasting injury or loss of earnings suffered as a result of participation in a research project.

With these minimum safeguards as a precondition to the ethical participation of this vulnerable group, we believe that medical research in prisons can be beneficial to society, to the prison system and to the prisoner himself. Without them, we must agree with philosopher Hans Jonas that "society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having."

[From the Journal of the American Medical Association, July 1, 1974]

Commentary—The Prisoner as an Experimental Subject

Too often the only concern of researchers working with prisoners is how best to use their subjects, with little regard for the institution, or for the inmate as a person.

This article is an attempt to help researchers to understand the effects of prison and imprisonment on a prisoner's capacity to enter into a research contract, and to aid in establishing criteria that will permit experimentation in prisons. Several crucial issues that are prerequisites for participation as an experimental subject will be explored.

The Special Problem of Informed Consent in Prison

Informed consent for a research subject requires that the experimental subject have and understa.d the information about the experiment, understand if a risk exists, and be in a position to evaluate what is an acceptable degree of risk. Information about the experiment can be provided by the researcher, but a judgment about an acceptable degree of risk requires contact with the free world as opposed to the prison environment. What may be perceived as an acceptable risk for a person inside prison may be totally unacceptable for that same person outside. Likewise, what may be a socially acceptable risk at one point in time may be unacceptable later.

Lasagna[1] states that consent from a prisoner should pose no special problem since all volunteers are captives of a type; yet prisoners do pose special problems. A prison is a closed society that controls and restricts the flow of information and human contact. By so doing, it creates and fosters artificial mores and conduct, often under the guise of providing an environment conducive to rehabilitation. The lack of unimpeded access to information, absence of advice from a physician friend of the prisoner's own choosing, the lack of legal counsel, the censorship of mail, and the long-term isolation from the changing ideas of society greatly restrict the prisoner's ability to evaluate the magnitude of his risk and thus to make an informed decision about a research contract. Informed consent cannot be given when the institution permitting the research restricts and controls the flow of information available to the experimental subject. The fund of knowledge that we take for granted in our own environment is not readily available to the prisoner.

PROTECTION OF THE EXPERIMENTAL SUBJECT

Prisons erode the doctor-patient relationship by limiting a prisoner's access to a physician of his confidence. The doctor-patient relationship is discussed by Guttentag[2,3] as a partnership where the physician's prime interest is the welfare of the patient and in which the patient can have blind and total reliance on his physician as a physician friend. The relationship of experimenter to experimental subject is not one of helping but is to prove or disprove a hypothesis, and the results are of no value to the person subjected to the research. This difference in relationships was recognized by the World Medical Association in the declaration at Helsinki in 1964.[4]

In most other institutions, the patient is protected by the critical eye of colleagues, review boards, and administrators, as well as friends, family, and a lawyer, but primarily, he is protected by a physician in the role of a physician friend. In the prison environment most of this is absent. The lack of contact with a physician friend as opposed to a physician experimenter and the isolation from family and friends provides a situation where the experimental subject is relatively unprotected.

FREE WILL IN A CLOSED INSTITUTION

The Nuremburg Code[5] stresses the voluntary coercion-free power of choice that is necessary prior to involvement in research, and is similar to the Helsinki declaration that states "clinical research on a human being cannot be undertaken without his free cousent" and "the subject of clinical research should be in such a mental and physical and legal state as to be able to exercise fully his power of choice." Beecher[6,7] expresses a similar philosophy. Prisons interfere with free consent and tend to be coercive.

Several important types of coercive pressure occur in prison. It is implicit that the incarcerated individual is under considerable pressure to acquiesce to the wishes of his keepers. A large measure of this control derives from the need that a prisoner has for his jailers and the feelings he develops vis-a-vis the guards and the institution. The infantilizing, depersonalizing, helplessness, and anonymity that occur within a prison environment force the prisoner into a state of total dependency. This is conducive to a relationship not unlike that found between parent and child.

The prisoner frequently develops a transference toward his keepers, which can be manipulated to encourage compliance. In addition, the degree and willingness to which a prisoner bends and cooperates is measured and documented. Written reports about him go not only to the committees within the prison (classification committee) that decide on his restrictions, but frequently go to the parole boards. Clearly, one of the most valuable items to man is his degree of freedom, even if it is relative.

Living on the research ward or having the time out of a cell to go to and from the area of the research project can be a powerful inducement to cooperate. When information regarding a prisoner's cooperation or lack of cooperation in research is available to parole boards, it is blatantly coercive. This was well recognized by the Green Commission[8] and Ivy.[9] They both agree that drastic reduction in sentence as a result of cooperation in a research project is a questionable practice. However, they avoid the issue of defining what is meant by drastic. The ultimate goal of a prison is to change a prisoner's values and behavior from "bad" to "good." When medical research is identified as "good" behavior, the coerciveness of the situation is apparent.

Prisons almost universally prevent an inmate from taking any gainful employment outside the institution, and small sums of money (five to ten dollars a month) are often the incentive used by the experimenter both to establish a client relationship free of some legal responsibilities and to encourage prisoner participation. By participating in several projects at the same time, research is often the only way to earn enough money to buy canteen supplies. It can also be the only way for an inmate to buy his family or other visitors a bus ticket to the prison for a visit. Thus, the money offered by the experimenter becomes a very powerful inducement for the prisoner with no outside source of income or family support, but the money is out of proportion to its real value. Although the experimenter cannot be held responsible for the deprivation found in a prison, he can be held responsible if he exploits it for personal gain.

The absence of meaningful employment raises the issue of another form of subtle pressure. Prisoners may participate in research to escape from boredom or to better their surroundings by being on the research ward. Clearly, the implication is that the environment is intolerable and the escape from monotony, even with bodily risk, is welcome. Would a researcher be as comfortable accepting a fugitive from physical pain such as a whipping, as in accepting a fugitive from the emotional or mental pain induced by isolation and boredom? Either would be reprehensible.

One of the cruelest and most obvious pressures results from the separation of an individual from contact with those who care. The loss of these affective ties and the ensuing void creates a hunger for affection that is not easily filled in a prison. When a physician, generally thought of as one who cares, appears, the inmate will often misperceive the opportunity to particiapte in research as an opportunity to have contact with a caring figure.

PRIVACY AND THE PRISONS

Frequently research, particularly psychological or psychiatric research, is aimed at collecting data and information of a very personal nature that ultimately can be used in a manner detrimental to the well-being of the inmate. According to Beecher,[10] research requires the making of an equitable contract between equals in which the experimental subject can be guaranteed that the as yet unknown results of cooperation will not be used against him in any way. This cannot be guaranteed if confidentiality of all records is not guaranteed. Confidentiality cannot be assured where the records are the property of the state or are open to scrutiny by correctional officers.

CONCLUSIONS

The issues raised are but a few of the many constraints on research in a prison setting. Under the conditions existing today in most American prisons, medical research involving the use of human subjects appears to be out of keeping with standards of ethical or professional conduct.

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Many of the factors can be changed not only to permit the research that can best be carried out under the conditions of a controlled population, but also to improve the functioning of the prisons. The most pressing change is to permit unimpeded, uncensored mail and telephone contact with the outside world. Equally important is the need to permit unhampered access to lawyers, the physician friend, and to those in a prisoner's life who care about him.

These two improvements would give much greater validity to an informed consent and provide some measures of protection for the experimental subject.

More difficult to change, but equally important if subjects are to be paid, is the availability of meaningful employment. The current practice of keeping men in enforced unemployment is not only very costly for the state, but also converts payment given to research subjects into a coercive force. This point is especially applicable to individuals incarcerated for long periods of time where their personal resources become exhausted. Although prisoners are generally opposed to the total elimination of research, I doubt that this would be true if they were given an alternative for meaningful and gainful employment.

Coercion as an institutional policy is also incompatible with research. When information regarding a person's participation is used in formulating decisions about a prisoner's degree of freedom, research is not possible. Similarly, when the environment is intolerable and participation is used to considerably improve living conditions, again experimentation is out of the queston.

In every instance, responsibility ultimately rests with the investigator. It is he who must assure that conditions compatible with current social mores are present prior to starting a project.

Where conditions in an institution make experimentation questionable, the investigator should either take an active role in pressuring for change that will permit research, or find another population to work with.

GEORGE BACH-Y-RITA, MD.

SAN FRANCISCO.

REPORT ON HUMAN EXPERIMENTATION CONDUCTED OR FUNDED BY THE U.S. ARMY

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from New York (Mr. Downey) is recognized for 30 minutes.

Mr. DOWNEY of New York. Mr. Speaker, I submit the following report on human experimentation of the U.S. Army:

"REPORT ON HUMAN EXPERIMENTATION CONDUCTED OR FUNDED BY THE U.S. ARMY

"(By Congressman Thomas J. Downey)

"INTRODUCTION

"Experimentation with hallucinogenic drugs by our Armed Services is by now a well known fact. In July of this year news reports revealed the existence of programs for drug testing at Edgewood Arsenal. I was disturbed at these disclosures and undertook to learn more about experimentation being conducted by the Army, Air Force, and the Navy.

"For many weeks, as I uncovered more and more information about the testing programs, my concern deepened. I learned of Army testing procedures that appeared to be inadequate, of disturbing effects of the drug tests on a number of individuals, and that at least one volunteer had died as a result of the drug experimentation.

"I am grateful that the House Armed Services Committee has undertaken an investigation of the matter, an investigation that I first asked for on July 17. The following report that I have prepared reviews the results of my own investigation for use by Committee members as the Committee today opens its hearings. The Report deals with several areas:

"Research conducted at the Edgewood Arsenal.

"Research conducted under contract with private research facilities.

"The death of Harold Blauer.

"Nerve gas experiments.

"Biological experimentation.

"Medical records and volunteer consent.

"In each area I make a number of recommendations. Some of these are fairly procedural changes that can be effected immediately by the Defense Department

or the individual services. Others will involve legislative action. I have developed a number of legislative proposals which I will transmit to Committee members for their consideration shortly.

"I undertook this investigation for two primary reasons. First and foremost, I wanted the assurance that the individuals who have been or might in the future be involved in such experimentation be fully protected. Beyond that, we need to know whether these programs have been cost effective. We have spent millions of dollars on these programs which have had undetermined ill effects on the people who volunteered to participate in them. Ultimately the question we must answer is: Did these costly programs contribute significantly to our Nation's defense and to the security of the American people?

"SUMMARY OF RECOMMENDATIONS

"1. The Army should undertake an extensive follow-up program of physical and mental examinations for all past and future volunteers in drug experiments.

"2. The Army should be required to maintain on-site inspectors at each human experimentation program that is funded by the Army to assure the soundness of experimentation practices and to protect the volunteers.

"3. Certain specific changes in Army regulations should be made to ban or at least restrict the use of prisoners and psychiatric patients in Army sponsored research.

"4. Army regulations should be amended to require that volunteers *must* be made to appreciate the high risks of such experiments if they are conducted in the future.

"5 The Armed Services Committee should evaluate the ability of other agencies to accomplish the work being done at Fort Detrick and carefully evaluate the need to continue the Army's biological experimentation on humans.

"6. Each military volunteer who participates in an experimental program should have placed in his medical file the date of his participation and the drug or chemical administered to him.

"7. The Army should be required to portray more accurately in its recruitment program the nature of its drug experimentation program.

"8. The Army's standard of informed consent should be amended to require that each volunteer be fully informed as to the nature of the substance to be tested on him, the risks involved, and that he be provided such information with sufficient notice to allow time for a reasoned judgment as to whether or not to participate.

"9. Army Regulation 70–25, entitled 'Use of Volunteers on Subject of Research' should be changed to remove the provision allowing the Army to withhold information from the volunteer if the Army believes that otherwise the experiment will be 'compromised.'

"10. The Investigations Subcommittee of the House Armed Services Committee should investigate what appears to be the deliberate cover-up of the death of Mr. Harold Blauer.

"11. Finally, the Armed Services Committee should undertake, with the assistance of the General Accounting Office, an evaluation of the value of drug experimentation work performed by outside contractors to determine the accuracy of Dr. Van Sim's statement that much of this research was 'useless.'

"I. RESEARCH CONDUCTED AT EDGEWOOD ARSENAL

"Over the past twenty years, the Army has conducted drug experiments on nearly 7,000 servicemen at the Army Chemical Center at Edgewood Arsenal, Maryland. These experiments were performed on human volunteers in an effort to develop both antidotes to chemical agents possessed by our adversaries and new drugs and chemicals to add to our own arsenal of offensive weapons. In the course of these tests volunteers were administered everything from alcohol to deadly nerve gas in an effort to bolster this country's chemical warfare program.

"The volunteers were told that they were being given a 'chemical compound which might influence their behavior,' but they were not told before or *after* the test the specific name of the drug used (such as LSD) or the effects (such as hallucinations) that the drug might cause. Neither did the Army advise these men of possible prolonged after-effects of drugs like LSD, even though scientific literature appearing early in the 1950's called attention to the appearance of

serious after-effects such as the 'flashback phenomenon' and the susceptibility of many volunteers to drug-induced paranoid schizophrenia.

"As a result, many volunteers experienced adverse physical and mental effects from the drugs without knowing the cause. One retired Air Force sergeant with whom I spoke said that he did not realize that the periods of deep depression which he suffered after participating in an experiment were probably a side-effect of the drug LSD. He told me that he first learned of the reasons for his behavior during an interview with Army officials set up by my office in July—nearly 30 years after the initial experiments.

"Another man who contacted my office reported that his father went into deep depression after participating in an Army-sponsored test. He said that his father eventually committed suicide. The son said that he never knew the reasons for his father's depression or suicide.

"A former Army colonel who took part in such tests stated that in the months following, he experienced a series of epileptic seizures and other 'flashback' effects from what he now believes to be exposure to the drug LSD. The colonel said he was never told LSD would produce after-effects. He also said no one bothered to conduct followup examinations on him.

"In fact, until 1973 the Army followed up on only two of the 1,500 military and civilian volunteers who participated in LSD experiments.

"It is simply inexcusable that after the experiments the Army did not tell its subjects what drug they had received. As it was, the volunteers had no understanding of what was happening to them when after-effects appeared.

"RECOMMENDATION

"I will therefore recommend that this committee give serious consideration to legislation which I will introduce that would require the Army to (a) fully inform volunteers of the nature of the substance which they are taking and its possible after-effects, and (b) undertake an extensive follow-up program of physical and mental examinations for all past and future volunteers.

"II. RESEARCH CONDUCTED UNDER CONTRACT

Almost two-thirds of all LSD experiments funded by the Army were not conducted by Army doctors but by civilian researchers under contract to the Army. Private research organizations tested a variety of chemical agents on thousands of civilians through Army funding. The Army signed approximately 225 contracts with private researchers over the last 20 years. Much of this research involved human experimentation. Furthermore, these contracts were very costly. The Army's expenditures on the 17 contracts which I have had an opportunity to review amounts to almost $2 million.

"The Army's supervision of the work of these outside contractors has been totally inadequate. Although the Army's Human Use Review Board did meet monthly to review and approve the protocols—the documents setting out the procedural guidelines to be followed—and contracts for each experiment, the Board made no real effort to monitor the day-to-day operations of the experiments to insure that the protocols were indeed being followed. The Board essentially relied on the contractors' promises to follow the procedures outlined in the contract and protocols.

"Moreover, Dr. McClure acknowledged that under this practice the Army might never find out about a death or serious injury resulting from a contractor's experiment unless the contractor were to come forward voluntarily to report it. He conceded that there may well have been deaths or serious injuries at these outside experimentation sites about which the Army has yet to hear.

"RECOMMENDATION

"As a corrective action I will recommend to this committee that the Army be required to maintain on-site inspectors at each human experimentation program that is funded by the Army. Dr. McClure has told me that four or five inspectors could handle all of the Army's contracts at any one time. On-site inspection is an accepted principle in construction and assembly of weapons systems by contractors and it should be adopted here to assure the soundness of experimentation practices, as well as to protect the volunteers.

"There is also a very real question as to the value, over the years, of the work conducted by outside contractors. Dr. Van Sim told a member of my staff that

most of the research reports forwarded to the Army were 'useless' and 'not worth reading.' He indicated that the entire program of contracting out these experiments related more closely to the continued financial support of research groups than to the substantive needs of the military. This raises the possibility that millions of dollars were wasted and thousands of lives endangered needlessly in a massive promotion of chemical and biological welfare. This is a most serious possibility. Accordingly, I have asked the General Accounting Office to review Dr. Sim's assertion.

"Much of the research conducted under contract used prison inmates and psychiatric patients as subjects. There is significant question as to whether informed, voluntary consent was obtained from these subjects in each case. Dr. McClure and his associates have conceded that they do not know by what means voluntary, informed consent was obtained from prison inmates and psychiatric patients. Indeed, there is a legal question as to whether such persons are capable of informed consent at all, given the circumstances of their confinement.

"I have requested that all consent forms obtained from these individuals be made available by the Army. I will also ask for copies of any materials used to inform prisoners or psychiatric patients of the experimental program.

"RECOMMENDATION

"After conferring with members of the Judiciary subcommittee on Courts, Civil Liberties and the Administration of Justice—which is presently reviewing legislation in this area—I will recommend to this Investigations Subcommittee specific changes in Army regulations that would ban or at least limit the use of prisoners and psychiatric patients in Army-sponsored research.

"III. THE DEATH OF HAROLD BLAUER

"There appears to have been a deliberate effort to conceal the death of a patient in an Army-sponsored experiment in 1953. The records of the death of Harold Blauer were reviewed and initialed at least twice—in 1959 and 1967. In addition, the records were enclosed in an envelope marked: "Not to be opened without authority of Dr. Van Sim"—the former chief civilian researcher at Edgewood Arsenal. Furthermore, on numerous occasions since mid-July the Army has strongly denied any reports of deaths resulting from any of its programs

"The Army *first* disclosed the death on August 11—22 years after it had occurred and five days after my visit to Edgewood when I was specifically told that no deaths had occurred in any Army sponsored experiments.

"Additionally, the Army contends that the annual reports and protocols which were submitted to the Army by the researchers who conducted the fatal experiment on Mr. Blauer are now missing. Moreover, the contract which the Army signed with those researchers was apparently destroyed, under questionable circumstances and for unknown reasons.

"Even if the experiment was classified, there was no reason to keep the death a secret. If for example, a pilot was to die while engaged in a classified test flight of a new fighter, his death and the fact that it occurred during tests of an aircraft would certainly be reported, even if the details of the accident were kept secret.

"RECOMMENDATION

"For over 20 years the Army has systematically kept secret its connection with the Blauer death. It is the responsibility of this Committee to determine why this information was concealed. I will ask the committee to carefully investigate what appears to be a deliberate coverup of the death of Mr. Blauer.

"IV. NERVE GAS EXPERIMENTS

"A drop of nerve gas on the skin can kill a human in 10 to 15 minutes. Compared with nerve gas, hallucinogenic drugs are relatively safe substances with which to experiment. The hallucinogenic dosage of a typical psychochemical like LSD is about one-thousandth of the lethal dose. In other words, with hallucinogenic drugs there is ample room for error.

"On the other hand, an hallucinogenic dosage of nerve gas is roughly one-half the lethal dosage. The slightest error could result in death.

"The Army experimented on humans with at least five different types of nerve gases, known to pharmacologists as anticholinesterese compounds. The Army tested this deadly nerve gas on at least 1,011 volunteers without fully explaining to them the grave risks which such experiments may have entailed. Dr. Van Sim and Dr. Frederick R. Sidell have told my staff that volunteers were often told only that the drug might produce 'a runny nose' and 'slight tightness of the chest.'

"RECOMMENDATION

"This practice should not be condoned. I will recommend to this Committee that Army regulations be amended to require that volunteers *must* be made to appreciate the high risks of such experiments.

"For the Committee's review I have attached to this Report a list of all of the chemical agents and drugs which the Army has tested on humans since the inception of the program (Appendix A). Among the items on that list, at least 'GA,' 'GB,' 'GD,' 'GF' and 'VX' are nerve gas compounds.

"V. BIOLOGICAL EXPERIMENTS

"The Army conducts extensive tests of dozens of biological agents on humans. These agents fall into three general categories:

"(1) Various strains of malaria, encephalitis and other exotic diseases.

"(2) Agents causing diarrheal diseases such as typhoid fever, cholera, plague, yellow fever, tularemia, and

"(3) those that cause less-harmful flu-like illnesses.

"The Army has tested these agents on three groups of volunteers. The first group consists of almost 2,000 Seventh Day Adventists (SDA's) drafted into the Army between 1958 and 1973 and assigned I–A–O (noncombatant conscientious objector) status. These men were recruited during their basic and Advanced Individual Training at the U.S. Army Medical Training Center, Fort Sam Houston, Texas as a part of Project Whitecoat. All soldiers who had indicated a preference for the Seventh Day Adventist Church received a two-hour briefing session given by the Director of the U.S. Army Medical Research Institute of Infectious Diseases (USA–MRIID), Fort Detrick, Maryland and the Director of the Church's National Service Organization. Mr. Clark Smith, the present Director, told my staff that about 95% of the Seventh Day Adventists who were briefed on the program volunteered for duty at Ft. Detrick.

"Persons who declined to volunteer for the biological program became medics. During the late 1960's and 1970's many of these men went to Vietnam as medics.

"This program all but ended in 1973 when the draft was discontinued. Although there is now a special arrangement with the Department of Defense whereby SDA's can enlist as CO's to be assigned to Ft. Detrick, very few have chosen to do so.

"The second group of volunteers consists of prisoners at the Maryland House of Correction at Jessup, Maryland. Over the last ten years, more than 3500 prisoners have been used as subjects of experiments conducted by doctors associated with the University of Maryland. These prisoners are paid $2 per day for their participation. In addition, at the prisoner's request, the researchers will send a letter to the prisoner's parole board certifying that he has participated in the program. The total cost to the taxpayers of this program at Jessup has been about $2 million. Further, there has been no indication from any source that any follow-up study has been done on any after effects these 3500 prisoners may have experienced as a result of the experiments. For the safety of the prisoners and for at least some assessment of the effectiveness of the program, it seems the Army would have followed up its experiments. This program is continuing at the present time under the supervision of Dr. Richard Hornick.

"The third group of volunteers consisted of professionals—members of the research team at Fort Detrick who used themselves for experimentation. Since the end of the draft in 1973, nearly all of the biological experiments have been performed on these persons. In addition, according to Joseph F. Metzger, the Commanding Officer of Fort Detrick's biological program, all experiments conducted in connection with the offensive biological warfare program were conducted on in-house professionals.

"The Army has advised me that at least two volunteers died in the course of these experiments and that the details surrounding their deaths would be forthcoming. Obviously, these mishaps should be subject to close scrutiny by this

Committee, and I hope the Inspector General of the Army will include this matter in his Report.

"In addition, I would point out that practically all of the biological research done—and indeed much of the research conducted over the last 15 years—has been routine medical research into infectious diseases. Indeed, it is not clear to me why this research must continue to be conducted by the Army under the guise of a biological warfare program. This is particularly puzzling in light of our national policy renouncing use of offensive biological weapons. Such research would be more appropriately done and is most probably duplicated by the Bureau of Biologics of the Food and Drug Administration or one of the National Institutes.

"RECOMMENDATION

"I will recommend that this Committee carefully evaluate the need to continue the Army's biological experimentation on humans after evaluating the ability of other agencies to accomplish the work now being done at Fort Detrick. In addition, I will ask the General Accounting Office to aid the Committee in answering these questions.

"VI. MEDICAL RECORDS

"The Army conducted drug and chemical experiments on 6,940 servicemen over the last 20 years. Each one of those 6,940 was given a Letter of Commendation, a Certificate of Appreciation and a kind of graduation photograph when he completed the program. Yet the Army never inserted anything in the medical records of any of those men which would have indicated that the man had been in an experimental program.

"If after leaving Edgewood, and being restationed elsewhere a soldier were to become ill as a result of the experiment, the Army medical officer examining him might never know about his patient's previous exposure to dangerous drugs because there would be nothing in the soldier's medical record to indicate that he had been in a drug or chemical program.

"RECOMMENDATION

"This practice is inexcusable. Corrective legislation which I will recommend to this Committee will require that the date of participation in an experimental program and the drug or chemical used be recorded in the medical file of each military volunteer.

"VII. THE ARMY'S DRUG PROGRAM RECRUITING EFFORT

"Beginning in 1957, the Army determined that it needed at least 30 volunteers from military units each month in order to conduct its experimental program in offensive and defensive chemical warfare. It began a recruiting program which eventually involved roving recruiting teams, recruiting posters, and recruiting films.

"This recruiting program portrayed the Army's drug program as a luxurious junket for enlisted men. The program was presented to the soldiers as an assignment that would involve no drills, no inspections, extensive leave time, automatic three-day passes every week, liberal travel allowances, and duty pay (an extra $45 per month). Prospective volunteers were shown pictures of women swimming on sunny beaches and were told of the close proximity of Edgewood to the cities of Baltimore, Washington, and Philadelphia.

"Volunteers were also told that upon successful completion of the program a certificate would be awarded to them and a letter of commendation would be inserted in their Personnel files.

"For the information of the Committee I have attached to this Report a copy of a recruiting poster which the Army uses today (Appendix B). I also request that the Army make available to the members of this Committee the recruiting film which I viewed when I toured Edgewood Arsenal.

"Each military volunteer was furnished a document entitled 'Medical Research Volunteer Program' and was asked to sign an Army consent form. This form was clearly meant to establish that the volunteer's informed consent had been freely given and to absolve the Army of legal liability in the case of accidental injury or death. I have attached to this Report a copy of the briefing document and consent form which was in use until two months ago (Appendix C).

"The three-paragraph consent form reads in part—

" 'I recognize that in the pursuit of certain experiments transitory discomfiture may occur and when such reactions seem especially likely to occur I will be so advised.'

"Some have pointed out that the only indication a volunteer has that he might experience more than transitory discomfiture is the request for the name, address, and telephone number of the volunteer's next-of-kin.

"I present to this Committee this question: Do these documents adequately advise soldiers of the nature of this program for which they were volunteering? It would appear that if the men who volunteered were given any meaningful appraisal of the nature of the experiment, it came only shortly before the experiment when peer pressure and self-consciousness made the prospect of 'backing out' of the experiment a totally humiliating and unacceptable experience for any solider who had second thoughts.

"RECOMMENDATION

"I will recommend to this Committee that the Army be required to portray more accurately in its recruitment program, the nature of its drug experimentation program.

"VIII. STANDARDS OF INFORMED CONSENT

"Army Regulation 70–25 (eff. 15 Sept. 1974), entitled 'Use of Volunteers as Subjects of Research' presently permits the Army to withhold drug and chemical information from the volunteer if the Army believes that the experiment will be 'compromised.' Dr. Claude McClure, Director of the Biomedical Laboratory at Edgewood Arsenal, has told me that this exemption could be eliminated without adversely affecting the Army's chemical warfare program. There does not seem to be any reason to permit the Army to test dangerous drugs on individuals without advising them of what they are taking. HEW guidelines, for example, do not permit this exemption.

"RECOMMENDATION

"The Army guidelines should be changed, and I intend to submit legislation which will accomplish this for the consideration of this Committee. I will recommend to this Committee that the Army's standard of informed consent be amended to require that each volunteer be fully informed as to the nature of the substance to be tested on him, the risks involved, and that he be provided such information with sufficient notice to allow time for a reasoned judgment as to whether or not to participate.

"The concept of 'informed consent' generates many difficult questions. "Fine lines" abound, and I, for one, do not for a minute believe that these hearings can reach definitive solutions to this dilemma. But we can certainly agree, from the evidence on the record, that minimal standards acceptable to most of the scientific and medical communities have not been met by the military experimenters. These standards must be revised, and not by a military team working in isolation.

"The effects of BZ and nerve gas are not minor inconveniences anyone is likely to undergo voluntarily in the interest of science or even the national defense. It is not customary for humans in large numbers to subject themselves, their bodies, and their minds to that kind of treatment.

"If experimentation on human guinea pigs is vital to the national defense, then let us require that responsible physicians follow the very highest and most rigorous standards of informed consent."

"APPENDIX A: DRUGS

"1955–1959: EA 1778, EA 1476, 792, DM, CS, CN, Chloropicrin, GB, Nasal Toxic Inhala, 5HTP, Atropine, Mustard, Skin Lipids, Stypen Coagula Time, Malathion Powder, Dibenz.

"1960 to March 1962: VX, GB, Thorazine, LSD, SNA, PAM–PS, CS, BSP, Atropine, Urecholine, TMB, GF, GA.

"Neostigmine, Ampetamine, like cpds. BZ, ThA, D-tubocurarine, DMPH, Creosol/ethylmorpholine, Detran (JB329), Dexedrine, Carare, Disodiumfluorescinetethyleneglycol, Seco, Barbitol, Dibulaline.

"March 1962 to present:

"EA 2233, EA 3148, Win 19362, 18437, CS 27349, EA 3443, EA 3528, EA 3580, EA 3580/VX/PAM.

"CAR 302,034, 302,089, 302,368, 301,060, 302,282, 302,668, 302,582, 302,196, 220,548, 226,086.

"EA 2227 (BZ), EA 3834, McN–JR–4929, EA 3167, BSP, BZ, CS, DFP, GB, GB c PAM.

"Vasoxyl, Valium, GD, 1CG, PABA, PAH, PAH c PAM, PAM, PAM/ATRO, P_2S, THA, VX.

"VX/SCOP, VX/PAM, Atrophine, Homatropine, Methyl Atropine, Amyl Nitrate, Antipyrine, BAT, Benactyzine Benac/Atropine, Benac/TMB.

"Caffeine, Compazine, Dexadrine, Ditran, Dilantin, Ethanol, Ethanol c Ritalin, Ethanol c Thorazine, Ethanol c Scopolomine, Ethanol c Valium.

"Heparin, Inderol, Isuprel, Lanoxin, Lidocaine, Pamine, Phenobarbital, Physostigmine, Prolixin, Ritalin.

"Sodium Amytal, Sodium Nitrate, Sodium Pentobarbital Sod Pento c Scopolomine, Scopolomine, Scop and Physo., Scop and Thorazine, Scop and Prolixin, Secobarbital, Thiamine, Thorazine, Toxogonin, Trilafon."

"APPENDIX B

"CAN YOU QUALIFY FOR MEDICAL RESEARCH VOLUNTEER PROGRAM

"ENJOY ITS BENEFITS WHILE YOU SUPPORT THE DEFENSE OF YOUR NATION

"Inquire at your Orderly Room for Details."

"APPENDIX C

"U.S. ARMY CHEMICAL WARFARE LABORATORIES MEDICAL RESEARCH VOLUNTEER PROGRAM, ARMY CHEMICAL CENTER, MD.

"1. Military volunteers are needed each month by the Department of the Army to participate in medical research investigations.

"2. For several years the Army Chemical Corps has been developing and perfecting methods of defense against chemical warfare agents. The methods ultimately prescribed for use by the soldiers, sailors, and airmen are the outgrowth of continuous investigation. But before a method, procedure or technique may be standardized for military adoption, numerous tests must be conducted with individual subjects. Both military and civilian members of our laboratory staff are participating in these tests, but the increased scope of the activity now requires additional volunteers to support this important work.

"3. Participation of military personnel in these medical research investigations will materially assist the program designed to strengthen the defenses of the United States against chemical warfare attack, and is considered to be in keeping with the highest traditions of the military service. It will be given official recognition through letters of commendation and certificates of participation. These documents will become a part of the volunteer's permanent Army file.

"4. Volunteers will be placed on thirty (30) days temporary duty at Army Chemical Center, Maryland. At the expiration of the thirty day period, or sooner if he should request it, the individual will return to his parent unit. The volunteer group is attached to a troop detachment for administration and supply. The group is not subject to fatigue or special duty details and will at all times be entitled to the customary pass and recreational facilities privileges. During normal duty hours (0800–1630) the volunteer appropriately identified by his volunteer arm brassard will be on duty at the Chemical Warfare Laboratories. Since the majority of the tests require more observation time than actual performance, a combination day room and clinical facility has been established approximately 300 yards from Chemical Warfare Laboratories in the Dispensary Area, where adequate medical facilities are available at all times. Here the volunteer will be provided with the best recreational facilities available and visits from friends and relatives will be encouraged.

"5. The investigations are conducted at the Chemical Warfare Laboratories at Army Chemical Center, Maryland. Some examples of the tests are:

"a. Evaluation of chemical warfare equipment

"Various designs of gas masks and protective hoods are worn for short periods to test the relative merits of each model. If the item leaks the wearer experiences a slight eye irritation which is not even sufficient to produce tears. If this oc-

curs, the volunteer leaves the test chamber immediately. The eye effects disappear within several minutes from the time of leaving the chamber.

"b. Adaptation of defensive items to natural human capacities

"Certain items of protective clothing are worn under controlled conditions to determine their value to the soldier under varying conditions which might be encountered in the field. There will be little or no discomfort or fatigue.

"c. Effects of toxic agents

"The effects of certain agents are determined by inhalation of very small amounts. The volunteer test subject will be thoroughly informed about all procedures and what can be expected prior to each test. Every precaution will be taken to protect the volunteer against danger or serious discomfort as a result of participating. In attendance at all times will be physicians and scientists, most of whom have also participated in the same tests. Applicants must meet the following prerequisities for selection:

"(1) Aptitude Area I—Score; 80 or higher
"(2) Completed basic training
"(3) Physical profile—PUHLES—1 or 2
"(4) Age group 17–35 years
"(5) At least three (3) months remaining service
"(6) Security Clearance—no adverse information in organization or Army files.

"6. Military personnel who are interested in volunteering for these medical research investigations being conducted at Army Chemical Center, Maryland should contact the orderly room for additional information.

"Application forms are available at your orderly room."

"U.S. ARMY CHEMICAL WARFARE LABORATORIES, ARMY CHEMICAL CENTER, MD.

"VOLUNTEER PARTICIPATION AGREEMENT

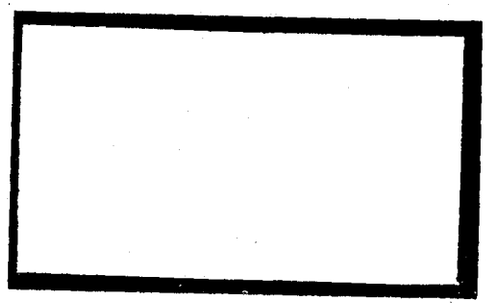
"Name.
"Age.
"Race.
"Grade.
"Serial No.
"Organization.
"Name of Nearest Relative.
"Address of Nearest Relative.
"Telephone Number of Nearest Relative.

"I _____, certify that I have received, read and understand a document entitled, 'Medical Research Volunteer Program', copy of which is annexed hereto, and that the general nature of the experiments I have volunteered to participate in have been explained from the standpoint of possible hazards to my health. It is my understanding that the experiments are so designed, based on the results of animal and previous human experimentation, that the anticipated results will justify the performance of the experiment. I understand further that experiments will be so conducted as to avoid all unnecessary physical and mental suffering and injury, and that I will be at liberty to request that the experiments be terminated at any time if, in my opinion I have reached the physical or mental state where continuation of the experiments becomes undesirable.

"I recognize that in the pursuit of certain experiments transitory discomfiture may occur and when such reactions seem especially likely to occur I will be so advised. I recognize, also, that under these circumstances, I must rely upon the skill and wisdom of the physician supervising the experiment to institute whatever medical or surgical measures are indicated to protect me.

"I certify that there has been no coersion, element of fraud or deceit, undue moral suasion or other adverse pressure brought to bear in my volunteering for this duty. I have done so of my own free will, completely aware of all hazards, rewards and recognition involved.

"Date.
"Witness.
"Signed.
"Witness."



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BIOMEDICAL EXPERIMENTATION ON PRISONERS

Review of Practices and Problems

and

Proposal of a New Regulatory Approach

Health Policy Program
Discussion Paper

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by

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SUMMARY

Within both public and scientific circles there has been growing concern for protection of the rights of prisoners when used as subjects in biomedical experimentation. In response, the Health Policy Program, University of California, San Francisco, has developed this analysis and policy proposal.

The first section contains background information on existing experimental practices, central ethical issues, and major theoretical formulations.

We then propose a new conceptual framework designed to meet the policy needs of government officials and institutional review committee members. This "inversive risk-rating" system forms the basis of a regulatory mechanism for determining the propriety of specific research proposals in given settings.

Experiments would be rated for the potential physical risk imposed on prisoners. Penal settings would be rated for the "risk of ethical impairment" inherent in their characteristics. The purpose would then be assurance of an inverse relationship between the levels of physical and ethical risk.

The more the characteristics of an institutional setting compromise the inmates' exercise of free and informed discretion over their participation in research, the lower the risk of experiments which would be permitted there. Conversely, the more closely institutional conditions approximate conditions in the free living world, the higher the risk of experimentation permitted.

The deficiencies of the existent procedural safeguards can be seen in the abuses which have fueled the current debate over medical experimentation in prisons. The need for a thorough reassessment of the ethical basis for experimentation and development of an implementable system of regulation has become increasingly obvious.

The proposed system of "inversive risk-rating" avoids questionable inquiries into individual motivation and removes from consideration equally speculative statements regarding expected societal benefits. It considers only two kinds of risks: the physical risk to subjects of a given experiment and the "risk of ethical impairment" or impediments to free and informed inmate decision making imposed by the penal environment.

The "inversive risk-rating" approach offers policymakers a defensible basis for compromise between the extreme apologists and critics of prison experimentation. It provides a consistent ethical basis for policy based on specific, objective institutional characteristics. Concrete standards can be developed and translated into statutory and regulatory language.

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Introduction

Ethical dilemmas inherent in scientific research and technological advance are commanding increasing attention in the scientific community. Nowhere are the effects of such decisions more immediate or more profound than in the field of medical science. Much interest is concentrated on the ethical issues involved in the application of new medical technologies. Even more basic are questions regarding appropriate uses of human experimentation to develop new knowledge and test new technologies.

Other issues receiving a great deal of current attention in policy circles are the purposes and efficacy of our penal institutions. Many are questioning present regard for the rights of the incarcerated.

Both problems converge and are accentuated in the role of prisoners in medical experimentation. However, evaluation of the impact of research on prisoners on medical advance and the complex ethical questions involved has only recently begun within scientific circles. Public pressure and the desire of scientists and policy makers to come to grips with the crucial questions of individual and societal rights and needs in this field have stimulated the Health Policy Program (HPP), University of California, San Francisco, to survey available information on human experimentation in prisons and to define areas for future consideration. Review committees of the University are frequently called upon to make judgements about protocols involving research on prisoner subjects. The decisions of institutional review committees in the past have lacked a consistent rationale for allowing or disapproving research on prisoners. The obvious need for information which could lead to the development of some clear and consistent standards for committee decisions and governmental regulation led to the formulation of this initial project.

I. A Record of Abuse and Inadequate Regulation

Medical advance has always depended on human experimentation. Alleged improprieties in the present use of human subjects are set against a lengthy and sometimes ignoble history. The leaders of ancient Persia and Egypt are said to have utilized criminals as expendable subjects for study. Princess Caroline of Wales in the eighteenth century tested a smallpox vaccination on prisoners before usage on her own children.[1] Similar unethical practices moved the French experimentalist Claude Bernard to call for an end to prisoner experimentation as early as 1856.[2] Wide-ranging experimentation with prisoners continued. Prisoners were infected with diseases such as syphilis, gonorrhea, and malaria.

In response to the atrocities conducted in the name of medical research on prisoners in Nazi Germany, the judgement at Nuremberg called for an end to this "crime against humanity".[3] However, wide use of prison populations in the United States has continued. In the absence of adequate legislative or administrative regulation of prisoner experimentation, the most flagrant examples of abuse have found their way to the courts. The experimentation of Austin R. Stough, M.D., in the prisons of Oklahoma, Arkansas, and finally Alabama represented the most flagrant of exposed abuses. A successful 1972 lawsuit brought by an ex-inmate exposed Strough's drug and plasma experimentation which had been implicated in several prisoner deaths. The Federal District Judge who tried the case characterized Alabama's prison health facilities and research program as "shocking" and "barbarous to the conscience".[4] As a result of this case, human experimentation was terminated in the Alabama correctional system. Still, some questionable use of prison subjects has continued in other American jurisdictions. In the absence of effective legislative or administrative safeguards, victims and prisoner advocates continue to look to the courts for redress of grievances.[5]

II. Prisoner Experimentation - Knowns and Unknowns

Reticence in dealing with abuses in medical experimentation is, in part, due to a dearth of facts confirming or discrediting rationales for prisoner usage and inadequate information on the types of research, procedures, and locations of prisoner experimentation. Although a free exchange of information is an important theoretical tenet of scientific inquiry, neither the prisons nor the competitive profit-making industries that frequently fund prison research are known for their openness to public inquiry. Manufacturers, though perhaps open to retrospective inquiry, are protective of information concerning current research and development.

A. Rationales for Prisoner Usage

Prisons are said to be ideal experimental sites because they provide a constancy of experimental variables. Life in the prison is simple and routine. All prisoners eat the same fare, participate in similar programs of work and recreation, and share similar quarters. Consequently, when introducing an experimental variable -- a cosmetic or a medication -- only a few factors typically have to be controlled for research purposes. Other justifications for prisoner usage concentrate on the stability of the population. Free world mobility is thought to make long-term, prospective studies difficult and ineffecient, if not impossible. The imposition of investigative procedures on daily routines is impractical and bothersome for non-prisoner populations. Prisoners, however, are said to welcome the variety such procedures supply to the boring routine of prison life. Also human experimentation is believed to arouse such apprehension that it has been difficult to attract experimental subjects from the population at large. Daniel C. Martin et al. have confirmed this notion by showing prisoners to be more easily recruited for potentially hazardous experiments than free-living population groups.[6] The final advantage of experimentation of prisoner populations is the reduced cost to investigators of securing subjects. Free-living subjects command higher compensation than do prisoners whose wages are set to low prison wage scales.

Among the rationales for prisoner experimentation, two appear defensible and devoid of major ethical problems. Prisons do provide a relatively greater constancy of experimental variables which limit the degree of environmental variation confounding the research conducted there. In addition, the simplicity of prison life imposes few demands which might discourage full participation by prisoners. The stability of the prison population and the ability of researchers to follow subjects over a protracted period of time, however, is debatable. Dr. Harry Weller, of the Federal Bureau of Prisons, notes that of the 22,000 inmates of the federal prison system, 14,000 come and go every year.[7] Even our highly mobile free-living society cannot approach this yearly mobility rate of 64%. The remaining rationales, the greater tendency of prison populations to subject themselves to experimentation and the cost-savings in utilizing inmates, present complex procedural and ethical problems dealt with in succeeding sections.

Questionable justifications for the use of inmate populations and inadequate safeguards against the potential abuse of captive populations have stimulated exploration of alternative subject populations. Representatives of the National Institutes of Health (NIH), in particular, are encouraging more serious consideration

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of alternative subject populations.[8] Students, especially those in the health sciences, have long served as subjects for medical research. Investigators, under attack for controversial prison studies, such as University of Maryland researchers at the Jessup facility, are beginning to rely more heavily on university students as alternatives to incarcerated subjects. "The new arrangement is not a substitute for the school's prison research unit at Jessup, Maryland, which has come under mounting attack in recent years, University officials say. But it's clear NIH wants to wean investigators from dependence on prisoners except as a last resort."[9]

Another frequently used source of free-living volunteers is the beneficiaries of the Veterans' Administration (VA) hospital system. Charles Fried, in Medical Experimentation, notes the advantages of this population as the subject of research. "Thus, Veterans' Administration hospitals have been particularly apt places for the conduct of RCT's [randomized clinical trials], because of the comprehensive nature of the records they keep, the fact that patients moving from one part of the country to another could be kept within the experiment, and because administrative coordination between many hospitals is particularly convenient, thus leading to more valid, general results."[10] Members of the armed forces have also been used for experimentation, stimulating questions similar to those raised in prisoner research regarding use of proper safeguards against coercion.

Military personnel and VA beneficiaries are now used in different kinds of experiments than prisoner subjects. Typically, ill servicemen and veterans are used in therapeutic trials testing the efficacy of new drugs. Prisoners, however, are used as healthy "normals" in the toxicity and dosage testing which precedes use on affected patients.

Real or presumed limitations of these subject groups are spawning consideration of more novel alternatives. One option gaining interest is that of conducting more studies in Europe where human experimentation is less rigidly controlled. More radical are suggestions of general conscription of normal, healthy Americans as subjects in experimentation through a process similar to our selective service system.

B. Types of Experimentation

Much of the public concern over prison experimentation, particularly that publicized by Jessica Mitford, centers upon behavioral research in our penal institutions.[11] Examples of abuse of prisoner rights, such as occurred in the Vacaville "Anectine" program, are unmistakable.[12] However, the ethical questions posed by behavioral research are predicated on assumptions about the rehabilitative role of the penal system. Medical research utilizing inmates only as prototypes of normal, healthy individuals pose quite different ethical dilemmas. For this reason the present analysis concentrates exclusively on the latter category.

Of central interest in this analysis are the strictly biomedical experiments analyzing the effects of pharmacological and cosmetic products and biomedical devices on prisoner populations. Information on the proportion of experiments which fall into each category is not available. The testing of products such as deodorants and an infinite variety of other non-medicinal preparations for toxicity and efficacy follows less stringent protocols than drug experimentation. Pharmacological investigations on human subjects are preceded by extensive chemical and biological tests in laboratories and on animals before man becomes the final test site. Both these early studies and the eventual human experimentation follow formalized procedures outlined and controlled by the Food and Drug Administration (FDA) and the Department of Health, Education and Welfare (HEW).[13] It is presumed that the great majority of drug research in prisons comprises Phase I of the

three stages of human experimentation which precede FDA approval or disapproval. During this stage, healthy subjects are administered a drug product in order to determine such pharmacologic properties as absorption, metabolism, excretion, dosage range, and toxicity. Increasing scientific caution in recent years has extended both the numbers of subjects and lengths of studies in Phase I experimentation. In the succeeding stage, Phase II, subjects with the specific diseases the drug is believed to affect are administered the drug, usually in hospital settings. If proven to be safe and effective, the drug then enters Phase III testing, where 1,000 to 1,500 patients participate in final "clinical trials" testing. Drugs successful in this final stage are then submitted to the FDA and, if approved, are then used in general medical practice.[14]

C. Logistics of Human Experimentation in Prisons

The literature contains few references to methods of selection of inmates to participate in various studies. There is some indication that slots on the more benign, higher paying experiments have been used in building patronage for inmate gang leaders.[15] Irvin Gilchrist, in his call for the closure of the Infectious Disease Area (IDA) within the House of Correction in Jessup, Maryland, describes the recruitment process there:

> Often prisoners are informed about these medical projects by advertisements in the prison newsletter, through word of mouth, through discovery of an IDA form placed surreptitiously in newly issued clothing or by the IDA (prisoner) public relations agent who is compensated by receiving a commission (paid for being listed on a test which does not exist) for each prisoner that is successfully recruited for the tests. The techniques employed are as varied as one's imagination allows.[16]

After expressing interest in participating in a particular study, prisoners are typically given a general medical examination to discover any abnormalities which might expose them to additional risk or prejudice the research results. The experiment and its presumed risks and benefits are described to the inmates, and they are asked to express their "informed consent" by signing a form attesting to their knowledge of the experiment's procedures and risks, and their willingness to participate. Past practices, in violation of HEW and FDA guidelines, included inmate signing of waivers of their right to sue for damages.[17] Though waivers have been disregarded in the judicial system, they can still serve to protect investigators because prisoners are unlikely to know their legal rights. As Mitford writes, "the psychological effect of signing the waiver, along with the general helplessness of prisoners, make lawsuits a rarity."[18]

Funding for prison experimentation is quite difficult to trace. Procedures range from direct drug company establishment of laboratories and hospital wards within Michigan's Jackson State Prison to a non-profit corporation set up within California's Vacaville Medical Facility to receive drug research monies via physician-investigators.[19] The magnitude of these programs is seen in the $150,000 which Vacaville inmates are paid annually for their participation, an amount equal to that provided by the State of California in compensation for all other labor in that institution.[20] The amounts and methods of funding of non-pharmaceutical research simply are not known.

The literature offers no estimates of the percentage of research monies which go directly to the subjects themselves. Most experiments provide prisoners about $2 daily, a level of compensation usually well above other prison jobs. These inmate wages are generally considered to be about 10% of the wages free living subjects would command.[21] Although in some cases researchers make additional contributions to prisoners' welfare funds, total costs to the companies and investigators conducting prison experimentation unquestionably fall below costs for research done outside.

D. Experimental Locations

State and federal policies continue to permit medical experimentation involving an estimated 20,000 of the nation's 200,000 state and federal prisoners.[22] The exact locations of experimentation are difficult to document. State policies, due to recent public concern, are in a state of flux. In January of 1973, Mitford listed 25 states purported by the FDA to be current sites of prison medical experimentation.[23]

In order to update and expand data on state practices, a survey was conducted under the auspices of the Health Policy Program in April of 1974. Questionnaires were sent to Departments of Correction in the 50 states and the Federal Bureau of Prisons requesting information on human experimentation. The following table summarizes the findings of this survey and the data from Mitford's January 1973 survey with additional results from a January 1975 analysis by the Urban Information Interpreters on "prisons where medical research posing health risks is being conducted on healthy prisoners."[24]

Important summary points include:

1. Comparison of 1973, 1974, and 1975 data graphically demonstrates changing attitudes regarding prison experimentation. In 1973, 25 states reported the conduct of medical experimentation involving prisoners in their penal institutions. By 1974 only 8 states reported such experimentation in their prisons. Two additional states which did not respond to the 1974 survey were found to be conducting studies in 1975 and can be assumed to also be conducting research in 1974. Thus, from 25 states conducting research in 1973, only 10 still carried out studies a year later. In the 1975 data, again 10 states reported current research. Two of the states conducting studies in 1974, however, were replaced with two others. The remaining states which permit experiments involving prisoners typically have fairly large programs.

2. Some jurisdictions have declared moratoria in order to reassess their programs. Other jurisdictions allowing experimentation indicated in response to the 1974 survey that they had halted their programs in the past and then resumed. Connecticut is an example. Still others (e.g., Pennsylvania, Vermont) have terminated their programs and have not started up again.

3. None of the respondents to the 1974 survey acknowledged any special parole consideration given to inmates who participated in experimentation programs. All but one of the jurisdictions had eliminated pay for correctional personnel used in a supervisory capacity, thus eliminating a source of abuse in the past. Most of the respondents included a statement of the review procedures which were used to screen research protocols. In most cases, many different reviews are required prior to approval.

TABLE I

State Policies Regarding Prison Experimentation

State	Mitford 1973 Conducted	HPP 1974 Permitted/Conducted	UII 1975 Conducted	Parole Consideration +	Laws on Books +	Moratorium Declared +
Alabama	Yes	/no			?	Yes (1969)
Alaska		/no			No	
Arizona		/no			Yes	
Arkansas	Yes	/no			?	?
California	Yes	Yes/yes	Yes	No	?	No
Colorado		/no			No	
Connecticut	Yes	Yes/yes		No	No	*
Delaware		/no			No	Yes
Florida	Yes	/no			No	?
Georgia	Yes	/no			No	?
Hawaii		/no			?	
Idaho		/no			?	
Illinois	Yes	Yes/no	Yes**	No	No	Yes
Indiana	Yes		Yes			
Iowa	Yes	Yes/no			?	Yes (10-72)

+ Data from HPP 1974 survey
* A moratorium called in 1972 was ended when 400 inmates requested resumption of experimentation. Currently a lack of appropriate review board members has led to a modified moratorium.
** Program to be phased out in 1975

State	Mitford 1973 Conducted	HPP 1974 Permitted/Conducted	UII 1975 Conducted	Parole Consideration +	Law on Books +	Moratorium Declared +
Kansas						
Kentucky		/No	*		No	?
Louisiana	Yes	Yes/no		No	No	Yes
Maine		/no			?	
Maryland	Yes		Yes			
Massachusetts	Yes	Yes/yes	Yes	No	No	Yes (1972) program resumed
Michigan	Yes	/yes	Yes	No	Yes	?
Minnesota		/no			?	?
Mississippi						
Missouri	Yes					
Montana	Yes	Yes/yes	Yes	No	Yes	No
Nebraska		/no			No	
Nevada		/no			?	
New Hampshire		/no			No	
New Jersey	Yes	Yes/no			No	Yes
New Mexico		/no			?	
New York	Yes	/no			?	?
North Carolina		Yes/no			No	

* Experimentation conducted within a federal institution

State	Mitford 1973 Conducted	HPP 1973 Permitted/Conducted	UII 1975 Conducted	Parole Consideration +	Law on Books +	Moratorium Declared +
North Dakota		/no			No	
Ohio	Yes	Yes/yes		No	?	No
Oklahoma	Yes	Yes/yes	Yes	No	Yes	No
Oregon	Yes	/no			Yes	Yes
Pennsylvania	Yes	Yes/no			?	Yes (1972)
Rhode Island	Yes	/no			No	?
South Carolina		/no			No	
South Dakota		/no			No	?
Tennessee		Yes/no		No	Yes (Bill permitting experimentation passed & signed 5/74)	
Texas	Yes	Yes/yes	Yes	?	?	?
Utah		/no			?	
Vermont	Yes	/no			No	Yes (1971)
Virginia	Yes	/no	Yes		?	
Washington		/no			?	Yes (1970)
W. Virginia		Yes/no			No	
Wisconsin		/no		No	?	No
Wyoming						
Federal Bureau of Prisons		Yes/yes		No	?	No

The most striking aspect of the responses is their diversity. Some states conduct vigorous programs of experimentation in which they take great pride, while others (e.g., Vermont and Oregon) have prohibited experimentation because they maintain that no prisoner, by virtue of confinement , can give truly voluntary consent. Although there has clearly been a trend towards discontinuance of research programs, it is not uniform. Tennessee has recently passed legislation facilitating experimentation under tight regulation for the first time in the state's history. Still other states have resumed experimentation following a moratorium. A consistent pattern governing this volatile period is presently undiscernible.

III. Ethical Issues

This diversity of governmental policies derives from an equal breadth of opinions concerning the ethical dilemmas posed by experimentation on captive populations. The issues basic to formation of appropriate policy transcend a simple calculus comparing risks and benefits. However, factual information and informed opinions on the motivations of the parties involved present a useful starting point for consideration of the ethical propriety of medical experimentation on incarcerated persons.

A. Risk/Benefit Considerations

1. Society

Private and governmental investment in biomedical research reflect a broad endorsement of the unprecedented medical advances that have emerged in this century. These investments have increased rapidly since the 1930's when the clinical usefulness of sulfonamides ushered in a period of rapid advance in the treatment of infectious diseases. These very advances, combined with improvement in prevention led to the emergence of congenital disorders, mental illness and the chronic diseases and disabilities associated with aging as the major disease problems. These problems have proved less amenable to application of medical technology. No data are available to establish a return rate for present investments in biomedical research. The societal benefit of research into the physiological effects of still more cosmetic products is even less certain. Clearly toxic products should not be foisted on an unsuspecting public. However, the societal need for the multitude of cosmetic products and devices on the market is questionable at best.

Current evaluative techniques and available data make assessment of the level of societal benefit from biomedical experimentation on prisoners an impossibility. For the present it must be assumed that there is sufficient public benefit from continued research to at least warrant consideration of appropriate populations and regulatory procedures.

Many observers feel that even evidence of clear societal benefit from experimentation does not justify a greater proportion of risk being borne by one segment of the population. Such unequal sharing of risk is exacerbated when that segment singled out for experimentation is often the victim of other inequities. As Charles Fried writes, "Assuming that racial prejudice or widely unequal distribution of income constitutes injustice in the basic structure of society, then singling out these vulnerable groups to sacrifice them to the interests of the larger society is simply a further example of the injustice to which they are subjected."[25] The concentration of risk on the typically lower socio-economic prisoner population would pose a thorny problem even if the resulting benefits were equally shared by all members of society. The unequal distribution of the benefits of such research greatly compounds the problem. Sophisticated and expensive medical procedures and drugs benefit the economic strata of the population most heavily represented in America's prisons less than the middle and upper classes which have ready access to medical care. Thus both the distribution of risks and benefits of human experimentation are believed to confound the validity of general societal benefit as a useful calculation in evaluating prison experimentation.

2. Institutions

a. Manufacturers

Motivation for prisoner experimentation only occurs in small part at the abstract level of societal need. It is the institutional subsets - the drug companies and medical device manufacturers, the academic world of medical scientists, and the prisons themselves - that have jointly created prison research programs. Although these parties to experimentation can be expected to share society's regard for the advancement of medical science, more complex and immediate motivations weigh heavily in their participation in prison experimentation.

The drug companies and other manufacturers derive considerable gain from experimentation on prison populations. The prison environment greatly eases the logistic problems inherent in the mandatory human experimentation which must precede marketing. Because of the extremely low pay scales for other prison jobs, prisoner compensation for research participation is set very low. Although payment of research subjects often exceeds pay for other prison work the low wages produce, in effect, a sizable research subsidy to the pharmaceutical industry. This subsidy has been conservatively estimated to be $75 million per year.[26]

Not only are prisoners paid low wages for participation, but those who fund prison research also benefit by hiring prisoners at equally low wages as nurses, technicians, and clerical personnel. Mitford reports that at the California Medical Facility at Vacaville these inmate salaries are comparable to an approximate subsidy of $70,000 to $80,000 a year.[27]

The envelope of secrecy and segregation from the mainstream inherent in the prison system is also believed to benefit manufacturers by protecting competitive information and shielding research practices from the public eye. Only recent interest in penal institutions has begun to open this cloistered environment to public scrutiny. Subsequent criticism from prisoner advocates has introduced the risk of political prohibition into manufacturers' risk-benefit calculus.

b. Researchers

Researchers, particularly those academic scientists involved in pharmacological, bacteriological, and other investigations, derive not only satisfaction of scientific curiosity but also the benefits of publication and professional advancement for quality research performed on prisoner populations. The nature of this subject group enhances the investigator only secondarily, to the extent that the constancy of environmental variables in the prison and stability of the population contribute to an unbiased research design. Much like the manufacturers, investigators experience little immediate risk in their utilization of prisoner populations.

c. Prison Administrators

Prison administrators, however, must weigh a mixed bag of risks and benefits in setting experimentation policy. Not only do experimental programs contribute logistical problems to prison officials, but those charged with the safekeeping of prisoners are more visible and vulnerable to growing criticisms of the propriety of prisoner experimentation. Increased communication with outsiders in research programs enhances the opportunity for contraband to enter the prison. In addition, the introduction of sizable amounts of new money into the environment can increase chances of corruption. Although personal profiteering by guards and patronage development through control of experimental assignment by prisoner gangs occur rarely today, opportunities are present where experimentation is conducted that would not otherwise exist. A nearly universal administrative problem imposed by experimentation is the additional strain on manpower. Both the increase in prisoner movement and the greater dispersal of the inmate population in research centers call for more guards to maintain security levels.

As reflected in responses to the 1974 survey conducted by the Health Policy Program, some administrators consider these costs warranted by the rewards of the programs while others clearly do not. Tangible benefits to the participating penal institutions include payment of rent on facilities and salaries for guards by the research interests.[29] Other tangible benefits to cooperating prisons often include donations of equipment necessary to the research. Mills and Morris report a typical trade-off. When an Indiana facility agreed to an experimental program, "in turn the prison got a dishwasher, a remodeled hospital, high school supplies, an improved library and athletic equipment, and of course, Lilly got its Phase 1 test results."[29]

Finally, the prisons receive means of employment of inmates with private compensation. A tight labor market has forced the nation's prisons to withdraw from almost all profit making enterprises, leaving administrators with inadequate means of keeping prisoners busy and able to provide for a few of their necessities.[31]

Inmate employment provides other intangible benefits to the prison administrators. As Ralph Urbino, director of the Vacaville facility, noted, "...the main benefit to the Department is that the research programs cut down on disciplinary problems. A man has to have a relatively infraction-free record to qualify as a volunteer subject. And the Department figures if he has thirty dollars a month to spend on canteen, he'll be a lot quieter."[30]

Many commentators feel that extramural participation also aids in "inmate management" by the mere presence of the researcher. Davis et al. laud this facet of research, noting, "...research participation and warm and meaningful contacts with research staff might very likely serve as a desirable and beneficial component of the institution's treatment, as well as inmate management programs."[31]

3. Individual Prisoners

The tradition of experimentation on prisoners in this country was created and has thrived largely because of the benefits it affords researchers, manufacturers, and prison officials. Yet the success of these research programs hinges on the acquiescence of sufficient numbers of individual inmates. It is at the individual level that the crucial risk-benefit calculations must be made. Much of the literature on human experimentation addresses the question of the subjugation of the individual for the good of society. Opinions vary from Claude Bernard's dictum that it is "a principle of medical and surgical morality [never to perform] on man an experiment which might be harmful to any extent, even though the result might be highly advantageous to science"[33] to Louis Lasagna's statement, "There is nothing intrinsically more noble about a concern for the individual than a desire to aid the many; in fact, it might be argued that the opposite underlies the democratic process or the social contract in general."[34] Regardless of philosophical inclination, policymakers must make judgements on the propriety of individual acceptance of risk. Such an evaluation can only be made with a broad

knowledge of motivations that move subjects to participate. As noted above, societal justifications for human experimentation in general do little to structure an effective means of analyzing research on special population groups. Not only are our prison populations drawn disproportionately from the lower socioeconomic strata and ethnic minority groups, but there is clear evidence that inmates respond differently from their social peers to requests to volunteer for medical experiments. Martin et al. reported 73.3% of prisoners studied willing to participate in a study for which only 34.6% of the lower income and 3.6% upper income non-prisoner subjects would volunteer.[35] Whether typical prison populations are different by nature or respond uniquely because of special environmental pressures is immaterial at this point. What is critical is the development of a thorough understanding of the motivation of prisoners to participate. Only against this backdrop can the risks and regulatory mechanisms be evaluated.

a. Obvious Motivators - Altruism, Money, and Parole

Three volunteer motivations acknowledged throughout the literature are the abstract goal of altruism and the concrete goals of monetary reward and favorable parole consideration. Although many assume altruism and the related presumption of inmate penitence and repayment of infractions against society to be central to volunteering motivation, there is little evidence to support its importance. In a study on free-living subjects, Gray reports two of 51 subjects or 4% to be "committed subjects who give altruistic reasons for agreeing to be research subjects".[36] Although Wells et al. report a high inmate response to a structured question exploring the altruism in their motivation, only 3.1% of inmate volunteers mentioned altruism in open-ended interviews as a factor in their participation in prison research.[37]

Conclusive data is also unavailable on the importance of monetary rewards in inmate motivation, but there are many indications of the preeminence of this motivator of inmate participation. From a series of interviews with inmates who had participated in human experimentation projects, Martin Miller, once a research subject himself, takes the position that the perception of research by prisoners is substantially different from that of investigators.[38] The high ideals of research held by experimenters rarely permeate prisoners' perceptions. One of the clearest findings of Miller's work is the degree to which compensation dominates prisoner attitudes towards experimentation. A statement offered by an inmate illustrates the importance of remuneration: "Hey, man, I'm making $30 a month on the DSMO thing. I know a couple of guys had to go to the hospital who were on it -- and the burns were so bad they had to take everyone off it for a while. But who gives a shit about that, man? Thirty is a full [canteen] draw and I wished the thing would go on for years -- I'd be lost without it. If someone else woulda turned me out I'd be in some other kinda hustle to make some dough."[39]

In the absence of conclusive motivational research, monetary inducements can be assumed to play a large role in volunteer behavior. An excerpt from the American Civil Liberties Union class action suit against the Jessup research unit succinctly states the prisoners' economic plight:

> The prisoners are not provided with sufficient necessities to maintain health and personal hygiene. In order to supplement the prison diet, it is necessary to purchase food from the commissary. Clothing must also be bought, as well as toothpaste, soap, shaving cream, razor blades, deodorant, etc. All this

> including any minimal amenities such as extra clothing, paper, envelopes, stamps or cigarettes, must be purchased through the prison commissary at inflated prison prices, e.g., at a cost the same as or greater than those charged at private supermarkets. Money for these purchases may be obtained either through prison wages, money from outside sources, the prisoner welfare fund or IDA. It is estimated that costs for such necessary supplies would run a minimum of $11.00 every 2 weeks.[40]

In the absence of financial help from families or friends, prisoners are dependent on prison employment to buy the modest goods which make their lives more tolerable. Some inmates also find motivation beyond immediate gratification in research wages. Mills and Morris cite one inmate's reminder that, after discharge, the state would grant him $50, "enough to buy a gun and a few bullets." However, as a "long-time participant in the Stateville Malaria Project, he will instead take with him about $300 in accumulated research pay, enough he says, to make a fair stake for a new start."[41]

Compounding the financial motivation to participate in medical experimentation is the consistent variation between wages for experimentation and other prison jobs. Although inmate research wages fall far below payment to free living volunteers, they are typically three to five times that accorded other prison occupations.[42] At the Texas State Penitentiary in Huntsville, there is not even a differential. Research subjects get $5 a day compared to no compensation for other prison work.[43]

Furthermore, constraints on the prison job market provide an additional impetus for prisoners to take positions on studies when available. At the Jessup facility, for example, almost one-third of the inmates have no institutional job and are forced to wait up to five months before any job is available.[44]

The impact of the monetary reward on inmate participation is unmistakable. The key issue is determination of the point at which just compensation ends and coercion begins within the unique prison environment.

Two major criticisms surround present payment practices. Interestingly, the obvious solutions to each exacerbate the other problem.

First is the criticism, alluded to earlier, that the manufacturers are purposefully taking economic advantage of an abject labor pool and profiting from the savings from what would be paid free living subjects. In response to charges of enjoying this subtle subsidy, drug companies have expressed willingness and have, in some cases, paid some additional monies into prisoner welfare funds. However, these contributions do not bring expenditures up to the costs of securing subjects outside the prison and do not accrue directly to the inmates experiencing the risk.

The second contradictory criticism focuses on the wage differential that already exists in many institutions between research compensation and other prison wages. Most observers are agreed that extreme wage differentials favoring research participation clearly amount to coercion. Short of following the novel federal experiment of raising all prison compensation to the minimum wage, solution of one problem will merely exacerbate the other. If experimental compensation is lowered so as to not represent undue inducement when compared to

other prison wages, the presumed subsidy to the manufacturers is increased. If research wages are raised to approximate compensation afforded subjects not in prison, unquestionable coercion on inmates to participate is introduced. Broad ramifications of solutions in this area demand careful consideration of compensation alternatives.

One of the most controversial motivations for inmate participation is the equivocal impact that cooperation has on parole. It appears that growing awareness of prisoners' rights achieved an early victory in at least implicit agreement on the impropriety and coercive impact of predicating early release on research participation. As noted in TABLE I, all states responding to the question of "parole consideration" reported that cooperation had no impact on release policy.

There may exist, however, a great difference between explicitly stated policy and implicit understandings and perhaps actual practice. As M. H. Pappworth points out in his book, Human Guinea Pigs, coercion exists, even if there is not actual relationship, if the link merely exists in the inmate's mind.[45] Miller's interviews with inmates clearly establish that participation is perceived by inmates as germane to their release possibilities. He quotes one inmate to show the disillusionment such intended or incidental deception can cause:

> When I went to the board last time I tol' them I was doing research, but they said they didn't care -- like it wasn't nothin' to them. I didn't dig it man; didn't they want me to ... I mean, wasn't it helping no one?[46]

The reason the parole board did not express approval may have been that it is often a condition of research that no parole consideration be given to participants in such programs. Nevertheless, the statement illustrates the different perceptions of the prisoner, the investigator, and the parole board. Despite the official position the prisoner nevertheless believed that his participation would favorably influence the parole board.

Mills and Morris, in contrast, feel that prisoners "... do not deceive themselves that volunteering has more than marginal influence on their chances for parole. Prisoners tend to see parole decisions as so capricious and unprincipled that participation in medical experiments cannot be a reliable key to unlock prison gates."[47]

Less obvious than these motives of altruism and the concrete rewards of money and parole consideration are two additional groups of motivations for inmate participation. The first deals with secondary tangible benefits and the latter includes the more intangible psychological needs fulfilled by participation.

b. Subtle Motivators - Secondary Benefits

Secondary gains which research subjects enjoy include improved surroundings, better medical care, and enhanced protection from other prisoners. Mills and Morris describe the fringe benefits of participation in Lilly drug studies: " ... a ward without guards as well as cigarettes, books, barbering, craft and hobby materials, color television, exercise rooms, [and] daily rather than bi-weekly visiting privileges...."[48]

Passing a portion of their prison terms in enriched segregated surroundings affords participants protection from the violence which often erupts from the

deprivations of prison life. The amenities that research wages provide combine with more pleasant surroundings to lend a "cooler" demeanor to those on research wards.

The limited medical care available to prisoners in many institutions is believed to encourage participation in research projects. The comprehensive medical attention afforded subjects clearly surpasses the normal care given inmates. Monitoring subjects' physical condition assures investigators valid, reproducible test results and is perceived by inmates as an important benefit of participation.[49]

Little controversy surrounds the impact of these concrete secondary benefits. A good deal of discussion, however, has been devoted to the propriety of inducing participation through the contrast between the research and normal prison environment. John Arnold et al. stress the importance of the inherently "negative" nature of the prison experience as the prime reason prisoners agree to participate in studies regarded by outsiders as wholly unpleasant.[50] Some cite these improvements on the extreme deprivations of prison life as important reasons for continuing or expanding research - thus justifying experimentation on "humane grounds" as Lasagna terms it.[51] Although urging caution, he feels that "until such time as prisons are made more pleasant places in which to serve sentences, the outlawing of properly done research will only make the prisoners' unhappy lot even more miserable."[52]

Others have drawn quite the opposite conclusion. Many, like Claire Cooper of the American Civil Liberties Union, feel offering prisoners a brief reprieve from the banal nature of regular prison life amounts to unfair coercion. She writes that "if a clinic were not a better environment than a cell, prisoners would not want to go into clinics rather than cells." She continues, "...all of the benefits ... would not be benefits if the prison system worked correctly."[53] Critics of these fringe benefits also argue that the palliative role of sporadic, limited improvements will delay much needed prison reforms.

c. Psychological Motivators

Psychological factors influencing prisoner motivation derive from individuals' responses to their social environment and the prison life style. Martin et al. stress the impact of inmates' social network on volunteering motivation: "The decision to participate is made within a social context. Human beings adopt and operate on values and attitudes of the group in which they hold membership."[54] Like any other human environment, the social infrastructure of the prison can dictate inmate reaction to research programs. When leaders within the inmate hierarchy value cooperation, lower-ranking inmates will be made quickly aware that participation is reinforced within the prisoner network. As Martin et al. make clear, the human propensity to organize the social environment does not terminate at the prison wall, but "... a system of privileges and status does operate within the prison itself."[55]

A benefit to the prison administration's objective of enhanced "inmate management" mentioned above is derived from the impact of volunteering on the individual participants. Lasagna concurs with Wells et al.[56] that:

> The prisoner volunteer may also profit considerably from his contacts with the clinical investigator or technical staff, whose relation to the prisoner is likely to be a more cordial and sympathetic one than most of the relationships experienced by the convict in the past, either in or out of prison. The prisoner need not be suspicious of, or antagonistic toward,

> the doctor, who is not a part of the penal system and can serve as a friend or advisor.[57]

Regardless of benefit to inmates from increased contact with the outside world, some see the inherent power differential between inmates and physician-investigators as a coercive influence independent of the benefit of their interaction. Gray stresses the potential impact of the role relationship by quoting Anna Freud's opinion " ... that all doctors use the transferred positive relationships from their patient for their own advantage. The patient is in a state of submission, admiration, obedient to the doctor."[58] The deference prisoners feel toward doctors, then, may contribute significantly to their decision to participate as normal subjects in medical studies. Gray makes clear the ethical implications of such transference. He quotes Blumgart in making an important distinction:

> The doctor-patient relationship has the welfare of the patients as its primary objective and may be characterized as a therapeutic alliance. The experimenter-subject relationship, on the other hand, has the discovery of new knowledge as its primary objective and may be termed a scientific alliance.[59]

This difference can result in an investigator gaining consent, in part, due to a trust based on a presumed role he or she is not necessarily fulfilling at the time.

Internal psychodynamics, particularly inmate responses to the boredom of prison life, are believed to play an important role in prisoner motivation. John McDonald's[60] findings, based on his own experience with prison research, show prisoner motivation to be based on "thrill-seeking." Prison life is clearly boring and routine. Research participation, even when the dangers are clearly understood, offers an opportunity to engage in an activity not available to all. Several studies, including Reznikoff's[61], have shown that prisoners magnify the harmful aspects of tests in order to make them sound more daring and exciting.

Some believe this risk-taking reinforces the negative self-concept of many convicts. Particularly when the tests are painful or dangerous, it is assumed that some prisoners are seeking gratification of their desire to be punished. Others see the motivation as a constructive one based on a sincere desire to help humanity and thereby enhance personal esteem. Wells et al. in their complex study of the psychological characteristics of prisoner-subjects, reported enhanced self-esteem as the most significant change in self-perception among volunteers.[62]

A related and perhaps more basic benefit to inmates within the routine of prison life is the decision making opportunity afforded by research participation. Inmates are allowed almost no meaningful options in their daily lives. Yet a decision to take part in a study can appreciably change the nature of their day-to-day lives. It is believed that the mere exercise of an option holds an allure for an individual who is submerged in monotony. As one inmate writes,

> Medical research is one of the very few free choices a man has in prison. Where every action is governed by a mass of rules and regulations ... he is allowed ... to pursue a program that benefits society, his family and himself.[63]

A final psychological need motivating participation was explored by Wells et al. in their comparison of prisoner groups which opted for placement on drug and "social interest" studies. They found that 36.3% noted a specific interest in a

drug experience as contributing to their decision to take part in the pharmaceutical study. Components of this category of motivation included "curiosity about the drug," "desire for drug effects in general," and "gain greater insight into own drug problems." The authors feel that this desire to participate in drug studies is evidence that many formerly addicted inmates are attempting to change their attitudes toward drugs.[64] Regardless of intent, curiosity about drugs, no doubt, contributes to the decision of many inmates to volunteer for pharmaceutical studies.

d. Risks

Personal risks to inmates vary widely with the experiment. Publicized "horror stories" have confirmed the exposure of prisoners to life-threatening risk in isolated cases and have inspired investigation of the propriety of such experimentation. Such isolated cases, however, contribute nothing to our knowledge of general patterns. What little is known about the physical risks experienced by inmate subjects is often guarded either by manufacturers or the FDA.

Enough anecdotal material exists, however, to confirm that prisoners clearly have been exposed to physical discomfort, if not permanently debilitating injury. While many are concerned with the possible physiological ill effects of experimentation, others, such as Mitford, fear more for the psychic costs to prisoners. This concern is seen in her description of the inmate subject: "Systematically impoverished by his keepers, denied a decent wage, the prisoner is reduced to bartering his body for cigarette and candy money."[65] The psychological costs of imposing ill-defined risks on one's health for any of the motivations mentioned will never be accurately measured but should be considered in a general way in any risk-benefit analysis.

e. Prisoner Attitudes

All of the benefits and risks noted in the preceeding pages are known and evaluated, even if subconsciously, by individual prisoners. Unquestionably enough prisoners respond favorably to keep research programs flourishing in some institutions. However, adequate information on prisoner attitudes is not available. Apologists find articulate prisoner advocates and point to expressions of favorable inmate attitudes, such as a majority letter sent by inmates of a Lancaster County, Pennsylvania, prison expressing their displeasure with a moratorium on experimentation.[66]

Although some prisoner advocates, such as members of the American Civil Liberties Union's Prison Project have been outspoken opponents of experimentation, others have equivocated. Conner Nixon, speaking as a representative of the 13,000-strong Prisoner's Union, would go only so far as to demand the removal of corrections department control over research programs. He noted at the Pharmaceutical Manufacturers Association - National Council on Crime and Delinquency (PMA-NCCD) Conference., "We advocate a cooperative control over the medical delivery and research between the recipient of the medical delivery and the local medical communities, without any intervention of the corrections department."[67]

Wells et al. are able to document many benefits to prisoners from medical experimentation. Yet, when given a chance, 41.7% of their volunteers resigned from the drug study preferring to participate in the "social interest" alternative study.[68] In spite of many secondary psychological benefits to volunteers, the decision of almost half the inmates to be taken off the medical study when given the option is illustrative of the power of restricted choice in volunteer behavior.

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These findings do confirm inmates' desire to take part in research, but they also attest to many subjects' ability to discriminate among preferable risks.

B. Informed Consent in a Coercive Environment

"Informed Consent" is central to any justification of medical experimentation on prisoners or other subjects." Gray writes, " The concept of informed consent obviously contains two elements. There must be a free decision that is based on adequate information."[69]

1. Information - Comprehension

Critical risks and benefits converge on the individual, and the potential subject must make a theoretical calculation. As Beecher points out, "The gain anticipated must be commensurate with the risk involved." Such calculations even on the informal, subconscious level where they usually occur, must be based on a measure of comprehension which approaches the loose standard of "informed consent."

Failures in communication of experimental information to research subjects are due to inadequacies of both subjects and investigators. Among hospital research subjects Schultze et al.[71] found only 52% to be adequately informed about the benefits and risks of their participation. Volunteer failure to understand potential risks and benefits is particularly notable in prison settings. It is claimed in the ACLU suit that 60% of the Jessup inmates are "functionally illiterate."[72] Not only are inmate populations characteristically undereducated, but, as Heller points out, it is highly problematic that anyone lacking a Ph. D. in biology would be capable of comprehending the research protocols.[73] Prisoners are also unlikely to demand clarification of particular aspects of research studies. As Wells et al. summarize:

> They are reluctant to admit to an interviewer that they have not understood even rudimentary clinical language he has employed, that they have not been able to read a document he has placed before them, that they are so ignorant of bodily functioning and anatomy as not to grasp even the elementary medical realities involved and that their memory of what they are hearing may be so meagre as to be almost completely nonretentive.[74]

Investigators should be aware of the pressure that role differences, between themselves and undereducated inmates, impose on those potential subjects. This failure of researchers to bridge social, educational, and racial gaps is further complicated by the tendency of many investigators to minimize or euphemize the potential ill-effects of the experiments. Other investigator tendencies may also play a part. Researchers may place too great a stress on the altruistic benefits of the research or may introduce a threat of exclusion if the inmate persists in questioning. Miller records this inmate account of the informed consent procedure:

> 'This doctor, I think he was, asks me to sign the 'release' and I say could I read it, and he says, there's a long line of guys waiting and if I want to read it, it's perfectly all right, but I'll have to get out of the line and take it back to the cell. Then if there is any room next week, I might be able to get on it. I need the dough, so I signs it.'[75]

Investigator breakdown in communication of the relevant data to subjects can also occur in the most scrupulously designed procedures when there is a division of labor and delegation of research responsibilities. When assistants obtain the "informed consent," a conscientious principal investigator may utilize subjects who are quite uninformed about the research risks and purposes.[76]

Although Gray contends that the presence of some well-informed volunteers in his hospital study shows informed consent to be a realistic goal, his own data along with that of others show that truly knowledgeable consent is a rarity under current procedures.[77] Martin et al. report that prisoners in a Missouri prison who signed malarial study consent forms and were given additional study information knew no more about the study than those who were not exposed to the information.[78] Wells et al. note that, after two weeks, only 6.2% of their inmate drug subjects could recall all of the intended uses of the drug and only 12.5% could recall all of the side-effects of which they had been warned.[79] Present procedures clearly are insufficient to meet a minimal standard of subject understanding of the risk-benefit trade-offs which influence responsible decisions.

2. Conceptions of Freedom

Jessica Mitford introduces the second critical aspect of the viability of informed consent: "Is not free consent by a prisoner a contradiction in terms?"[80] Some clearly answer an unqualified "yes." They contend that free choice is absolutely precluded in an environment which was designed to deny freedom and operates by force and submission.

Such arguments are, at least in part, based on a belief that "freedom" does exist outside the prison setting, that man, without the duress of the state, is capable of operating as a free agent. Lasagna argues for a more relativistic conception of human freedom: "It has been argued that the prisoner is 'captive' in a special sense, but is not the person in need of money a captive to poverty?"[81] In behavioral terms, all human action is determined by the contingencies of different decisions, as perceived by the actor. All people, prisoner or free-living, respond to specific sets of necessities. The students' desire for good marks from their experimenter-teacher or the clinic volunteers' desire for $20 may have as much or more power to make them act against their own physical self-interest as $2 and use of a color TV can to a prisoner.

3. Research Impact

A further difficulty with the informed consent prodedure is the impact that information about expected medical effects may have on the data that the subject ultimately reports. Traditional research methodologies have called for "blind" and "double-blind" studies which preclude the possibility that suggestibility or transferred expectations will influence and bias the research results. These methods of avoiding biased results depends, of course, on withholding information about the nature and purpose of the study and possible risks from the subjects. Courts have found, however, that the needs of the researcher may not supercede the rights of subjects to make truly informed decisions with regard to their own bodies.[82]

IV. Regulation of Experimentation

A. Traditional and New Regulatory Mechanisms

The regard that society accords each individual member has an unmistakable impact on the nature and quality of society as a whole. Care must be taken that moral considerations do not succumb to the scientific needs of progress. In spite of the profound, though subtle, societal risk inherent in decisions regarding human experimentation, regulation was long the sole province of the experimenter. In spite of growing governmental regulation in recent years, many still feel intra-experimenter control to be the most reliable. John Romano, recalling his own experience in human experimentation both as subject and experimenter, contends that the moral principles of the investigators afford greater protection to the subject than specific governmental regulations. He argues that "there may have been certain waivers or forms that touched on consent, but I do not remember them playing a very great part in our studies. Whatever we did to others, and whatever we had done to us, I believe we were guided by the traditional ethical principles of medical practice with which we were acquainted, particularly primum non nocere, in the first place, do no harm, and by the great wisdom of the Golden Rule."[83] In agreement with Romano is Frank Ayd, Jr., who argues that breaches in ethics have been few. He notes, "There is no ethical problem associated with drug studies in prisons that cannot be overcome by the assiduous efforts of a responsible clinical investigator..."[84] Ayd argues that the concept of "peer review" is untenable because no one is really qualified to make judgements about the ethics of a research experiment save the experimenter himself. He quotes Beecher's dictum that " 'A study is ethical or not at its inception.' This being so, it is obvious that only the clinical investigator can assure that a trial is ethical."[85]

Beecher defends experimenter regulation of research propriety but not on the basis of an unblemished record. In his research, he reviewed 100 human experimentation projects. His objective was to evaluate the protections afforded research subjects. In 12 of the 100 experiments Beecher found a gap between ethical ideals and the actual practices of researchers. The remedy he proposed, however, was not increased governmental regulation, but an appeal to the medical profession to put its own house in order.[86]

Other commentators presented with similar findings have come to quite different conclusions. For example, Bernard Barber et al. in their book entitled Research on Human Subjects report a study of the responses of clinical investigators to a set of hypothetical experiments posing ethical dilemmas.[87] Several cases posed to the investigators involved varying degrees of risk to the subjects and varying degrees of potential gains in medical knowledge. Each of the investigators, using his or her professional judgement, was asked to assess the advisability of each experiment. Barber found, to his surprise, that many researchers favorably viewed studies which promised information of only marginal value and represented substantial risk to the subjects. As a result, Barber concluded that there are two patterns of investigator behavior: a "strict" pattern of ethical standards in which the researcher refuses to conduct experiments which do not protect the rights of the subjects and a "more permissive" pattern in which the knowledge (or, in some cases, the increased prestige of the investigator) to be gained from the experiment is used to justify questionable research protocols. He estimated that the number of researchers whose standards were "more permissive" was as high as 28% of those undertaking human experimentation projects.[88]

Improving an ethical review system completely dependent on investigator discretion would be quite difficult. As Gray notes, "Social control is an interesting problem in the professions, because these occupations are characterized by a particularly high degree of autonomy."[89] He is pessimistic about the utility of ethical training as a tool to more reliable investigator safeguarding of the rights of subjects.[90] Gray believes "honest, conscientious, compassionate" physicians have been led to behave contrary to their own ethical standards because of defects in the system itself.

Alexander Capron goes even further in his belief that " ... it is doubtful that even with review by professional colleagues, they [researchers] have the proper capability or authority to weigh all the societal benefits against the costs or consequences involved in their research. Thus, it is not only appropriate but very necessary that the United States Congress take part in answering a fundamental question: 'When may a society, actively or by acquiescence, expose some of its members to harm in order to seek benefits for them, for others, or for society as a whole?'"[91]

In spite of the controls on human experimentation suggested by the Nuremburg Code, the U.S. Congress and administrative agencies were slow to act. As the Code lacked enforcement mechanisms, little change occurred for almost two decades outside of calls for internal house cleaning. Finally, in 1966 the U. S. Public Health Service adopted institutional review requirements in the conduct of Public Health Service sponsored research. However, hearings before the Senate Subcommittee on Monopoly[92] in 1969 and the exposure that year of the unethical practices of Austin Stough made apparent the need for further governmental intervention.

In 1971, the Department of Health, Education and Welfare published an "Institutional Guide to DHEW Policy on Protection of Human Subjects."[93] All institutions receiving funds from DHEW were to be required to follow the guidelines in the design and conduct of experiments. The principal protections derived from the use of consent forms for all subjects and a requirement that all research protocols be subjected to peer review in order to insure compliance. Peer review committees were to be comprised of members of participating institutions. These guidelines, however,merely expressed Departmental policy.

Regulations were finally issued in 1974 governing experimentation on general populations and requirements proposed for research on special subjects including prisoners.[94] Under the proposed regulations, organizational review committees are called upon to carry out additional duties including investigating undue inducements to participation and "'taking into account such factors as whether the earnings, living conditions, medical care, quality of food, and amenities offered to participants would be better than those generally available to prisoners.'" They are further to assure that levels of compensation do not exceed other employment possibilities and that withdrawal from a study for medical reasons does not result in loss of anticipated wages.[95]

The National Commission on the Protection of Human Subjects,established in July 1974 by Public Law 93-348 Title II, represents a commitment by Congress to play a constructive role in the development of DHEW's policy regarding experimentation on special populations, including prisoners. This Commission is expected to review and suggest improvements upon the 1974 proposed regulations.

Congressional action in creating the Commission appears to represent only the beginning of legislative involvement. Most definitive of proposed actions is a

bill, H.R. 16160, introduced by Congressman Parren Mitchell in July 1974, which would forbid all experimentation on federal prisoners.

B. Problems with Current Policies and Suggestions for Improvement

Much of the criticism surrounding current regulatory mechanisms focus on methods of "peer review." Research instigated by academic investigators is first submitted to Human Experimentation Committees on the investigator's campus. Here, advantages and disadvantages of research can be openly and informatively discussed. Prison review committees, mandated in the 1974 proposed regulations, can expect greater problems, for open discussion is not ordinarily a feature of prison life. Moreover, medical expertise is generally scarce. Rarely will prison personnel be able to comprehend the scope and implications of a given research protocol sufficiently to address critical questions. The Council of Health Organizations states the dilemma: "It is unclear who on the staff of a prison, for example, is a 'peer' of the investigator. In our view, to speak of a 'peer group' in a prison is a non sequitur."[96]

Other critics of current practices see the initial review process as far less essential to the assurance of ethical practices than adequate means of continuous review or monitoring. Gray points out the tendency to ignore this monitoring aspect while placing too much reliance on the initial professional review because "... funding is contingent primarily on the first stage. Since funding is less likely to hinge on the continuing review, a committee of busy people is less likely to find sufficient time to police the conduct of its peers."[97] Gray concludes that "...prior review is not effective in assuring ethical behavior in clinical investigation, particularly with regard to informed consent."[98] Gray suggests in a later work that review committees initiate a registry of research subjects and periodic sampling of subjects to test their informed consent.[99] The shortcomings of exclusive reliance on initial protocol review which Gray found within a hospital setting could only be compounded within prison walls. He, like Lasagna, asserts that initial review must combine with a regular monitoring process to assure that the subjects understand the risks, benefits, and alternatives, and that they feel free to decline participation.

Another problem inherent in the consent procedure and noted above is addressed in the PMA-NCCD Proceedings.[100] In response to the informational deficit resulting from the poor retentive ability of many subjects, conference participants suggest providing inmates with a copy of the consent form including sponsors, purposes, and names of the review committee members.

Broader, systemic innovation is also proposed by the conferees[101] and by Mills and Morris. All support broad institution of a no-fault compensation system similar to that established in Washington State. This insurance pool would assure compensation for any medical expenses or for decreases in earning capacity which arise out of research participation. As Mills and Morris note, "The prisoner may properly volunteer to bear the physical risk, but he should not be expected to volunteer to bear the economic risk."[102]

Another suggestion is Beecher's notion that those who publish the results of medical experimentation on human subjects should play a larger role in weeding out research based on inappropriate methodologies which are disrespectful of the rights of subjects. Beecher feels journal reports should include assurances that ethical proprieties have been observed.[103]

Although many commentators have put forward specific procedural recommendations, none noted above has proposed broad conceptual change of prison research policies, short of absolute prohibition. Hans Jonas' philosophical approach to human experimentation contributes a unique reassessment of defensible conditions under which an individual should be exposed to risk for the good of society. He points out that, at best, the imposition of a request to "volunteer" introduces an element of conscription which precludes truly voluntary action.[104] To Jonas, experimental subjects presenting the least ethical problems would be those who share the goal of advancing medical science. Noting the numerical limitations of the scientific community, he then asserts that "...one should look for additional subjects where a maximum of identification, understanding, and spontaneity can be expected—that is, among the most highly motivated, the most highly educated, and the least 'captive' members of the community."[105] This novel inversion of the documented tendency to select the most vulnerable individuals as research subjects represents a conservative standard, admittedly close to the old conception of noblesse oblige. Whether such a high standard of subject selection is practical remains quite problematic. Jonas makes clear, however, the moral impediments that are introduced as one moves away from this ideal in subject selection: idealism is transformed to docility, high-mindedness to compliance, and judgment to trust. Jonas' challenge to avoid docile, compliant, trusting subjects may be unrealizable in a pure form, but it contributes a valuable new approach to structuring defensible conditions for experimentation on inmate populations.

The only other novel conceptual approach suggested in the literature is a brief suggestion in the PMA-NCCD Proceedings that penal institutions be evaluated for their provision of "....adequate facilities to handle the risk" of experimentation.[106] This germinal notion, though lost in a multitude of piecemeal approaches, represents a major step toward conceptual revision of this present regulatory system. We expand upon it in our proposal of "inversive risk-rating."

V. Inversive Risk-Rating -- A New Conceptual Framework for Policy Choices

Concentration on the risk inherent in the experiment and the conditions in the penal institution offers much more than just another layer in a complex of regulatory safeguards. This dual focus forms the basis of a comprehensive regulatory approach.

The intent of the proposed "inversive risk-rating" system would be to assure an inverse relationship between the physical risk imposed by a given experiment and the "risk of ethical impairment" which is inherent in the conditions of a given penal setting. Both experiments and institutional settings would be classified or rated as to risk. The more the characteristics of an institutional setting compromise the inmates' exercise of free and informed discretion over their participation in research, the lower the risk of experiments which would be permitted there. Conversely, the more closely institutional conditions approximate conditions outside the prison, the higher the risk of experimentation permitted.

The proposed system of "inversive risk-rating" avoids questionable inquiries into individual motivation and removes from consideration equally speculative statements regarding expected societal benefits. It considers only two kinds of risks: the physical risk to subjects of a given experiment and the "risk of ethical impairment," that is, impediments to free and informed decision making imposed by the penal environment.

"Inversive risk-rating" offers policymakers a defensible basis for compromise between the extreme apologists and critics of prison experimentation. It provides a consistent ethical basis for policy based on specific, objective institutional characteristics. Concrete standards can be developed and translated into statutory and regulatory language.

A. The Need for a New Conceptual Scheme

The need for a new conceptual approach follows the failure of other regulatory approaches to provide realistic mechanisms for control of prison experimentation. One common analytical approach addresses the issue of informed consent as an individual psychological event. The realization that all the elements of the ethical dilemma converge on the individual and move the potential subject to act in certain ways has led to a good deal of interest in the motivations for inmate decisions.

Most conceivable motivating factors inducing research participation have been described, at least anecdotally. However, empirical assessment of mitigating influences on individual free decision making, as seen in the Wells et al.[107] study, has been fraught with problems. Many opportunities exist for the introduction of bias. The validity of measurement devices within the prison environment are questionable. Further, the idiosyncratic character of the influences on each prisoner - in specific penal settings, confronted with specific studies - suggests the dubious value of individual motivational assessment.

Efforts aimed at methodological or procedurel refinement of motivational assessment would provide safeguards against coerced or uninformed participation only through an elaborate, impractical system of testing and monitoring. Elimination of subjects whose motivations fall too far from an acceptable level of free

and informed consent would be a laborious process which could be easily subverted within the social network of the prison.

A second conceptual scheme suggested throughout the literature derives from the economic cost-benefit model. Physical risks are matched with expected scientific benefits in a theoretical calculus which is capable of justifying specific experimental programs.

Further development and formalization of risk-benefit comparisons as a basis for more rational regulation of proper research and subject populations present three problems. First, the existence, nature, and relative importance of benefits are difficult to assess. Just as with the probability of physical harm, the probability of derivation of benefit from experiments is unknown. Benefit calculations are further complicated by differences between benefiting population groups and the nature of the benefits themselves. The number of individuals standing to benefit would have to enter the calculus, as would characteristics of those individuals (e.g., young versus old) and the importance of the contribution (e.g., marketing of life-saving drugs versus cosmetic products).

A second, perhaps more critical problem with the risk-benefit approach is the dubious ethical basis for allowing benefit considerations to dominate a policy calculus. From Claude Bernard[108] to Beecher[109], investigator-philosophers have made strong stands against justification of individual sacrifice on the basis of presumed societal benefits. Jonas adds a new twist by noting the impropriety of imposition of altruistic research motivations on subjects who, though accepting all the risk, may not care to further those societal goals or consider the results as benefits.

Finally, risk-benefit calculations ignore the ethical complexities of singling out population subgroups for study. Inequalities between those exposed to risk and those who stand to benefit deny such comparisons a common denominator. The special ethical constraints of the prison environment introduce additional problems unamenable to simple risk-benefit comaprisons.

The inversive risk-rating system may seem to deprecate the role of expected benefits as a factor in justifying research. This is not the case. No risk to human well-being can be justified without expected benefit to the experimental subject or, with specific qualifications, to others. Review Committees must inevitably assess expected benefit. Nevertheless, the social benefit factor is deliberately omitted from the inversive risk-rating system. Although research may promise important social benefit, it is not, on that ground alone, warranted in prisons. A Review Committee, having satisfied itself that some benefit is possible, must then ask, regardless of this benefit, should this research be conducted within specific correctional modalities? The inversive risk-rating is designed to answer this question.

B. Theoretical Bases

The utility of a conceptual scheme depends upon its ability to organize and apply factual information in the fulfillment of clear policy goals. The policy goal envisioned here is not, in inself, either permissive or prohibitive of prison experimentation. The goal is the adequate protection of human rights. The objective of this formulation is the development of standards which will make it possible to judge whether protection of human rights requires prohibition, or is

compatible with permission of specific experimentation in specific penal settings. The formula, in itself, says neither "yes" nor "no" but merely sets out a procedure for doing so. Two kinds of risks characterize human experimentation. Most obvious are the risks to physical well-being which are inherent in almost every trial of biomedical substances and procedures. These risks would be assigned rankings based upon analogous experience and physiological parameters.

The more subtle risk is the chance that vital moral and legal entitlements of the person could be compromised by the conduct of experimentation. Institutional compromise of these entitlements will be referred to as "risk of ethical impairment." This crucual half of the formulation rests upon a rough standard of "voluntarism." This notion, first explained by Aristotle[10], is the historical basis of our contemporary notion of "informed consent." Two factors compromise voluntarism. The first is coercion, the second ignorance. The influence of coercion or ignorance on approximation to a standard of voluntarism, however, is not viewed as a psychological event, but is inferred from the external features of the environment.

The approach hinges on assessment of evidence of institutional characteristics which may constitute a coercive influence and which may impede the flow of information and its comprehension. Whether they actually do so, in terms of the "psychological acts" of single individuals within the institutions is beyond the scope of evidence, much as in a court of law. It may be presumed, however, that if institutional arrangements can be described as having a high risk profile for ethical impairment, that individuals within the setting are unable to offer "informed consent."

The standard of individual exercise of voluntarism based on evidence derived from institutional arrangements can be described in another way. Voluntarism is enhanced and "risk of ethical impairment" reduced where institutional profiles display greater approximation of the free-living state. The "free-living state" refers to the state in which individuals, for the most part, act at their own discretion. It is obvious that there are many risks of ethical impairment in every human condition. People live within social structures, in accord with social mores, under economic constraints, as objects of a variety of discriminations. However, these behavioral determinants are more the result of a convergence of events or accidents than of planned and purposeful design. In the free world, these influences are less designed, less susceptible to monitoring and control, more readily avoidable accompanied by relatively acceptable alternatives, and entail no inevitable punishments. On the other hand, "risk of ethical impairment" is a deliberately designed feature of penal institutions. Constraints on choice of occupation, free movement, and unhampered information are intrinsic to incarceration.

However, the levels of "risk of ethical impairment" do differ in degree and kind among penal modalities. We suggest, then a method of regulation based on determination of proper risk relationships between the physical risks of the experimentation and the degree to which an institutional profile approximates the free-living state.

C. Application of Inversive Risk-Rating within the Penal Institution.

Experimental and institutional characteristics, germane to the comparative risk-rating system outlined above, present some problems of measurement, but

constitute a realizable methodological task.

1. The Experiment

Experimentation, by definition, involves unknowns. Yet it is clear that any sample of experimental protocols includes a broad range of levels of risk of physical discomfort or harm. Relative risk levels are comprised of two aspects. The first is the severity of the physical trauma which might be imposed on subjects. Probable impairment of physical well-being can vary from minor, short-term discomfort to long-term disability or death. The second aspect to be considered is the probability that these possible negative effects will be experienced by the subjects. For example, most would concur that the risk of driving an automobile is less than the risk involved in the sport of racedriving. Both activities can be life-threatening, but are perceived as having different probabilities of occurrence. These two facets, severity and probability, comprise an often subconscious calculus in any human decision involving risk.

Phase I drug studies are always preceded by extensive laboratory and animal studies. The F.D.A. only approves the initiation of Phase I testing if it is satisfied that the risk of toxic side effects does not exceed a critical level. Yet even when the animal studies have included primate research, much remains unknown because of human idiosyncracies. As a result, physical risk must be evaluated on a relative scale. Until investigators are able to define the severity of side effects and the probability of their occurrence much more concretely, the trade-offs between these aspects of risk will have to remain within the discretion of experienced evaluators.

2. The Institution

Risk of ethical impairment peculiar to specific penal settings derives from characteristics which coerce participation in research or limit the transfer of knowledge necessary for informed decision making. A great deal of variation exists in the institutional influences on inmate behavior imposed by different penal institutions and even within single institutions. The concept of modalities of correctional approach is helpful in sorting out these variations. At the most rigid, coercive end of the spectrum are the maximum security sections or institutions. Minimum security, physically similar to the former but less rigidly structured, represents the next modality, followed by community based "halfway houses" and parole programs at the least coercive end of the corrections spectrum.

Some of the most important coercive influences are the conditions surrounding the monetary reward for participation. Inmates could be expected to exercise voluntarism free from monetary coercion to the extent that parity exists between the compensation for research and other prison jobs. The availability of other work alternatives should be evaluated along with the kinds of goods inmates must provide with their salaries.

Another crucial determination would be the impact of the expectation of parole consideration on inmate behavior. At the most free, noncoercive end of the spectrum are correctional modalities where experimentation is allowed only after parole has been set or where determinate sentencing precludes the impact of parole discretion from influence on prisoners. Parole programs and halfway houses, by definition, eliminate the problem of parole as a motivation and have added benefits in the greater approximation of other elements of the free world which they afford their inmates. Pre-parole penal settings should be evaluated on the basis of their efforts to inform inmates that parole should not figure in their

decisions to participate in research, if in fact it has no impact.

Penal settings should be categorized by differential levels of environmental amenities, medical care, and visitation privileges afforded research subjects as compared to non-participating prisoners. Settings which allow subjects to benefit from equipment and activities unavailable to other inmates in the same correctional modality are admitting additional incentives peculiar to that institutional setting. Levels of access to medical care for all inmates can easily be assessed to determine the coercive impact that better medical care for subjects could impose. Variation between visitation privileges should be recorded along with other secondary benefits provided in experimental programs which are not features of normal prison life.

The second facet of approximation to a standard of voluntarism or the free-living environment concerns the institutional characteristics affecting the transfer of information needed for knowledgeable decision making. Knowledge or comprehension levels, much like psychological components of motivation, are difficult to assess within one prisoner and exponentially impractical on an institution-wide level. In lieu of directly testing each potential subject's understanding of experimental protocols, prisons should be evaluated on the basis of their provision of indirect safeguards against victimization through ignorance. Such safeguards should assure the inmates cannot be bound to agreements that they later determine to be against their own interests. Institutional safeguards could include creation of inmate representatives. Their duties might include monitoring of the informed consent process and evaluating investigator adherence to promised information transfer. Perhaps more importantly, inmate representatives should be available at all times to subjects to answer questions about the experiment and to act as inmate advocates. In settings most closely approximating the free-living world, inmates should have non-punitive procedures available and explained to them whereby they could protest unacceptable practices in experimental protocols and could remove themselves from studies at any time.

Clearly forces other than these institutional characteristics influence inmate participation in research. Sociological and psychological factors, however, produce infinite idiosyncratic variations which are peculiar only to specific individuals within specific social environments. These factors revolve around individual variation, just as in the free world. Because they are not directly related to the nature of the planned prison environment, they are excluded from the evaluative scheme outlined here.

3. Inversive Synthesis of Experimental and Institutional Ratings.

Evaluation of correctional modalities for their provision of these safeguards against the compromise of voluntarism by coercion and ignorance, then, provides a method of rating experimental sites by the amount of risk of ethical impairment imposed on the inmates. Clearly much empirical and conceptual work is needed to develop indices of coercive influences and the quality of procedural safeguards against the impact of subject ignorance.

The innovative contribution of such a classification system is the rationality it provides to the critical trade-offs in decisions regarding research propriety. Assessment of the impediments to voluntarism inherent in a given institutional environment provides at least an ordinal measurement to be compared to the relative level of physical risk imposed by the experiment. The goal would be to establish

an inverse relationship between the risk of ethical impairment in a specific correctional setting and the physical risk imposed by a given experiment. While Jonas[111] proposed subjects be gathered from the most free members of society, this conceptual approach expands such a notion to include the level of physical risk, customizes it to respond to unique features of the prison environment, and simplifies the evaluative method by concentrating on the level of institutions.

The spectrum of proper matchings would begin with permission of experiments imposing no or extremely low physical risk in correctional settings which impose the higher risk of impairment of prisoner voluntarism. As the physical risk inherent in the research increases, a greater approximation of freedom and knowledge would be demanded of institutions conducting such research. Some correctional modalities might be determined too coercive to allow experiments of even the lowest risks; others, like halfway houses, might be found to require no special safeguards beyond those employed in the free world.

This approach allows discrimination within the gray area between the status quo and complete prohibition of prison experimentation. It provides for development of a concrete methodology for determining the propriety of specific research. Ethically acceptable research formats are not rejected out of hand and yet safeguards of prisoners' human right to exercise voluntarism are greatly expanded.

We are aware, of course, that in any such evaluation, judgments about particular trade-offs and cut-off points are value loaded. We do not anticipate neutral data in a value free calculus. We merely wish to propose a system of putting down as many of the factors as possible in such a way as to allow reasoned value judgments.

D. An Agenda for Future Research

The development of a system of inversive risk-rating places a number of items on the agenda for future research. The foregoing pages provide only a sketchy outline; the details need to be filled in through the development of new methodologies and currently unavailable information.

1. A thorough survey should be made of the kinds of medical research undertaken in state and federal prisons throughout the United States. Efforts should be made to develop normative data on the range of physical risks inherent in recent and current experimental programs. Rankings of degrees of risk could then be developed for proposed experimental protocols consistent with past experience and explicit determination of the relative rankings of different kinds of possible physical risk.

2. A survey of types of penal modalities and existing institutional guidelines and practices should be compiled and analyzed as a beginning step toward the institutional component of a risk-rating system. A profile of existing institutional practices should serve to highlight those characteristics of institutions which most obviously pose risk of impairing freedom.

3. Development of a profile of correctional settings, their policies concerning experimentation, and a typology of experiments should be followed by detailed analysis of institutions presently conducting research. Subtleties of the institutional characteristics in the complex prison environment suggest the need for analysis by direct observation.

4. An analysis should be made of the total dollar volume of biomedical research conducted in prisons in the United States. Various funding sources should be identified and an analysis made of the percentage of all costs paid to prisoners as compensation, to prisons as overhead or for physical improvements, and to investigators as compensation. Further inquiry will be needed to develop realistic estimates of the cost of eliminating differences in the amenities provided within research wards and the regular prison environment. Consideration should also be given to means of payment which would eliminate those inducements which impair the exercise of free inmate discretion over their actions.

5. Serious consideration should also be devoted to the most effective and appropriate institutional components to evaluate correctional modalities, define a typology of levels of physical risk, and establish the appropriate relationship between levels of ethical and physical risk. In addition, the proper locus for assessment of the risk inherent in each proposed experiment must be determined.[112]

This "inversive risk-rating" idea is put forward in the hope of bringing the discussion of the propriety of prison experimentation to a level of practical rationality, capable of timely resolution. The present stage of development does not warrant explicit assignment of various responsibilities. Still, decision makers, long concerned with problems in prison experimentation - from the FDA and HEW officials to correctional administrators and academic review committee members - would all have critical roles to play. Policymakers at state, federal and even county levels will hopefully find this initial formulation useful. Timely development of the conceptual and factual details outlined above may bring this scheme to a level of significance for those who must determine the propriety of biomedical experimentation on incarcerated persons.

Footnotes

[1] Louis Lasagna, "Special Subjects in Human Experimentation", in Paul A. Freund, ed., Experimentation with Human Subjects (New York: George Braziller, 1969), p. 262.

[2] Ibid., p. 264 and Bradford H. Gray, Human Subjects in Human Experimentation, (New York: John Wiley and Sons, 1975), p. 9.

[3] Irvin Gilchrist, ed., Medical Experimentation on Prisoners Must Stop! (College Park, Maryland: Urban Information Interpreters, Inc., 1974), p.6. The code provides that voluntary consent to experimentation is mandatory, that experiments be predicated on a clear benefit to society, and that the risk to the subject be minimal.

[4] Newman v. Alabama 349 F. Supp. 278 (1972).

[5] Most recently the American Civil Liberties Union filed suit October, 1974 against experimentation in the Maryland House of Correction in Jessup. The case is chronicled in Gilchrist, op. cit..

[6] Daniel C. Martin, et al., "Human Subjects in Clinical Research - A Report of Three Studies", New England Journal of Medicine, 279 (1968), pp. 1426-31.

[7] Dr. Harry Weller in Proceedings of the Conference on Drug Research in Prisons, ed. by Research Center - National Council on Crime and Delinquency (Davis, California: Pharmaceutical Manufacturers Association and National Council on Crime and Delinquency, August, 1973) p. 191.
Due to typically longer terms in State institutions mobility might be less. No comparative data is presently available.

[8] Ibid., Remarks of Dr. Robert C. Backus, Division of Research Grants, National Institutes of Health, p. 137.

[9] Gilchrist, op. cit., p. 74, Excerpted from "Drug Research Reports". See also The Hastings Center Report, Vol. 5, No. 2 (April, 1975), p.2, for an update on the student volunteer program, financed by a $520,000 contract from NIH.

[10] Charles Fried, Medical Experimentation - Personal Integrity and Social Policy, (New York: American Elsevier Publishing Company, Inc., 1974), p. 63.

[11] Jessica Mitford, Kind and Usual Punishment - The Prison Business, (New York: Vintage Books, 1974).

[12] See Jay Katz, ed., Experimentation with Human Beings, (New York: Russell Sage, 1972) pp. 1016-18.

[13] Herman L. Blumgart in Freund, op. cit., p. 44.

[14] Proceedings ..., op. cit., pp. 12-13.

[15] Interview with T. L. Clanon, M.D., Superintendent, California Medical Facility, Vacaville, California.

[16] Gilchrist, op. cit., p. 8.

[17] Ibid., p. 37.

[18] Jessica Mitford, "Experiments Behind Bars - Doctors, Drug Companies and Prisoners." Atlantic Monthly, Vol. 231, No. 1 (January 1973), p. 65.

[19] Ibid., p. 69.

[20] Clanon, op. cit.

[21] Mitford, "Experiments ...," p. 71.
See also The Hastings Center Report (April 1975), op. cit., reporting $20 wages to students in tests comparable to these for which Gilchrist, op. cit., p. 15, reports prisoners receiving $2.

[22] Alvin J. Bronstein (Director of the ACLU National Prison Project), in article by Victor Cohn, Washington Post (February 20, 1975), p. 3.

[23] Mitford, "Experiments ...," p. 69.

[24] "Medical Research on Prisoners: Recent Developments No. 1," Clearinghouse to End Medical Experimentation on Prisoners, (College Park, Maryland, Urban Information Interpreters, Inc., January 1975), p. 2.

[25] Fried, op. cit., p. 63.

[26] Peter B. Meyer, Medical Experimentation on Prisoners: Some Economic Considerations (Washington D.C., American Bar Association, 1975) p. 42.

[27] Mitford, "Experiments...," p. 71.

[28] Acknowledged by Mr. Ralph Urbino, Administrative Director of the Solano research facility at Vacaville, California, to run approximately $32,000 a year. Cited in Mitford, Ibid., p. 71.

[29] Michael Mills and Norval Morris, "Prisoners as Laboratory Animals," Society 11-5 (July/August 1974), p. 61.

[30] The size of these contributions can be seen in the California figures noted on page 8.

[31] Mitford, "Experiments ...," p. 72.

[32] Stephen H. Wells, Patricia M. Kennedy, John Kenny, Marvin Reznikoff and Michael H. Sheard, Pharmacological Testing in a Correctional Institution, (Springfield, Illinois: Charles C. Thomas, 1975), p. 47.
See also Marvin Heller, "Problems and Prospects in the Use of Prison Inmates for Medical Experimentation," Prison Journal 47 (Spring-Summer 1967), pp. 21-38, for a cogent presentation of the positive contribution of research to the atmosphere of a prison.

[33] Quoted in Gilchrist, op. cit., p. 6.

[34] Lasagna in Freund, op. cit., p. 274.

[35] D. C. Martin, J. D. Arnold, T. F. Zimmerman, and R. H. Richart, "Human Subjects in Clinical Research - A Report of Three Studies", New England Journal of Medicine 26 (1966), p. 1428.

[36] Gray, op. cit., p. 128.

[37] Wells et al., op. cit., pp. 34-37.

[38] Martin B. Miller, " Manipulation of the Disenfranchised; Some Notes on the Ethical Dilemma of Experimentation with Prisoner-Subjects", unpublished paper, UC Berkeley, 1970.

[39] Ibid, p.2.

[40] Appended to Gilchrist, op. cit., p. 103.

[41] Mills and Morris, op. cit., p. 65.

[42] "Medical Research ... Recent Developments", op. cit., p. 4.

[43] Ibid, p. 64.

[44] Cited in the ACLU suit, appended to Gilchrist, op. cit., p. 103.

[45] M. H. Pappworth, Human Guinea Pigs: Experimentation on Man (Boston: Beacon Press, 1968), esp. pp. 60-68.

[46] Miller, op. cit., p. 5.

[47] Mills and Morris, op. cit., p. 64.

[48] Ibid., p. 61.

[49] See letter of inmate Frank Hatfield to the Journal of the American Medical Association, Vol. 222, No. 13, (September 23, 1974), p. 1721.

[50] John D. Arnold, et al., "A Study of One Prison Population and Its Response to Medical Research", in Irving Ladimer, ed., New Dimensions in Legal and Ethical Concepts for Human Research, in Annals of the New York Academy of Sciences 169 (January 21, 1970), pp. 463-470.

[51] Lasagna in Freund, op. cit., p. 265.

[52] Letter of Louis Lasagna in Journal of the American Medical Association, op. cit., p. 1720.

[53] Claire Cooper, in Proceedings ..., op. cit., p. 146.

[54] Martin et al., op. cit., p. 1430.

[55] Ibid., p. 1427.

[56] Wells et al., op. cit., p. 53.

[57] Lasagna in Freund, op. cit., p. 265.

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[58] Gray, op. cit., p. 88.

[59] Ibid., p. 224.

[60] John McDonald, "Why Prisoners Volunteer to Be Experimental Subjects", Journal of the American Medical Association 202 (1967), pp. 511-512.

[61] Marvin Reznikoff et al., "Pharmacological Testing in a Correctional Institution: Volunteer Characteristics and Motivations/Social Psychological and Attitudinal Implications", unpublished manuscript, 1973.

[62] Wells et al., op. cit., p. 41.
15.2% of the drug volunteers studied scored increases in their self-esteem. For a summary of psychological characteristics see p. 23.

[63] Frank Hatfield in Jama, op. cit., p. 1722.

[64] Wells et al., op. cit., p. 34.

[65] Mitford, "Experiments ...", p. 72.

[66] Noted in Mills and Morris, op. cit., p. 63 and The Hastings Center Report, Vol. 3, No. 3 (June, 1973), p. 5.

[67] Conner Nixon, remarks in Proceedings ..., op. cit., pp. 158-159.

[68] Wells et al., op. cit., p. 33.

[69] Gray, op. cit., p. 204.

[70] Henry K. Beecher, "Ethics and Clinical Research," New England Journal of Medicine, 274 (1966), p. 1360.

[71] Amelia L. Schultze, Geraldine P. Pardee, and John W. Ensinck, "Are Research Subjects Really Informed?", The Western Journal of Medicine 123 (July 1975), p. 78.

[72] Appended to Gilchrist, op. cit., p. 108.

[73] Melvin Heller, "Problems and Prospects in the Use of Prison Inmates for Medical Experimentation", Prison Journal 47 (Spring-Summer 1967), pp. 21-38.

[74] Wells et al., op. cit., p. 49.

[75] Miller, op. cit., p. 3.

[76] See Gray, op. cit., p. 214

[77] Ibid., p. 243.

[78] Martin et al., op. cit., p. 1427.

[79] Wells et. al., op. cit., pp. 50-51.

[80] Mitford, "Experiments ...", p. 63.

[81] Lasagna in Freund, op. cit., p. 268.

[82] See Hyman v. Jewish Chronic Disease Hospital 251 N.Y.S. 2d 818 (App. Div. 1964). Also Little, "Experimentation with Human Subjects," Atomic Energy Law Journal 13 (Winter 1972), pp. 305-329.

[83] John Romano, M.D., "Reflections on Informed Consent", Arch. Gen. Psychiatry 30 (January 1974), p. 130.

[84] Frank Ayd, Jr., "Drug Studies in Prisoner Volunteers," Southern Medical Journal 65 (1972), pp. 440-44.

[85] Ibid., p. 440.
Beecher's contention was that studies had to be ethical in themselves. The discoveries that result from an experiment could not make the experiment "ethical post-hoc - ends do not justify means." (Beecher, op. cit., p. 1360).

[86] Beecher, "Ethics and ... Research", pp. 1059-67.
See also Amitai Etzioni, "Regulation of Human Experimentation", Science 182 (December 21, 1973), p. 1203.

[87] Bernard Barber et al., Research on Human Subjects (New York: Russell Sage, 1973).

[88] Ibid.

[89] Gray, op. cit., p. 6.

[90] Ibid., p. 247.

[91] Alexander Capron, "Medical Research in Prisons - Should a Moratorium Be Called?", The Hastings Center Report, Vol. 3 No. 3 (July 1973), p. 4.

[92] Hearings Before the Subcommittee on Monopoly of the Select Committee of Small Business United States Senate (91st Congress), First Session on Present Status of Competition in the Pharmaceutical Industry - Part 14, June 19, August 7 & 12, 1969.

[93] U. S. Department of Health Education and Welfare, "Policy on Protection of Human Subjects," (DHEW Pub. No. NIH 72-102, Washington D.C. GPO, 1971).

[94] HEW "Protection of Human Subjects - Proposed Policy," Federal Register, Vol. 39, (August 23, 1974).

[95] Cited in "Medical Research...Recent Developments", op. cit., pp. 7-8.

[96] Council of Health Organizations, "Comments on Proposal for Peer Group Committee Review of Clinical Investigations of New Drugs on Human Beings," reprinted in Katz, op. cit., pp. 904-5.

[97] Gray, op. cit., p. 16.

[98] Ibid., p. 250.

[99] Bradford Gray, "An Assessment of Institutional Review Committees in Human Experimentation," Medical Care, Vol. 13 No. 4 (April 1975), p. 326.

[100] Proceedings ..., op. cit., p. 21.

[101] Ibid., p. 17.

[102] Mills and Morris, op. cit., p. 65.

[103] Beecher, "Ethics and ... Research, " p. 1360.

[104] Hans Jonas, "Philosophical Reflections on Human Experimentation," in Freud, op. cit.

[105] Ibid., p. 18.

[106] Proceedings ..., op. cit., p. 61.

[107] Wells et al., op. cit.

[108] Claude Bernard, quoted in Henry K. Beecher, Research and the Individual - Human Studies (Boston: Little, Brown and Company, 1970), pp. 80-81.

[109] Ibid.

[110] Aristotle, Nichomachean Ethics III, Chapter 2.

[111] Jonas, in Freund, op. cit., pp. 18-19.

[112] Though external to the regulatory approach outlined here, some thought should also be given to the duties and responsibilities which follow from the societal subsidy to manufacturers. Meyer has noted, "the grant of a subsidy to entities which are not a part of the corrections process is not inherently an inappropriate course of action for the corrections systems of the nation to take. However, any such subsidy should be scrutinized." (Meyer, op. cit., p. 45) Perhaps manufacturers should be required to make public the results of each study benefiting from public institutions. Perhaps the subsidy should be removed to allow fiscal pressures to discourage any unnecessary research on prison populations. This subsidy clearly supplies a leverage point which effective public policy should utilize to assure societal benefit from prison research and compliance with ethical standards.

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On Jan. 6–8, 1976, the First National Minority Conference on Human Experimentation was sponsored by the National Urban Coalition under a grant from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. More than 200 scientists, government officials, concerned lay persons, and civil rights leaders met for a series of workshops on the subject of human experimentation and its effects on minorities. Their recommendations will be presented to the National Commission. The following materials represent the statements and recommendations of the various workshops, as well as the summary reports and a conference paper on prisons.

Summary Report and Recommendations on Prisons

National Urban Coalition, President—M. Carl Holman,

National Minority Conference on Human Experimentation, Conference Chairman—David A. Browne; Conference Director—Geraldine Brooks; Assistant Director—Evelyn Armstrong; and Secretarial Staff—Joann Hysan/Patricia Lightfoot.

This report was prepared by the NMCHE staff.

Introduction—Summary of Plenary Sessions

The attached summary represents a comprehensive, but far from complete, survey of the papers, plenary sessions and workshop tapes relative to prison research. Due to time constraints on staff in an auditing of the tapes and review of the papers, we would like to apprise the Commission that we regard this as still not as comprehensive a report as desirable. Without a personal audit of the actual tapes, it is difficult, if not impossible, to get a true picture of the sessions involved. We would recommend, therefore, that we have these tapes professionally transcribed for your further review.

Participants—Plenary Session—Prisons

Moderator—Professor Heywood Burns, J.D., NYU Law School, New York, New York; Presentors of Papers—Joyce Cooke, Ph.D., Department of Philosophy, Howard University, Washington, D.C.; Larry I. Palmer, J.D., Cornell University Law School; L. Alex Swan, Ph D., J.D. Fisk University, Nashville, Tennessee; Respondents—Lewis Douglas, Executive Deputy Commissioner Corrections, State of New York; Richard "Mafundi" Lake, Director IFA Defense Committee, former inmate Alabama Prison System; and Frank Pogue, Ph. D., Professor Department Chairman, State University of New York at Albany.

Summary of the Plenary Sessions and Workshop Sessions

Use of prisoners in human experimentation

A careful and thoughtful perusal of the papers presented before the plenary session on research in prisons allows the reader the opportunity to appreciate the excellence of these in-depth, scholarly pieces of work. A review of the workshop recommendations made to the Commission on this subject provides a tense, concise set of guidelines designed for action rather than philosophical discussion. However, listening to the tapes made during the plenary session—the presentation of the papers and the responses to their delivery—and to the following workshop sessions provide the auditor with the real essence of the problem of human experimentation in prisons. No other medium has captured the interplay of diverse ideas, the diversity of the Conferees, the final symbiosis achieved.

Debate ranged from the complete abolition of the prison system to a more realistic—and hopeful—change through government intervention and the eventual establishment of a national model for research design. Between these extremes, even without lengthy discourse on the more horrendous examples of abuse in prison-based experimentation, there appeared a serious concern for the moral and civil rights of this captive/coerced subject group and the minority population which they represent; an immediate need for a research moratorium to investigate and evaluate both behavioral and biomedical research in the prison setting; and the establishment of permanent safeguards for prisoner-experiment subjects.

There are basic ethical considerations about the prison system in society and the relationship betwee the needs of the state and the prison system. Experiment subjects are viewed as not only subjects of research but subjects of the state; that the imposition of the will of the state is an imposition on the will of the subjects. The relationship of the issue of race, religion and nationality and scientific experiments on human beings looms large because of the Nazi concentration camp experiments on captives during World War II. Since there is a disproportionate Third World representation in prisons today, it is agreed that the issue of prisoners and race are merged. It is unethical to ask minority prisoners to bear the greater portion of risk when benefitting society at large. Any required risks should be evenly distributed in the prison society itself as well as among all ethnic groups is society.

There appears to be an obvious correlation between human research in prison and the kind of health care services available to those people who usually become prisoners: the poor and the minorities. The lack of adequate health care delivery to this widespread population, therefore, must bring up the question of the fine line between research and treatment. As this inadequacy is shared by the poor, both in and out of prison, it is felt that the two concerns cannot be separated; that prisoners and the poor share the same inducements, the same lack of knowledge, the same lack of legal redress as research subjects. That, in fact, the poor are the same victims as the prisoners in human experimentation.

The principle of informed consent, first formulated in the Nuremberg Code spells out requirements governing medical experimentation on human beings. This principle is of paramount importance to the legality of using prisoners as subjects. A basic tenet of the Code states: "The *voluntary* consent of the human subject is absolutely essential." The prison environment, regarded as intrinsically coercive, casts serious suspicion upon the very concept of authentic consent, insofar as the latter implies autonomy. Few decisions of any nature can be made in the prison setting which are free, which are unpressured, which are informed. Whereas there can be no consent without sufficient information, there can be no consent without willingness. Hence the Nuremberg Code stresses the voluntary nature of consent. Voluntary consent means free and full affirmative judgment. By definition, no informed consent is possible within the context of confinement in prison with its coercive environment as the backdrop of such choices. Without the ethical requirements of informed consent, it is impossible to justify the legal requirements now accepted.

Yet some prisoners insist that they have a legal right to participate in research experiments. Proponents of the establishment of a research model feel that by including prisoners in the complete research process, this facet—as part of the entire research project—can be legitimized. The prisoner as volunteer should be viewed as a participant in the experimentation process from the valuation of the project's purpose, and its risks and benefits, subject selection, project progress review to final evaluation.

Obviously, prisoner participation in the research process is just a portion of future guidelines and safeguards delineated. A general consensus of opinion was voiced for a complete moratorium, rather than a total ban, on research experimentation until a national investigation is completed to determine the nature and current status of all experimental research design. The process of human experimentation and the allocation of public, professional and subject decision-making authority within that process must be understood to avoid the abuses of the past. The policies that determine how and why human experimentation is started is important to the manner in which value conflicts are resolved, whether the process can achieve the desired degree of social control.

A careful examination must be made of the purposes of any research that proposes to involve prisoners as subjects. Other questions to be answered: Are prisoners the appropriate subjects for this particular form of experimentation? What are the societal needs? What are the possible types of risk of harm that may flow and what steps have been taken to minimize those risks of harm? Who sets the priorities of these experiments? Who selects the subjects? Who monitors the project's progress? Who makes the necessary ethical and legal evaluation of the project's outcome?

The major method of reviewing the decisions throughout the process of human experimentation in prisons and the consequences of such experiments is through public scrutiny. Toward the end goal of a national model, it is recommended that a research unit which will affect all funding agencies and all prison administrators and all researchers, composed of inmates themselves and designated persons, should crystalize and set up guidelines for all prison research activities. Every prison experiment must involve a stage where either state or professional participants evaluate the research design and the scientific merits of the project. Before the question of consent is even presented to any prisoners, a host of other issues should be resolved in the formulation of research policy and in the administration of research. All prisons should establish an ongoing, in-house ethics committee to regularly discuss the absence of health care services and misuses on prisoners in biomedical, psychological, criminal and social research. The findings of these committees would act as active control in the process. Further, the process model forces the investigators, sponsoring agencies and prison administrators to articulate their own values about the purpose of incarceration, use of experimentation as a part of this purpose and the use of the incarcerated as subjects. Some serious questions of personal and professional morality must be faced before—as well as during—the project's undertaking.

In articulating the position of the Conference on human experimentation on prisoners, it was stated that it was not necessarily what position to take about experimentation in general or about no experimentation in society, but a question of strategy. It should be considered a political reality that human experimentation will continue and a political reality that it will be continued in the prison system. The political reality, therefore, is to focus on how best to protect, to safeguard the subjects of these experiments. It is the obligation of the Conference, the Commission and Congress to safeguard prisoners'—subjects'—rights. And, just as doctors cannot regulate doctors and lawyers cannot regulate lawyers; a permanent commission should be established not with the purpose of learning for society, but a body directed toward protecting the subjects of society's learning process.

STATEMENT ON CONFERENCE RECOMMENDATIONS

A cursory examination of the recommendations to the Commission from Workshops #7 and 8 on the use of prisoners in human experimentation would initially appear to be contradictory. For example, an item recommending a complete ban on all research may be in juxtaposition with a recommendation to establish a permanent Commission to evaluate and monitor prison research.

We would point out that this apparent contradiction reflects only the fact that from the outset recommendations were formed from a consensus of opinion rather than unanimous vote. The first line of #7's Preamble best illustrates this . . . "for a variety of reasons and from divergent perspective . . ."

Despite these sets of seemingly polarized viewpoints and recommendations, we would draw your attention to the fact that the composite recommendations show a similarity in pattern to the various alternatives suggested in the plenary session: a question of the validity of the prison system itself; a question of the use of the minority population within prisons as subjects; a question of the fine line between research and treatment; a question of the validity of informed consent in the prison setting. Additionally, there is a moratorium suggested allowing investigation and evaluation as well as for the establishment of a permanent oversight body to conduct and monitor any future human experimentation on prisoners.

WORKSHOPS 1 AND 2

RESOLUTION AND RECOMMENDATIONS OF THE WORKSHOP ON PSYCHOSURGERY

NATIONAL MINORITY CONFERENCE ON HUMAN EXPERIMENTATION JANUARY 8, 1976

Preamble

"The ocean that separates Man from his self-knowledge remains to be charted. Crossing it will require money, dedication, ingenuity and the development of a whole new field of science and technology. The explorers of the brain have embarked on a journey even more significant than the voyage of Columbus in 1492. Columbus "discovered" a new continent. The explorers of the brain may well discover a new world." From "Exploring the frontiers of the Mind." Time Magazine. (January 14, 1974)

Examining the histories of people of color in the country after Christopher Columbus' "discovery" of America is enough to make one wary of this paragraph.

Crimes committed against minorities: experimentation on Blacks since slavery time, germ warfare on Native Americans, atomic warfare on Asians, and similar exploitation of other peoples have been standard procedure of policy makers in this country and will continue to be unless something is done to alleviate the continuing exploitation, oppression, discrimination, and economic and social deprivation of our peoples.

Realizing the historical pattern of the subjugation of minorities and its implications, we feel we must safeguard ourselves against Psychosurgery as a possible means to further victimize us.

People become neurotic as a reaction to environmental conditions in which they live. Reactions such as anxiety, depression, etc., are reasonable and appropriate responses especially among those who are oppressed. Furthermore, anxiety among those who are oppressed can be a very positive thing for society as it motivates people to fight against the oppressive conditions in which they live.

The social context of institutionalized racism in this country insures the *use* of the least powerful as the major source of subjects in human experimentation. We are cognizant that procedures such as psychosurgery have been and can be misused by those in power against the powerless and society. With this constant fear in mind, we have approached the issue of psychosurgery (not neurosurgery) in a very cautious manner, fearing that the door to further abuse from the people in power may be opening wider.

We are concerned that, as is the case with many relatively novel methods of the therapeutic intervention, there might evolve a prejudiced tendency towards this "panacea", psychosurgery, that would ultimately preclude any significant development of methods of prevention of diseases for which these therapeutic measures are indicated. The danger in such a trend lies in the highly probable understanding of the social phenomena that have continued to create internal and external stresses on minority populations in a society whose majority rarely, if ever, experience the negative effects of its own pressures—social, economic, political, and cultural.

Cultural

We are concerned with the lack of respect and understanding of cultural differences and the intent of policy makers.

We understand that consent is almost never "informed"; that duress and intimidation are important, dominant elements in the relationship between subject and researchers; that the policy makers are arrogantly insensitive to the human rights of potential subjects.

We demand that the policy makers raise their consciousness about these differences. Through lack of self-awareness their actions deviate from human, moral and ethical values; these values should be their primary focus when they consider research on persons.

Whenever such action is considered (research on humans) it is absolutely necessary to be clear on the basic principles such research objectives are based.

Those who would experiment and research, *on* humans should have uppermost in their consciousness the dictum ". . . above all, do no harm."

Social

Because of the pattern of institutional racism in our society, we are convinced that the least powerful in American Society will eventually be used as human subjects.

"Captive" communities—those with the least capacity to defend themselves against the onslaught of researchers lie incarcerated, children, old people, prisoners, the institutionalized—are exploited under the guise of "the good of society."

Historical

Experimentation on blacks since slavery times.

Germ warfare on native Americans.

Atomic warfare on Asians.

80% of human experimentation in the U.S. has been done on the impoverished.

Involuntary sterilization of women, especially women of color.

CONTINUED

6 OF 7

Moral

The moral issue in psychosurgery is, to us, compelling. We believe that anything as irreparable, as final, as psychosurgery must be restrained in its use. Some members of our workshop hold that the procedure must not be done at all. This position is supported by the marginal effects of the treatment and its undesirable side effects.

It appears that the major effect of psychosurgery is to subdue the subject. Side effects of the "quieting" can include lowered attention span and vegetable-like behavior.

Of the small number of such procedures carried out currently, only a small percentage can be said to be helped. Clearly, more must be learned about the brain; for instance, no one knows the effects, all the effects, of this procedure.

Definition

Psychosurgery is brain surgery performed to alter behavior patterns, personality characteristics, emotional reactions and thoughts *where there is no known brain pathology.*

RECOMMENDATIONS

1. There should be no psychosurgery performed on prisoners and other persons involuntarily confined in institutions.
2. There should be no psychosurgery performed on sexual deviants, political deviants, or social deviants.
3. Psychosurgery is clearly experimental and therefore poses substantial danger to research subjects, and should only be considered after all alternatives have been exhausted.
4. Monies for research should not be accepted from law enforcement agencies, pharmaceutical companies or other institutions that do not hold paramount the patient's personal welfare.
5. There should be extensive animal research in an attempt to define an animal model for behavior modification surgery. There should also be social-psychological study of behavior abnormalities which psychosurgery addresses. Such research should be closely scrutinized, supervised, and administered by the NIMH. There should be minority representation on the NIMH review committee and advisory committees. This minority representation should include minority neurosurgeons, psychiatrists, ethicists, and behavior scientists.
6. Protocol should be set up to govern the selection of patients. Each case should require the approval of review committee, assuring that all alternatives have been exhausted and *informed consent defined and validated.* Members of these review committees must be economically, professionally and emotionally independent from all individuals involved in the patient's care. The review committee *must be* multidisciplinary to include neurosurgeons, psychiatrists, ethicists, behavioral scientists, social workers, clergy, consumers, and other consultants specially needed for the particular case. Such a committee should have the power to prevent psychosurgery if it considers surgery not to be advisable.

If, however, a patient wants to receive such surgery, the patient and his physician can appeal the committee's decision. There also should be a national appeal committee with the final authority for decisions.

7. There should be detailed clinical assessment and followup of the patients for several years by the review committee, with all data going to a central depository. Such information should be available to the public with appropriate measures to conceal the personal identity of the patient.
8. If incarcerated persons are believed by institutional medical authorities to have *organic* brain disease as the source of their abnormal behavior then they should undergo intensive neurodiagnostic workup in a medical setting outside the institution. If organic brain disease is diagnosed, after appropriate judicial review, persons should be released from that institution for the specific purpose of participating in the above mentioned protocol.
9. Substantial penalties should be imposed to insure compliance to the above; including, at minimum, loss of license.

WORKSHOPS 3 AND 4

Preamble

We call for an immediate halt of experimentation and research on healthy children until such time relatively adequate numbers of minority (sic) professionals are trained and involved in the process of design, implementation, and monitoring such activities. As a concurrent alternative we recommend that proposed research be submitted to a panel of minority (sic) peer representatives of the researchers and minority (sic) peer representatives of the subject(s) who will monitor the procedures and process of the proposed research. Without the approval of the panel the proposed research would not be approved.

Definition of experimentation:

Deliberate attempts at inducing or altering body or mental functions, directly or indirectly in individuals or groups primarily for the advancement of health, science, and human welfare using untested procedures, drugs and sources. The categories of experimentation are: 1) physical; 2) behavioral (psychological and emotional); 3) political, social and cultural and they are 1) controlled and uncontrolled; and 2) reported and unreported.

A. Statements

1. The boundaries between research and treatment—Definition of treatment: The use of approved standards and procedures that are not harmful or experimental.
   a. Maximum safeguards must be provided to prevent abuse and purposeful misrepresentation of research and treatment by providers. Maximum consumer advocacy must be considered.
   b. Individuals, particularly children, should not be denied the best in treatment and should not be experimented upon as a result of that denial.
2. The use of risk/benefit criteria in determining the appropriateness of research involving human subjects. Such criteria must:
   a. Properly address the rights of individuals.
   b. Be closely monitored.
   c. Be well defined.
   d. Maximize benefits to the individual subject.
3. Guidelines for the selection of subjects:
   a. Prohibit exploitation/use of any one segment of child population as subjects.
   b. Incarcerated children should not be used for experimentation unless they are not disproportionately represented in total selection of child subjects. They should be represented in the numbers proportionate to their minority (sic) representation in the country. In addition, no research on children should be conducted unless that research is designed to specifically improve that particular child's condition.
4. There should be no practice of psychosurgery.
5. Informed Consent
   a. No parent or legal representative or guardian shall be permitted to consent to a non-therapeutic experiment unless there is also obtained the informed consent of a third party representing the interests of the child and having no affiliation with the persons or institutions sponsoring or conducting the research. Explanation to child and third party advocate of the risks and benefits of the procedures proposed should be maximum to the point of understanding prior to obtaining informed consent. In addition, the subject and advocate must be informed of the name of the researcher, the institution, foundation or agency conducting or sponsoring the research, the source of funds and the qualification and prior experience of the researcher.
   b. No child over age 7 shall be the subject of non-therapeutic research without the child's informed consent.
6. Because of lack of concern for human and/or limited knowledge about experimentation.

Because Research Centers and "Researchers" are removed and/or deliberately walled-off from the community. We recommend the following:

Whereas research oftentimes affects the local community directly and indirectly, Research Centers must be closer aligned with the local community.

Whereas the local community must be notified with public announcement 60-90 days prior to any experimentation with any human subject. Be allowed the opportunity to advise and contribute to that particular research project throughout the completion of that research project.

WORKSHOPS 5 AND 6

Recommendations

GUIDELINES FOR THE SELECTION OF HUMAN SUBJECTS

1. Biomedical or behavioral experimental procedures or research should not be conducted on the institutionalized mentally infirm unless all the following criteria are met:

A. the individual has a medical, clinical, or psychological condition demanding investigation and treatment, and

B. the proposed experiment offers a reasonable likelihood for yielding results leading to the control or cure of the condition in question.

C. alternative medically established and accepted procedures to treat that condition do not exist or are inadequate, and

D. the research cannot be accomplished outside of the institutional setting.

2. Very strict safeguards should be enforced against the disproportionate use of certain powerless groups, i.e., racial, ethnic, and low income groups as subjects of research.

3. Prior to the commencement of experimentation the appropriateness of the subject's institutionalization should be re-evaluated by at least two clinical professionals not affiliated with research team.

Informed consent

1. No one should be a participant in an experiment against their will, regardless of mental competency or incompetency.

2. Within reasonable limits the prospective participant may secure outside opinions, at no cost to the participant.

3. Evidence that the guidelines for informed consent procedures were appropriately followed must be available to the public for inspection.

4. The confidentiality of research participants must be protected.

5. Patients should be given full information regarding an experiment including the results of previous studies and the possibility of being part of a research control group.

6. The informed consent procedure should insure that the subject is voluntarily giving consent and be witnessed by at least two people not connected with the institution, nor with the research project.

7. Any professional explanation provided to a prospective participant must be presented and written in the primary language on the educational level of the prospective participant and one other spokesman. The explanation should be fluent enough so that the prospective participant and the spokesman are fully informed.

8. The consent form should specify financial responsibility or liability in the event of untoward results occurring from the experiment which would require extensive or prolonged care. Liability should be borne by the federal government in federally sponsored research.

9. Subjects shall have the right to withdraw from the experiment at any time without the loss of any privilege or right and with assurance of continued treatment by the best available alternative procedures. This right shall be included in the consent form.

10. The consent form should allow for the signature of prospective participants who are minors but are seven years of age or older.

11. The participant should be given a conformed copy of the consent form.

The Institutional Review Committee

The committee's composition should:

(1) be composed of a majority of community representatives

(2) reflect the racial, ethnic, economic, lingual and other sociological characteristics of the subject populations.

(3) rotate periodically

(4) include some representation of previous subject populations and/or present consumers of institutional health services.

The institutional Review Committee's functions should:

(1) review every grant application in light of the benefit and risks to the subject

(2) be reviewed in light of criteria for acceptable experimental procedures or research on the institutionalized mentally infirmed.

(3) periodically review the experiment and all information related to the experiment.

(4) periodically reevaluate the appropriateness of the subjects institutionalization and research participation.

(5) monitor the "consent process" to insure that all criteria for consent are adhered to and that it is truly voluntary and informed.

(6) carefully scrutinize the inducements used to attract the subject group.

(7) insure regular feedback to the subject, as to the experiment progress.

General

1. It is recommended that there be established a permanent Minority Commission to give ongoing input for the protection of human subjects in experiments.

2. Mechanisms should be developed to monitor and regulate biomedical and behavioral research conducted by all federal agencies. In the absence of such mechanisms, all research should be prevented.

3. Research findings both positive and negative should be reported to participants.

4. Initial studies in humans should be conducted with adults rather than children, where possible.

5. Research funds should be discontinued if periodic monitoring reveals violation of guidelines, which are not connected within a reasonable period of time.

6. That the National Commission for the Protection of Human Subjects commend Geraldine Brooks for bringing together, for the first time, a group (of this type) to discuss human experimentation.

WORKSHOP 7

Preamble

For a variety of reasons and from divergent perspectives, all of us believe that the prison system is in need of fundamental modifications. Some of us believe that prisons should be abolished. Others seriously question whether all of those presently incarcerated should be there. Therefore, our recommendations on biomedical and behavioral research reflect our honest skepticism about making recommendations for institutions whose social utility is in doubt.

I. RECOMMENDATIONS ON BIOMEDICAL RESEARCH ON PRISONERS

We recommend an immediate moratorium on all nontherapeutic biomedical research on prisoners until such time that comprehensive evaluation is made of the current status of human experimentation and health care delivery in prisons. By "nontherapeutic" research, we mean to include all biomedical research on healthy prisoners, i.e., prisoners who have not been accorded status as "patients."

During the moratorium, we recommend that there be a thorough and systematic attempt to develop methods to adequately control research in prisons. This attempt should include consideration of the following:

1. The purpose of the research.
2. Criteria for selection of subjects.
3. Assessment of risks of harm before actual implementation of any proposed research.
4. The responsibility of state and Federal regulatory bodies for administration of any prison research.
5. The responsibility of professional organizations for prison research.
6. The role of prisoners in the supervision of prison research.
7. The need for mechanism for monitoring and evaluating the prison research.
8. The supervision of current research in prisons.

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9. The need for special legislation to control certain types of treatment.
10. Methods of reviewing the consequences of human experimentation.
11. Legislation to fix financial responsibility, including responsibility for any physical or other harm to prisoners who are subjects of experiments, on someone or institution other than the prisoner.
12. Providing means for prisoner access to court, legislatures, and national commissions.

II. RECOMMENDATIONS ON BEHAVIORAL RESEARCH ON PRISONERS

We understand neither the risk of harm nor the potential benefit of the wide variety of ongoing behavioral research programs in our prison system. First, we recommend that the focus of behavioral research be redirected. Any further deliberation on behavioral research in prisons should address the question of what is there about our social institutions that generates the need for so many behavioral research programs aimed at modifications of individual behavior. Second we recommend that there be a shift of emphasis in all future inquiries away from behavioral research focusing on the individual prisoners to research endeavors aimed at understanding the nature of these institutions, and their effect on individual prisoners.

III. RECOMMENDATIONS ON INFORMED CONSENT

We are unwilling at this time to delineate the requirements of "informed consent" for research involving prisoners because of our doubts about the prison environment and whether true "informer consent" is possible in our nation's prisons.

WORKSHOP 8

Policy:

Long range goal

The group realizes a distinct need for change and advocates abolition of the prison system as it presently exists in the United States.

We also recognize the necessity of federal, state, and local government making new commitment to eliminating dehumanizing conditions in prisons and creating viable community based alternatives in incarceration.

Therefore, the following Recommendations are of an interim nature in order to enhance and facilitate attainment of the foregoing long-range goal.

RECOMMENDATIONS

1. That the Congress consider and legislate the establishment of a permanent Commission to develop guidelines, and to regulate and monitor human experimentation. The composition of this Commission should adequately reflect the diversity of the citizenry regarding race, sex, age, status, etc. This Commission should have the powers necessary to enforce regulations regarding human experimentation and set penalties for violations of such guidelines as they may establish.
2. That composition of the present Commission be altered to include black and other minority males, and representation of those persons who become subjects of human experimentation.

We express our dissatisfaction at composition of the present Commission.

3. That all bio-medical research and human experimentation in prisons and jails be banned.
4. That Human Review Committee with prisoner representation be established.
5. That psychosurgery on all prisoners be banned.
6. That the U.S. Department of Health, Education, and Welfare or the proposed new Commission be mandated to provide technical and legal resources to persons particularly, prisoners who are potential subjects of human experimentation.

WORKSHOP 9

Human experimentation must be justified by the biomedical necessity and scientific validity of the experiment. Priorities of human need must govern decisions as to the necessity of the experiments undertaken and their nature.

These experiments must adhere to ethical, moral and nondiscriminatory values. Protection of human subjects must be paramount.

To this end we recommend that:

1. The policies, priorities and practices of health care institutions should be monitored by (1) independent community organizations composed of nonscientists and (2) independent patient ombudsmen with subpoena and other legal powers in order to insure the faithful observance of the ethical, moral values and guidelines presently existing or to be promulgated.

Augmenting these outside monitoring devices should be the following:

(a) Joint monitoring by federal and other funding agencies and recipient institutions of biomedical research projects to insure compliance with original research designs prior to and *after* the grant has been made.

(b) Laws and/or regulations requiring public disclosure by all researchers and health care institutions of proposed and ongoing biomedical research.

(c) Federally funded local groups who actively educate patients *in their own language* as to their *rights* with regard to a variety of health care practices, e.g., admittance, services due, experimentation.

2. It must be recognized that a significant amount of family planning (birth control) is an experimental procedure which has implications for future generations; and unknown risks to those currently involved, and is also discriminatory in that recruitment is primarily among the poor and that most programs are targeted almost exclusively toward women.

It is therefore recommended that (1) there be equitable representation of both sexes and *all* socioeconomic background in *all* family planning (birth control) research. (2) And that ongoing evaluation of the risks of such programs and the implications for future generations should be undertaken.

3. It is a fact that more information, care and concern is typically bestowed upon those patients and subjects of the same race and social status as the majority of medical professionals. This represents the highest standard of medical care available. In order to insure that this standard of medical care is available to all, it is therefore recommended that there be an equitable representation of non-minorities and persons of upper-level socioeconomic backgrounds as subjects in all experiments, especially those biomedical research projects involving great risk to health.

4. If human experimentation should be addressed to priorities of human need, it follows that the positive and beneficial results of such experiments should be immediately available to those who are the subjects of the research, frequently the poor and minority groups, as well as others.

It should be a necessary prerequisite of human experimentation that it will offer support to the improvement of health care delivery.

In order for this actually to occur, funding for human experimentation should be closely tied to adequate support of the health care delivery system.

The current cuts in Medicaid and Medicare and other health programs present a serious problem to health care delivery and tend to negate any beneficial effects to the poor and minority groups from the progress of human experimentations.

It should therefore be a priority to restore our ability to deliver the medical care that medical progress has already achieved before additional funding for human experimentations is granted.

5. The definition of human experimentation should be expanded to include protection of patients receiving their general medical care on "teaching services," e.g., those services students and post graduate students are involved in the delivery of medical care.

The well publicized abuses of health care professionals and researchers in violation of ethical and moral standards, with their attendant tragic consequences for poor and minority persons (e.g., the large number of hysterectomies performed on minority women) reveals a serious lack of ethical consciousness on the part of their medical personnel. It is therefore recommended that all medical personnel be required to receive training in ethics with special emphasis on the requirements of informed consent and case studies of abuses to minorities and women and how to prevent them.

Where patients are treated in teaching hospitals every effort should be made to assure that said patients are fully informed of the training status of the medical students, that the patients have some choice regarding acceptance of treatment from students, that consistent and persistent supervision be available, that all appropriate alternatives regarding prescribed treatment be reviewed with the patient, and that *no* adverse actions be taken, or treatment denied to

patients requesting consultation or the services of a fully trained physician or health professional.

6. The informed consent statement signed by subjects willing to participate in human experimentation must include a proviso that, in the event the subjects experience physical or psychological harm as a result of participation in the experiment, appropriate compensation, including monetary compensation, will be received. The determination of physical and psychological harm will be made by parties independent of the given institution or research site, with such a group containing professionals and laymen, at least one third of whom must be socio-economic peers of the subject claiming injury or harm.

7. The science of medicine, whether as practiced in highly sophisticated Bicentennial America or by curanderos in the remotest villages of Mexico, embodies an intricate system of knowledge which the healer possesses and the patient does not. A knowledgeable patient is able to take more responsibility for his own health and to make intelligent decisions regarding the care he receives. The poor minorities in this country have the greatest health problems and are least equipped to cope with them or to make informed decisions whether those decisions involve seemingly simple medical choices or family planning, or participation in a research project.

We therefore recommend that the Commission assume leadership in the establishment of public health education geared toward the enlightenment of minorities regarding human experimentation and its specific implications for them, including their specific rights.

WORKSHOP 10

Recommendation #1—Regulatory Body

It is recommended that a special permanent national office be established to speak to the question of the protection of minorities used in experimentation. This office should have at least 10 funded regional centers corresponding to DHEW regions, staffed by basic scientists, physicians, and community representatives reflecting the minority composition of the region. It shall be the responsibility of this special permanent national office and its regional offices to:

(a) Review all proposals from that region involved with the use of human subjects with regard to subject selection, voluntary consent and the protection of subjects rights and welfare;

(b) Monitor the implementation of guidelines of ongoing human research projects;

(c) Assess the progress of regional projects to insurance compliance with guidelines.

Recommendation #2—Representation of Minorities on Existing Reviewing Bodies

The study group viewed with alarm the exclusion of Spanish speaking Americans, the second largest minority ethnic population, as well as the absence of Native Americans, and Asian Americans on the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The study group therefore strongly recommends that the membership of the Commission be expanded to include representation from these ethnic groups.

Further, the study group recommends that minorities in sufficient numbers, be placed on all review committees in Federal departments, commissions, and agencies funding or conducting research using human subjects; and that such persons be reviewed and given approval by an *outside group* of minority professionals to assure that their credibility and interest is acceptable.

Recommendation #3—Subject Rights

It is recommended that Federal policies, guidelines, and regulations be amended mandating that institutions conducting research involving human subjects must:

1. Provide for substantial participation in the review of procedures by the immediate community from which the subjects are selected in order to safeguard the rights and welfare of subjects at risk.

2. Provide for the conduct of such research in the way most appropriate to the language and cultural patterns of bilingual-bicultural communities.

3. Employ bilingual-bicultural researchers wherever a significant number of such subjects at risk reside in the community.

Recommendation #4—Health Care Delivery vs. Research

It is recognized that there is a great amount of research and experimentation in the health care delivery system itself. As it may be difficult to separate pure health care delivery from research aspects, it is recommended that DHEW guidelines regarding "patients at risk" be applicable to *all* Federally funded programs.

Recommendation #5—Subject Protection

It is recommended that all initial and continuation grant and contract requests, including delivery of health services under Medicaid, Medicare, and other third party payers, include a statement of assurance to protect patients from unknown and unauthorized participation in human experimentation. The Health Systems Agencies established under Public Law 93-641 should be required to approve those statements of assurance as part of the review process for all such requests.

Recommendation #6—Subject Selection

The National Academy of Sciences has reported that 80% of human research subjects are poor. Since ethnic, social, and socioeconomic minorities constitute a disproportionate number of the poor, it is recommended that selection of human subjects should reflect the makeup of the relevant community population with regard to ethnic, social and socioeconomic status.

Recommendation #7—Non-HEW-Funded Research

It is recommended that the National Council of Foundations be required to develop a policy statement regarding human experimentation for distribution to its membership. Further, such a policy statement should strongly urge private foundations *not* to fund projects where human experimentation is taking place without voluntary consent, and that DHEW guidelines regarding human subjects be adhered to by private foundations.

Recommendation #8—Informed consent

Since voluntary consent cannot be obtained in certain situations, e.g., children under age seven (7), prisoners, and the institutionalized mentally infirm, it is strongly recommended that human experimentation under conditions such as these *be discontinued forthwith.* (In instances where participation in research has been an inducement and a part of a reward system, e.g., in prisons, we strongly suggest that reward systems that include access to health care or other benefits be abolished. Further, we strongly encourage that alternative and humane reward systems be initiated that are compatible with prisoners' well-being, and that they are clearly disassociated from inducements to participate in human experimentation).

Recommendation #9—Education

Since education is a crucial component of research and services, and therefore should *not* be separated from the two, it is recommended that the issues of subjects' rights and welfare, voluntary consent, risk-benefit assessment, and research ethics be incorporated as integral parts of all programs encompassing the training of biomedical, sociomedical, behavioral, and health services researchers and providers.

WORKSHOPS 10 &11

RESOLUTIONS

(1) *Whereas,* racism in the United States of America has not abated since the Presidentially-appointed Kerner Commission concluded, in 1968, that "White Racism" was at the root of contemporary social disorder in our nation, and

(2) Whereas, as long as there is experimentation and research on human subjects, the need exists for continuous monitoring of safeguards, and

(3) Whereas, the National Commission for the Protection of Human Subjects of Bio-Medical and Behavioral Research too narrowly represents minority persons and groups, and

(4) Whereas, some experimentation and research on human subjects now threaten the survival of specific racial and ethnic groups, and are detrimental to mankind, and

(5) Whereas, we regard psychosurgery as mutilation of the human mind rather than medical therapy, and

(6) Whereas, current research development and experimentation impact with particular gravity on the lives and welfare of blacks and other minority people, and

(7) Whereas, those so poorly represented on the Commission hold great promise as a resource for an appropriate and effective understanding of the crucial and peculiar problems presented by research and experimentation on human beings, and

(8) Whereas, the need exists for more effective sharing of information, procedures, and developments in the area of human research and experimentation, and

(9) Whereas, the horizon of human experimentation has moved into the area of modifying the behavior of selected groups, such modified behavior potentially detrimental both to the selected groups and to the society at large, and

(10) Whereas, the mass media increasingly serve totalitarian ends by controlling and detrimentally modifying the behavior of media audiences,

(11) Whereas, the overwhelming importance and significance of the issues raised above require greater resources and time for in-depth deliberations then were available to the National Minority Conference on Human Experimentation conferees.

It is therefore resolved that:

1. The Commission immediately establish and support a liaison group of no fewer than eleven (11) black and other minority persons, such group being multi-disciplinary and multi-cultural in its make-up, and including persons in attendance at this conference as well as non-professionals who would serve as a continuing resource to the Commission.

2. Certain human experimentation and research such as cloning and other forms of genetic manipulation, such as extra corporeal human growth and development (total test tube birth and development), and selective extirpative (color-sensitive) experimentation including psychosurgery—be banned as crimes against humanity.

3. There be Congressional appointment of a special panel of minority citizens to study and make recommendations with respect to media monopolies and the problems caused by them; and

4. There be an extension of the Federal Communications Commission's Fairness Doctrine to cover parties aggrieved and/or concerned by racist, violent, or other kinds of programming shown to have harmful effects on the behavior of individuals in the broadcast audiences.

5. That the Congress of the United States enact legislation to continnue the life of the Commission or to establish its permanence and such action be completed expeditiously so that no hiatus occurs in the monitoring of safeguards for humans in experimentation and research; and that such a Commission be expanded from its present composition of 11 members by at least 5 additional members representing Blacks and other minorities who are of the scientific community.

There are many issues and concerns in the area of human experimentation and research that are of particular significance to minority people. The social, economic, ethical, and political considerations involving "informed consent", multi-lingual and multi-cultural staffing of research projects, for example, are such that they deserve further and continuing investigation. They, therefore, should be of special concern to the proposed liaison group.

ISSUES AND CONCERNS

1. Change terminology i.e., "subject" to "participant" and "selected" to "recruited" or "volunteered".
2. Stop federal funding of genetic experimentation.
3. Acquire parental consent prior to experimentation with children.
4. Legislate operational nature and definition of informed consent.
5. Establish legislation for waivering informed consent.
6. Informed consent must be in written form (subject, participant and researcher).
7. Destruction of experiment results at discretion of subject/participant.
8. Acquire outside peer group approval of experiments.
9. Compensate for physiological/psychological damage.
10. Integrate all social experiments.
11. Conduct impact studies prior to social research.
12. Government should establish and train experimentation review boards composed of community members.

13. Encourage interrelationships of researchers and community members, e.g., ministers.
14. Develop legislative process to match research with institution conducting research—selection criteria.
15. Establish committee to review human research on multidimensional basis: social, physical, behavioral, biomedical.
16. Develop valid and reliable psychological tests for minority groups.
17. Establish mechanisms for insuring compliance with legislative guidelines for psychological testing.
18. Government should act as purveyor of all social research.
19. Multilingual staffs needed in activities involving informed consent, i.e., research papers, review boards.
20. Need policing of researchers and implementing of research results.
21. Employ minorities in policy making position.
22. Affirmative Action in DHEW should assure minorities are adequately represented at all levels of research administration.
23. More Black and other minority researchers should be funded, especially in Black and Native American colleges and universities.
24. A larger proportion of social (biomedical/behavioral) research dollars should be allocated to train minority researchers, especially in Black and Native American colleges and universities.
25. Behavioral science projects investigatory strengths in minority communities must be given priority to balance the current preoccupation with pathology.

The National Minority Conference on Human Experimentation

CONFERENCE PAPERS: PRISONS

The Problems of Informed Consent Focussing on Prisons

(By Joyce Mitchell Cook, Ph.D.)

INTRODUCTION

"Informed consent" has been identified by a majority of writers as the central, though not exclusive, ethical issue raised by the research activity called human experimentation.[1] This activity is, in my judgment, more accurately to be thought of as (human) experimentation *on* human beings. The reason I propose that we think of this type of research activity as experimentation *on* human beings is two-fold: 1) Since we can conceive of no experimentation being carried out by giraffes, gorillas, gnus, and the like, we may safely assume that all experimentation is human experimentation, in view of which assumption 2) we are the more likely to keep steadily in mind the crucial fact that such research activity is carried out by human beings *on* human beings, who though commonly referred to as human subjects are, in point of fact, human objects for the purposes of the experiments.

Adequately to address the issue of informed consent we must consider both aspects, not merely in isolation from each other but in the context in which they are raised. To appreciate the point I am making is to see that we cannot justify a given experiment carried out on human beings simply by pointing out that the experiment by its nature and design violates no commonly accepted ethical principles. For one implication of the two-sided ethical question we may raise about any such experiment is that Experimenter Jones may perform exactly the

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[1] Jay Katz. *Experimentation with Human Beings* (New York: Russell Sage Foundation, 1972), p. 1030; Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects," in Paul A. Freund, ed., *Experimentation with Human Subjects* (New York: George Braziller, Inc., 1970), p. 5; A. R. Jonsen and P. R. Lee in unpublished manuscript, "Coercion and Choice: Human Experimentation in the Prison," December 1974, pp. 2, 23ff; also testimony before Senate Health Subcommittee and House Subcommittee on Public Health and Environment Hearings Concerning Biomedical and Behavioral Experimentation Involving Prison Inmates.

Dr. M. H. Pappworth (in *Human Guinea Pigs*, London: Routledge & Kegan Paul, 1967) makes the telling observation that "In fact, the ethical problems associated with the use of prison inmates as subjects for medical experiments are largely of artificial creation, because the basic problem of the essential purpose of prisons and punishments has not been solved." (p. 64). Nonetheless, we must consider the general case before proceeding to the special groups of experimental subjects.

same experiment on Mr. Smith and on Mr. Brown and his action may be ethical in the case of Mr. Smith but unethical in the case of Mr. Brown. A further implication is that it may be ethical for Mr. Smith to submit to Experimenter Jones' action but unethical for Mr. Brown to submit to the same action on the part of Experimenter Jones. In short, strictly speaking experiments are neither ethical nor unethical.[2] Experimenters may be ethical or unethical; and those who submit to such experiments may be ethical or unethical by their submission.

It will be the burden of this paper to argue these points and to spell out the ethical requirements, addressing the problem of informed consent as directed by the conference organizers by focussing upon the problem of experimentation on prisoner/inmates. At the conclusion of our analysis we shall be in a position to recommend a proposal for the consideration of this body.

When we perceive the research activity in this way we are the more readily perceptive of the main ethical issue here, which has two aspects not always clearly brought out in the growing literature on the subject. On the one hand there is the question of the ethicality of the experimenter insofar as he is acting *on* another human being, on the other hand, there is the question of the ethicality of the human being who agrees to serve as object-being-acted-upon by the experimenter.

Our set task is not to address the ethicality of experimentation on human beings in general. Rather we are to consider the problem of informed consent. It seems advisable straightway to point out the relationship between the two problems.

In addition to informed consent the following issues have been identified as requirements for human experimentation: equality, the competence of the experimenters, prior animal experiments, prohibited subjects, and proper records.[3] It is not clear to me whether these are altogether distinct from the issue of informed consent. How, for example, can the subject be informed of risks if there have been no previous animal experiments? How can the subject be informed if the researchers are incompetent? Depending upon our characterization of informed consent, some classes of persons may be excluded from participation as subjects. Pappworth in defending equality as part of the code for governing experimentation argues that "no experiment should be contemplated, proposed or undertaken to which, if he were in circumstances identical to those of the intended subjects, the experimenter would even hesitate to submit himself, or members of his own family, or anybody for whom he had any respect or affection. This principle of equality should be the corner-stone of the whole edifice of any code. It is essentially a restatement of the Golden Rule. . . ."[4]

Hans Jonas makes a similar point when he argues that "it would be the ideal, but is not a real solution, to keep the issue of human experimentation within the research community itself."[5] By this Jonas means that the call for volunteers as experimental subjects should first be put to those persons who may best, by virtue of their knowledge and dedication to the cause, identify with the aims of such research.

Both Pappworth, a physician, and Jonas, a philosopher, seem indirectly to suggest that whereas informed consent may be the central ethical issue raised by experimentation, other ethics should be upheld in experimental medicine. The quality of consent obtained, in their opinion, leaves much to be desired.

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We begin by asking what, in the language of Pub. Law 93-348, is the " . . . nature and definition of informed consent in various research settings," and, secondly, how shall we " . . . identify the requirements for informed consent to participation in biomedical and behavorial research by children, prisoners, and the institutionalized mentally infirm."[6] The enabling act calls further for an investigation of what in effect is being done in regard to these matters. It is well at the outset to appreciate the fact that the question of *what is being done*

[2] cf. Dr. H. K. Beecher's statement that "an experiment is ethical or not at its inception. It does not become ethical post hos—ends do not justify means." Dr. Beecher summarizes 22 experiments which he contends violate ethical principles. My point is that it is the experimenters, not the experimentees who may be said to violate ethical principles. (H. K. Beecher in *New England Journal of Medicine*, 1966, 274, 1354, Cited in Pappworth, *op. cit.*

[3] See Pappworth's list in Human Guinea Pigs, op. cit., p. 189.

[4] *Ibid.*

[5] Hans Jonas, *op. cit.*, p. 18.

[6] P.L. 93-348; 88 Stat. 349; Sec. 202(a)(1)(B)(iv).

is an empirical question not an ethical question. This point seems to have escaped the notice of Dr. Lasagna, for example, when he observes that "the problem [of informed consent] boils down to a sober weighing of costs and gains, not a preoccupation with moral cliches and stereotyped mottoes. Much has been written . . . on the need for 'informed consent', but little research has been conducted on what this *term actually means*. What do we consider a 'fair shake' as far as the subject is concerned? How much tailoring of our presentation is required by differences in age, personality, or I.Q. among patients? What minimal information do we want conveyed before we ask whether a subject is willing to participate in an experiment? . . ."[7]

I submit that Dr. Lasagna mistakenly thinks that empirical research is required to answer each of his questions, whereas, I should contend that the meaning of the term "informed consent" invites analysis rather than empirical research. More importantly the question of fairness is also a philosophical (value) not an empirical question.

In what follows I shall examine the definition of informed consent (Section I) Section II addresses the special group category, focussing on prisoner/inmates; Section III considers difficulties peculiar to behavioral research as opposed to biomedical research, again chiefly with reference to prisoners. Finally in Section IV, I offer conclusions and recommendations.

I. INFORMED CONSENT—NATURE AND DEFINITION

There is considerable confusion in the literature over whether informed consent is a concept or a principle. This is no mere semantic confusion, but a confusion that tends to disguise the ethical issue in human experimentation. Thus some authors speak of the concept of informed consent and having indicated what they take it to mean, proceed to refer to it as a process that admits of steps researchers might follow to ensure that they obtain it. A signature on a consent form may "prove" that informed consent has been obtained. But a signature on a consent form does not prove that the ethical requirements for informed consent have been met.

Certainly there is a concept of informed consent, just as there is a concept of a promise and a concept of truth-telling. But truth-telling is also the name of a principle and is defended by some persons as a moral principle governing statements people make. The distinction between truth-telling as a concept and as a principle may most readily be grasped in terms of the kinds of questions appropriate to each. One sort of evidence is called for if we are attempting to ascertain whether someone is telling the truth and another type of evidence or justification is called for if we are attempting to defend the principle of truth-telling.

Similarly, in regard to the problem of informed consent, there are two separate questions calling for two kinds of evidence. If we want to know whether informed consent has been obtained in regard to a given experimental subject, we look for certain determinations of fact, such that the subject was given such and such information, that he said he understood, and that he seemed quite eager to sign the consent form, and so on. The emphasis on the part of the researcher must be to inform; the emphasis on the part of the prospective experimental subject must be to consent—willingly, not reluctantly. But if informed consent indicates an ethical principle, as many writers have contended, something more than a recital of facts is called for if we are to attempt to establish the principle. What reasons may be addressed in favor of the principle of informed consent? What is the precise formulation of the principle?

According to Richardson, the principle of informed consent was first formulated at Nuremberg " . . . after the Second World War as a specification of the wrong done by German doctors who used concentration camp prisoners for medical experimentation. These doctors reasoned in a humanitarian way. They knew that the prisoners were marked for an early death and that they themselves were utterly helpless to prevent this or ameliorate their condition. In principle, the prisoners were as good as dead and, separated from all friends and family, now experienced only the torment of anticipating their doom. Since the prisoners were going to die anyway, the doctors reasoned, why not take advantage of the situations to benefit all mankind? Why not use them for medical experimentation?"[8]

[7] Louis Lasagna, "Special Subjects in Human Experimentation," in P. A. Freund, *op. cit.*, p. 274.

[8] Herbert W. Richardson, "What Is the Value of Life," in D. R. Cutler, ed., *Updating Life and Death. Essays in Ethics and Medicine.* Boston: Becon Press, 1969, p. 169.

Lest we wrongly assume that German doctors invented what Pappworth, among others, has condemned as a violation of medical morality, let us recall that a number of these doctors during their trials cited as precedents for their own experiments published research describing similar experiments carried out elsewhere in the world, including three American experiments. Nor should we assume that experimentation with prisoners began with those cited by German doctors at Nuremberg in 1947, for indeed, such cases have been recorded for centuries.[9]

I would have us consider this history at this point merely to reinforce my contention earlier on that it is not experiments per se that are ethical or unethical but rather experimenters and experimentees. If Pappworth is right, the vast majority of published accounts of experiments on patients examined in his book fail to mention whether informed consent was sought and obtained, sought and not obtained, or not sought at all.[10] This omission seems to suggest (though it does not prove) that the researcher/writers regarded the consent issue as irrelevant to the conduct of their research activity.

Secondly this historical note should make us wary of leaving such questions of ethics to the researchers themselves, whether they have the endorsement of peer groups or not. Nor can we agree that the late Justice Felix Frankfurter's claim with respect to lawyers should apply to medical researchers. According to Frankfurter, "there were no courses on ethics [in law school], but the place was permeated by ethical presuppositions and assumptions and standards. On the whole, to this day, I am rather leery [sic] of explicitly ethical instructions. It is something you ought to breathe in.[11] Frankfurter seems not to have appreciated the difference between courses in ethics and ethical instruction. Courses in ethics do not provide ethical instructions (families, churches, friends do that) but rather they provide training in identifying ethical issues, in formulating ethical principles in exposing presuppositions, assumptions, in assessing alleged justification for ethical principles, and so on. Justice Frankfurter in the quotation under review here has made the common mistake of confusing morals with moral philosophy, of confusing morality with ethics. As for the notion of breathing in ethical (moral) instruction I am tempted to observe that pollution is an acute problem in our society in recent times.

If I seem to dwell too long on preliminaries I do so for what appears to me to be a very good reason. Facts are relevant to ethical decisions but the latter are not reducible to the former without remainder. *The principle of informed consent may be construed as a proposal for regulating the conduct of interested parties in the context of experimenting on human beings.* It is not to be thought of as being handed down from on high, nor is it to be construed as an eternal verity. But notwithstanding these caveats, we may ask whether the proposal represents our best insight into moral situations and this question in turn inevitably leads to a discussion of values including the value of persons.

The wholesale condemnation of the practices of some German doctors to which we have already alluded is predicated upon the compromise of the intrinsic value of persons. *The principle of informed consent is a proposal to ensure that the intrinsic value of persons acting and being acted upon in biomedical experimentation shall not be compromised.* Thus the Nuremberg Code, grandparent of modern codes, spells out in ten clauses requirements governing medical experimentation on human beings. We shall cite here only parts of the first clause:

"The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or

[9] Pappworth, *op. cit.*, pp. 60–61.
[10] *Ibid.*, p. 194.
[11] Cited in Jonsen and Lee, op. cit., p. 31 as excerpted from John Romano, MD., "Reflections on Informed Consent," *Arch. Gen. Psychiatry* 30 (Jan. 1974), p. 130.

person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity." [12]

It is instructive to note that this code spells out not only the consent component but the informational component as well and that it does this in a way that implies that there can be no consent without sufficient information. Whereas there can be no consent without sufficient information, there *can be* consent without willingness. Hence the Nuremberg Code stresses the voluntary nature of the consent. The second sentence in the passage cited elaborates the first voluntary consent *means* free and full affirmative judgment.

In subsequent formulations and discussion of the principle subtle shifts have taken place and it is our purpose to see what they are and also to ask why. I have been unable to trace back to the first occurrence of the shift from labeling the issue "voluntary consent" to "informed consent," The 1946 statement of the American Medical Association on requirements for human experimentation includes the older expression: "1. The voluntary consent of the person on whom the experiment is to be performed must be obtained." [13] Similarly the committee appointed in 1948 by then Governor Green of Illinois emphasized the same point, "That the subjects must be volunteers informed of the possible hazards. Volunteering exists when a person is able to say "yes" or "no" without fear of being punished or of being deprived of privileges due to him in the ordinary course of events." [14]

Webster's Dictionary tells us that consent indicates "a complying, granting, or yielding, willing or reluctant, to request or demand." Thus to speak of voluntary consent is to remove the ambiguity concerning whether the consent is willing or reluctant. Nor, since consent may be willing or reluctant, is the expression redundant as is "informed consent" as we shall show anon.

But consent also implies cognitive awareness of what is being consented to. One cannot say "I consented to x, but I had no idea what x was." Consent is not a blank check upon which the consent giver writes his name, leaving the amount to be filled out by the experimenter/endorsee notwithstanding the fact that all experiments carry some risks, however small.[15] If consent then implies being informed of that to which one consents, why the expression informed consent, which clearly is redundant? To speak of informed consent is erroneously to suggest that consent may be blind or uninformed.[16] Worse yet, and this is why I belabor the point, it turns our attention away from the crucial ethical emphasis which lies with the voluntary nature of consent, not with the informational aspect. Notice that when we speak of informed consent, it always makes sense to ask whether it has been freely given; but if we speak of voluntary consent we can neither ask whether it has been freely given nor whether it is informed. To ask the former is to betray a lack of understanding of what "voluntary" means; to ask the latter is to fail to observe the cognitive component of consent. If "voluntary consent" is a superior label to "informed consent" why have we adopted the latter label?

I submit that the shift here noted benefits someone, namely the researcher upon whom the responsibility for obtaining consent is said to rest. Although it is no easy task to inform the prospective experimental subject, who in many cases is poorly educated—one writer has claimed that it is necessary to have a Ph. D. in biology in order to understand some of the experiments being done [17]—it is still less easy to blink the numerous evidences of reluctant consent. This is particularly true of some of the special groups we shall examine in the next section of this paper.

[12] Cited in Pappworth, *op. cit.*, p. 188.
[13] *Ibid*, 189.
[14] *Ibid.*, p .63.
[15] Pappworth quotes Dr. McCance, former president of the Royal Society of Medicine, "All experiments involve some risk. It may be an infinitesimally small one, but it is always there. If the experiment involves special techniques, then the risk is considerably enhanced." *Op. Cit.*, p. 19.
[16] On my analysis, so-called "misinformed consent" turns out not to be consent at all. If, for example, I say that I consent to x, but I mistakenly take y for x, then I have consented to y, not to x.
[17] Melvin Heller, "Problems and Prospects in the Use of Prison Inmates for Medical Experimentation." *Prison Journal* 47 (Spring-Summer 1967): 21–38. Cited from Jonsen and Lee, *op. cit.*, p. 29.

It is not only the language of the Nuremberg Code that has been abandoned in contemporary discussions of ethical requirements governing human experimentation, it is also the stricture against using certain classes of persons as experimental subjects. I believe that the two points are connected. Thus, whereas the Nuremberg Code would proscribe the use of prisoners, children, the mentally infirm, and seriously ill persons presumed incapable of free choice, contemporary guidelines invoking the legal concept of consent by proxy or third-party consent tend to bend the concept of voluntary consent to comprise as many classes of persons as possible. The neo-Procrusteans among us find the principle of informed consent to be almost as flexible as the types of research they can conceive.

In the remainder of this section we shall focus on the ethical principle of informed consent with a view toward defending its relevance to the ongoing debate as to what ought to constitute the ethical requirements for experimentation on human beings.

The concept of a person it seems to me is a moral concept. As such, it holds the key to most of the ethical issues that are examined in the relatively new field called variously medical ethics or bioethics. Is it morally right to pull the plug from a heart-lung machine in the case of a patient who is irreversibly comatose? Is it morally right to have an abortion? Is it morally right for parents to refuse permission to operate on a seriously defective child who will die without the operation but who will live on with the defect after the operation? To answer these questions we must have a clear moral concept of a person.

The ethical requirement of informed consent—voluntary consent I shall prefer to call it—is no less dependent for its full explication upon the moral concept of a person. Needless to say, I cannot here undertake to attempt to establish a moral theory of persons. Suffice it to note that a person is the locus of values and as such is above all values. Persons have dignity, a famous philosopher has argued, and are therefore priceless. Persons are coequal centers of freedom.

Jonas shows the interconnection between the problem of human experimentation and persons in the following passage:

"What is wrong with making a person an experimental subject is not so much that we make him thereby a means . . ., as that we make him a thing—a passive thing merely to be acted on, and passive not even for real action, but token action whose token object he is. His being is reduced to that of a mere token or sample." [18]

The principle of informed consent is a proposal to legitimize on ethical grounds the experimenter's intrusion upon the inviolability of the personhood of the experimental subject. Since, in the experiment, violence [19] is going to be done to someone's personhood, the violence must be redeemed by the full and free consent of the person in question. The immorality of violating personhood cannot be redeemed by the results obtained, and by results we mean to include material benefits, extraneous to the purpose of the experiment, that may accrue or falsely may be believed to accrue from participation in the experiment, whether on the part of the experimenter or experimentee. Thus the motives of the participants are crucial to a determination as to whether ethical requirements are being met. Not only must the motive of the experimental subject be to promote medical progress and/or the public good, but also the motive of the researcher must have this end in view.

The ethical requirement of informed consent is justified by reference to the inviolability of persons and thus implies a test for the selection of subjects as well as of experimenters. To permit any other motive an outlet in the experimental context may well be to encourage disrespect for persons, whether on the part of the subject or the experimenter. In this light one may readily accede to Jonas' claim that the research community itself constitutes the ideal pool to which to direct appeals for volunteers. Prima facie, the research community, better than other communities, can identify with the goal of medical progress.[20]

If the number of research community volunteers is too small for research needs, the appeal will be directed beyond.[21] Nothing we have said thus far

[18] Jonas, *op. cit.*, p. 3.

[19] The term "violence" is used here in a broad sense that includes, e.g., the puncturing of the skin with a needle.

[20] See page 5 above.

[21] I concur with Jonas also in his point that we are not to assume that the more medical progress the better, certainly not if medical progress is bought at the price of corroding the moral fabric of society.

precludes on ethical grounds the use of persons drawn from the public at large, provided there is informed (voluntary) consent and the motive that redeems loss of personhood. But it does seem, from what we have said, that there will be a class of prohibited subjects. In the next section of this paper we shall indicate the boundaries of this class.

II. INFORMED CONSENT: SHOULD SOME CLASSES OF PERSONS BE EXCLUDED FROM PARTICIPATION AS SUBJECTS IN BIOMEDICAL EXPERIMENTATION?

In the preceding section we have outlined what appear to be reasonable ethical requirements governing the use of human beings in biomedical research. We must now consider whether the ethical requirements as outlined can be met in cases in which the experimental subjects belong to certain groups, groups identifiable by special settings (i.e., prisons or mental institutions) or by special circumstances (i.e., by the circumstance of being a legal minor, or of being aged, or of being terminally ill, or of being psychiatrically ill).

There is an expression in the literature that bridges both the special setting and the special circumstanced group, namely, "captive groups." Although the term does not include all the groups I have mentioned, it does include two of the three groups emphasized by Pub. Law 93-348; prisoners and the institutionalized mentally ill persons. Since the third group of interest to us will not be intended when subsequently we shall use the expression, "captive groups," I propose that we begin this section considering them first.[22]

A. Infants and Minor Children Generally

As we have seen the principle of informed consent has been tailored with a view toward keeping the class of "prohibited subjects" as small as possible. Thus, in the case of infants and children, the burden of informed consent must necessarily fall upon the researcher and a third party, whether parent(s) or legal guardian. The use of members of this group as subjects in biomedical research is problematic, nonetheless. On the one hand, there is the sick child whose parents or legal guardian may be presumed to be anxious upon learning that known, tested procedures or treatments are ineffective. It is conceivable that an anxiety factor may impair free judgment, a prerequisite to consent to an experimental therapy. However, I see no objection on principle to the use of sick children in biomedical experiments, provided 1) there is the relevant third-party informed consent and 2) the experimental procedure or treatment is directly related to the particular illness of the child to be experimented upon.[23]

As to a second category comprising children who are well, the situation strikes me as quite different. In the case of healthy children who have nothing themselves to gain from the experiment, it appears to me that for their parents or guardian to consent to their use in experiments is to offer them upon the sacrificial altar of medical progress, about which we have spoken earlier on. Even if the parents/guardians themselves have volunteered as subjects in biomedical research—and I would propose that they do so as an acid test of their commitment to medical progress (or to the public good, if they prefer to see it in this light)—it is by no means evident to me that a parent has a right to consent to the use of his minor offspring in such contexts as we are here discussing. Nor is the right to give consent established in the case of older children who themselves indicate a willingness to participate in such experiments.

If the state can legitimately interpose itself as the ward of a minor in order to secure medical relief for children whose parents, on religious or other grounds, refuse consent, ought not the state afford equal protection to physically well minors whose parents may have forgotten that experiments, by their very nature, are risky, no matter how small the foreseeable risks? Public policy, it seems to me, ought to extend to these cases at least to the extent of ensuring a) the competence of the parents, b) the competence of the researchers, c) the quality of the research design, d) the favorable cost-benefit ratio; and, in the case of children judged old enough to understand what to expect from their participation, e) the willing consent of the prospective child so indicated. By monitoring these parameters of the research project, the public shall have safe-

[22] A case can be made for construing minor children as captive groups. Among authors I have read, Jonas is the only one who excludes prisoners when he speaks of captive groups See below, p. 28.

[23] The ethically redeeming principle here is the well-being of the patient.

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guarded its interest in the right to life and limb of its healthy children, if not to the full extent it has been known to take in some sick children, at least to a greater extent than it obtains at present.

With this proposal of safeguards relative to healthy children, we come short of facing the ethical verdict on biomedical experimentation on healthy children. To sharpen the ethical issue I now cite a case reported by Dr. Lasagna, which seems to fall in between the two categories of sick and healthy children:

"One experiment with retarded children that superficially seems disturbing turns out to be unobjectionable, in my opinion, on full examination. Newly admitted children to the Willowbrook State School in New York State have actually been infected with hepatitis virus by dosing the children with serum from Willowbrook patients with hepatitis. This seems at first glance abhorrent, but in fact everyone admitted to the school appears to develop hepatitis anyway during the first six to twelve months. In the inoculated children, the dose can be adjusted, and immunity can be acquired by experiencing a disease that is no more severe than the usual (rather mild) illness clinically acquired. Furthermore, the experimental group can be housed separately and exposed to the hepatitis virus without simultaneous infection from other organisms endemic in the institution. In this case, the protocol was reviewed and approved by several agencies, informed consent is always obtained from the parents, and the use of children who are wards of the state is scrupulously avoided." [24]

I, for one, cannot agree with the author that the initial abhorrence disappears upon further examination of the case as reported here. Three observations seem pertinent: First of all, is this a case of biomedical research, notwithstanding the reference to "experimental groups"? If it is experimental, what is its purpose, for there appears to be no new knowledge forthcoming in regard to the aetiology and management of hepatitis. But if it is an experiment, the argument "I shall deliberately dose you with hepatitis, because you are going to get it anyway," seems to me to have slided down the slippery slope of the German doctors at Nuremberg who attempted to defend their experiments on the grounds that their subject/victims were going to die anyway. Shall we allow this sort of rationale to range over the terminally ill, who are going to die anyway, so why not experiment on them? Shall it extend to the public at large—we are all going to die anyway?

I would make a second observation to the effect that cases such as Willowbrook (and I might add the Tuskegee Syphilis Study and the experiments of Dr. Stough) merely add to the wariness engendered at Auschwitz of entrusting ethical requirements to the professionals, which relates to my third observation. Let me indicate it briefly in this fashion: if children institutionalized at Willowbrook generally contact hepatitis, why nto direct efforts toward improving the physical conditions under which the children live, instead of regarding the disease as inevitable? Or is it much cheaper to dose the children with serum than to attack the conditions that spawn its high incidence? And to tie in with my previous point, why are institutionalized children who are wards of the state, "scrupulously avoided" in such experiments? Why cannot the other children receive equal protection from risks of experiments? It seems to me that a case could be made out of making all mentally retarded children who are institutionalized (publicly not privately) wards of the state thus to protect them from being used in biomedical research unrelated to actual illnesses they might have.[25]

As a final point on the subject of the participation of children in biomedical research experimentation I think it is instructive for us to update the biblical story of Abraham and Isaac. In the modern version we have only to substitute medical progress "or the public good" for God to see contemporary Abrahams offering their children as sacrifices, though without in return having any promise that they will get them back "as good as new" nor any justifiable appeal to the idol of medical progress (or the public good). According to one influential analysis of the Abraham story,[26] Abraham was remiss, from an ethical point of view, for he would violate the moral law that a father should love his son. Moreover, Abraham was remiss, ethically speaking, in keeping from Sarah his

[24] Lasagna, *op. cit.*, p. 271.

[25] Here I agree with Richardson that the "mark of a caring person or society is the protection and special advantages it accords to the weak, to those unable to fend for themselves." *Op. cit.*, p. 170.

[26] S. Kierksgaard, *Fear and Trembling* (New Jersey: Princeton University Press).

wife and Isaac his son, the purpose of his journey to Mt. Moriah. In short, the divine command to sacrifice Isaac entailed a "teleological suspension of the ethical."

What Abraham resolved to do, from an ethical point of view, deserves the name "murder"; religious (and higher) expression for this is that Abraham would "sacrifice" Isaac. Granting that most experiments involving healthy children pose minimal risks, I should contend that the analogy still holds, since one must trust, i.e., have faith in the researchers on this point. Thus our updated version of the Abraham story raises the question how far in the name of medical progress (or the public good) we want to suspend the ethical requirement that persons and would-be persons be respected as co-equal centers of freedom. I reiterate my contention that we ought not experiment on healthy children at all.

B. CAPTIVE GROUPS: PRISONERS AND THE INSTITUTIONALIZED MENTALLY ILL

The use of criminals in medical investigations appears to be as old as the history of "medical art" itself. In former times criminals were known to have been donated outright to medically curious practitioners.[27] What arguments, if any, were construed to justify this trafficking in human flesh I cannot say. I can only conjecture that the status of being a criminal afforded no residue of rights for the criminal insofar as his life and limb are concerned. A criminal donated for medical research was not a person, whether the term "person" be taken in a moral or legal sense.

In our enlightened age, we hear much about the "right of prisoners" to volunteer as subjects in biomedical research experimentation. Nonetheless, a recent study concludes that "There is enough evidence to support the termination of human experimentation in the prison, even if the evidence doesn't demand it." [28] Others favor the continuation of inmate participation, a position advocated by Drs. Hodges and Bean, who have written as follows: "We feel that the use of prison volunteers for medical research is justified and highly desirable for the investigator, for the subjects, and for society. It not only permits the conduct of human investigation under ideal circumstances, but it enables the participants to feel that they are serving a useful function as indeed they are." [29]

In the paragraphs that follow we shall rehearse and criticize the arguments both favoring and disfavoring the use of prisoners in biomedical research. Among issues to be considered are 1) what motives prompt the prisoner's interest in being subjects and what motives prompt the researcher's interest in using prisoners as subjects; 2) what benefits, if any, redound to the prisoners themselves; 3) what interpretation is to be put upon the notion of volunteering within the confines of a prison, and 4) the ultimate question: is the use of prisoners in biomedical experimentation consistent with the ethical requirements outlined in Section I. (The empirical question, Does the current practice in regard to participation of prisoners as subjects in biomedical research meet the ethical requirements will not be stressed here. One must note, however, that even those who favor prisoner participation readily acknowledge abuses in the present systems and qualify their advocacy by the proviso of further safeguards to prisoner safety and prisoner rights to follow-up treatment.)

1. Motives: Why do healthy prisoners volunteer as subjects in biomedical research—if, indeed, they do volunteer? Why do researchers invite inmate participation?

Such information as we have concerning the motives of prison volunteers is based on scattered direct testimony of prisoner participants. Acknowledging the absence of systematic studies of prisoners motives, we need not take this testimony at face value. Nor should we be overly concerned as to which, among multiple motives, may be assessed as the dominant motive. For our purpose it suffices to consider whether any of the motives reported in the literature strikes us as sufficiently worthy so as to count in the debate over continuing biomedical research in prisons.

[27] Pappworth, *op. cit.*, p. 60.

[28] Jonsen and Lee, *op. cit.*, p. 62.

[29] Robert E. Hodges, M.D., and William B. Bean, M.D., "The Use of Prisoners for Medical Research," *Journal of the American Medical Association* (JAMA), Vol. 202, No. 6 (Nov. 6, 1967), p. 515.

The recorded list of prisoner motives includes the following: 1) the motive to escape the boredom of ordinary prison routine; 2) the motive to escape possible violence (including sexual violence) at the hands of other inmates; 3) the motive to increase self-esteem by contributing to a worthy cause; 4) the motive to impress other inmates in regard to daredeviltry; 5) the motive to improve chances of getting a job, once released from prison; 6) for those prisoners who regard themselves as "loners," the motive of acquiring a "substitute parent" in the person of the research physician; and 7) almost uniformly reported, hence, the universal, if not dominant, motive of earning money.

Other variations on these motives have also been recorded.[30] For example, when the research is being carried out in prison wards in free-world hospitals, there is the motive to escape into the free world.[31] In the words of one writer, there sometimes is the motive to gain "feminine proximity." [32] One may enlarge the list simply by referring on the one hand, to the conditions of prison life, and on the other hand, to the value persons, including prisoners, place upon freedom.

Discrepancies in direct testimony provide the wedge for rejecting some testimony at face value. For example, the same prisoners who exaggerate to other non-participating prisoners the risks incurred by them in the experiment, tend to minimize such risks when discussing these matters with their families.[33] There is also the possibility that prisoners report what they think investigators want to hear. Moreover, many prisoners believe, despite disclaimers to the contrary, that their participation in experiments will influence parole boards in their favor.[34]

Two of the reported motives deserve special attention, since they bear directly upon the determination we shall make of whether to continue human experimentation in prisons. In regard to the motive of contributing to society (or to medical progress), we note that it has been convincingly argued elsewhere that no society that places a premium on the individual as over against the state can with logic consistency demand pure sacrifice, that is to say, sacrifice without personal gain, from any of its members. Speaking specifically of human experimentation, Hans Jonas observes that "What is asked goes decidedly beyond, even runs counter to what it is otherwise deemed fair to let the individual sign over of his person to the benefit of the "common good." Indeed, our sensitivity to the kind of intrusion and use involved is such that only an end of transcendent value or overriding urgency can make it arguable and possibly acceptable in our eyes." [35]

Jonas considers a declaration of war, but not the cause of medical progress, to posit an overriding urgency.

Although I can readily agree with much of Jonas' careful analysis of the ethical issues raised by human experimentation, I cannot concur with his opinion that prisoners might be allowed to volunteer for medical experimentation. Whereas Jonas is prepared to prohibit the use of captive groups in medical experimentation, he remarks in a footnote that captive "refers to captives of circumstances, not of justice. Prison inmates are, with respect to our problem, in a special class. If we hold to some idea of guilt, and to the supposition that our judicial system is not entirely at fault, they may be held to stand in a special debt to society, and their offer to serve—from whatever motive—may be accepted with a minimum of qualms as a means of reparation." [36]

It is this line of thinking that pervades the arguments of a number of writers who favor use of prisoners as experimental subjects albeit the rationale is only obliquely indicated. Let us give it a full-dress review.

According to Jonas in the passage just cited, the moral acceptability of participation of prisoners presupposes two things: 1) the idea of guilt and 2) the supposition that our judicial system is "not entirely at fault."

[30] *Ibid.*; see also John C. McDonald, "Why Prisoners Volunteer To Be Experimental Subjects," JAMA, op. cit., pp. 511–12. McDonald writes that "The inmate does not volunteer because he expects his sentence to be shortened, nor does he volunteer for financial reward. Actually he does so for much more immediate reasons, which are quite apparent to him and which seem quite sound (p. 511). Among other "reasons" McDonald reports thrill-seeking and he notes that some inmates felt justified "in accepting risks for the common good which they themselves would not accept if they were outside."

[31] Reported by Hodges and Bean, *op. cit.*

[32] *Ibid.*

[33] Jay Katz, *op. cit.*, p. 1023.

[34] Jonsen and Lee, op. cit., p. 10, p. 35, p. 50.

[35] Jonas, *op. cit.*, pp. 9–10.

[36] *Ibid.*, fn 9, p. 30.

Apropos the first point, I would ask whose sense of guilt is intended here, the prisoners' or ours—the judging public? If Jonas is saying that the prisoner must have a sense of guilt in order for his participation in biomedical research to be morally acceptable, then he indirectly is proposing a criterion of selection for inmate participation. Ought we then to require that a prisoner demonstrate a sense of guilt to be eligible to participate in biomedical research? On the other hand, perhaps Jonas is saying that we, the public, must have an idea of guilt by reference to which we comprehend the prisoner's motive to expiate his guilt. Either interpretation points to a sense of guilt on the part of the prisoner, and the attendant notion of settling accounts.[37]

We come now to consider a critical difficulty in this view; incarceration, apparently, is not a sufficient penalty for the crime. Having stripped the prisoner of all rights we value, we find it morally acceptable to invite him to exercise the one right most of us disvalue, namely, the right to surrender his toehold on personhood by becoming a subject in biomedical experiments! I submit that this is curious rehabilitation to say the very least. Let us reiterate Jonas' remark, cited in part above, which, it seems to me, decisively puts the moral issue raised by human experimentation: "What is wrong with making a person an experimental subject is not so much that we make him thereby a means (which happens in social contexts of all kinds), as that we make him a thing—a passive thing merely to be acted on, and passive *not even for real action*, but for token action whose token object he is. His being is reduced to that of a mere token or "sample . . . compensations of personhood are denied to the subject of experimentation, who is acted upon for an extraneous end *without being engaged in a real relation* where he would be the counterpoint to the other or to circumstance. Mere "consent" (mostly amounting to no more than permission) does not right this reification. Only genuine authenticity of volunteering can possibly redeem the condition of "thinghood" to which the subject submits." [38] (Emphasis added)

Unwittingly Professor Jonas has hemmed himself into an indefensible position. Either he must say that a prisoner is not a person to begin with (in which case he is incapable of genuine authenticity of volunteering) or he must say that merely by being passive, by *neither acting nor by being engaged in a real relation*, a person may after all do something, i.e., make amends for his wrongdoing. I need not elaborate the logical howler this latter alternative poses. It seems to me that it is the former alternative, the tendency for the most part, to view the prisoner as a non-person that accounts for the lack of moral qualms over his use as an experimental subject. But since the advocacy of his right to volunteer presupposes the prisoner to be a bit of a person, those who argue for this right also espouse the irony of the view that a valid expression of personhood is the resolution to become a thing. We shall have more to say about the prisoner's right later on.

We began this discussion by noting that prisoners have sometimes reported that they are prompted to volunteer for experiments in order to contribute to medical progress or to the public good. By way of evaluating this motive, I have attempted to show that by the very same stroke by which the prisoner freely consents to be an experimental subject, he forfeits his toehold on personhood qua experimental subject. His contribution to society therefore is the final capitulation to the image entertained by others of him in the first instance, in that he becomes the non-person others regard him to be. My assessment of his motive, therefore, is that it fails to be worthy to count in the deliberation of whether or not to continue human experimentation in prisons. It goes without saying that I am not denying that prisoners may be motivated to contribute to medical progress or to the public good. What I am saying is that we ought not to permit a self-stultifying outlet for this motive. One cannot, it seems to me, recover the dignity of persons by becoming a thing.[39]

[37] For a careful analysis of the historical connections between the concept of responsibility and accounting terms, see William Kneale, "The Responsibility of Criminals," in *Moral Problems*, ed. James Rachels (N.Y., etc.: Harper & Row Publish., 1971).

[38] Jonas, *op. cit.*, p. 3.

[39] In Section I, I have argued along lines suggested by Jonas that the moral wrong posed by human experimentation lies in the loss of personhood on the part of the experimental subject. In effect this means a surrendering of what is the source of all personal values. But a prisoner, by virtue of his status as prisoner, has already lost his autonomy to a very great extent. Thus it is not clear to me that he has sufficient moral autonomy for so momentous a moral act—his toehold on personhood lacks sufficient redemptive power to offset the action of the experimenter upon him.

At this point I shall address the widely reported motive of earning money. Let us not quibble about the small pittance involved. As researchers are quick to point out, it is the prison officials, generally speaking, not they who determine the *quid pro quo*, and the latter also are quick to point out (if, indeed, they speak at all) that they deliberately keep the sums small so as to discourage the money motive. To this I should remark that if prostitution is not legal in the free world, why should it be legal within the confines of a prison? For where the money motive predominates in the decision to volunteer as an experimental subject, make no mistake we are dealing with prostitution—the selling of one's body for financial gain. The price is thus a secondary issue. As I see it, the money motive is to be discredited along the same lines as the altruistic motive, i.e., that it leads to a self-stultifying expression.

The inviolability of persons is not the only ground from which to reach the same conclusion. On utilitarian grounds as well one may discredit the money motive. A utilitation view regards the best motives as those that regularly lead to right acts and the worst motives are those that least frequently lead to right acts. Considered in this light, the money motive of prisoners appears to lead to a network of wrong acts and should not be encouraged.

The same authors who concluded their study by observing that there is enough evidence to terminate human experimentation in prisons even though the evidence is not conclusive have reached their conclusion independently of the considerations we have just entertained. In point of fact they leave the door open to further experimentation in prisons by observing that "most inmates appear to favor experimentation; and since it is their bodies which serve research, their preferences should be more heavily weighted. . . .

"It would be easy to conclude based on the current record, that human experimentation in prisons should be abolished. But to do so would violate one important principle: the right of inmates, subject to strict safeguards, to make real choices. To force the inmate, effectively or directly, to participate, *or* to prohibit the inmate from participating, both violate this principle. . . .

"The importance of prisoner attitudes cannot be underestimated. In any calculus, the views of inmates should be given as much, if not more, weight than the sage opinion of disinterested experts, and certainly more than the assuagements of researchers." [40]

It seems to me, on the contrary, for the reasons I have shown above, that the views of inmates point to a need for a consciousness-raising program. Given the limited range of options for time-use projects, given also the conditions of prison life, the preferences indicated by prisoners need not be construed as sacrosanct.

The second part of the question at hand focusses on the motives of researchers. We raise this question because, as argued earlier, the ethicality of human experimentation turns upon not only the subject being experimented upon but upon the experimenter as well. Researchers are commonly said to be motived by a desire to further medical progress (and/or the public good). How far this is a genuine motive, divorced from interest in advancement of personal careers, we need not attempt to determine. The increasing emphasis on Peer Review Committees apropos research proposals may be taken as an acknowledgement of the fact that pure altruism alone is not a sufficient safeguard of the experimental subject insofar as ethical and scientific requirements are concerned. There may be, in fact, though not necessarily, a direct connection between zealous commitment to medical progress and moral myopia in regard to means—end considerations.

Our scrutiny of the motives of researchers favoring the prison setting must not blink the fact that in the words of Drs. Hodges and Bean, already cited, "the use of prison volunteers for medical research . . . permits the conduct of human investigation under ideal circumstances." Drs. Jonsen and Lee make the same point as follows: "Prisoners and prisons offer to research something rarely found elsewhere: constancy of experimental variables. Life in the prison is simple and rudimentary. All prisoners eat the same fare, participate in roughly the same programs, and share approximately the same quarters. The living conditions of most prisoners are comparable to those of experimental animals. Consequently, when introducing an experimental variable—a cosmetic or a medication—only a few factors have to be controlled for research purposes. For this reason prisons have been natural targets for experimentation requiring human subjects. Based

[40] Jonsen and Lee, *op. cit.*, pp. 48, 55, 59.

on fragmentary data, most of the activity appears to have been bio-medical in nature; but food, personal products, and cosmetic interests have also been involved." [41]

If it is morally acceptable to carry out human experimentations within the prison setting, researchers are extremely fortunate indeed to have available such ideal (and not easily duplicatable) conditions under which to conduct their experiments; if on the other hand, it is not morally acceptable, the ethical requirements for conducting such experiments may always be bent.

Finally, on the subject of motives, we may observe that whereas it is important to consider motives if we are to understand why we are faced with this problem in the first instance, it is not important to consider motives as pivotal to the question of ethical requirements governing human experimentation in prisons, unless they meet the specification of those requirements in Section I. Whatever position we take on this larger question, motives such as we have discussed here are likely to keep the question a live issue. I trust that I have indicated some possible interpretations to put upon known prisoner protests against declared moratoria on human experimentation in prisons.[42]

2. Benefits: What benefits, if any, redound to the prisoners themselves?

We may treat very briefly the question of prisoner benefits, in view of our extended discussion of motives. Motives, after all, imply ends-in-view—in this case benefits to the prisoners. A number of benefits to prisoners have been pointed out, including relief from boredom, personal satisfaction stemming from contributing to a worthy cause, improved self-esteem, money with which to purchase cigarettes from the commissary and so on.

Most of these benefits, I should think, are not inextricably connected to participation in biomedical research. If prisons afford very little opportunity for gaining these benefits by some means short of participation in experiments, so much the worse for prisons, or more pointedly, so much the worse for the public that countenances prison systems. Here I shall dwell upon the alleged benefit of the prisoner resulting from his participation in decision-making so far as biomedical research is concerned.

Again I am citing Jonsen and Lee: ". . . a more important 'benefit' [than financial compensation] may be inmate decision-making. Prison drastically reduces the number and quality of decisions for the inmate. Prison life is routine and regimented—the only 'real' decisions are often rebellious." [43]

A real decision, these authors argue, is made concerning whether or not to participate in biomedical research. Moreover these authors and others as well contend that prisoners have a right to decide for themselves whether they shall participate in experiments.

The question of the prisoner's right surfaces again and again in the present debate. It is implied that the exercise of this right is precisely what brings about benefits such as improved self-esteem. The devoted advocacy of prisoners' rights (in the limited context we have in mind here) from such quarters as we have seen (mainly from research-minded persons) in undoubtedly without parallel in the annals of the American Medical Association.

We now raise the hard question: does the prisoner have a right to participate in biomedical experimentation? I have no intention of entering into the centuries' old discussions among philosophers as to the nature of rights. Suffice it to notice that we should be wary lest we are forced into what I consider to be an untenable position, namely, that of construing human experimentation in prisons as obligatory on the one hand or construing prisoner's rights as unenforceable on the other hand. As I see it, although human experimentation may be desirable in some contexts, we must reject the notion that human experimentation is necessary in any context, except in the sense identified by Dr. Beecher when he wrote that "Every act of a doctor soundly to relieve or cure a given patient is experimentation of an easily justifiable kind." [44]

It may well be that writers who support the notion of a prisoner's right to participate in biomedical research actually are thinking of a *privilege* rather than a right. For whereas rights are thought of as entitlements to press claims and to obligate, privileges have no such standing.

[41] *Ibid.*, p. 1.
[42] *Ibid.*, p. 14.
[43] *Ibid.*, p. 47.
[44] Cited in Pappworth, *op. cit.*, p. 9.

We must conclude, I think, that prisoners at most may have a privilege, not a right, to participate in biomedical research. Since privileges, unlike rights, are conferred upon persons and may be revoked at will, it is not clear to me that prisoners, by deciding to offer themselves as experimental subjects are exercising the degree of autonomy some writers have attributed to them in this context. Drs. Jonsen and Lee have contrasted the decision to participate in experiments with the decision prisoners make concerning whether to learn to paint, finding the latter to fall outside the category of "real" choices. In the light of our distinction between privilege and rights, the same finding may apply to the decision to participate in biomedical research. I would go so far as to suggest that the dangling of such a privilege in front of prisoners is itself an inducement on a par with inducements such as escape from intolerable conditions. Nor can I think of a better way to insure a sufficient supply of prison "volunteers" than to encourage prisoners to think they have rights to volunteer. Of course, if it should be demonstrated that I am wrong, then prisoners who volunteer but who are not selected for participation in a given experiment may legitimately seek redress.

How then to summarize my position on the alleged benefits of prisoner participation in biomedical research, considering such participation to presuppose privilege rather than rights? In a word—prisoners should beware of Greeks bearing gifts!

3. *Volunteers—What interpretation shall we put upon the notion of prisoners' volunteering themselves as experimental subjects in biomedical research?*

Privileges, no less than rights, are exercisable with or without restraint. The institutional setting in which prisoners live is regarded by a number of writers as intrinsically coercive. Hence they argue that prisoners cannot be said to give voluntary consent to their use as experimental subjects.[45] In Section I we observed that consent may be willing or reluctant. Reluctant consent does not satisfy the ethical requirement. Shall we construe the "quality" of consent obtained from prisoners as willing or reluctant?

Again prisoner's testimony may have some bearing on the question although it remains to be seen whether such testimony ought to be taken at face value. The acid test appears to me to lie in isolating the motive to serve society or medical progress. I have already argued that this altruistic motive should be discounted in the determination of the fate of human experimentation in prisons.[46] Here I might add the observation that the very existence of multiple motives having no intrinsic connection with the purpose of the experiment reveals the extent to which the decisions of prisoners to participate in experiments are made under pressure and, hence do not meet the ethical requirement of free or willing consent.

Martin Miller reports the testimony of one prisoner as follows: "When I went to the [parole] board last time I tol' them I was doing research, but they said they didn't care—like it wasn't nothin' to them. I didn't dig it man; didn't they want me to . . . I mean, wasn't it helping no one?"

A second prisoner is quoted: "This doctor, I think he was, asks me to sign the 'release' and I say could I read it, and he says, there's a long line of guys waiting and if I want to read it, it's perfectly all right, but I'll have to get out of the line and take it back to the cell. Then if there is any room next week, I might be able to get on it. I need the dough, so I signs it."[47]

To be sure, there is testimony of different tenor, as for example, to quote one inmate: "Medical research is one of the very free choices a man has in prison. Where his every action is governed by a mass of rules and regulations . . . he is allowed . . . to pursue a program that benefits society, his family, and himself."[48]

Even this apparently conflicting testimony about the quality of choice is conjoined with a pointed indication to the coercive environment that is the backdrop for such choices.

[45] See Response from States of Vermont and Oregon to survey conducted by Jonsen and Lee, op. cit., p. 11; see also, *Ibid.*, pp. 15 and 26–27.

[46] The public, it seems to me, ought to be prepared to see early releases of those prisoners who have truly reformed to the point of genuinely having altruistic motives. Having such motives puts them a cut above most free-living mortals.

[47] Jonsen and Lee, *op. cit.*, 35—35.

[48] *Ibid.*, p. 47.

Recognizing the weight of pressures upon prospective volunteers, Professor Jonas has argued that the research community itself, ideally speaking, should supply volunteers in the first instance and that "one should look for additional subjects where a maximum of identification, understanding, and spontaneity can be expected—that is, among the most highly motivated, the most highly educated, and the least 'captive' members of the community."[49] As we have noted Jonas would exclude prisoners from the class of captive persons, but having set aside his double penalty theory, we would include prisoners when he observes that "The ruling principle in our considerations is that the wrong of reification [becoming a thing/object for the purposes of the experiment] can only be made 'right' by such authentic identification with the cause that it is the subject's as well as the researcher's cause—whereby his role in its service is not just permitted by him but *willed*. That sovereign will of his which embraces the end as his own restores his personhood to the otherwise depersonalizing context. To be valid it must be autonomous and informed."[50]

Volunteering is genuine (willing) volunteering only if the end to be pursued in the experiment is an end to which the volunteer is devoted. Wherever motives operate for ends other than those pursued in the experiment, there is no devotion to redeem the depersonalization of the experiment. Given the extraneous motives of prisoners who "volunteer" for biomedical experimentation we must conclude that most prisoner "volunteers" give reluctant consent and hence are volunteers in name only.

Before leaving the subject of volunteering I should like to meet one objection raised by Lasagna and others, to the effect that some form of coercion, for all we know, may infect the decisions of all volunteers, not just the decisions of prisoners. It may well be true that a twin to use Lasagna's example, is under more coercion to donate a life-saving kidney to his twin sibling, than is a prisoner in volunteering as an experimental subject in biomedical research.[51] However, the twin's motive to save a particular life is not extraneous to the procedure to which he submits and hence escapes the criticism noted above.

4. *The Ultimate Question:* Is the use of prisoners in biomedical experimentation consistent with the ethical requirements outlined in Section I?

To answer the question that introduces this part of the paper we have to reiterate the ethical requirements outlined in Section I and to summarize our findings in regard to prisoners' motives, benefits, and volunteer status. In Section I we noted that

(1) the principle of informed consent may be construed as a proposal for regulating the conduct of interested parties in the context of experimenting on human beings,

and that

(2) the principle of informed consent is a proposal to ensure that the intrinsic value of persons acting and being acted upon in biomedical experimentation shall not be compromised,

furthermore, that

(3) the principle of informed consent is a proposal to legitimize on ethical grounds the experimenter's intrusion upon the inviolability of the personhood of the experimental subject.[52]

Professor Jonas comes very close to admitting that this principle cannot, by itself, ensure the ethicality of human experimentation when he writes as follows: "The mere issuing of the appeal, the calling for volunteers, with the moral and social pressures it inevitably generates, amounts even under the most meticulous rules of consent to a sort of *conscripting*. And some soliciting is necessarily involved. This was in part meant by the earlier remark that in this area sin and guilt can perhaps not be wholly avoided. And this is why 'consent,' surely a non-negotiable minimum requirement, is not the full answer to the problem."[53]

Thus Jonas is led to direct the appeal for volunteers to the research community itself: "With the fact of self-solicitation the issue of consent in all its insoluble equivocality is bypassed *per se*. . . . By himself, the scientist is free

[49] Jonas, *op. cit.*, p. 18.

[50] *Ibid.*, p. 19.

[51] Lasagna, *op. cit.*, p. 268.

[52] See pages 9–10; 10, 15 above.

[53] Jonas, *op. cit.*, pp. 16–17.

to obey his obsession, to play his hunch, to wager on chance, to follow the lure of ambition." [54]

Criteria for selection of volunteers, if based on Jonas' description of the ideal pool of volunteers, include being highly educated, highly motivated to the point of being able to identify with research aims, and being free from coercion as far as possible (unless being touched with the divine madness is itself a form of coercion). The profile of the average prisoner seems a long distance away from the profile of the dedicated scientist. Far from being highly educated, prisoners have been reported to have a low verbal ability.[55] As Jonsen and Lee have put it, "some inmates lack even rudimentary skills." [56] Citing Miller's study, they hold that "rarely do the high ideals of research held by experimenters permeate prisoners' perceptions," [57] and further, that "Inmates are generally less likely to be literate, many research protocols and accompanying consent forms could as well be Sanskrit." [58]

In the light of these considerations, as well as those put forth above in regard to prisoners' motives and expected benefits, it seems to me that it would be the rare prisoner indeed who would by his participation meet the ethical requirements we have outlined. Thus, as I see it, the appeal for volunteers from prison populations ought not generally to be made; I would go so far as to hold the experimenter morally responsible for issuing his appeal to the "right" persons—that is, to persons who enjoy the perquisites of personhood. On the other hand, if the experimenter can identify with the subject in accordance with the principle of equality defended by Pappworth and cited above,[59] then he is being morally responsible in issuing his appeal; otherwise, not.

Finally we should here recall that the prison environment casts suspicion upon the very concept of authentic consent, insofar as the latter implies autonomy. If experimentation intrudes upon personhood, the prisoner's inviolability as person (a moral, not a legal concept) is already intruded upon by his being a prisoner.

This strikes me as penalty enough for the kinds of crimes that pass the screening test of prison officials for prison volunteers, not to mention the American Medical Association.[60] Certainly if informed consent as an ethical principle is seen to derive from the moral concept of a person, the loss of perquisites of personhood should also be seen as the most severe penalty, short of death and possibly physical torture, exactable from persons. In a word, prisoners are diminished persons and as such should not be solicited or permitted to give most to a society from which they have gained least.

III. INFORMED CONSENT: SPECIAL DIFFICULTIES IN BEHAVIORAL RESEARCH

Our discussion thus far has referred specifically to biomedical research, but one area in which experimental subjects are human beings. Another area, behavioral research, poses special difficulties in its use of human subjects. We cannot here explore all such difficulties, not even the majority. Given that our problem is still that of informed consent, and our focus on the special groups enumerated in the preceding section, we shall here point out the nature of the difficulty of meeting ethical requirements as far as some kinds of psychological research are concerned.

Of the ten ethical principles adopted by the Council of Representatives of the American Psychological Association in December 1972, we cite two here that seem to enunciate a principle of informed consent.[61]

[54] *Ibid.*, p. 17.
[55] Katz, *op. cit.*, p. 1020.
[56] Jonsen and Lee, *op. cit.*, p. 29.
[57] *Ibid.*, p. 34.
[58] *Ibid.*, pp. 48–49.
[59] See pages 3–4, above.
[60] In 1952 the American Medical Association, House of Delegates, adopted the following resolution: "Resolved, that the House of Delegates of the American Medical Association express its disapproval of the participation in scientific experiments of persons convicted of murder, rape, arson, kidnapping, treason, or other heinous crimes, and also urges that individuals who have lost their citizenship by due process of law be considered ineligible for meritorious or commendatory citation." Quoted from Katz, *op. cit.*, p. 1025.
[61] *Ethical Principles in the Conduct of Research with Human Participants* (Published by the American Psychological Association, Inc., 1200 Seventeenth Street, N.W., Washington, D.C., 20036). Drafted by the Ad Hoc Committee on Ethical Standards in Psychological Research, consisting of Stuart W. Cook, Chr., Leslie H. Hicks, Gregory A. Kimble, William T. McGuire, Phil H. Schoggen, M. Brewster Smith. Hereafter abbrev. APA; p. 1.

3. Ethical practice requires the investigator to inform the participant of all features of the research that reasonably might be expected to influence willingness to participate and to explain all other aspects of the research about which the participant inquires. Failure to make full disclosure gives added emphasis to the investigator's responsibility to protect the welfare and dignity of the research participant.

4. Openness and honesty are essential characteristics of the relationship between investigator and research participant. When the methodological requirements of a study necessitate concealment or deception, the investigator is required to ensure the participant's understanding of the reasons for this action and to restore the quality of the relationship with the investigator.

Close attention to the wording of these principles (as well as to the other eight and to the commentaries accompanying them) reveals that the principle of informed consent is given a qualified endorsement only. On the one hand, "ethical practice requires the investigator to inform the participant. . . ," on the other hand, "failure to make full disclosure gives added emphasis to the investigator's responsibility to protect. . . ."

Similar left-handed giving and right-handed taking away may be seen in the statement of other "principles" as well, e.g., in Principle.

8. After the data are collected, ethical practice requires the investigator to provide the participant with a full clarification of the nature of the study and to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding information, the investigator acquires a special responsibility to assure that there are no damaging consequences for the participant.[62]

The first sentence of Principle 8 clearly takes for granted that the participant will not be provided with a full clarification of the nature of the study *before* he consents to participate. To appreciate the full force of this claim, we must recall that, whereas in psychological experimentation as in all experimentation the outcome cannot be foreseen in every detail, the *nature* of the study is assured by the research design. Thus, Principle 8 is a continuation of Principle 4—the Principle of Informed Deception.[63]

Admittedly, to attempt to conform to the principle of informed consent as we have outlined it in Section I would be to imperil much psychological research of designs so far conceived of by psychologists. Of course, no one knows what ingenuity might produce if informed consent were to be accepted as a requirement for experiments on human beings. The framers of the ethical principles concede as much when they observe that "Practices such as those just mentioned (failure to obtain informed consent, deception, exposure to stress and possible harm, invasion of privacy, withholding of potentially beneficial experiences from members of a control group) raise important ethical issues. *Responsible psychologists will obviously avoid using them in pointless and unnecessary ways.* They will invest their ingenuity in discovering ways of conducting research that avoid or minimize these problems." [64] (Emphasis added)

Far from being a requirement for psychological research using human subjects, the principle of informed consent, as we have seen is tentatively endorsed. The rationale for this tentative endorsement appears in the following statement:

"Many psychologists believe (although some question this) that to obtain valid and generalizable data, it is often essential that the research participants be naive. The requirements, of research may thus seem to demand that the participants be unaware of the fact that they are being studied, or unaware of what is being studied or of the hypotheses under investigation. Or deception may appear to be necessary if a psychological reality is to be created under experimental conditions that permit valid inference." [65]

Here we have a double appeal to the end-justifies-the-means principle. First, the requirements of research (as end) justify the withholding of information or pro-

[62] APA, p. 2.
[63] The drafters of APA distinguish, wrongly I think (see p. 13 above and note 16 above) between a participant's being *uninformed* and *misinformed*. As I have urged earlier on, consent to x implies knowing x. Thus where the participant is misled as to the nature of the research, I would say that he has not consented to participate in the research at all (unless he is one of our not-so-naive participants who is on to the ways of some psychological research on human beings and thus does give blanket consent (see page 50).
[64] APA, p. 9.
[65] *Ibid.*

viding misinformation (as means). Second, creating a psychological reality (as end) may necessitate deception (unreality? as means). In fact, the end-justifies-the-means clearly emerges as the overriding principle—I hesitate to call it an ethical principle. This may be seen to beat the principle of informed consent into hasty retreat throughout the detailed discussion of the ethical guidelines for psychological research using human subjects. "The general ethical question always is," the manual claims, "whether there is a negative effect upon the dignity and welfare of the participants that the importance of the research does not warrant." [66]

The framers of these Ethical Principles in the Conduct of Research with Human Participants take care to disavow advocacy of ethical absolutes.[67] It becomes apparent, however, that the end of benefitting all mankind serves as an ethical absolute wherever the end-means principle is invoked. A number of assumptions are made. I shall pass over the contention that ethics is an empirical science,[68] a point I have touched upon earlier on. This assumption allows the psychologist to pass easily between speaking of their scientific obligations and their ethical obligations: ". . . for psychologists, the decision not to do research is in itself a matter of ethical concern since it is one of their obligations to use their research skills to extend knowledge for the sake of ultimate human betterment." [69]

Again, under the heading *The Scientific Obligation*, they report, "We begin with the commitment that the distinctive contribution of scientists to human welfare is the development of knowledge and its intelligent application to appropriate problems. Their underlying ethical imperative, thus, is to carry forward their research as well as they know how." [70]

I submit that there is a gross confusion exhibited in these statements. Ethical imperatives, I should have though, address themselves to men *qua* men—to persons *qua* persons—not to men *qua* psychologists, or to men *qua* medical researchers, or to men *qua* philosophers. Professional obligations are one thing; ethical obligations, another.

Apart from offering themselves as the saviors of mankind, the psychologists make a further assumption that people generally want to know the truth about human behavior, or that those who want to know it, want to know it at any cost. Many ethicists who argue for the inviolability of persons would demur to the following statement, "on the one hand, there is the contribution that the research may ultimately make to human welfare, on the other, there is the cost to the individual research participant. But in these stark terms, the essential conflict is between the values of science to benefit all mankind and the values that dictate concern for the research participant." [71]

Finally, I would note that some of the ethical dilemmas faced by psychologists doing research—they say "with", I say "on"—human participants may be traced to core assumptions underlying much of the enterprise of psychology. Because psychologists believe there is often a difference between the unobserved behavior and the observed behavior of a given participant, and because they wish to be able to "observe the unobserved behavior" of participants, they sometimes use deception. But the problem may pose not only an ethical but a logical dilemma as well. A participant is deemed "naive" provided he does not know the exact nature of an experiment; lacking this knowledge, he may not be so naive after all, if he happens to know something about the practices of psychologists.

Moreover, insofar as informed (willing) consent is concerned, psychologists ask: "What does it mean to speak of the research participant's 'freedom of choice' when one considers that such choices are the lawful psychological consequences of past and present influences in the environment? And how can we propose that a person deciding whether or not to participate in research should be free from coercion and at the same time maintain that all decisions are motivated and that they are affected by forces that act upon the decision maker? [72]

We juxtapose to these questions that statement of Principle 5, which seems to blink the determination implied in this passage and raises another point of logical consistency:

5. Ethical research practice requires the investigator to respect the individual's freedom to decline to participate in research or to discontinue participation at

[66] APA, p. 11.
[67] *Ibid.*
[68] APA, p. 3-4.
[69] APA, p. 7.
[70] *Ibid.*
[71] APA, p. 10.
[72] APA, p. 39.

any time. The obligation to protect this freedom requires special vigilance when the investigator is in a position of power over the participant. The decision to limit this freedom increases the investigator's responsibility to protect the participant's dignity and welfare.[73]

Research on prisoners is singled out as an example of the investigator's being in a position of power over the participant and although the guidelines exhort vigilance against extreme coercive measures to gain the prisoner's participation in research, they find it acceptable for investigators to attempt to persuade the prisoners that such research is for their own benefit.[74]

Quite unintentionally, in the next but last passage cited, the psychologists have lent support to my contention argued in the previous section that the coercive setting of a prison spawns motives extraneous to the ends of biomedical research, motives that ought not to count in the debate over whether to continue biomedical research in prisons. For if the psychologists are right that "freedom of choice" is a nonsensical notion, on the grounds that choices are "the lawful psychological consequences of past and present influences in the environment," the case against inmate experimental subjects in biomedical research may be reformulated. Coercion in the prison setting consists precisely in the fact that choices—they mean options—are too much the product of present influences and not enough the product of past influences. For if the motive to serve the public good is the product of past influences, how does the prisoner come to be in prison in the first instance; but if the motive to serve the public good is the product of present influences, meaning prison influences, has not the prisoner been rehabilitated to the point of deserving release from prison?

We cannot advance the same case in regard to psychological research designed to benefit the prisoner-participant himself. But we will raise this question: If the end of the research in question is to rehabilitate the prisoner are we not implicitly acknowledging that prisons are institutions for socially ill persons? Pappworth, among others, has pointed to this problem by observing that the "basic problem of the essential purpose of prisons and punishments has not been solved." [75]

IV. CONCLUSIONS AND RECOMMENDATIONS

Our statement of the principle of informed consent has received three formulations, that are offered to show the *intent* rather than the *letter* of a moral principle. We have reasoned that it is easier to cover myriad cases if we are quite clear about the intent of the principle and less easy to handle diversity if we try to apply the letter of the principle.

The first formulation refers to interested parties, and is broad enough to include the public interest as well as interest of researchers and experimental subjects or their legal guardians. By defining the principle of informed consent as a proposal, we have intended to reflect the widespread view in ethics that there are no rationally justifiable ethical ultimates. Basic ethical values are arbitrary.

The second formulation postulates the intrinsic value of persons thus setting itself against a consequentialist ethics or an ethics based on the end-justifies-the-means principle. Finally, the third principle imposes on researchers who comprise the inviolability of personhood an obligation to legitimize their action by obtaining the informed (willing) consent of their experimental subjects.

These are not to be thought of as three separate principles, but as successive elaborations of a single principle. By considering the *concept* of informed consent, we also should have indicated the nature of the content of the principle of informed consent. In this connection we noted the shift from the expression "voluntary consent" to "informed consent" and we reiterate our recommendation that the former expression be adopted, not only because it escapes the redundancy of the expression informed consent, but more important than the point of logic, because it emphasizes the intent of the principle of informed (willing) consent to ensure the ethical legitimacy of any intrusions upon the inviolability of persons.[76]

We have attempted to apply this principle of informed consent to special groups, focussing on prisoners. By appeal to the principle of informed consent as herein outlined, we would exclude as a general rule, from biomedical experimentation all healthy persons qualified by special circumstances of institution-

[73] APA, p. 2.
[74] APA, pp. 39–42.
[75] Pappworth, *op. cit.*, p. 64.
[76] See esp. pp. 10–13 above.

alized settings or minority age. Exceptions might be made depending upon close scrutiny of motives, in the case of prisoners, and competence of parent/guardian as well as sincerity of their own commitment (as indicated by their own history of participation as experimental subjects) to the cause of medical progress.

As far as behavioral research is concerned, we stopped short of anything more than tentative directions pointing to the moral admissibility of research that directly benefits participants, where the benefits are consistent with the ends of the research in question. We expressed criticisms of the American Psychological Association's guidelines for experimentation on human subjects, noting their divergencies from the principle of informed consent.

Our most important finding is that, given the extraneous motives of most prison volunteers in biomedical research and given also the ethical requirement of informed (willing) consent, experimentation on prisoners ought to be abolished. Where the money motive predominates among prisoners experimenters may be seen as solicitors of human flesh and prisoners may be viewed as prostitutes. We have argued that only the altruistic motive of benefitting society through medical progress can redeem the depersonalizing context of becoming an experimental subject and we have queried whether prisoners, having been divested of the perquisites of personhood can in their coercive environment make the morally redemptive act of informed (willing) consent.

We have said very little about the risks of experimentation, since to appreciate the ethical question is to focus elsewhere in the discussion. Nor have we said much about a minority perspective for the same reason. By this I mean to imply that if certain kinds of experimentations are morally offensive in certain contexts, they are offensive regardless of whether the subjects are blue, green yellow or what have you. At this juncture, however, we shall permit ourselves the following observation. One writer, after noting that human experimentation is necessary for medical progress to be made notes that risks of research "cannot be evenly distributed among the members of society, the many will continue to benefit from the contributions of the few." [77]

It seems to me that historically when the few have contributed to the many, they have been treated as heroes not to be denied rewards of a grateful public. But a double standard seems to be in effect on this issue, insofar as prisoners' contribution to medical progress are concerned. Such money as prisoners are paid for being human guinea pigs is deliberately kept small in order to discourage the money motive. Yet the sums, however, paltry, do provide incentive nonetheless to impecunious prisoners. Thus a supply of volunteers is ensured.

There is an overwhelming irony, it seems to me that on the experimenter's table, no less than on the autopsy table, true equality is achieved, for the experimental subject, like the corpse is to use Jonas' words, "a token object for token action." For my part, I should like to see equality first in the free-living world, and secondly, may it filter into the prisons.

In view of the foregoing considerations, I should like to recommend for the scrutiny of this body,

1. That biomedical experimentation on prisoners be abolished.
2. That experimentation on healthy children be subjected to public scrutiny.
3. That behavioral research on prisoners be conducted in hospital wards and be limited to therapeutic treatment or procedures.
4. That behavioral research on the institutionalized mentally infirm be limited to therapeutic treatment or procedures.

Biomedical and Behavioral Research on Prisoners: Public Policy Issues in Human Experimentation

(By Larry I. Palmer)

INTRODUCTION

Our increasing awareness and uneasiness about the course of biomedical and behavioral research in this country has led to the establishment of yet another National Commission. The creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to study the "problem" and make recommendations can be interpreted as a national statement that we have a problem of enormous complexity. Ordinarily such national self-recognition should be applauded. However, our most recent attempts to resolve our national problems such as "crime" or "violence" through the commission process should make us question the efficacy of our present approach. If we think the ability of the nation to face the fundamental issues and to increase the nation's understanding of the "problems" is the purpose of the commission process, some of our previous attempts at commissioning a "problem" should be termed failures.[1] The reasons for failures by this standard are numerous and extremely complex, but I will suggest two explanations. Perhaps those participating in the debates of the previous national commissions failed to ask themselves what the "problem" was that led to the creation of the commission. Or perhaps those participating in the debate and the nation as a whole looked too quickly for "solutions" without a firm grasp of the enormity of their tasks.

By these standards the potential for "failure" looms large for this National Commission, this Conference, and my special topic. We are going to discuss basic ethical issues of "biomedical and behavioral research" [2] without any working consensus as to the meaning of those terms. In other words, we are faced with the question of what is the "problem"? Furthermore, we have added the present confusion surrounding public policy considerations inherent in any topic on prisoners to the murkiness surrounding the ethical issues. Finally, by trying to ascertain the special perspective of minority communities, this Conference has added to our other two difficulties, the social psychological, economic, and moral ambiguity that race, nationality, and religion engender in this country. If these three inherent difficulties are not faced explicitly in our discussion, we are in danger of not even developing a dialogue and not coming forward with any recommendations.

Rather than offer a solution to our first difficulty of defining the "problem" before us, I will face the issue through a frank acknowledgement of its existence and enduring power. The terms used in the Commission's statutory mandate, "biomedical and behavioral research", could be narrowly or broadly defined. In its broadest sense, behavioral research could include certain sociological investigations that involve graduate students doing participant observation or prisoner responses to a simple questionnaire. In a more narrow sense, behavioral research might be interpreted to mean certain types of psychological experiments that are designed to change the behavior of the prisoners. Such experiments in "behavior modification" could include the use of "token economies" in prisons. The term biomedical research is full of similar difficulties since the term might include everything from the testing of new drugs to psychosurgery on prisoners. There is nothing in the statutory language that argues for either a broad or a narrow definition of these terms. The confusion inherent in these terms is exacerbated by the statute's specific instruction to the Commission to distinguish between biomedical and behavioral research and the "accepted and routine practice of medicine".[3] Rather than attempt to give definitional contents to the terms, "biomedical and behavioral research", or distinguish these terms from something else we would have to define, I propose to use terminology that encompasses all of these ambiguities.

The term used by the Conference organizers—human experimentation—is broad enough to encompass all of the widely diverse issues we might want to consider.

Clearly within the Conference's consideration are the testing of new drugs on prisoners. Non-therapeutic medical research on prisoners that is not related to drugs such as cures for malaria are also within the notion of human experimentation. Testing new cosmetics, bandaids, or hand lotions is perhaps less clearly within our concern but certainly contains some of the risks of harm to the subject inherent in the notion of human experimentation.[4] In addition we must include methods of "treating" prisoners to cure their criminality within our discussion, since these methods raise the question of the distinction between routine medical

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[77] Lasagna, *op. cit.*, pp. 273–74.

[1] For an excellent critique of the National Commission on Crime, *see generally*. Lehman, *Crime, The Public and the Crime Commission: A Critical Review of the Challenge of Crime in a Free Society*, 66 MICH. L. Rev. 1487 (1968).

[2] Pub. Law 93-348, § 202(a)(1)(A).

[3] Pub. Law 93-348, § 202(a)(1)(B)(i).

[4] *See*, Mills and Morris, *Prisoners as Laboratory Animals*, 11 *Society* 60 (July/August 1974).

practices and biomedical and behavioral research. Examples of known proposed experiments utilized so far on prisoners include "aversion" therapy for "acting out" prisoners, and social experiments involving early release for some prisoners.[5] Perhaps farthest removed from the core meaning of the notion of human experimentation is a sociological study of prison life. Nonetheless, such studies must be included since they are representative of the pervasiveness of the scientific or research ethos in this society. I will thus employ the term human experimentation to describe certain phenomenon knowing that at the perimiters we will have disagreement.

I will also discuss human experimentation as a process involving various actors and events. Looking at human experimentation as a process means that I will attempt to identify the participants, their purposes, and the values they seek to uphold in western man's desire to increase knowledge about the world and to ensure respect for individual worth and autonomy. The actors in the human experimentation process may include, for instance, drug manufacturers, investigators, physicians, hospitals, prisoner-volunteers, and ultimately the recipients of their services—members of the general public. I will be keenly aware of ways in which the various participants in the process may have conflicts with regard to their purposes and values. I will also pay close attention to how these conflicts are and should be resolved.

Besides helping to illuminate value conflicts within my specific topic, my approach to human experimentation allows for a division of our discussion into functional stages where the decisions and underlying values of the participants can be analyzed more fully. For the purpose of this paper, the process of human experimentation is divided into three distinct but interrelated stages.[6] These stages are:

(1) the formulation of research policy;
(2) the administration of research; and
(3) the review of research and its consequences.

If for some reason these functional stages are inadequate ways of addressing the problem, other divisions are possible. Regardless of the analytical framework adopted, you will have to resolve the value conflicts that I identify, and decide if the process method of dealing with the issues is sufficient to meet your own definitions of the problems before this Conference.

The other major advantage of the process approach is that the explicit assumptions that I bring to the other two difficulties in my topic—prisoners and minorities—can provide a means of stimulating discussion and furtherng much needed dialogue. Since a large percentage of human beings incarcerated in prisons in this country are members of minority groups,[7] we might assume that the issues of prisoners and race are merged for the purposes of our discussion. Yet both issues are so inflammatory that we should be explicit rather than implicit about the relationship of race and prisoners within the process of human experimentation. The explicit assumption that guides the following discussion is that the fact that a large percentage of prisoners are members of minorities means we should not try to separate out the "minority issues". There are two reasons for my assumption. First, the most determinative factors in guiding the actions and decisions of the investigators, prison administrators, courts, and prisoners are the public policy decisions that are explicitly and implicitly made about human experimentation in prisons. Therefore, this Conference cannot ignore the difficult issues of what kinds of research, if any, should public and professional authorities allow in prison?

Second, and ironically, in order to make explicit the moral lessons we have learned or failed to learn about minorities and human experimentation, we must first see the public policy issues. The relationship of the issue of race, religion, and nationality and scientific experiments on human beings looms large in our

[5] N. Morris, *Impediments to Penal Reform*, 33 U. Chic. L. Rev. 627, 646–653 (1969).
[6] *See generally*, Katz, *Experimentation with Human Beings*, 1972 [hereinafter *Katz*].
[7] The adequacy of the statement depends upon how one defines minority. In New York, for instance, if we take Black and Puerto Ricans as our definition for minority, 70% of the prisoners are members of minorities. *Sostre* v. *Rockefeller*, 312 F. Supp. 863, 876–877. In California Blacks and Chicanos constitute nearly 40% of the prison population. Ridenour, *Who is a Political Prisoner?* 1 Black Law Journal 17 (1971). If we use "poor" or "socially disadvantaged" to define minority, the percentage would be probably larger. I am unable to document the exact percentage of "minorities" in prison. For the purposes of this paper, the exact figure is irrelevant

western consciences because of the Nazi Concentration Camp experiments on captives during World War II.[8] A careful examination of those horrifying experiments convinces me that we must understand the process of human experimentation and the allocation of public, professional, and subject decisionmaking authority within that process to avoid such future holocausts. It is also too easy for the participants in this Conference to evoke the Judgment in the Nuremberg Case without giving any explicit guidance to the persons involved in the decisionmaking process that leads to the use of minority prisoners as subjects of experiments. Rather than build special mechanisms for the control and promotion of experimentation on minority prisoners, my assumptions lead me to argue that the special methods are needed for experimentation on all prisoners.

I will thus use a process method to identify three major issues that must be resolved in order to design the necessary kinds of special mechanisms of control for research involving prisoners. I will first develop some guidelines surrounding the formulation of research policy for studies involving prisoners as human subjects. The policies that determine how and why the human experimentation is started are important to the manner in which value conflicts are resolved, and whether the process can achieve the desired degree of social control. Second, I will propose that we look critically at how research involving prisoners is administered. At this point, I will be particularly concerned with who should participate in these administrative decisions. Within this discussion, I will be able to address the issue of the "consent" of prisoners to human experimentation as required by the Commission's statutory mandate.[9] Thirdly, I will address the question of how the decisions and consequences of research on prisoners can be reviewed. Review mechanisms, however, are not the only means of control that will be included in my recommendations. Within these discussions I will include my overall recommendations, derived from my process approach. These recommendations will avoid absolutist positions on the various issues that I raise. By the time I conclude this short discussion of an enormously complex problem. I hope you will see that this Conference is a part of the process of human experimentation.

I. THE FORMULATION OF RESEARCH POLICY FOR RESEARCH INVOLVING PRISONERS AS SUBJECTS

First, we should insist upon a careful examination of the purposes of any research that proposes to involve prisoners as human subjects. Examination of the purposes of research before it is implemented will increase our awareness of the value conflicts inherent in any proposed human study. Such a requirement has the additional purpose of helping those engaged in research to become more articulate about how their own values and goals are furthered by the proposed research. Such general scrutiny of research rather than assuming research should go forward, will help us understand the powerful social forces that lead humans to experiment with other humans. We should not be surprised that without such an approach prisoners were used in experiments to develop vaccines[10] long before our present heightened awareness of the issue of prison research.

The purpose of the requirement of careful scrutiny is to alert all the participants—individual investigators, the sponsoring agencies, and the prison administrators—in the research formulative stages that the use of prisoners as subjects is a special case of human experimentation with high risks to fundamental values. This level of scrutiny should lead those engaged in research policy formulation to ask and resolve for themselves in a satisfactory fashion three issues. First, are prisoners the appropriate subjects for this particular proposed form of human experimentation? Second, what are the societal interests to be gained from the proposed experiment and how do these relate to other pressing societal needs? Third, what are the possible types of risk of harm that may flow from the experiments and what steps have been taken to minimize those risks of harm to the subjects? Ideally, unsatisfactory answers to these inquiries could lead to the decision not to implement some proposed human experiments. An examination of previous cases will demonstrate, however, that too often research involving prisoners goes forward without this type of "strict scrutiny" before implementation.

[8] *See United States* v. *Karl Brandt*, reprinted in *Katz* at 292–311.
[9] Pub. Law 93-348, § 202(a)(2).
[10] As early as 1906, there are reported instances of prisoners being used to test a vaccine against the plague. *Katz* at 1014–1016.

The participants in research policy formulation should begin with a presumption that prisoners should not be chosen as subjects of experiments. For instance, the investigator might ask if there are others in a non-captive setting who are willing to volunteer as healthy subjects to help find a cure for malaria. In point of fact we know there are few, if any, "free world" volunteers for such non-therapeutic biomedical research endeavors. Despite the "fact" that prisoners are the only potential subject pools, our method of strict scrutiny should alert us to the research policy implications of our limited knowledge about why prisoners volunteer. One study indicates that prisoners who volunteer for non-therapeutic biomedical research may view longterm and shortterm risks in a different manner than that of the free population in general.[11] On the other hand, another study indicates that the social position of prisoners within the institution was more determinative in the decision to volunteer, than was their attitude toward risks.[12] While the studies tell us different things about why prisoners volunteer, they are nonetheless useful in developing policy on how prisoner-subjects are recruited. First, the study makes the decision-maker go beyond the issue of the boredom and general level of fear in most of our state prisons and jails in deciding whether or which prisoners to attempt to recruit as subjects. Second, depending upon what is known about the particular institution as research policy is developed, we might try to eliminate certain prisoners from the potential subject pool according to the studies' criteria.

The investigators, sponsors, and prison administrators would try to determine, for instance, if the level of fear of harm is so high in the particular institution that all "loners" without protection are likely to volunteer. Or the participant may try to develop a means of eliminating those prisoners with the least aversion to risk from the potential subject pool.[13] I am not suggesting that such tasks are easy, but they are better means of developing subject pools in prisons than those previously suggested in the literature. Investigators should not eliminate prisoners as "unworthy" of participating in the "great" scientific enterprise as was suggested by one professional organization.[14] Nor should the subject pool be developed by categories of offense, for instance, 'eliminate those convicted of rape, murder, arson, kidnapping, treason, or other heinous crime".[15] If, for instance, we concentrated on "aversion" to long-term risk as our criterion of selection, we might well discover that the persons convicted of violent crimes are more averse to long-term risks than a repeated petty thief incarcerated in a jail facility. The formulators of research policy must face directly the issue that incarcerated prisoners generally want most research to continue,[16] regardless of the prisoner motivations. If the prisoners are to be denied the opportunity to participate—be it to relieve boredom, earn money, etc.—that decision should be as explicit as possible. In general the value conflicts inherent in using prisoners as subjects is made more clear if the volunteer pool is developed so as to ensure that the subjects are those with the maximum opportunity to refuse to participate. In general, researchers should be required to explain why prisoners were chosen as subjects. The failure to develop an adequate subject pool for the proposed study according to the method of criterion chosen by the investigators and administrators should lead to a decision not to proceed with the experiment.[17]

The process of requiring those engaged in research to decide about societal interests and priorities will lead to the rejection of certain research under certain circumstances. This process further forces the investigators, sponsoring agencies, and prison administrators to articulate their own values about the purposes of incarceration, and their attitudes toward the human beings who

[11] *Katz* at 1022.
[12] *Katz* at 1024–1025.
[13] The formulators of research policy would have to decide if some form "testing" of volunteers is ethical. For instance, a general questionnaire on "risk-aversion" might be administered to all volunteers. Would it be ethical to administer the proposed questionnaire without telling the volunteers that its purpose was to eliminate some volunteers from the study?
[14] *See, e.g.*, a statement from the American Medical Association that expressed disapproval of "citations" to prisoner-subjects, in 1952 as well as criticized "early release" for volunteer reprinted in *Katz* at 1025.
[15] *Id.*
[16] *See supra* note 4.
[17] In the well known psychosurgery case of *Kaimowitz* v. *Department of Health*, Civil No. 73-194 34-AW (Cir. Ct. Mich., July 10, 1973), the research protocol called for at least 24 subjects. When only one subject meeting the investigators' own criteria could be found, shouldn't the investigation have stopped?

are incarcerated. Two kinds of examples can highlight the usefullness of the second stages of decision-making about proposed research. First, it was once suggested that those sentenced to capital punishment be given the opportunity to volunteer for medical experimentation instead of receiving the death penalty.[18] At one level it might be deemed more "worthy" to die in the pursuit of some scientific advance rather than suffer a "useless" death in the gas chamber. But if the issue is phrased in another manner, we will see that some serious questions of personal and professional morality must be faced before the project is undertaken. Does the investigator agree with the apparent social decision that the condemned person's life is useless? Are the administrators of the prison entitled to authorize such an experiment if the public's attitude about capital punishment and the purposes of punishments in general are in doubt?[19] A more likely example involves the use of inmates at a city jail facility, for the purposes of conducting a controlled experiment involving "heroin maintenance".[20] If the purposes of legal confinement of heroin addicts is to "treat" them,[21] would a jail administrator of the city jail be justified in deciding that a pilot program might be tried? I will not answer this question since the answer depends upon one's theories of heroin addiction, upon one's attitude towards the prevailing ethos of "treatment of prisoners" which is under heavy attack, and upon one's attitude about the efficacy of the alternatives—jail, methadone treatment[22] or outright release.

The third part of designing research policy that uses prisoners is to decide about harm. Here it is useful to articulate as precisely as possible the types of harm—psychological, physical, privacy and self-determination, etc.—involved in any proposed research. The purpose of this inquiry is to force the investigator and the sponsoring agency to identify the kinds of additional risks of harm involved in the proposed research, so as to minimize those risks. However, it is important in dealing with prison research not to romanticize the harm that the proposed experiment adds to the prisoners' life. Moreover, it is never possible to eliminate all risk of injury. Nonetheless, greater care could be taken to provide, for instance, for psychological counseling in the research design, if the threat of psychological harm was recognized before the project began. Similarly, biomedical research should include backup medical facilities for the prisoners. These kinds of precautions have often not been taken because of the failure of the researchers to engage in the type of strict scrutiny proposed here.

II.

ADMINISTRATION OF RESEARCH INVOLVING PRISONERS AS SUBJECTS

We need not go back to Nazi Germany to realize that the administration of experiments on human captives should include persons other than individual investigators. Several well publicized incidents in this country in recent years indicate that we cannot leave Phase I testing of drug or blood plasma testing to the discretion of individual investigators.[23] The essential question then becomes—who besides the individual investigator should participate in the administration of research on human subjects in prison? There are four basic issues that must be resolved before we can answer the essential question. First, in response to these well publicized abuses on captive populations, we are naturally inclined to look to state regulation as one solution. But that question is still essentially—who among the variety of state officials with the power to regulate research should administer the process? Second, we will address the question of who should participate in the professional regulation of research in prison since professional controls are possible alternatives or complements to state regulation of research in prisons. Thirdly, we will discuss whether the special status afforded prison research in the research formulation stage should lead to a process of monitoring and evaluating the design and scientific merits of any

[18] Keyorkian, *Capital Punishment or Capital Gain*, 50 *J. of Criminal Law, Criminology, and Police Science*, 50 (1959) reprinted *Katz* at 1027–1028.
[19] The nine opinions in the Supreme Court's first decision on the Death Penalty in the United States represents great disagreement about the purposes of punishment. See, *Furman* v. *Georgia*, 408 U.S. 238 (1972).
[20] Such an experiment was proposed in recent years by the Vera Institute in New York City, but dropped after public criticism.
[21] *See generally, Robinson* v. *California*, 370 U.S. 660 (1962).
[22] The efficacy of methadone programs is under some attack. Epstein, *Methadone: The Forlorn Hope, The Public Interest.*
[23] *Katz*, at pp. 1041–1050.

project that is implemented. Finally, we will discuss whether the consent of the prisoners to the experiments should be supervised in ways that are distinct. In general, we will find that the elements of "consent" are not the overwhelming issue in prison research that we might assume from the statutory mandate to the National Commission. Rather, defining the functions of consent in the human experimentation process in prison will remain the most difficult issue to resolve once the research design has been implemented.

State regulation of the administration of prison research might ordinarily be a matter of ensuring that volunteers for research projects are not given special institutional advantages such as better chances for parole as a reward for participating in the project. But two larger issues loom in the public eye today. First, whether the legislatures should prohibit all rseearch in prisons. Second, whether the legislatures should require special kinds of administrative structures for certain kinds of human experimentation in prisons.

As to the first issue, I would urge this Conference to refrain from recommending a complete prohibition on all research involving prisoners. Not only would such a position not deal adequately with what we do and do not know about the complexities of the situation, but also the prohibition is likely to lead to the recruitment of new subjects. Such subjects, for instance, for Phase I drug testing, are likely to be "disadvantaged" by some standard. It has been suggested that the drug manufacturers would be encouraged to seek volunteers in poor and less developed countries if there were a complete prohibition in this country.[24] In other words, a complete prohibition in this country will simply displace the value conflicts we already have about research on prisoners, but not eliminate those conflicts.

As to the second issue of whether some form of legislation is needed for certain types of special treatments utilized in prisons, I agree with the growing consensus that such legislation would be useful to the proper administration of these types of experiments. These types of experiments, usually called treatment, aversion therapy, or organic therapy,[25] are crucial to this Conference because of the statute. These types of experiments are the prisoner's version of the distinction between "biomedical and behavioral research" and "routine medical treatment". Even though aversion therapy has been utilized on free world population, in our discussion the label "treatment" might hide the potentially extra coercive effect of these kinds of biomedical and behavioral interventions. We should bear in mind that the definition of prison used in the statute includes ". . . any place for the confinement or *rehabilitation* of . . . individuals charged with or convicted of criminal offenses".[26] Thus the treatment or rehabilitation aspects of the definition of potential subjects means that our area of concern should include a host of treatment programs. We might need to consider whether any treatment offered or forced upon individuals confined in a specialized institution for "defective delinquents" should have special administrative mechanisms for what the officials call ordinary treatment. At the other extreme we should consider whether "social experiments" such as a decision to conduct a controlled experiment on early release should also be the subject of special legislation, or left to the administrators of the prison and parole boards. At this stage of our development I would suggest only special legislation for "organic therapies" such as psychosurgery, a special topic addressed by others at this Conference. I would be wary of relying on legislatures to develop effective legislation that singled out "aversion therapy" or organic theraples for special treatment. The present state of public awareness ought to lead correctional officials to question whether any proposed therapy to cure the prisoners of their criminality is authorized without special legislative authority. We must also insist that other regulatory bodies, such as the Federal Drug Administration, share responsibility for research in prisons.

Our apparent public posture that more state regulation of prison research is needed ought to alert us to the need for professional regulation to control those areas where state regulation is likely to be ineffective. As an adjunct to state regulation, we might easily agree that all professional organizations whose members do any research involving prisoners ought to develop guidelines for

[24] *See supra* note 4.

[25] *See generally*, Shapiro, *Legislating the Control of Behavior: Autonomy and the Coercive Use of Organic Therapies*, 47 S. Calif. L. Rev. 237 (1974).

[26] Pub. L. 93-349, § 202(a)(2) refers to 42 U.S.C. § 3781 for a definition of correctional institutions.

their investigators. But a more controversial question is whether prisoners, as a source of potential subjects, ought to be included as part of the professional regulation of research involving prisoners. For instance, is it not possible that a sociologist engaged in certain types of "advocacy research" [27] in prison might come to conclusions that are "harmful" to prisoners? What if his honest scientific conclusions were that more frequent use of "isolation" would in fact eliminate certain types of prisoner behavior deemed undesirable? Would not an even greater claim for prisoner participation in the research project be made by an assertion by the advocacy researcher claiming that his research would "benefit" prisoners?

The claim for prisoner participation in the professional regulation of at least some research in prison becomes more plausible if we consider that the prisoner as a volunteer ought to be viewed as a participant in the human experimentation process. In addition, we should be skeptical of those professionals who would resent any prisoner participation since professionals are protective of themselves when it comes to the risks of human experimentation. It is noteworthy that some of the leading medical schools prevent the use of their own medical students-professionals—in experiments that involve "risks to health and well beings".[28] Why shouldn't the prisoners—the professional subjects for vast numbers of experiments—be allowed to develop some means of self-protection that is binding on the other professionals in experiments? While I have no specific suggestions as to the form that prisoner participation in professional regulation should take, I can point to a tentative direction from a combination of the two guidelines.

Investigators who claim that the research will "benefit" the prisoners as a group should be required to include some prisoners in the administration of the research. Prisoners are in some sense the best determinators of what is a "benefit". On the negative side prisoners are also in the best position to see the adverse social, psychological, or moral consequences of race in the appropriate institutional setting. If professionals are unwilling to see the prisoner-subjects as true participants in cases of alleged benefits to prisoners, we might begin to question the meaning of the supposed "benefit". On the other hand, with regard to non-therapeutic research on prisoners, for example, the malaria experiments, ironically might be conducted without prisoner participation since there is no claim of benefit to prisoners as a primary justification for these experiments.

Every prison experiment must involve a stage where either state or professional participants evaluate the research design and the scientific merits of each project. One purpose of this stage is to see if the violation of the explicit guidelines developed should lead to cessation or modifications. As mentioned earlier, a lack of sufficient volunteers could lead to termination of a project.[29] Another purpose of the evaluation of the design and scientific merits of prison experiments is to develop over time some sense of the kinds of research that should be conducted in prison. We will find that those experiments most in need of research design evaluation because of their public policy implications—social experiments—are the most difficult to evaluate because of our ethical doubts. For instance, to do a controlled experiment on early release, it might be necessary for the correctional officials and the investigators to employ the technique of "deception".[30] And yet the requirement of evaluation should not frighten off the researcher seriously interested in these kinds of empirical tests, provided he can meet the ethical objections or doubts. More importantly, we should insist that the evaluation of both the research design and the scientific merits of other kinds of research be undertaken, e.g., the evaluation of Phase I drugs tests in prison. Not only is such evaluation relatively easy, but the results of such tests have wide social implications since the marketing of a new drug or product is dependent on the prison experiments. Again our awareness of past abuses and our interest in self-protection indicates that research design and scientific merits of prison research should be be prophalytic requirements.

Our final issue in establishing a structure for the proper administration of experiments involving prisoners—whether consent should be supervised—is the

[27] I do not mean to imply that this type of research is necessarily good scientifically.

[28] Harvard Medical School Rules Governing the Participation of Medical Students as Experimental Subjects, reprinted in *Katz*, at 1036.

[29] *See supra* note 17 and accompanying text.

[30] *See supra* note 5.

most confused. Congress apparently thought the National Commission should determine the "requirements" of consent for prisoners.[31] Unfortunately, we cannot identify the elements of consent for prisoners because we have not understood the notion of consent in human experimentation generally. Our public discussion indicates, for instance, that some notion of voluntary consent can eliminate issues such as whether there is sufficient scientific merit in the experiment to allow any human being to consent. Second, we forget that "consent" is not a well developed legal doctrine in therapeutic settings.[32] Thus the functional relevance of "consent" to the human experimentation process generally, and prison experiments in particular, ought not to be assumed. Third, we often fail to realize that there are inherent limitations to the function of "consent".

The issue of whether consent should be supervised is best seen if we concentrate on the "informed" portion of the notion of "informed consent". Essential to this notion is a willingness on the part of participants to share knowledge with the subject.[33] The imparting of knowledge to the prisoner-subject thus requires certain preliminary measures of maximum information-gathering and dissemination to the prisoners-subject pool. In practical terms these notions require diagnostic screening of all subjects. For instance, in a drug test, one of the requirements of an informed consent is that the prisoner knows his present medical condition. The medical diagnosis should be documented and given to the potential subject in both written and oral form before his "consent" can be deemed informed. The dialogue would thus include a discussion of the risks vis-a-vis what is known about this particular person rather than simply the general risks. These rather elaborate processes will help to alert the investigator to whether their facilities are adequate to take care of all known risks. Besides hospitals or medical resources, in some experiments the investigator would be required to provide and inform the prisoners of psychotherapeutic aids if there were psychological risks apparent in a particular experiment. All of these remedial measures for handling the risks must be offered to all prisoners without charge so as to avoid their possible use as an inducement to volunteer.

We must then delineate the consent issues very carefully in prison research so as to further the purposes of consent. Prisoner consent cannot authorize an experiment but it is a necessary ingredient to the ethical legitimacy of prison research. Nor should we be afraid to face the possibility that consent is limited and not determinative of all issues. Before the question of consent is even presented to any prisoners, a host of other issues should have been resolved in the formulation of research policy, and in the administration of research.

The supervision of consent in the context of prison research thus plays an important part in the proper conceptualization of human experimentation. Consent does not, however, categorize a legal relationship between the prisoner-subjects and the public authorities and investigators. Rather consent seeks to assure that the subject is a full participant in the process of human experimentation.

REVIEWING THE DECISIONS AND CONSEQUENCES OF HUMAN EXPERIMENTATION IN PRISONS

The major method of reviewing the decisions throughout the process of human experiments in prisons and the consequences of such experiments is through public scrutiny. This Conference and the National Commission is an important part of the review mechanism governing experimentation with human beings. It is apparent that we need more public scrutiny of the current experimentation being carried out in prisons. One way to subject this experimentation to public scrutiny would be to require all prison administrators to make public all the research that they have authorized in the various institutions that they administer. Other governmental agencies such as the Federal Drug Administration or HEW should develop means of reviewing research in prisons where they have some means of controlling or regulating such research. For instance, each prison should be required to have an institutional review board for all experiments.[34]

[31] *See supra* note 9.
[32] *Katz* at 523.
[33] For a discussion of consent in a therapeutic and experimental situation see Canron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. Pa. L. Rev., 340 (1974).
[34] *See supra* note 4.

Such boards could include prisoners who are not subjects, as well as various types of professionals some of whom are not connected with the correctional system or with human experimentation.

The other method for reviewing the consequences of experimentation is a willingness to allow the subject access to legal process for the vindication of all claims of injury. While it is noteworthy that a few courts have insisted that lower courts consider the claims of prisoners subjected to "experimental therapy" by public officials for damages against those officials,[35] these decisions have not eliminated all issues of access to court and the public. It is more important to focus upon the emerging issues of whether the state can incarcerate a person for the purpose of "treatment" without adequate treatment. However, the "right" to be out of state control may be more important to the subject-captive than whether or not he receives treatment.

Included in these discussions of giving access to the courts is the notion that all research in prison should be done on a "non-fault" basis.[36] That is, the prisoner need not assume the risks of physical injury and need only prove his participation in the experiment and the resulting injury. Such proof should be relatively easy to establish if there is adequate screening and documentation of the subject's physical condition before the experiment is undertaken. As to psychological or emotional injury, I am not as certain that such matters ought to be subject to suit. But HEW and all federal agencies should require that as a condition of obtaining funds for an experiment in prisons there be a special contract proviso prohibiting the waiver of defenses, and requiring an authorization to bring suit on the basis of any injury without regard to consent. In other words, consent will not be used as a "defense" to any lawsuit.[37] In order to prevent the non-fault proviso from creating a "moral hazard" and in effect increasing the amount of experimentation, the first issues of access to court to question the public officials is the more important means of public scrutiny.

IV. SUMMARY

My general recommendation is for this Conference to avoid absolutist positions. There is little justification for a complete ban on all research in prison at this time. On the other hand, I should reiterate that our experience with race and human experimentation means that we should similarly eschew the position that we can leave the ethical issues to the individual investigator. The forces that led to the abuses of the Nazi concentration camp experiments are deeply engrained in our culture. It is not just that "racism" is so endemic, as it surely is in this society, but that the need to experiment with human beings is also so endemic. With such a positive force to contend with, we must understand that force in order to evaluate the kinds of risk of danger to prisoners in the experimentati process. Then finally, we must articulate the dangers to minorities inherent in the process of experimentation on prisoners. Values about race, religion, and nationality are part of the value conflict that must be resolved in prison research.[38]

From my process approach, I would recommend that the Commission be instructed to inform Congress and the society at large that the decision to experiment on prisoners requires very careful scrutiny because of the subject's status and because of the minority status of most prisoners. I would further recommend that we avoid trying to scrutinize the "ethnic authenticity" of investigators in order to deal with this problem. Just because the investigator gives assurances of his "civil rights" background or his own minority status does not adequately deal with the problem. Rather the process of scrutiny of the values involved in the fashion that I have proposed is the only remedy I can suggest at the present time. Thus, along with the policy statement on the experimentation on prisoners, I would suggest that all persons sponsoring research in prison require from the investigator a statement explaining why prisoners are chosen for this particular experiment rather than "free world" volunteers. Such a statement should include a clear delineation of the kinds of harm, and the measures taken to insure that harm can be avoided. The statement should also require an explicit dis-

[35] *See, e.g.*, 1141 *Knecht* v. *Gillman*, 488 F.2d 1136 (8th Cir. 1973) ; *Mackey* v. *Procunier*, 477 F.2d 877 (9th Cir. 1973).
[36] *See, e.g.*, *People ex rel Blunt* v. *Narcotic Addiction Control Commission*, 295 N.Y.S. 2d 276, aff'd, 296 N.Y.S. 2d 533 (1968) ; portion reprinted in *Katz* at 1050–1051.
[37] *Cf. O'Connor* v. *Donaldson*, 43 U.S.L.W. 4928 (1975).
[38] *See supra* note 4.

cussion about the societal interests and priorities for the particular research project, as well as a discussion of how consent is to be supervised. Finally, the public officials and professionals should readily grant the prisoner the right to question in court of law and other public forums any harm resulting from the experiment. Such prisoner access will help to assure the kind of public scrutiny of human experimentation that we are engaged in at this Conference.

Ethical Issues in Research and Experimentation in Prison

(By L. Alex Swan, Ph.D., LL.B.)

Historically, the prison as an institution in society has been a place for the research activities of many social and behavioral scientists. Some have not concerned themselves with an immediate practical result but rather with investigating fundamental facts, processes, and phenomena. On the other hand, there are those social and behavioral scientists who have established research projects within the prison which were designed to answer specific questions usually for control purposes, that arise within the prison system in the process and pursuit of administrative goals. Those who have been innovative and have produced progressive ideas have for the most part, left their findings to the discretion of prison and state officials to interpret, translate into policy and apply.

Research in prison has traditionally been undertaken under the guise of determining the causes of criminal behavior, and the development of approaches and programs that would assist the inmate to live more successfully in society. Because most research attempted to locate causes in the individual "offenders" the program and approaches have focused on changing the personalities of the offenders. The problem here is that the approaches were generally applied to selected offenders who had to follow certain programs regardless of the true nature of their guilt.

In the last 30 years the Federal Government and private foundations have developed an interest and concern in research in corrections. So much so that an enormous amount of money has been spent in an effort to develop plans and programs to deal more successfully with "criminals." Not only has research been undertaken to add to our fund of knowledge about criminal behavior and society's response, but to evaluate the effectiveness of the new techniques and approaches in the programs in corrections.

A considerable amount of cooperation has always been extended by institutional administrators to researchers who seem to recognize the need for involving social and behavioral scientists in applied research and solving problems in correction. More recently, a more important and practical reason for institutional administrators interest in research is their concern for enhancing the effectiveness of rehabilitation programs. Somehow, this defined need has been recognized by officials, working professionals, and social and behavioral scientists. Sellitz and others have argued that: "Historically, the scientific enterprise has been concerned both with knowledge for its own sake and with knowledge for what it can contribute to practical concerns."[1]

The real question is whose concerns have social and behavioral scientists served and what is the principle ideological guide for research in prisons? When we engage in research we must concern ourselves with our particular concerns and the ideological principle that undergirds the research.

The Prison Condition

To deal adequately with the issue of research in prison we must first look at the relationship between the needs of the state and the prison system. Almost everyone who has visited prisons agree that they are probably the worst places in all the world for human habitation. Guards have been oppressive and repressive and have created certain conditions which forced some inmates to carry out atrocities such as beatings and floggings against those inmates who defined their presence in prison in political terms, and attempted to organize political action against oppressive conditions. Inmates are required to work every work day and the labor is practically free to the state. Inmates do not benefit from their labors

[1] Claire Sellitz, Marie Jahoda, Morton Deutsch and Stuart W. Cook, *Research Methods in Social Relations* (New York: Holt, Rinehart and Winston, 1961), p. 4.

which bring income and profits to the prison system and to the state. The inmates did not wear clothes from the cotton they grew, neither did they eat any of the fresh vegetables they grew on the prison farms. Instead, they ate leftovers and rotten potatoes. No money went to the inmates or their families, and very little money was spent to improve the living conditions in prison. Slave labor, brutal treatment, and inhuman living conditions, inadequate medical attention and insufficient dental care, characterize the majority if not all of America's prisons.

These conditions have persisted because the prison system serves the same purpose today as it did thirty years ago—that of exploiting the labor of poor and working-class people who have been judged by state officials to have violated the criminal law for which they have been convicted.

Prison conditions are the function of the definition of inmates as subjects of the state and prison officials as agents of the state in terms of the needs of the state and the powerless nature of the presence of inmates in the prison system. It is within this context that research in prison may be understood and the associated ethical issues discussed. Research by social and behavioral scientists within the prisons must take as its concern exposing oppressive conditions and the material and psychological needs served by prisons, and the relationship between the prison system and the state.

Consequently, the aim and major objective of research in prison must be to promote the basic ideological principle of human liberation. Under the basic concept there are certain issues to be addressed in prison research:

(1) Exposing the nature of colonization in prison.
(2) Exposing racial practices and policies in prison.
(3) Exposing the capitalist nature of the prison system.
(4) Translating theoretical knowledge into methods for change.
(5) Exposing the parasitical relationship between the prior subsystems of the criminal justice system and the prison system.

To provide state and prison officials with information to oppress powerless people and the exploitation of prisoners' labor is unethical to the basic principle of freedom. Consequently, it is unethical to violate the basic ideological principle of human liberation for a system which is oppressive against powerless people who are in prison.

Prior to 1957, so called minorities in the prisons were model prisoners who submitted to the power arm of the state through prison officials. Since 1957, however, we have witnessed the rise of a powerful people's movement outside of and inside the prison for equality, justice, and an end to oppressive conditions, repressive racial policies and exploitation. The liberation movement in the United States and the Third World movement in general have influenced events in prisons in America. The struggle included young students and other working-class people who attempted to change the way in which the society conducted its business against oppressed people and the way prisons conduct their business against confined inmates. The response of the rulers was to resort to force through the use of the police, attorneys, courts, and prisons. Open oppression of the most militant individuals characterized the earlier stages of the movement, but as more people got involved in the struggle, and the economic situation reached crisis proportions for working-class people the prisons became overcrowded with blacks, browns and other poor people who had become more critical of society and its oppressive apparatus, including the criminal justice system. More importantly, many of these new breed of inmates had developed a political conscience which afforded them an understanding of their presence in prison in political terms. Some had even suggested that if oppressed people defined their presence and conditions in the American society as oppressive, then anything done by such people to change those conditions should not be defined as criminal.

Control of prison inmates became more difficult to achieve and the concern for control increased. As the prison population increased the prison conditions got worse. Consequently, those who were involved on the outside began to involve themselves in bringing about change on the inside. However, some have come to realize that no real change will come to prison conditions if there is no real change in the nature and function of the American system of racism and capitalism. These systems establish a need relationship between the police and the state and a need relationship between the prison system and the state. These relationships translate themselves into repressive action against the oppressed and are facilitated by the powerlessness of racially oppressed groups in

American Government agencies and commissions. These agencies have suggested certain liberal and conservative changes; courts have issued decrees, and other private organizations and individuals have made certain recommendations for change, however, these recommendations, suggestions and decrees have not been implemented or complied with. Instead the State through its agents—prison officials—have allowed social and behavioral scientists to conduct research in prisons which is designed to control the behavior of the politically conscious and active prisoners who are defined as "trouble makers." In this sense social and behavioral scientists are used by state agents to facilitate control of prisoners who are critical of the State, prisons and prison officials and who define their presence in prison in political and economic terms.

Although some researchers would argue that social science research has in some sense enhanced a more liberalized climate in the American society, oppressed people who have had to intensify their struggle for liberation and freedom would argue that social science research has been a part of the colonial relationship which exist between institutional power and oppressive control over the prison population.

To the prison population of inmates, in the presence of their raising consciousness, social and behavioral scientists have begun to look like other agents of the power structure. They are perceived to be outsiders who entered the prison system to advance personal and institutional goals that are defined and determined outside of the interests of the prison population of inmates. The "new" consciousness demanded self definition, the rejection of officials definition as "criminals" and "trouble makers;" self-determination and the move to decolonize research. These moves made it apparent that the norms of pure disinterested scientific investigation were inadequate. Moreover, prison officials recognized that the scientist's control over the research enterprise, including all the intergroup interaction which he/she sets in motion, is supported by the norms of professional autonomy and expertise and may be organized to support and enhance institutional power and control over prisoners. Within this context, the view is held that only the social scientist can define a suitable problem for research because he alone knows the theories of the field and the methods by which theories are tested. In this model of science there is no place for the prison community of those studied to share in the determination and the outcome of research objectives. This stance is unethical and contrary to the basic ideological principle of human liberation. The life problems and needs of the prison community affect us directly and indirectly and should be the starting point for all prison research. Therefore, the traditional gulf between the researcher's purposes and the subject's awareness of what the investigator and his research instrument is all about can be closed.

The in-depth interview is used in prison research and "it is expected that the respondent will spill his guts about various aspects of his personal life and social or political beliefs. The interviewer is supposed to be a neutral recorder revealing nothing in return about his own life, feelings and opinions."[2] The attempt to avoid "bias" in the data and its interpretation has also produced certain questions of ethical proportions. "The monopoly, domination and control continues through the stages of analyzing and publication of the results of the studies."[3] The prisoner's unique outlook and specific responses are typically lost in the aggregate of data which are subjected to standardized statistical summaries, ideal type classifications, or some other operation. Because social and behavioral scientists write for other scholars and "experts," those who are studied usually cannot make head or tail of the research report toward which their own responses contributed. Whenever there is a markedly unequal exchange between two parties and this inequality is supported by a discrepancy in social power, exploitation is manifested.[4]

In social research, subjects give up some of their time, energy and trust. In the process they get nothing from the transaction. Social scientists get grants and research awards which pay part if not all of their salary. Their professional status is enhanced and through the publication they are advanced in status, income, and rank.[5] The gap is further widened between the subjects and the

[2] Blauner, Robert and David Wellman, "Towards the Decolonization of Social Research." in *Racial Oppression in America*. Harper and Row, 1972.
[3] *Ibid.* p. 6.
[4] *Ibid.* p. 7.
[5] *Ibid.* p. 8.

scientists. It is unethical to exploit the subjected in or out of the prison in this manner. Because it is unethical to use oppressed people as objects, things, and as means only to our own ends in our research projects means that there is need for change.

The poor and racially oppressed in prison have been promised much from social science, but these groups with their pragmatic sense and sensitivity to phoniness know before the social scientists that no tangible change will be achieved in those conditions which oppress them.

Pay off must come from closing the distance between the theoretical and empirical concerns of research activities and the life problems and situations of the inmate population, and from the organization of power to implement and influence change.[6]

Research in the prison, therefore, must begin with the idea of building into it specific strategies that might permit the social and behavior scientist to transcend the exploitative dynamics of the research process. One principle to follow is to pay the respondents for the time they spend talking with researchers or otherwise involved in the research. The money should be defined as a wage for labor-time not a bribe for information. The other principle is that funded research on oppressed communities, including the prison inmate population, should include sizeable grants to the prison population and their organization for development and the enhancement of their programs.

Another principle is for social and behavioral scientists to be honest about the nature and purposes of the research and the difference it would make. Because prisons have been a complete failure by most definitions, it must be clear that there is dissatisfaction with the way social and behavioral scientists have approached research of oppressed people especially in the prison. We cannot change the total situation through research and we should not make such promises. Nonetheless, every effort must be organized to expose the relationship between the state and the criminal justice system, especially the prison system of which the inability to realize significant liberating changes is a function.

It is unethical for social and behavioral scientists to take sides with those who are defined by inmates as their enemies since they see themselves in a life-and-death struggle with prison officials and the state. Within the context of the principle of liberation it is also unethical to create labels of inmates that distort or humiliate and place them in insidious categorical bags. The principle of human liberation for inmates requires that the gaps between research and action be bridged. This means that certain positions must be taken, and the social and behavioral scientist may also become partisan. Consequently, such scientists cannot consider themselves dispassionate researchers without responsibility for possible misuse of their research findings and recommendations.

More Specific Issues

There is turmoil in corrections today concerning more specific unethical issues which are secondary to the issues of the need relationship between the state and corrections.

Although most of us, if not all, experience some degree of behavior modification in the process of development and growth, the individual takes the initiative and makes the decisions as to which behavior would be changed or challenged.

Behavior modification in the prison are activities instituted by correction officials for the defined purpose of changing the so-called "criminal" behavior patterns of those incarcerated. It is defined so that most of the efforts are focused on repeated offenders and the so-called "trouble makers." It must be understood that the first offender is most vulnerable to being a repeat offender whether guilty or not, and the subjects most subjected to behavior modification techniques are the politically active who have defined their behvior and presence in the prison in political and economic terms.

Various methods to alter behavior in prison fall under the broad categories of surgical and psychological techniques. Group therapy, drug dosages, reward and punishment conditioning, psychosurgery and shock therapy constitute the major approaches. These techniques are used in human experimentation programs in the prison to change behavior as well as to test new medical techniques. Prison officials and the state, through their agents, (social and behavioral scientists) have defined the involvement of certain inmates as informed consent. That is,

[6] *Ibid.* p. 8.

the prisoners had been given all of the necessary information concerning the experimentation before consent is requested. However, by definition no informed consent is possible within the context of confinement in prison. The very fact that certain prisoners are defined and selected to be informed about the techniques and programs are developed to alter the behavior patterns of prisoners suggest that informed consent does not exist in prison and is not possible given the nature of coercion in prison.

The essential issue is the ability of the individual to exercise the fundamental right of freedom of choice and the freedom of man to make decisions which affect her/his own body and life. What is unethical is the imposition of the will of the state through prison officials and social and behavioral scientists, by manipulating the will of prisoners within the context of incarceration. To operate in prison in this manner violates the ethical principle of integrity and makes void the dignity of man especially in prison.

It is also unethical to use these techniques and procedures for disciplinary or punitive purposes. It is cruel and inhuman to practice dehumanizing experimentation in prison by psycho-surgical behavior modification methods. The attempt to alter the behavior of selected persons in prison cannot solve the socio-phychological and political-economic problems which are basic to the nature of the society and related to those incarcerated.

Special programs are established in America where those defined as "aggressive" by the state through their agents in a correctional institution, attempt to take short-cuts to the problems of crime by victimizing the victims who are exploited, oppressed and repressed in a system which places more emphases on property rights than human rights. The right to read, have visitors, have exercises daily, have certain personal property, to take a shower more than once per week are basic and fundamental constitutional rights. Punishment is implicit in the sentence to be imprisoned upon conviction for an accused violation of certain moral values upheld by legal principles. Therefore, to use strategies and techniques in the absence of informed consent (which is impossible to obtain in the prison context), to attempt to alter the behavior of selected prisoners is cruel and unethical.

It is also unethical to force the oppressed and exploited to accept responsibility for their behavior in a society that has been violent to them; a behavior which has not been defined by the legal system as criminal.

Most programs in the prison which attempt to alter the behavior of prisoners are anti-resocialization and anti-rehabilitation because they seem to suggest that behavior can be changed permanently without altering the very nature of the American society and the socially developed attitudes of individuals. More importantly, is the force used through these programs of experimentation to facilitate the adjustment of inmates to the prison environment which is contrary to the principle of human liberation and the goal of self-respect, self worth, independence, and the development of the individual's ability to cope with the responsibilities of society. Consequently, the goal of submission, and the destruction of initiative is cruel and unusual punishment.

Another question in prison research and experimentation is the question of the definition of subjects. In order to establish certain tests, or determine sets of relationships or correlations, the definition of "uncontrollable aggression" is applied to rapists and those who have been convicted for murder. Now it must be understood that the tests do not establish causation. If they are organized correctly, the researchers can show correlations and relationships regardless of how significant. From such, most researchers also talk about causation.

It is dishonest to talk about causation or give the impression that the correlations are the causal factors to explain the behavior. Most rape is political since men attempt to gain power and control of the body of women. This is why resistance is so essential to a rape and the rapist. This behavior is an extension of the behavior in the general society where power and control is used against people defined as powerless. Most murders by black people are secondary acts to robbery, burglary and the like. They are secondary crimes to the primary crimes of survival. This is also behavior which is an extension of the historical crimes of exploitation, oppression, violence and racism, employed by white power elites and their agents who talk about these crimes in the history books with pride. However, they have not defined them in criminal terms, and those against whom the criminal acts were perpetuated have never had the power to define them as such or to put their definitions into operation. The danger to the oppressed communities is that once their subjects are used as guinea pigs to determine whether or not there is a relationship between electrical discharges in the brain, and

aggressive behavior, their communities which lack the power to defend themselves, are the natural subjects for the exercise of control. For every twelve personality types in prison today, there are twenty-four similar personality types in the so-called free society.

It was after the 1967 riots that it was suggested by a few white scholars that "phychosurgery might be an appropriate way for society to deal with violent-prone dumb young male participants." The riot participants in the Detroit and Harlem riots were black. However, the participants in the 1917 East St. Louis riots, and those who initiated the Chicago riots were white. In fact, we have not since witnessed a riot as destructive to human life and property as the 1917 East St. Louis riot. The question is whether or not this procedure (psychosurgery) restores the individual to the community? No, its design is to make him more manageable in the prison. There is no answer in these procedures to the essential principle of human liberation. A further question is who would make the decisions if it were found that the procedures can restore the individual to the community? Clearly, the use of these behavior altering procedures within the prison context is evidently for political purposes and points out the danger to the American society as a whole.

There is no question in my mind that most scientfic research in America is politically determined, controlled and manipulated in order to repress healthy dissent and legitimate disagreement in a society which has used violence to solve its problems and only condemn it when others resort to it.

The American society, because of its very capitalist nature to exploit and oppress the powerless, limits achievement and advancement in employment, education and politics for this group. The prison is a manifestation of the failure of society and reflects its inability to address the basic needs of powerless people who are racially and economically oppressed.

SUMMARY ISSUES

1. Any technique or procedure that invades the inmate's body and/or his personality involuntarily within the context of imprisonment is unethical and cruel.
2. The prison system is inherently coercive, consequently, it is not possible for an inmate to freely consent to risky procedures to alter his/her behavior. Therefore, informed consent is a myth in the context of confinement in prison.
3. To intrude upon the brain through experimentation to alter the behavior is unethical because it violates the inmate's right to privacy. Further, it violates the rights of the individual of free speech and impairs the individual's power to create and generate ideas.
4. Psychosurgical and biomedical research on violence to pacify, and other experimental techniques which curtail the individual's initiative, independence and freedom of thought are repressive and oppressive.
5. Labeling individuals in the prison as violence-prone and agressive for the purpose of experimental research is dishonest, dangerous and serves the same purpose of political control as the definitions of militant, radical and subversive.
6. Constitutional liberties are seriously in danger when certain behavior modifying techniques are allowed to be operative in a closed setting as the prison system where these liberties should be protected.
7. In a custodial setting where coercion is operative, due process and voluntary participation is impossible. Behavior modifying techniques erode the right to privacy and individual dignity and destroys the development of self-respect and self-esteem.
8. Research which does not promote human liberation, independence and freedom is oppressive, repressive and destructive to human growth and the progress of society.

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AMERICAN CORRECTIONAL ASSOCIATION,
College Park, Md., March 4, 1976.

Hon. ROBERT W. KASTENMEIER,
Member of Congress, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN KASTENMEIER: You will recall that on October 1, 1975, I wrote to you regarding the position of the American Correctional Association on medical experimentation. The letter indicated that our Board of Directors would be voting at its February, 1976 meeting on the issue of whether to continue allowing medical experimentation.

I am pleased to inform you that our Board did vote on February 20, 1976, to recommend to the correctional community throughout the United States the abolishment of all medical experimentation. Enclosed is a copy of that particular resolution.

Thank you for your concern, and we hope that this information will be of significance to your committee.

Peace,

ANTHONY P. TRAVISONO,
Executive Director.

POSITION STATEMENT—THE AMERICAN CORRECTIONAL ASSOCIATION

THE USE OF PRISONERS AND DETAINEES AS SUBJECTS OF HUMAN EXPERIMENTATION

The American Correctional Association has long viewed with concern the use of prisoners as subjects of medical, pharmacological experimentation. This concern is shared by many—the courts, legislatures, administrators, professional bodies, and the community at large. The Association is aware that many state correctional systems have already adopted policies precluding, or sharply limiting such experimentation. It now urges that efforts to eliminate such practices be undertaken by responsible bodies at the Federal, State, and local levels.

(1) While it is recognized that such experimentation can make a contribution to the health and well-being of all people and contribute to the achievement of legitimate objectives and goals of correctional systems, and

(2) Although it can be argued that the elimination of human experimentation from correctional institutions may deny the offender a measure of freedom of choice in determining the extent to which he may offer himself for experimental purposes;

(3) We have concluded that:

(*a*) A person confined in a correctional institution is incapable of volunteering as a human subject without hope of reward;

(*b*) It is very doubtful that prisoners who volunteer can be said to do so on the basis of fully informed consent;

(*c*) The assessment of risks attached to human experiments is ordinarily beyond the competence of those who bear the ultimate responsibility for approving human research projects.

(*d*) No fully effective protection against injury or death can be provided to prisoner volunteers in human experimentation programs.

(*e*) Nor can there be assured the necessary guarantee of adequate therapeutic or remedial services to prisoner volunteers who, as the consequences of participation, may require long-term medical assistance.

In the light of the foregoing, it appears that the authority which authorizes or permits prisoners to become subjects of human experimentation ignores his historic obligation as a custodian to protect and safely keep those for whom he assumes a legal responsibility.

Officially Adopted—Board of Directors, American Correctional Association, St. Louis, Missouri, February 20, 1976.

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END

7 Attachments