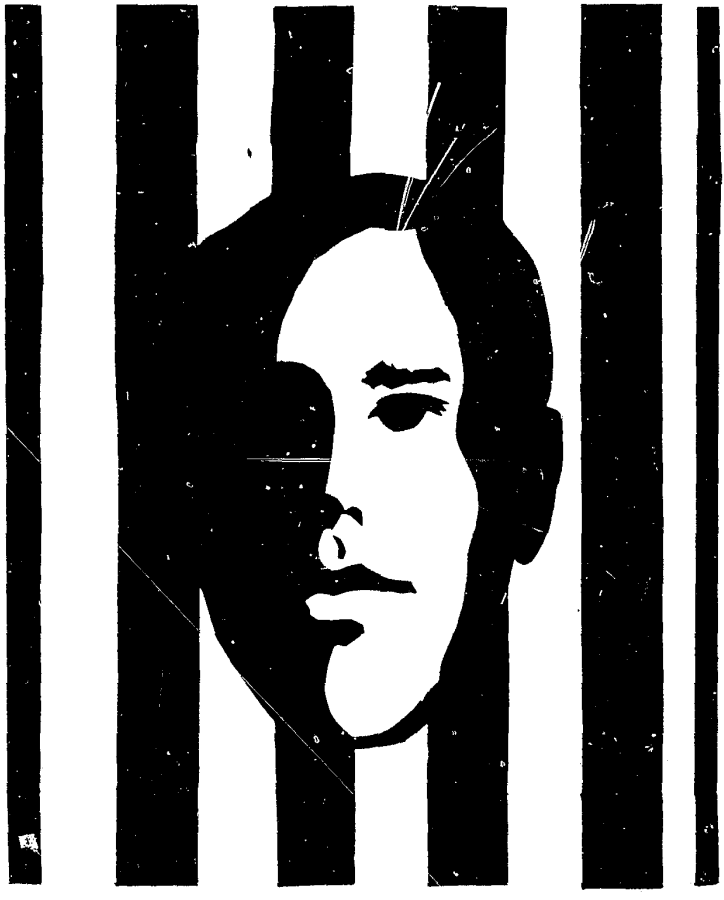
PRISONS INMATES AND DRUG TESTING



SUMMARY REPORT
OF CONFERENCE PROCEEDINGS

SPONSORED BY
THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION
AND THE NATIONAL COUNCIL ON CRIME AND DELINQUENCY

FOREWORD

Whenever longstanding practices are brought up for reconsideration in the general community, it seems inevitable that the earliest presentations are essentially one-sided. The process by which public attention is attracted to such a "closed issue" seems to require that to happen. Usually, the initial, relatively sensational revelations are followed by a more balanced and reasoned discussion of the issue, as people of substantial experience are brought together to focus on the issues being raised. And finally, and fortunately, public policy is usually determined on the basis of the latter kind of work.

The matter of biomedical research in the prison environment is now in the process of going through a major re-evaluation, sparked in substantial degree by increased public awareness of the subject. A group of individuals concerned about the sound administration of prisons in the interest of inmates, and the value of the prison environment in conducting well controlled biomedical research, decided, in the early summer of 1973, to join in the sponsorship of a wide-ranging conference to review the important issues with responsible representatives from a cross section of involved groups. And to seek identification of the generally acceptable approaches to drug research in prisons, out of which the pharmaceutical industry can develop a set of guiding principles for the use of member firms of the Pharmaceutical Manufacturers Association in their sponsorship of research in prisons and for the advice of correctional administrators and public officials.

This book is the product of the discussions which resulted from the PMA-NCCD collaboration. It is our hope that it will be a useful part of the process through which resolution of the questions surrounding drug testing in prisons will be intelligently achieved.

C. Joseph Stetler

C. Joseph Stetler
President, Pharmaceutical
Manufacturers Association

Milton G. Rector
President, National Council
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PRISONS, INMATES AND DRUG TESTING

Summary Report

of the

Conference on Drug Research in Prisons

August 6-8, 1973

Sponsored by

the

Pharmaceutical Manufacturers Association
and
National Council on Crime and Delinquency

Prepared

by

Research Center
National Council on Crime and Delinquency
Davis, California

PREFACE

The Pharmaceutical Manufacturers Association and the National Council on Crime and Delinquency jointly sponsored a Conference on Drug Research in Prisons, held at Airlie House, Virginia, August 6-8, 1973. This conference brought together clinical researchers, ex-inmates, correctional officials, representatives of pharmaceutical companies, government officials concerned with drug studies and experiments with human subjects, lawyers, and persons concerned with ethics, rights, and civil liberties. Each representative brought his own particular expertise and perspective to bear on the issues involved in drug evaluation on prison inmates.

The purposes of the conference were to focus on the many issues surrounding drug evaluation in prisons, to increase understanding among the groups who had concerns in this area, and, whenever possible, to consider how future drug evaluation in prisons ought to be pursued.

This summary report, along with the more detailed account of the proceedings, attempts to accurately reflect the nature and substance of the discussion of the work groups at the conference. It is hoped that this presentation will provide readers with new insights and perspectives from the breadth of backgrounds and experiences of the attendees.

It is important to note that the statements in this summary volume and in the longer proceedings volume do not represent a consensus on the part of the conference and it is likely that one or more conferees is in partial or full disagreement with the positions presented herein. The authors' endeavor has been to reflect a number of broad areas of agreement which were shared by a majority of the conferees.

ACKNOWLEDGEMENTS

The text of this summary volume is the product of a group of hard-working conference attendees (page 25), who gave liberally of their experience, time, thought and feeling to the conference. We are grateful to the officers and staff of the Pharmaceutical Manufacturers Association and the National Council on Crime and Delinquency for having selected such an excellent group of attendees. The conference staff, composed of Robert L. Emrich, Chairman, Charmian D. Knowles, Coordinator, and Bev Takata, Secretary, feel that the calibre of the attendees was such that the experience of working with them was most rewarding.

Deserving the lion's share of gratitude are the two men who recognized the importance of this subject and made the conduct of this conference and the preparation of these reports possible. They are: Mr. C. Joseph Stetler, President, Pharmaceutical Manufacturers Association and Mr. Milton Rector, President, National Council on Crime and Delinquency.

The accuracy and completeness of the record of this conference is due to the outstanding work of the four recorders--Mr. Robert Fish, Mr. Michael Mills, Ms. Carol Palley, and Mr. Barry Smith--who carefully prepared excellent summaries of the deliberations of the four work groups, contributing their time on a volunteer basis. We are also grateful for the care with which the attendees reviewed the draft materials for the proceedings volume, helping to ensure accuracy and completeness.

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1. SUMMARY

In August of 1973, a conference on the subject of drug research in prisons, sponsored jointly by the Pharmaceutical Manufacturers Association and the National Council on Crime and Delinquency, was held in Airlie, Virginia. The conference focused on the testing of new drugs in state and federal prisons. It is hoped that the ideas generated at the conference will serve to form the developmental basis of guidelines to ensure a higher ethical standard in the conduct of drug studies in prisons.

It is difficult for the public, as it was for many of the conferees, to distinguish the testing of new drugs from other forms of research carried on in prisons. Although the situation is not ideal, the drug tests are relatively low-risk and well-regulated. They have, however, acquired a poor reputation because of the "horror stories" associated with other types of biomedical research.

Another serious problem is that drug research is already controlled in the United States by detailed regulations, and unfortunately, further improvement in the protection and controls surrounding drug studies would tend to increase this burden. Accordingly, conference participants recommended that the Food and Drug Administration readjust its priorities, eliminating some of its existing regulatory burden, while adding new protection for prison inmate subjects.

A key consideration was the need to minimize any existing coercion on the inmate to volunteer as a subject. While some coercion exists as a fact of life in prisons and can never be entirely eliminated, it is a factor to be minimized in all possible ways. On the whole, it is being

addressed through the setting of minimum wages for serving as an experimental subject, and through improved consent forms and information sharing prior to acceptance as a volunteer. However, in the poorer prisons, the circumstances of prison life itself can be coercive. It was recommended that prisons be graded in terms of quality, and that no drug studies be conducted in prisons where no other activities are available to the prisoners. Studies should be carried out in more progressive institutions.

Besides monitoring subjects during experimentaion, it was suggested that follow-up procedures be instituted, and, more importantly, a system of no-fault insurance, which could be government sponsored if private insurance companies failed to start such a program. Any suggestion of early parole as a consequence of participation in experimentation was considered unacceptable.

Benefits for participants in research include: better health care, wages, and the opportunity to make decisions and participate in something of benefit to mankind. It also brings prisoners into contact with outside people in a constructive way, and the pharmaceutical firms frequently make donations of materials and money. From the viewpoint of prison reform, the scrutiny of an aware public, and access to institutions by trained professionals is desirable.

Besides suggesting further conferences to cover other areas of medical research in prisons, the conference suggested that a review committee should screen all protocols and monitor tests run in prisons in the United States.

2. WHAT THIS BOOK IS ABOUT

A variety of research is carried out in prisons, including: psychological studies; psychosurgery; the use of drugs to control violent behavior; studies of human physiology; and studies of the effects of drugs on human subjects. Recently, much attention has been given to abuses involved in such research by the public, the media, and officials at state and federal levels of government.

This book deals with one of these types of research, namely, studies of the effects of drugs on human subjects. Popular confusion regarding all these types of research has made it difficult to deal specifically with the ethical and other problems of this one area of research in prisons. The reader is asked to keep in mind that we are only talking about the testing of drugs in prisons.

3. A CONFERENCE WAS HELD

Drug research on human subjects in prisons is a complicated subject and requires several diverse perspectives for it to be fully explored and understood. Unfortunately, the kinds of individuals who can shed light on this subject do not normally meet to share ideas. Therefore, a conference on the subject of drug research in prisons was planned to integrate the varying views of inmates, pharmaceutical companies, clinical researchers, correctional officials, lawyers, regulatory agency officials, and other persons concerned with rights and liberties.

4. SOME KEY ISSUES

The following key issues, having broad consequences for contemporary American society, were addressed at the conference:

(1) Do we want a continuation of the high rate of therapeutic progress which has characterized the past quarter century?

(2) Are we in danger, through an excess of regulations, of bringing an end to significant drug research in the United States?

(3) Is continued drug research a contribution or an obstruction to prison reform?

(4) Can drug research contribute to an expansion of the rights of prisoners?

(5) Under what circumstances can an inmate volunteer, with a minimum of coercion, as a subject in a drug study?

(6) Can we regulate researchers to ensure adherence to a high standard of ethics?

The attendees dealt with these and other issues during the plenary session of the first day and during the meetings of four work groups during the last two days of the conference. These work groups represented four perspectives: (1) clinical research, (2) ethics, rights, and civil liberties, (3) corrections, and (4) procedures for ensuring high ethical and scientific standards. The conclusions of these work groups are reported in detail in the proceedings volume and integrated in this summary. The conference believed it important to continue drug testing in prisons in the interests of therapeutic progress and because of the contributions made to the inmates and the corrections system.

5. THE NEED FOR THERAPEUTIC PROGRESS

At the end of World War II, we did not have vaccines against polio, measles, mumps, and rubella. We had few antibiotics, no effective drugs to relieve mental illness, hypertension or cancer. Despite the extraordinary record of the past three decades we still have important needs for improved drugs, particularly in the prevention or control of cancer, and for the many forms of heart disease, which constitute a world-wide epidemic likely to affect almost all who read this volume.

Some seriously question whether further therapeutic progress is necessary in view of the attendant risks. The findings of this inquiry are based on the convictions that the continued good health of our nation and the continued high standards of excellence of medicine in the U.S. today, depend upon maintaining creative drug research in the U.S.

However, it is a characteristic of our times that everything is scrutinized and questioned. We are not automatically assured of a continuation of our past rate of achievement in therapeutic progress. Excessive government scrutiny, regulation and review can destroy the opportunities and incentives upon which significant drug research is based.

If the public ceases to value therapeutic progress, if in the pursuit of other values, we destroy the climate within which research flourishes, significant drug research will cease in the U.S. It is our hope that this conference might help to lighten the burden of regulations which are apparently crippling drug research in the U.S.

6. A NATIONAL MISUNDERSTANDING

Recent articles in the popular press and recent legislative hearings have brought to light a series of horror stories concerning research conducted in prisons. Very few of these examples, and, none of the worst ones, have occurred with regard to research on new drugs.

A variety of research is carried on in prisons, other than the testing of new drugs--e.g., studies of human physiology and metabolism; studies of new medical techniques; long-term programs for the inducement and treatment of specific diseases; and the use of various biological and psychological techniques for the control of anti-social behavior, especially violent behavior. In the latter category, the public is especially aware of psychosurgery and behavior modification research. It becomes very difficult for inmates, correctional officials, and the general public to distinguish among these various kinds of research. As a result, unsound, inhumane, and sadistic activities in any one of these areas is often ascribed to research conducted in prisons generally.

Given this atmosphere of suspicion and distrust of researchers working in prisons, it came as a surprise to a number of the attendees that the testing of new drugs in prisons, as elsewhere, is, with few exceptions, a humane, low-risk, well-regulated process.

It was clearly recognized that unless this widespread confusion about the different types of research conducted in prisons is cleared up, and unless the public discriminates between drug testing and other kinds of research conducted in prisons, it is likely that the notoriety which has been earned by these other types of research will

succeed in putting drug testing in prisons out of business. Such a result could have serious consequences for the lives of inmates, the quality of prisons, and the quality of health care in the United States.

In order to clear up this misunderstanding, it was proposed that a detailed inquiry be conducted into all psychological and biomedical research being planned and conducted in all the correctional institutions of the United States and Puerto Rico. As part of this inquiry, it was recommended that interested and independent organizations convene another conference to help put the entire subject of prison research into perspective. Furthermore, it was proposed that, subsequent to such a conference and the publication of its findings, an independent representative body be established to monitor, at the national level, the nature and quality of all research studies conducted in prisons.

Of special importance to the area of drug testing is the need to make information readily available to the general public regarding where such studies are being conducted, the general nature of the studies, and the nature of the review process by which the rights of subjects are protected. It was generally agreed that part of the bad name which drug testing has acquired with public officials, with legislators, and with the public has derived from the inability to obtain reliable information. It was felt that an open door policy would help put to rest the fears and suspicions which have currently placed drug research in prisons in such a precarious position.

7. HOW DRUGS ARE TESTED

In order to understand how drug research functions in the prison environment and the role which prison inmates play in drug testing, it is important to understand the current program whereby new drugs are tested and made available for use. This approach also applies to the testing of existing drugs for new therapeutic applications. There are four phases of drug testing in humans, as follows:

After extensive animal research, a drug is permitted to go into Phase One testing which is normally conducted on healthy individuals and is for the purpose of determining dose ranges, how the drug is absorbed, how it is metabolized, and how it is tolerated. Relatively few participants are involved, and the duration of the study is generally under six weeks. Very close supervision of the subjects is needed.

Phase Two is concerned with the effectiveness of the drug in fulfilling a specific therapeutic objective. Phase Two studies are conducted on individuals, usually in hospitals, who can expect to obtain therapeutic benefit from the drug.

If the drug is shown to have useful therapeutic value in Phase Two, it enters Phase Three, the "clinical trials" phase. The drug is administered to a sample of 1,000-5,000 patients to ensure that it is capable of being used by the average practicing doctor.

After successful completion of Phase Three, a new drug application is submitted to FDA for consideration. Following FDA approval, the drug is monitored in medical practice in order to detect side effects (or benefits) not observed in the pre-marketing studies. Such monitoring is required by law and periodic reports must be submitted to FDA.

8. THE NEED FOR INMATES IN DRUG RESEARCH

As a result of increasing scientific caution, Phase One drug studies in recent years have required larger populations of subjects and lengthier periods of testing. Specific Phase One tests may require control over the environment and the behavior of the subject, such as dietary and work habits.

There are few circumstances outside of prison life in which the conditions of Phase One drug testing can be readily fulfilled. To have drug research continue on the current scale and to maintain the present highly cautious approach to Phase One required by the FDA, the vast majority of Phase One testing must be performed in prisons or a new, as yet undefined, source of Phase One subjects must be identified.

Two possible alternatives to the heavy use of prison inmates were discussed. The simplest alternative, and one which drug companies are utilizing with increasing frequency, is to test new drugs in Europe, where new drugs are regularly taken from animals to sick patients without the tests on normal people which are required here. This alternative has two serious drawbacks for the United States: (1) Delays, sometimes running to years, are encountered in bringing the new drugs to the American market. (2) The practice carries the threat that clinical research capabilities and the talent associated with it may be lost through a "brain drain" abroad.

A more radical alternative suggested was the establishment of a selective service system whereby normal healthy Americans are conscripted and required to participate in Phase One tests.

9. THE NEED TO PROTECT THE INMATE'S RIGHTS

It was generally agreed that while participating in drug research, prison inmates ought not to lose any more rights than are forfeited by the primary facts of being convicted of a crime and sentenced to a penal institution. Further, it was recognized that inmates are in a particularly powerless position to protect their own rights. Therefore, all those individuals in institutions who are responsible for the conduct of drug research in prisons--the clinical investigator, the research review committee, the pharmaceutical company, the state correctional authority, and the Food and Drug Administration--share a responsibility to ensure that the rights of inmates are protected with regard to this activity.

It was generally agreed that inmates and ex-inmates should be permitted to review the design of Phase One drug studies to be conducted in prisons. Phase One studies can offer important opportunities for inmates to exercise their rights and to assume some control over their lives. The presence of inmates and ex-inmates on the research review committees would ensure that the inmate's viewpoint is taken into account in the design of the experiment, the selection of volunteers, the securing of informed consent, and the monitoring of the experiment throughout its execution.

10. SOME CONCLUSIONS

Much of the work of the conference was accomplished in the four work groups designated to cover specific areas of concern. Some areas of consensus, as well as points of contention and controversy, mark the conclusions of these work groups representing such diverse interests.

The conference as a whole did not seek to formulate any conclusions; therefore the conclusions of the work groups--summarized in the next four sections--are collectively the voice of the conference.

The four work groups, in order of presentation, addressed the problems of Phase One drug testing in prisons from the perspectives of:

- Research
- Ethics, Rights and Laws
- Corrections
- Procedures

11. WORK GROUP ON RESEARCH

The group concluded that all medical research, whether involving drugs or other modalities, must consider underlying obligations to the individuals at risk. These obligations are even more compelling when the persons involved are disadvantaged or captive, with limited ability to assure their basic welfare and civil liberties. The proper pursuit of therapeutic progress in a manner which fulfills these obligations depends upon good research design, effective monitoring, and the protection of the subject, his health and his civil liberties.

Granting that expanded new drug research is a desirable goal, inmate populations can perform an important service while continuing to serve as the principal source of Phase One subjects. Exclusion of prisoner participation would require major changes in the procedures for satisfying Phase One regulatory requirements. It is proposed that such research be permitted when it is conducted in strict adherence to a broad set of guidelines. These guidelines must include provisions to: assure, control and monitor the general health and safety of participants; identify and minimize all forms of coercion; and pay close attention to basic humanitarian principles.

It was pointed out that the responsibility for protecting the subject lies with many people. The investigator must ensure the safety of the subject both in his research design and in the execution of the project. The research review committee must review all procedures and conditions for the research, advise the investigator regarding his research design, keep the correctional system informed and notify them of any conditions adverse to the welfare of the prisoners involved,

and assure that FDA and other regulations are met. The state authority, having custodial responsibility of inmates, must demonstrate more sensitivity to ethical concerns and must be aware of the manner in which the subject is dealt with during testing. The sponsor should provide all information available to it, to the investigator, research review committee and prison involved.

The group recommends that the composition of the research review committee be changed in FDA regulations to: two physicians, one lawyer, one minister or social worker, two inmates of that prison, and one ex-offender not on parole. Members should be appointed by the governor or appropriate state authority. The manner of selection should ensure optimal objectivity and be subject to periodic review by the FDA.

For research to take place in a prison setting it was felt that certain conditions must be met, among them: adequate medical facilities to handle the risks of the research (e.g., 24-hour physician coverage, and access to a fully equipped hospital); good recordkeeping systems; definite limits to risks to which subjects may be exposed (e.g., no narcotic or hallucinogenic drugs in prisons, and no drugs showing severe toxicity in animal studies); adequate pre-test screening of subjects; appropriate post-test follow-up; continual tests for patient safety; and care of inmate subjects based on frequent observation by medical staff.

It was recommended that a no-fault insurance system for clinical investigation be established as is practiced in the State of Washington.

12. WORK GROUP ON ETHICS, RIGHTS AND LAWS

Given the controversial character of any ethical question, it is not surprising that the Ethics, Rights and Laws Work Group encountered many points of contention as well as some general areas of agreement.

Foremost, it was felt that the inmate is given an important opportunity to exercise responsibility for his actions when he is allowed to make a personal decision about participation in research--an opportunity otherwise sadly lacking in the prison environment. Taking this as desirable, how can the inmate subject's rights best be protected and the ethical conduct of the experimentation be ensured?

Though it could not be resolved whether it is possible for an inmate to make a truly free choice in prison, it was felt that when such consent is sought that it is the duty of the investigator, department of corrections, research review committee, and the sponsor to fully inform the volunteer of the nature of the experiment, its risks and its benefits. It was suggested that blanket consents were not adequate and that consent forms must be individualized for each protocol. It was urged that inmate volunteers should be permitted to retain a copy of the form. There was unanimous opposition to blanket waivers.

The level of compensation for participation in Phase One testing was seen as an area for possible abuse. Wages are set by prison administration and are usually kept at the level of prison industry, which is much lower than "free-world" levels. 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

testing. However, it was also suggested that the sponsoring company could donate to a fund, free from control by the prison administration, which would be used for the benefit of inmates. Such an amount might represent the difference between the amount paid to an inmate subject and the amount normally paid to a free volunteer.

There was a majority opinion that drug manufacturers should take a more active interest in the prison system. The degree to which drug manufacturers should accept responsibility for improving the prison situation could not be resolved. It was recognized that drug company testing in prisons very often improves the quality of medical care in prisons simply by virtue of its presence and the provision of equipment and personnel. Research also provides an opportunity for the inmate to have contact with persons from the "free world" and with activities outside of prison. Public disclosure of the contribution inmates were making to research was encouraged.

It was felt that inmates or ex-inmates should review ethical and moral aspects of protocols as members of the research review committee. The review committee should be actively responsible for the supervision of projects they approve, inmate subjects should have access to the committee, and consent procedures and forms should be reviewed for appropriate information and language.

A unanimous recommendation of the work group was for the institution of a no-fault insurance system similar to Workmen's Compensation to compensate the inmate subject for any injury incurred in the research.

13. WORK GROUP ON CORRECTIONS

In light of the many rumors and misunderstandings being circulated about research in prisons, the Corrections Work Group urged the release of information by drug manufacturers and the FDA demonstrating that Phase One drug tests are appropriately conducted in prisons, and recognizing the important contribution inmates are making in this field.

The work group resolved that: (1) the rights and well-being of inmate subjects are paramount; (2) though biomedical research is essential for the well-being of the community, it should not compromise the well-being of others; (3) another conference should be held to cover all types of biomedical research; and (4) a national independent watchdog committee should be established to collect information on all biomedical research on inmates, and take appropriate action to eliminate injurious or improper biomedical practices.

It was suggested that two review committees were necessary for adequate review of protocols: scientific and ethical. The scientific review committee would check the research design and the drugs being used and assess the risk/benefit ratio. This committee would be responsible to or be a subcommittee of the research review committee (ethical).

The research review committee would actively supervise each step of the project and assess risk to the inmate subject and the adequacy of the prison facilities for the risk involved. To ensure objectivity and avoid conflict of interest, non-medical and non-local persons should be included in its composition, i.e., lawyers, sociologists, correctional officials, clergy, inmates, and ex-inmates (generally

ex-inmates are less inhibited in expressing their viewpoint).

With regard to informed consent, the group recognized that too much information can be detrimental to the conduct of the research, encouraging the subject to display imaginary side effects. However, it was agreed that all inmates have the right to information concerning the nature of the test, its risks, and the right to withdraw from the experiment without penalty. The group additionally felt the consent form should include the name of the sponsor, the use to which results will be applied, and the names of the review committee members (allowing the subjects to raise questions), and that the subject should be given a copy of the signed form.

Though the degree to which an inmate can freely volunteer under the conditions of prison life is debated, that concern was not felt to be sufficient justification to discontinue drug research in prisons. Efforts to minimize possible coercion might include: increased effort to inform inmates that earlier parole will not result from participation in research; keeping wages for participation in research closer to minimum prison wages rather than maximum; and where there are no work alternatives, no research should be done (a minority felt research should continue in all correctional institutions).

Benefits to inmates and to the correctional institution seem to outweigh any negative aspects of drug research in prisons. Inmates benefit from better medical care, contact with people outside the correctional system, an opportunity to learn about research, feelings of self-worth resulting from participation in research, and contributions to the inmates' welfare fund, as well as improvements to facilities.

14. WORK GROUP ON PROCEDURES

The major concern of the Procedures Work Group was the ethical fitness of the investigator. FDA regulations ensure the scientific qualifications of the researcher but not his ethical fitness. Such an ethical determination can be done in the research review committee.

Because the research review committee has such an essential function, it is most important that its composition serve to avoid any hint of collusion between the committee and the investigator or sponsor. Although the procedures used to appoint members may determine the legitimacy of the committee, the question regarding how and who should appoint the committee was left unresolved, and subject to local implementation. It was recommended that a single committee bear prime responsibility for research review (lest the "buck is passed"), but that other resources always be accessible for consultation.

Besides the traditional scientists, physicians, lawyers and clergy appointed to the research review committee, it was felt that nurses and inmates or ex-inmates who represent a more subject-oriented perspective should be considered as members. Though an inmate may not truly represent the prison population, just as a physician cannot be expected to represent his profession as a whole, the consensus was that the inmate can nevertheless serve to sensitize the committee to the conditions of prison life.

The work group saw the following to be the functions of the research review committee: to assess ethical fitness of researchers (requiring a personal appearance of the principal investigator before the committee); to ensure the study design is appropriate for sound

scientific evaluation; to examine known and foreseeable hazards of experiments, weighing benefits against risks, to provide for continued monitoring of research projects, reviewing major modifications; and to ensure that prison conditions are appropriate for study and vice versa.

The work of the research review committee, in turn, needs to be supervised via annual summary reports and on-the-spot inspections. In addition, comprehensive public information concerning drug research in prisons should be disseminated to create a more open atmosphere. It was suggested that both the ultimate supervision and the public information service be provided by FDA or HEW or an organization independent of the correctional system or the sponsors.

The question whether an inmate can truly volunteer was not answered; the group took a more practical approach by defining a volunteer as one who consents by signing the consent form. It was pointed out that the original purpose of the consent form was to protect the investigator. More recently the consent form has been used to create a trust between the researcher and subject through an explanation of the project, as well as to protect the subject. All three purposes are seen as important and so it was recommended that the consent form include information re the nature of the study (why it is being conducted and by whom); what the risks are from procedures and drugs used; and the right to withdraw at any point in the experiment. Additionally, it was felt that the research review members should be listed as possible contact points for the volunteer, keeping in mind any security restraints (i.e., prison censorship) that must be observed.

15. FOR MORE INFORMATION

If the reader wishes to explore the issues raised in this booklet more fully, an indepth report of the conference can be found in:

Proceedings of the Conference on Drug Research in Prisons

Available through:

National Council on Crime and Delinquency
Research Center
609 Second Street, Suite D
Davis, California 95616
(916) 756-0808

For additional information the reader is encouraged to write to:

The Pharmaceutical Manufacturers Association
1155 Fifteenth Street, N.W.
Washington, D. C. 20005
(202) 296-2440

The National Council on Crime and Delinquency
Continental Plaza
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 488-0400

The U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852
(202) 655-4000

Information can also be obtained by writing to individual pharmaceutical houses, and by contacting state and federal correctional institutions and associations such as:

The American Correctional Association
4321-Hartwick Road, Suite L-208
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