

UNITED NATIONS
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PSYCHOACTIVE DRUG CONTROL:
ISSUES AND RECOMMENDATIONS

37307

UNSDRI
Rome, 1973
S.P. No. 5

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PSYCHOACTIVE DRUG CONTROL: ISSUES AND RECOMMENDATIONS

A summary of:
"Controlling Drugs:
International Handbook on Classification"
prepared by the International
Research Group
on Drug Legislation and Programs

Summary edited by
James J. Moore
C.R.B. Joyce
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EDITORIAL NOTE

As noted elsewhere, this publication is a summary of *Controlling Drugs: International Handbook on Classification*. It adheres to the structure of the larger volume, although the condensations of the various chapters are the responsibility of the editor of this volume, not of the original authors. The final chapter, *Issues and Recommendations*, remains unchanged. The authors of the original chapters are:

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INTRODUCTION

Controlling Drugs: A Handbook for International Drug Classification provides information useful to lawmakers, officials, professional people and citizens whose duties or interests have to do with the control of psychoactive drugs. This is a *summary version* of that larger volume. It allows the busy reader to glimpse the scope, some of the topics and issues, as well as the recommendations covered by the full text. It is our hope that the summary will stimulate the reader to want to read the full text,* for only through detailed presentation can the depth and implications of the logic and procedures for considering classification-and-control methods be appreciated. If, however, such full consideration is impracticable, this summary version may serve as introduction to the field and partial guide for deliberation and action.

In *Controlling Drugs: A Handbook for International Drug Classification*, special emphasis is placed on how drugs are or can be classified, what kinds of data, logic and analysis are useful aids in drug classification and related public programme decisions — including those of governmental control. Particular attention is paid to methods and prob-

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lems which arise in connection with drug evaluation, subsequent classification schemes and the evaluation of programmes for control. Special interest is taken in international aspects of drug classifications.

The volume does not attempt to serve as a reference text on psychoactive drugs, drug users, drug "abuse" or drug laws and programmes. It does seek to introduce the reader to the issues and considerations which ought to be kept in mind as one tries to decide what kinds of methods and programmes, especially those involving the development and application of international collaborative agreements, might best fit the needs and realities of individual groups and nations of the international community.

Since most laws and programmes rest on estimates of drug effects, particularly dangers and benefits, it is appropriate that our attention to classification schemes first look at the kind of data which assist in predicting or assessing drug outcomes and drug use correlates. Later sections consider typical laws and programmes that have arisen, nationally and internationally, in response to decisions about drug effects and drug classification. Following an overview and careful consideration of basic scientific medical approaches, the implementation of classification and control schemes, the matter of evaluating impact of laws and programmes, and the economic basis for the assessment of costs and benefits are considered. In a final section some of the major unresolved issues are presented and recommendations for action are offered. Several major themes will be found recurring in the volume. The reader is invited to keep these in mind from the outset.

Uncertainty: One theme is the state of uncertainty which characterizes estimates of drug effects and the consequent judgements which systems for classification and proposals for control entail. That uncertainty arises from the nature of scientific inquiry itself as well as from the variety of standards which are used in evaluating those drug effects which can be demonstrated. Uncertainty also occurs because drug effects vary depending on the circum-

stances of use, that is, as a function of drug-person-environment interaction, of drug-drug interactions within a person, or as a person is himself different from one occasion of use to another. Uncertainty also arises from the fast-changing nature of psychoactive drug use in the world today, from the fact that new drugs — or new uses for known drugs — are rapidly being introduced, and also because new knowledge as to the outcomes of drug laws, implementing institutions and actions, and of other forms of response is rapidly being accumulated. Uncertainty also occurs because political, social, moral, religious, health and other interests dictate changes in both laws and programmes. These in turn alter forms of drug distribution and use; thus the bases for evaluation of the effects of laws and programmes are themselves undergoing change. Uncertainty means that one must expect that today's drugs and drug effects may not be tomorrow's, that today's minimum needs for information on drug users or programme impact may be insufficient by tomorrow, and the classification schemes and legislative apparatus are inevitably temporary. The orientation which is common today with regard to drug production, use and control or toward standards for evaluating either drug users or programmes for affecting drug use, is very likely also to change. The fact of uncertainty as an element in science and in policy suggests that whatever the positions a nation or international bodies adopt as an immediate response to current needs, mechanisms for adapting to change should be incorporated.

Alternatives: Another theme is that policy makers in the field of drug legislation, control and programmes should consider as many alternatives as possible. Given the complexity of scientific information, of drug applications, of user populations, and of the social and political circumstances in which programmes are applied, it is evident that simple or singular approaches cannot adequately respond to diverse interests or needs. Knowledge of alternatives is a requirement for the international law maker as well as for the local community-based professional or official. At

the least, the policy maker will want to know about the many different kinds of treatment programmes available, about the several ways in which education can be introduced, about the alternatives within the administration of justice (informal disposition, referral to non-judicial agencies, probation, disposition to different correctional/rehabilitation settings, sentencing variations, parole, aftercare, etc.) and about community programmes. Knowledge of how various alternatives best fit the capabilities and requirements of a given situation — be that the medical needs of a patient or the law enforcement collaborative apparatus of several nations working together to reduce illicit traffic — will allow policy makers to create and implement activities which are more likely effective in particular circumstances.

A third theme is *evaluation*. Evaluation means that one be committed to learning as much as possible about how different drugs affect individual human beings in various settings, over different time periods or used at differing life stages, how various laws work in operating in diverse locales or nations, and how alternative programmes for preventing or treating drug-related problems turn out in practice. Evaluation implies knowledge of the various standards which can be used to judge drugs, people, programmes and laws. These standards are themselves diverse, embracing concepts of health, efficiency, economics and morality. Evaluation implies systematic information gathering about impact and, for wise policy making, the use (feedback) of what is learned in revising concepts, policies and programmes. The theme of evaluation, like uncertainty, like alternatives, implies that all public action in the drug field be designed as a continuing cycle: (a) information gathering prior to action, (b) action in response to immediate knowledge, needs and pressures, (c) mechanisms established for assessment of the consequences of the immediate action, and (d) mechanisms for revision in policies and programmes better to fit them to new knowledge and better understood future needs.

A fourth theme arises from the third, but is implicit throughout. It is the expectation that *policy should be based on knowledge*. One must acknowledge that much, perhaps most, national and international policy setting in the social problem arena rests on moral views, untested assumptions, political necessity or opportunism and other powerful but not necessarily reasoned or factually based decisions. Our assumption is that law makers will better serve their people, the international community and themselves if they fit their work in the drug field to the facts about drugs, about users, and about the impact of various programmes. Ignoring evidence about the impact of laws and programmes is very costly. The cost is not just in terms of immediate fiscal waste or the pain introduced into human lives by programmes that are either ineffective or produce more trouble than they prevent, but because future efforts must undo the tangle of the administrative apparatus, vested interests, and misinformed partisans before these revised, corrective endeavors can be of any assistance. Today's error, based on failure to use the admittedly limited information which does exist, creates trouble for tomorrow's citizens, professionals and lawmakers. It follows that all those with public responsibilities for drug legislation or programmes at any level (local, national, international) must seek out, consider and insofar as they are free to be rational in their own political circumstances, act on facts rather than emotion, guesses or very short-run political interests. It is the obligation of scientists, administrators and other professionals to gather information and make it available to lawmakers. It is to the advantage of lawmakers and programme administrators to attend to what has been learned. It is hoped that the reader will adopt as his own the theme of *alertness to facts* in using this volume.

UNSDRI has followed with great interest the preparations for this handbook. While it may not subscribe to all the opinions formulated in it, it is convinced that this new and at times critical look at the problems and

objectives which underlie the classification of psychoactive drugs for control purposes meets a real need. Undoubtedly the contributions made by the various authors will help policy makers — national and international — in their effort to devise controls which are both effective and consistent with fundamental human rights.

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June, 1973

AN OVERVIEW OF CLASSIFICATION

Although classifications for psychoactive drugs have existed for as long as men have used these substances to alter their mental states or change physical sensations, today such schemes and the control measures linked to them are of paramount interest to both policy makers and to citizens because they are the building blocks upon which national and international legislation and programmes are constructed. Indeed, the terms "drug problem" or "drug abuse" usually refer to a social matter of such urgency that it calls forth the use of criminal law, education, treatment, certain types of agricultural control programmes and other forms of social intervention. In this perspective, it is critical that those concerned with the designing of legislation understand the bases for the various systems of drug classification. In particular, profound interest in international classification efforts should be shown by those concerned about such matters as drug production and use, the outcomes and related factors of that use, the adequacy and, indeed, the propriety of the various means by which societies either assess drug phenomena or respond to and control those events which they define as drug problems.

It is no secret, of course, that there is currently a good deal of dissatisfaction among those engaged in fact-finding about drugs or drug users as well as those responsible for drafting legislation or for planning and executing related programmes. Their dissatisfaction focuses on the processes, elements and goals of drug classification as these presently stand. It arises from many causes — from the

frustration of the scientist who finds his theories and facts inadequate to match his curiosity, as well as the more practical frustration encountered by the practical man's compelling need for action to combat a problem that at times seems to defy conquering. Others are deeply convinced that the current or proposed approaches to the difficulties are faulty on either scientific, practical or moral grounds. Serious misgivings about the current state of affairs are also experienced by those most directly affected by programmes and services: farmers, manufacturers, police, drug users and offenders.

But in spite of dissatisfaction and misgivings, there is welcome agreement on at least two points. One is that the process of classification, its elements and its objectives are crucial to international action in the control of drugs; the other is that classification and control schemes can be improved. There is probably also general agreement that such improvements are urgent as well as feasible and that they will work to the benefit of mankind. Optimism arises from a recognition that the scientific experience of recent years has brought great increases in knowledge to the drug arena. There is also marked awareness of the way in which legislation bears on drug use and an appreciation of the alternative courses that exist. There is greater public sensitivity to the difficulties and greater governmental and other institutional capability for responding to the phenomenon.

At the same time there is pessimism. Pronouncements and programmes, laws and law enforcement, treaties and treatment, new edifices and education — none of these appear to have reduced overall the production and consumption of potentially unhealthy substances, eliminated the proliferation of myths and romance surrounding drug experiences, diminished the rate of arrests in connection with drug crimes or relieved the distress, fright, temptation or anger of ordinary citizens, viewing the various forms of drug use. Nor have our efforts to date created an international community or mechanism joined together in full and harmonious enterprise. In balance, it becomes evident

that for this century at least we are in a state of permanent change and chronic impermanence. In this state, no language will be enduringly sound, no scientific methods solidly right, no viewpoint unassailable and no system of classification and control more than an effort to adjust, temporarily and as best one can, to the changing world and our changing understanding of it.

This implies, then, that the methods for evaluating drugs, people and the settings in which they use drugs must themselves undergo constant evaluation of their contribution to practical matters. In the business of international legislation related to drugs, for example, scientific curiosity should be directed to practical affairs. In essence, curiosity must serve practicality, and practicality, in turn, must encourage curiosity.

There must be, further, a recognition that any classification scheme will be, at best, an estimate. The conditions which actually affect people's responses to psychoactive drugs include, at least, such matters as the potency and purity of the drug, how it is administered and how often, the time between administrations of the drug, what other drugs are also present in the body, the state of the individual's health, nutrition and metabolism, his expectations about drug effects and the way in which others respond to observed changes that may result. Thus, those interested in drug classification and control systems must appreciate the many different factors that contribute to what are called "drug effects" in the normal range of dosage.

A number of other special problems have arisen from the designing of present classification and control schemes. One of these has been the tendency to ignore information drawn from the citizen level regarding the impact of control systems in real life populations. Another is the high level of semantic confusion arising from the use of such terms as "drug abuse" (a term charged with moral and emotional loadings which means different things to different people) and "control" (which most often implies an effect rather than merely an attempt). A third special prob-

of intervention; (c) the values and philosophies of citizens and their governments with regard to determining the proper domains of freedom and responsibility for each.

Medical Chemical Classification: This system is based on the chemical structure of the drugs, categorizing them according to similarities in their molecular structure. Most of the categories for psychoactive drugs are new, having come into being with the development of hundreds of new compounds intended for the treatment of mental illness and emotional stress. Although this scheme appears straightforward, complex priorities and assumptions underly chemical classification schemes. Some scientific proponents of this approach reject classification by clinical effects on humans on the grounds that we lack knowledge of how the effects of the drugs are linked to their chemical structure. Chemical classification is made more complex, too, by the fact that different classes of chemicals can produce similar effects, and some effects (depending on what is measured) may vary with slight molecular difference among drugs within the same classification. To complicate matters further, differences in action at receptor sites in the brain do not necessarily lead to different effects in behaviour, and differing modes of action (aside from receptor sites) can lead to apparently identical changes. In summary, it is evident that the problems accompanying straightforward "simple" classification schemes are considerable when an effort is made to link a description of classes of drugs to the effects of the drugs at any behavioural level.

Pharmacological Classification: Pharmacological considerations have been widely employed over the last decades in the development of classification schemes which form the basis for recommended or actual legislation for control. Biochemistry, physiology and related disciplines contribute strongly to work at this level, and such pharmacological systems, integrated into psychiatric nomenclature and treatment goals constitute the core of psychopharmacology today. But there is much dispute about whether the so-called "medical model" and the associated "public health approach" should be the primary approach to social and

private drug use. This dispute bears directly on who should be given responsibility for classifying drugs and proposing control measures. Different groups have different ideas about the reasons for which drugs are used and the nature and significance of the associated conduct or resulting effects. In summary, this approach suffers from the myriad difficulties that arise when classification schemes move away from the laboratory to encompass social and private drug use, attempting to estimate effects without knowledge of how users will employ the substance.

Classifying Through Experimental Behavioural Data: Experimental psychology is the major discipline involved here, combining observations of internal processes or events with behavioural data using either animals or humans. At any level at which these data are obtained, it is possible to construct classes of drugs based on their similar or dissimilar effects under experimental conditions. However, for the most part, classification systems based on behavioural experiments are limited to the comparison of several drugs on a given psychological function. No classification system currently exists for all psychoactive substances based on the systematic combination of the major psychological laboratory tests for behavioural toxicity.

Clinical Pharmacological Classifications: Clinical classifications are those made by physicians as they evaluate their patients and the responses patients show to the drugs given. While there have been some systematic approaches taken in not only assessing drug classification by effects but in patient classification based on drug responses, nevertheless, clinical psychiatrists have tended to utilize existing psychiatric diagnoses and not to develop new classifications based on the predictability of response to particular drugs among patients with well defined characteristics as measured by carefully applied ratings or tests. Therefore, classifications based on drug effects on psychiatric populations have not generally been as specific as might be hoped. In addition, there are considerable weaknesses in clinical estimations either of diagnosis or of drug effects. These occur because of the low reliability of diagnosis per se and of

drugs. Further, to the extent that drug use is perceived as a "problem" by any vocal group, then that group becomes an interest group pressing for action. In considering these pressures, it is evident that classification and control schemes reflect many influences, not just the findings of one group of scholars or practitioners, but also of a variety of information, beliefs and interests. Where much is invested by way of belief, emotion, interest, money and power, then classification schemes and their resulting administrative apparatus and linked action programmes will very likely reflect multiple forces and their temporary resolution will be achieved through compromise.

Interest Groups: Because the use of psychotropic drugs is surrounded by highly charged moral, social and political issues, it is evident that considerations broader than those of health alone are involved in classifying drugs and designing control mechanisms. Many citizens are content to permit psychiatrists, for example, to describe certain behaviours associated with mental disturbances. However, there is no agreement, even within psychiatry and pharmacology, to use the psychiatric authority as the base from which to recommend public action. Challenges come from attorneys and law enforcement personnel, religious leaders, social scientists and, at times, from drug users themselves. From within each of these groups come challenges to existing classifications, effects and users. In many instances, moral views are the most strongly held and presented, due perhaps to the fact that some societies face moral diversity and conflict as well as heterogeneous behaviour. Against this background, "objective" standards by which to shape and judge laws will be called into play.

In summary, there are many different goals of drug control schemes, and many alternate ways in which these goals may be achieved. Classification schemes which serve control objectives can be improved if they are based on a broader range of information and more explicit and systematic procedures for their construction and revision. In

like manner the goals of legislation can also benefit from increased awareness of alternatives and improved information. But the first step — an awareness by policy makers of the information and methods available — must be taken, followed by a joining together, particularly in international settings, of those willing to put these tools to use and to create collaborating resources.

kind of effect. Depending upon the circumstances, one or the other may be seen as therapeutic or toxic. This is the case, for example, with the sedative antihistamines, or with the hypnotic thalidomide which also possesses immunosuppressive effects.

A final reason for the wide spectrum of effects produced by even small doses of simple substances is that accounts of drug actions depend to a great extent upon the training of those who examine them. The accounts of a chemist, a pharmacologist, a physician and a psychologist can all be accurate although they are in different terminologies and emphasize different aspects of the same series of events.

Brief mention of all these factors should make it clear that there is no chemical that cannot be used for a different purpose than that for which it is accepted today: for example, airplane glue, a substance which was not intended as a drug by its manufacturers and is not accepted by the medical profession as of therapeutic benefit, may nevertheless be used for its drug-like properties by those who have stumbled across them. It seems obvious that decisions about the risks and benefits to be obtained from the use of any single substance, or the class of which it is a member, are unlikely to be made by considering one kind of evidence only. Far from this being a limitation upon the decision-making process, the need to take into account evidence of drug action described in many different ways should be seen as a positive advantage.

MEDICAL SCIENCE AND THE CLASSIFICATION OF DRUGS

As viewed by the pharmacologist and medical practitioner, drugs are primarily benign, and greater attention is paid to their capacity to relieve pain and cure illness than to their power to produce ill effects. This tendency has guided mankind in his long search and use of drugs for curative purposes. And these same urges will continue to expand chemical therapies. The rapid growth of pharmaceutical medicine in the recent past justifies a prediction that many more drugs with more diverse and specific effects will be developed in the immediate future. The challenge to classification schemes and public action programmes, then, will be the development of more sophisticated ways of utilizing data obtained from many levels of investigation and structuring them for use in the various classificatory subgroups that are developed for various purposes.

Existing classification schemes can be useful and instructive in some areas of science and medicine, helping to display the range of psychoactive drugs, highlighted by one or another key feature (e.g. implying a family of chemical, neurophysiological or clinical correlates). But a problem arises when non-specialists rely on medical classifications and fail to appreciate the inconsistency and inadequacy of these criteria in an over-all scheme. Misunderstanding and misapplication can result from such a simplification of concepts and from a belief that key word descriptions are the sole qualities of the drugs.

Although classification schemes related to the psychoactive drugs have the most bearing on contemporary international law, nevertheless it must be kept in mind that of

PRINCIPLES FOR THE EVALUATION OF NEW THERAPEUTIC SUBSTANCES

The process of developing a new therapeutic substance begins either with its isolation from a natural source (in the case, for example, of antibiotics) or with its synthesis. Chemical modifications can produce a large number of compounds with sometimes dramatically different effects and it is therefore necessary first to screen all the new substances in a relatively simple, crude and economic way, for evidence of a least some biological activity. Substances that are thus shown to have positive effects are then passed through progressively finer screens, by means of which their relative potency and a fuller profile of their activity are established, both in terms of their potential useful and toxic effects, until only a small fraction of those which began the process survive.

Most such substances are developed by relatively large pharmaceutical companies, which at this point have to decide whether or not to experiment with the new substance upon human beings. In part, this decision is based upon marketing and other economic considerations, but without the scientific evidence obtained up to this point an adequate and ethical decision cannot be made.

The first human experiments are often made "in-house" - single progressively increasing doses, on small numbers. The purpose is largely to determine initial safety. To determine whether the predictions of efficacy from animal experiments are justified in medical practice it is next necessary to pass from volunteers to a small number of patients with an appropriate disease. If the results obtained

at this stage are promising, the further decision is taken to enlarge the scope of clinical trials.

In order to do this, it is necessary in some countries to get the permission of the drug regulatory authority. This is given or refused on the basis of the information available up to that point. In any case, however, before a drug can be introduced into the market, a submission for its registration must be made in each country where its introduction is planned. There are wide differences in the intentions or capacities of the regulatory authorities. Small or developing countries, for example, are less able to evaluate the often enormous amount of information reaching them than are the authorities of larger or developed ones. Many countries rely, before making up their own mind, reasonably it would appear, upon work of this kind which has been performed elsewhere (i.e., in those countries better equipped to do it.). Some will concentrate upon running their own analytical tests for purity or potency. Others are primarily concerned with evidence of potential toxicity, and some (an increasing number) demand evidence of therapeutic efficacy as well. The examination of the results obtained is often sophisticated but sometimes used as a delaying tactic by overworked officials. Although the ethical and scientific principles of clinical trials have been fully developed in the last decade and have received wide acceptance throughout the world, national practices still differ. In some countries, for example, it is essential to obtain the written or at least verbal consent of the patient before he enters a trial. In other countries it is considered undesirable to inform the patient that he is taking part in a trial at all and so consent is never asked. In consequence, the results of trials obtained in the second group of countries may be unacceptable to those in the first. This and other national idiosyncracies causes trials to be duplicated unnecessarily and potential risks to increase.

As far as evidence of toxicity (which includes, most importantly, teratogenicity, carcinogenicity and mutagenicity) is concerned, there is more general accord. Authorities increasingly require information about the pharmacokinetics

of drug distribution and excretion, as well as evidence that the active substance in the formulation proposed is properly released and thus available to the tissues upon which it is to act.

The decision of the regulatory authority, like that of the management committee of the producer, is based upon a comparison of potential benefit with risk. Extrapolation from the animal species is of varying degrees of relevance to therapeutic effects in man. It is also felt by some that toxicity testing on animals overstates the potential risk to man, resulting in frequent loss of potentially useful substances. More reliable estimates of risk and benefit are theoretically obtainable when the drug is eventually used on a wide scale in clinical practice. However, the results of large scale clinical use are seldom reported critically or in a way that can be evaluated scientifically; and the toxicity of a drug in large scale use is almost inevitably under-reported by busy physicians. Strong efforts are being made at national and international levels to improve the reporting of adverse reactions. Some regulatory authorities are also encouraging the use of so-called "monitored release" investigations, in which evidence of therapeutic usefulness is collected in a standardized and evaluable way.

The potential benefit of new psychoactive drugs, especially those with new types of action, is particularly difficult to work out on animal models. On the other hand, there are some animal models for the prediction of dependence liability on strong analgesics, sedatives, anxiolytics and hypnotics, though their relevance to human dependence is still subject to some dispute. Cost-benefit decision-making processes in regard to drugs of dependence therefore need to be particularly sensitive to the provision of new information, so that earlier decisions, once seen to be incorrect in either direction, can be speedily set right.

TESTING AND EVALUATING THE RISK OF DRUG DEPENDENCE AND ABUSE

Animal experiments are available to characterize those properties of psychoactive substances which may have a bearing on their dependence and abuse potential. In order to understand the limitations of such experiments it is necessary to distinguish between testing and evaluating. While the purpose of a test is to compare a substance of unknown properties with a substance of known properties using physical, chemical or biological methods, the actual risk of abuse under the prevailing circumstances must be evaluated. Since the international conventions stipulate the control of substances having similar properties and giving rise to similar abuse as the drugs already controlled, testing as well as evaluating is required for any substance considered for control.

The Single Convention on Narcotic Drugs, 1961, assigns to the Commission on Narcotic Drugs the final decision as to the establishment of controls, because social and other environmental factors were considered relevant for evaluating the risk of abuse. Likewise the Convention on Psychotropic Substances, 1971, provides for economic, social, legal, administrative and other factors to be taken into consideration in addition to the conclusions from psychopharmacological testing. To the extent that suitable methods to evaluate those factors are lacking, social legislation remains limited by inexact estimates of the risks involved and relies heavily on the narrow range of data obtained through the testing of psychopharmacological properties.

Difficulties in terminology have become increasingly apparent as new drugs have appeared and as the patterns of their non-medical use have altered. Since these developments were not adequately characterized by the existing definitions of "addiction" and "habituation", a term was sought which would embrace all kinds and forms of drug abuse. "Dependence" was elected by WHO to serve that function. For scientific reasons and also with a view to contemporary national and international programmes and legal provisions for prevention and control, the following types of dependence are currently distinguished: morphine (opiate)-; barbiturate-alcohol-; cocaine-; cannabis (marihuana)-; amphetamine-; and hallucinogen type. Khat (*catha edulis*) contains an active ingredient of amphetamine character and can thus be assimilated to the amphetamines. There would be no reason not to include other types of substance-related dependence, depending upon their consequences for public health and safety.

The state of dependence, whether physical or psychic in origin and outcome, is the result of the interaction between a chemical agent and an individual organism (human or animal). It is thus a biological phenomenon which should be amenable to scientific experimental investigation. In contrast, the development and pattern of abuse are contingent upon many environmental factors: anthropological, sociological, cultural, traditional, economic. The task of determining for preventive medical or legislative control purposes not only the dependence potential of a hitherto unknown substance, but also the risk of its being abused meets with considerable difficulties.

When studying the dependence potential of a drug one must distinguish between psychic and physical dependence. Whereas psychic dependence is characteristic of any type of drug liable to be abused, only morphine- and barbiturate-type drugs produce a physical dependence. Although its mechanism is not fully understood, physical dependence can be demonstrated by the appearance of characteristic signs and symptoms after withdrawal of the drug. The withdrawal syndrome differs between drugs of the mor-

phine and barbiturate type. An essential characteristic of any withdrawal syndrome, irrespective of the type of drug, is its alleviation or disappearance on re-administration of the drug which originated the dependence. The test for physical dependence of morphine type can be supplemented by the administration of a specific antagonist which will bring about immediately a typical abstinence syndrome.

Techniques have been developed for the study of physical dependence of morphine type in monkeys, dogs, guinea pigs, rats and mice. Tests in lower animals are mainly exploratory and useful for screening purposes. Results obtained with morphine-like substances in monkeys when unequivocally positive may, in the view of the 1969 WHO Expert Committee on Drug Dependence, be used as a sound basis for evaluating the liability of a drug to produce physical dependence in man.

For the detection of physical dependence on drugs of the barbiturate type, tests with monkeys and dogs are available. The experience gained with them so far would, however, appear not to be sufficient to credit them with the same predictive value as in the case of morphine-type drugs. The wide chemical, metabolic and pharmacodynamic differences in this group of substances is likely to entail great differences in respect of their capability to produce dependence.

Whenever experiments with higher animals give doubtful or negative results, studies with human subjects are in order. The 1958 WHO Expert Committee, recognizing the progress made in initial screening procedures for detecting dependence liability, considered that observations in man are still required for the final judgement as to the safety of any new compound.

A much stronger component in abuse than physical dependence is a state of psychic dependence. It is characterized by behavioural responses which include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects and to avoid discomfort caused by its absence. Since such psychological features appear to be the most powerful factors associated with abuse, it is of paramount importance to estimate a drug's

potential for creating psychic dependence. For this purpose primates are most often used. In self-administration experiments, monkeys can administer the test drug to themselves in fixed quantities by various routes and under variable environmental conditions which can be designed to imitate certain real life situations, e.g., stress. So far it has been possible to induce in the monkey drug-seeking behaviour analogous to that in man for cocaine, amphetamines and alcohol as well as morphine and barbiturates. Drugs which are more repetitively self-administered by animals under a greater variety of conditions are presumed to have a high potential for abuse in humans. Nevertheless, the 1969 WHO Expert Committee stated that none of these methods has yet reached a level of refinement and reproducibility that would make it acceptable as yielding conclusive evidence of the possibility of man's developing psychic dependence.

Psychic dependence on hallucinogenic substances such as mescaline, LSD and psilocybin is usually not intense. Animals do not usually self-administer these drugs. In animals, LSD and other hallucinogens can produce an increase in body temperature and provoke certain behavioural patterns. Irrespective of possible parallels between these animal effects and the hallucinogenic properties in man, animal tests with hallucinogens are of very limited predictive value with regard to how humans will behave when using them.

The demonstration of tolerance has occasionally served to characterize a dependence-producing drug. Tolerance means the adaptation of the organism in the sense of decreasing sensitivity to the effects of a drug so that increasing dosages are required to obtain the initial drug effect. Since human and animal organisms can become tolerant towards a great variety of substances, and since dependence on a drug can develop with or without the occurrence of tolerance, its demonstration is no proof of the development of dependence.

Not only the dependence and abuse potential of a drug but also the immediate and possibly toxic consequences of its use must be considered when taking a decision relative

to control. For the study of such direct "psychotoxic" effects animal experiments can yield much information, but the full picture will have to be obtained through clinical studies with humans.

The Convention on Psychotropic Substances provides that the degree of usefulness in medical therapy of a substance considered for international control should also be taken into account. "Usefulness" is not necessarily tantamount to "efficacy", the study of which requires the skills of many disciplines including toxicology, pharmacology, clinical pharmacology, biometry, biostatistics, and epidemiology. An efficacious drug found useful in one geographical area may be considered less so in others. The assessment of usefulness might become still more difficult if a comparison with existing drugs should be required, as might be the case under the terms of the Convention on Psychotropic Substances.

THE DESIGN AND MANAGEMENT OF EXPERIMENTS AND SURVEYS IN RELATION TO DRUG USE

Social action should be based upon policies that have been framed to take account of the best evidence available at the time, as well as of the best estimates of their own consequences. These considerations involve the concepts of evaluation and prediction. Depending upon its nature, evidence can be evaluated in different ways — scientific, legal or even theological. Broadly speaking, any method of evaluating evidence depends, in one form or another, upon judgements of plausibility, relevance, reliability and importance. Methods of scientific evaluation use rather strict definitions of plausibility, relevance and reliability.

Importance is a more subjective criterion, or is at least based upon common sense or common consensus of experience. Nevertheless, a close parallel can be drawn between the employment of scientific methods of enquiry and the formulation of constructive, fair and workable social policies. If the courses appear not to be parallel but to diverge, this is most probably due to unfamiliarity with the principles of scientific investigation, attention to which is likely to be rewarding.

The definition of a policy resembles the statement of the object of an experiment. What is the policy or the experiment intended to achieve? The scientist states his objective in precise terms and the policy maker should do the same. The scientist's purpose is not to "see if this drug works", but, for example, "to examine the effectiveness of a (specific) drug in relieving the pain of surgical

trauma without giving rise to phenomena, such as hallucinations or euphoria, associated with the presence of liability to induce dependence". Policies should not be aimed at "suppressing" or even "controlling" drug dependence, or illicit traffic in drugs, but should rather state a more precise objective — as, for example, "the reduction of the percentage of those (in a specified population) dependent (in a defined sense) upon heroin" to an exact figure: or "the optimal employment (of a specified fraction) of the community's resources upon detection or prevention of drug offences or rehabilitation of those physically dependent upon (specified) drugs".

After stating an objective, the scientist states his hypothesis: that if he carries out such-and-such an action (e.g. modification of the formula of a chemical in a certain way) the consequence will be so-and-so (e.g., loss of hallucinogenic activity within certain limits which he also defines). Otherwise he will not consider that a relationship between cause and effect has been demonstrated. The formulation of hypotheses in this way sometimes occurs when social policies are framed, but all too rarely; and it is exceptional for a policy to be abandoned, modified, or replaced when a social hypothesis of this kind is not substantiated. Once a policy has been initiated, it tends to resist change or evolution. It is suggested that any policy should incorporate its own self-evaluating machinery (and its own self-destruct mechanism if the result of the evaluation is negative). Not until the objective has been defined and the hypothesis or hypotheses identified is it possible to see clearly what kinds of subjects (animals, patients, experimental volunteers, etc.) will be most suitably chosen in order to find the answer, or to decide upon the appropriate measuring instrument (biochemical, pharmacological, psychological or clinical, for example) to be employed.

Of course, the feasibility and economic consequences of choices will interact with the hypotheses, and a process of mutual modification will often be necessary. Then it will be possible to decide upon the number of experimental objects required in the samples in order to detect differen-

ces of a specified size between the consequences of proceeding in various ways, and to choose the appropriate experimental design and method of analysing the results.

All such investigations should be comparative, and steps should be taken to eliminate or control known or suspected causes of difficulty in conducting or interpreting the experiment. It is particularly important that the bias of the subjects, or even of the experimenter, be he physician, sociologist or chemist, be prevented from influencing the work, especially where, as in matters affecting drug control, emotion is often allowed to replace evidence, or to result in disregarding evidence when it has been collected.

Every effort must be made to avoid systematic bias by applying the twin principles of randomization (of the subjects) and blindness (of the judge of the effects) in relation to the treatments or groups which are being compared. In this way, there can be greater confidence that a given result is meaningful rather than haphazard — or vice-versa. But regardless of the strictness with which such control measures are applied, the findings can never amount to certainty.

As noted above, the importance of even a meaningful result requires judgement by those who are affected by it, or who need to make use of it, and at this stage prejudice can again impair the quality of the best-controlled enquiry. It is usually necessary, in any case, to reach an agreement about such matters between several individuals, often coming from different disciplines. A related problem is the addition or comparison of evidence from several different sources, using different techniques, or even reaching different results although ostensibly designed to study the same problem in exactly the same way.

Methods of reaching valid conclusions in such circumstances are beginning to be available, but it is recommended that the policy maker or decision taker obtain sufficient familiarity with the logical (not necessarily technological) methods of scientific enquiry to enable him to reject some purported evidence with confidence, and to feel a proper degree of scepticism about accepting that which remains.

THE DEMONSTRATION OF DRUG USE, ABUSE AND DEPENDENCE FROM CLINICAL OBSERVATION

In the final analysis, the question of whether a drug is being used or abused or causing dependence requires an examination of the individual suspected of using it. Such examinations may be, and are, carried out by members of many quite different specialities — teachers, police officers, probation officers, sociologists and doctors. Only the techniques employed by the last (especially by psychiatrists and those who assist them with other technical skills, such as pathologists or laboratory workers) can have much hope of establishing the nature of the use and the drug used, or even stand a chance of *measuring* the degree of dependence which has occurred.

This is not only because the drug user is, in general, concerned to preserve the knowledge of his behaviour from all but those of his acquaintance whom he trusts or with whom he consorts. Other members of society than doctors have their own techniques of obtaining information that the respondent has no wish to impart. The physician's special skill should lie in separating the effects of drug-taking upon the individual from those aspects of the individual himself which may have led him to take drugs, which predispose him to continue to do so, or which reflect other kinds of pathology that require medical or social treatment. To do this, the doctor makes use of the chemical tests upon blood or urine that, with varying sensitivity, can indicate whether the individual has recently ingested drugs.

In fact, the physician can do little more than this from direct examination alone, although social attitudes towards his skills are often so ambivalent that while he is expected to be able to establish with absolute reliability whether a given individual is using drugs, he is at the same time considered to be completely gullible and prone to believe whatever his patient tells him. Such ambivalence reflects the great need for certainty in the face of what is seen to be a largely unintelligible and frightening phenomenon.

However, the psychiatrist, like other scientists, is particularly mindful of the need to check his observations and establish this reliability wherever possible by reference to independent sources. Although certain physical signs, such as the presence of injection marks in characteristic sites, or dilation or constriction of the pupils, are highly suggestive, they are not infallible. They can be present for other reasons (false positive) nor does their absence mean that the individual is not a drug user (false negative). Information must be obtained from relations, or friends, which must also be carefully interpreted in order to allow for the possibility that it is being presented in a special way for the informant's own reasons.

This, as is also pointed out elsewhere, is of even greater importance if the psychiatrist is also functioning or assisting as an epidemiologist. In this circumstance, he needs to establish the use of drugs in his subjects with the utmost reliability, perhaps by reference to quite different sources of information — such as hospital out-patient clinics and general practitioners. But he must also determine the extent to which their behaviour is representative of that of the social group or groups of which they are members, so that he can make a justifiable inference from them to the population at large. It should not be forgotten that individuals coming before any single social agency, whether it be medical, educational or legal, are inevitably not fully representative. They may be those who have volunteered, or for whatever reason have been sent, for treatment; or those who have been so unwise or perhaps deliberately demonstrative as to be caught; or whose behaviour has

brought them to the attention of some authority. Such selective factors operate in such a way that there is a greater risk of apprehension for drug-related behaviour in one community than in another, or one psychiatrist is liable to see more patients with drug-induced problems than another because of his known sympathy or interest in such matters. Thus, estimates of prevalence, or incidence, or trends, depend not only upon the techniques of the discipline whose members have collected them, but upon differences in the members of those disciplines as well. These are particularly important when much of the information is obtained by verbal interchange and by the practice of skills, the teaching and expression of which varies from one institution to another as well as from one country to another.

Such facts make the comparison of observations in different countries, or even at different times in the same country, particularly hazardous. The difficulties may be reduced by ensuring that data which is to be used as the basis of information for action is collected, as far as possible, by a team of specialists from different disciplines, adhering to a common protocol and using methods that have been validated by repeated use on different groups and in varying circumstances. All that has been said about the uncertainty of psychiatric methods in establishing drug use in a clinical setting (compounded by the fact that many drug users employ more than one drug) should also make one wary of the extension of these methods to surveys of populations in which the members have not volunteered for the enquiry in the way that a patient coming for treatment volunteers.

Finally, it should be remembered that a psychiatrist is bound by ethical considerations regarding confidentiality and the needs of the individual patient — not the needs of society. These requirements constitute an important bastion of the psychiatrist's position of strength in relation to usefulness to those who come to him.

EPIDEMIOLOGICAL METHODS IN THE SURVEY OF DRUG USE

Drug use of all kinds — licit and illicit, prescribed and excessive — is an epidemic phenomenon, and the use of epidemiological methods to study it is appropriate. These methods are descriptive rather than experimental but, using the logical techniques common to all sciences, comparative experiments are not excluded. They are difficult to perform because, amongst other reasons, the unit of study is the community or other group, rather than the individual, and samples of adequate size to justify firm inferences are not easy to acquire. Most contributions, therefore, have come from descriptive work, in which information is usually actively sought about the phenomenon under study by surveying records published for other purposes (births, deaths and marriage registers; tax returns; trade and other economic statistics; hospital and central health records, etc.), or by designing questionnaires or interviews to elicit the information desired in a more deliberately and appropriately designed framework.

This is not necessarily more economical, for the problems of securing a relevant response of adequate size are considerable. But it is certainly more efficient in terms of the amount of information which it should be possible to obtain in a single operation. In any case it is crucial to define the objective and to select the target population from which the sample is to be drawn. The problem of obtaining a satisfactory sample, moreover, is not solved simply by defining the sample. Particularly in the field of drug dependence, the behaviour of interest may be ignored, de-

nied or misrepresented. Thus it is especially important that, wherever possible, more than one method be used to check the results, or at least to assess their reliability. As an instance, differing estimates of heroin dependence in a single town may result from use of official governmental statistics, interviews with drug users and assessments of drug-related accidents and infections reported by various branches of the National Health Service.

It is valuable to bear in mind that the object and the purpose of an enquiry may differ. The object of the work is scientific and, as always, should be clearly, unambiguously and precisely stated. The purpose of the work is dictated by the motives and interests of the individual or the group which has caused it to be carried out, and these are not necessarily identical with those involved in executing the work. This should be kept in mind by both sides before, during and after the enquiry, so that the work may be correctly planned, executed, interpreted and utilized.

The uses of epidemiology have been defined, in one scheme, as historical description, community diagnosis, the monitoring of health services, the assessment of individual risks and changes, the "completion of the clinical picture", the identification of syndromes and the search of causes. Such a scheme can be applied to the uses of epidemiological methods in studying drug dependence. A good deal can be learnt, for example, from the history of drug use by other cultures and at other periods, especially if the phenomena are viewed operationally and not in terms of the value judgements of the contemporary society to which they are being related. "Community diagnosis" refers to the calculation of prevalence rates (e.g., the total number of existing cases) and incidence rates (e.g., the number of new cases in a given time). These, the relations between them, and their correct attribution for different sub-groups of a given population, are of inestimable value in helping those responsible for policy to decide whether a given problem is increasing, stationary or decreasing. At present they are seldom available for problems of drug dependence, since gross statistics, often collected on a different base at different

times and places have frequently been used. It may be noted that indirect methods of calculating these rates (that is, by using a measure, such as deaths from cirrhosis of the liver, which has been shown to have a strong correlation with "alcoholism" defined in other ways, and which is more accessible than the phenomenon of direct interest) have been little used outside the field of alcoholism, with the exception of heroin use estimates derived from overdose death rates, largely because such correlations are difficult to establish and frequently undergo change.

While information of this kind is also helpful in monitoring the efficacy of health services and in providing for necessary change, the emphasis is quite different, however, when the intention is to define individuals or groups who are particularly at risk in respect of drug dependence liability. Here, prospective studies (based, naturally, on hypotheses derived from retrospective comparisons) are necessary though difficult. The importance of such work can hardly be overestimated despite the risk that it will lead to unpopular conclusions, such as that some important factors in establishing drug dependence in the offspring are to be found in the behaviour of their parents.

"Completion of the clinical picture" and identification of syndromes are certainly important areas of epidemiological enquiry into drug dependence. However, although their relevance is in the first instance to medical diagnosis and treatment rather than to the concerns of the social policy-maker the establishment of new syndromes may well reveal the development of patterns of behaviour of which the policy-maker will eventually have to take cognizance.

On the other hand, epidemiological methods of searching for causes deserve further study. Not only are they relevant to all the problems mentioned above but they are not unlikely to help in the tracking of points of entry and pathways of distribution of undesirable substances.

LABORATORY AND FIELD INVESTIGATIONS: INTERACTION AND DIFFERENTIAL ADVANTAGES

The earlier sections of this Handbook have discussed laboratory and clinical research. Laboratory and clinical environments allow the investigator maximum opportunity to control and systematically change the forces affecting the phenomenon he is studying. Sensitive measures and sophisticated equipment can be used to record and analyze precisely the events under investigation. By contrast, the field research worker must adapt his measures to natural conditions, where events cannot usually be altered. Consequently, one expects more error in field studies; on the other hand, one observes phenomena with the full range of complexity in view and with all contributing influences operative.

The advantages of laboratory versus field study for acquiring information are such that there is often a complementary two-way interaction between them. Findings from rigorously structured laboratory investigations can be tested in field situations to see if they are important in natural settings. Conversely, information obtained from the field may be reanalyzed in the laboratory for better understanding as to how certain specific processes or elements operate. The following sections briefly describe the relative advantages of laboratory and field settings for acquiring information necessary for drug classification.

Laboratory Investigation

Laboratory investigation provides information for drug classification not readily obtained in other settings. Of

particular importance is identification and clarification of usual short-term drug effects. Since the laboratory investigator can select the exact materials to be used in the experiment, he can make precise determinations of the relative effects of the various drug constituents; for example, the extent of pharmacological effects of a given alcoholic beverage which result from ethanol per se and how much from other pharmacologically active ingredients in the beverage. Precise dose-response characteristics — that is, the varying behavioural effects resulting from different doses of the drug — can be ascertained, as well as time-action characteristics — the changes in drug effects during the time course of drug action.

Certain sophisticated measuring techniques, which can provide unique information for drug classification, are most readily utilized in laboratory investigation. For example, objective indications of drug-induced alterations of bodily functions are often difficult to establish without the use of sensitive techniques. If sensitive electro-physiological (EEG) measurements of attention show definite impairment under the influence of a given drug, one can expect that complex behaviour such as driving will be vulnerable to impairment during drug intoxication, and at least provisionally, classify the drug accordingly. Laboratory measurements of short-term drug effects may also aid in predicting the consequences of chronic, long-term drug use. These predictions may be based on the assumption that bodily functions most markedly altered during acute drug intoxication are the functions most likely to be chronically or permanently impaired when biologically susceptible individuals use the drug repeatedly.

Laboratory investigation also affords the opportunity of precisely identifying which of the many influences impinging on the drug user are relatively more potent and which are less so by permitting the systematic manipulation of the variables associated with drug use. For instance, until recently it was not clear whether amphetamine psychosis was a result of drug effects per se or other variables, such as poor nutrition, lack of sleep or premorbid person-

ality characteristics. Structured laboratory studies, which control for these variables, have now shown amphetamine effects per se can be the crucial determinant in the development of the amphetamine psychosis. When adverse drug effects have thus been delineated in the laboratory, a drug classification system designed to protect people from such effects would restrict the availability of the drug.

Field Investigation

Field investigation offers the major advantage of providing an opportunity to observe all factors influencing the phenomenon under study. These factors in drug research include not only pharmacological variables but also psychological, social and other non-pharmacological influences which although not obvious, may be important in drug classification. Field studies thus reduce the risks of inadvertent omission of important variables from consideration and permit testing situational factors that are impossible to replicate in the lab. For example, laboratory investigation of short-acting barbiturates would lead one to the reasonable prediction that, in social settings, these drugs would induce sedation and drowsiness in most individuals. However, actual field studies indicate that some short-acting barbiturates are associated with aggressiveness, obviously suggesting that there are important factors in natural settings influencing the behaviour of barbiturate users which are not replicated in the laboratory.

In addition to psychological and social factors, other non-pharmacological variables may exert important influences on drug-related behaviour and be important for drug classification. Field studies are obviously required to assess drug interactions with environmental factors such as air pollution or industrial chemicals.

Scientific or practical requirements such as appropriate subject selection and adequate sampling may also necessitate field studies. In some instances, rare phenomena which have important implications for drug classification occur so infrequently that they are unlikely to be detected

in laboratory research. For example, the teratogenic effects of thalidomide are operative only during a short period of fetal development; therefore, only a small percentage of women who used the drug delivered malformed babies. The amount of human laboratory study required to correctly associate such infrequent events with the use of thalidomide would have been impractical, and thus appropriate epidemiological field studies were required to detect the teratogenic drug effects.

Practical consideration of important long-term consequences of drug use may also preclude laboratory study and necessitate field investigation. The development of drug dependency occurs over prolonged periods of time (e.g. typically five to fifteen years for alcoholism at present) and hence requires study in natural settings. Other long-term consequences of repetitive drug use such as the health hazards of cigarette smoking are also determined most effectively with field studies.

Finally, ethical constraints on laboratory research require that certain information for drug classification be obtained from field studies. Although much drug use occurs among adolescents who, because of psychological and physiological immaturity, may be more susceptible to toxic effects of drugs than mature adults, laboratory investigators studying drug effects seldom use subjects under the age of eighteen. Similarly, in laboratory settings, psychoactive drugs are not given to women who are pregnant unless there are definite clinical indications; adverse consequences of drug use during pregnancy must be determined by field studies.

In sum, both laboratory and field investigations have inherent advantages and limitations in providing information for drug classification. Properly conducted laboratory studies, in which variables are systematically altered, are useful in determining the precise details of drug effects and making predictions about consequences of drug use in natural settings. Field studies permit the assessment of all the complex factors that may influence the drug user and provide information that cannot be obtained from labor-

atory investigation for scientific, practical or ethical reasons. The reader, when pondering a question of drug classification, might well ask himself, "What mode of investigation — laboratory or field — is most applicable?" If those investigations have not been completed or have been inadequately conducted, caution in classification is warranted.

STUDIES ON NATURAL GROUPS

Studies of "real life" or natural populations are useful in classification for several reasons. First, they describe drug effects under conditions of actual use. Secondly, we can learn something of the consequences of control systems by discovering how a community responds to the availability of certain psychoactive substances. This, in turn, can suggest conditions under which similar mechanisms elsewhere might work or fail. A third merit derives from the opportunity to gain perspective on value judgements about drug use and problems within the framework of the family and the religious and political backgrounds of individuals and groups. Fourthly, such studies may throw light on matters which bear not only on drugs, but also on other characteristics of society. For the policy-maker or politician, such discoveries can reveal previously unknown facets of the public they serve.

Field-Laboratory Exchange

The laboratory is an environment which allows the investigator maximum opportunity to control events which affect the phenomenon he is investigating. The worker doing field studies, on the other hand, takes people as they are and where they are, adjusting his measures to field conditions. It follows that one expects more error in field studies, although they enjoy the advantage of observing things as they are with a full range of complexity visible. The two-way street that links these two forms of research makes it possible to test laboratory findings in field situ-

ations, attempting to determine whether factors found important in the laboratory can also be detected in real life. Conversely, factors discovered in real life can be tested in the laboratory so that their operation can be better understood.

Field Study Methodology

Samples and Instruments: While the earliest field studies were often made by travellers who observed group life and recorded their observations, more frequently today an observer sets out with the primary goal of studying a group. He may aim at a general description of the group, or he may restrict his focus to some particular form of behaviour, drug use, for example.

As his investigation proceeds, he will become more systematic in the questions he asks and in the manner in which he records the information he acquires. Then, in order to check the accuracy of his general observations, he will move from casual to systematic sampling. Sampling takes place whenever one has to select certain individuals out of a larger, partially inaccessible "universe" of individuals; in other words to attempt to achieve a representative distribution. The scientist may use the technique of random sampling (i.e. every individual has an equal chance of being included in the sample); or he may use systematic devices (every *n*th case); or he may employ a technique called "matching", one example of which is to construct a sample having the same proportional representation or relevant characteristics as those in the total population. The size of his sample will vary with the degree of accuracy required.

Once his sample has been selected, the scientist must then construct a fact-finding instrument which is both reliable and valid. A reliable instrument will yield consistent results on different applications, in the hands of different people, and is also internally consistent. A valid instru-

ment measures what it purports to measure. Next, he requires trained personnel to use the instrument, investigators trained to avoid the introduction of bias or persuasion in the administration of the instrument.

Special Samples: At-times, the investigator may wish to concentrate on persons who cannot be identified as members of some real group to which access is easy. In that case, he will develop means for "case-finding" and further means for "case identification". In the former method, he may examine sample surveys and institutional records or may interview knowledgeable persons who can assist in scanning a population in which cases of interest to him are likely to occur. In the latter step, he will use some standard (medical or psychiatric examinations, psychological tests, health inventories, etc.) by which to judge individuals on the basis of their experience. Insofar as he is investigating past events, the orientation is retrospective.

Prospective Studies: Prospective studies, on the other hand, permit the scientist to follow a population forward in time. Persons exposed to some event may be contrasted with those not so exposed, and the inquiry is directed to its possible sequels. Or he may select a population at random, follow a specific outcome, and finally return to the data gathered over the years to see what variables are associated with the development being studied.

Special Goals and Methods: It must not be forgotten that the goals of the investigator will determine both his methods and the population he studies. He may evaluate programmes by interview and prospective studies. He may investigate special populations in their environments to determine whether certain types of behaviour can be predicted (e.g. drug use). He may use a participant observation technique, becoming part of a group and attempting to identify the factors which account for what he is observing. Or he may employ attitude scales or certain physiological tests to verify the information provided to him.

The Scientist's Orientation: The scientist's concepts direct his attention, define his focus of interest, influence

his choice of instruments and design and modify the method by which he processes data. They also influence his interpretation of the results. Therefore, unless the methodology he employs is sound, there can be no protection against the intrusion of bias in judgements, for example, with respect to drugs, drug users and drug intervention programmes. Even with sound methodology, biasing can occur. Only alertness and an openminded interest in bias as a determinant in human affairs can help scientists as well as policy makers and citizens to learn to think in terms of probability with each investigative effort designed to make one's estimates of what is happening in the real world more accurate.

Illustrative Studies

Historical Studies: In reviewing fieldwork, one begins with the library. Many earlier observations have been used by historians, anthropologists and, occasionally, ethnologists and epidemiologists. With respect to the use of psychoactive substances, much has been recorded regarding the ways in which drugs were used and the impact of their use on populations. Synthetic drugs, however, have for the most part been so recent that their study is made through direct scientific observation, rather than through historical review. Many such scholarly historical studies have been made, ranging from ether drinking in Ireland in the late eighteenth century to analgesic use in a Swedish factory town.

Contemporary Studies of Drug-Using Behaviour: An investigator interested in a contemporary group's use of drugs can directly view a population either in terms of a particular drug or of a particular group. If his interest is a drug, he must engage in case-finding and case identification. If he is studying a drug-using group, he must identify a naturally occurring group whose members engage in the behaviour in which he is interested. Many studies exist both with respect to specific drug use and to drug use correlates in normal populations.

Institutional Populations and Institutional Studies: Special studies have been made of such populations as medical and psychiatric patients, volunteers for experiments, institutionalized addicts and institutionalized criminals. They are sampled during routine contact, at which time it may be wished to relate either their past or present natural drug use or their subsequent behaviour to some social, personal or physiological variable by means of natural observations, interviews, tests, etc. But it may also be necessary to study the person prescribing the drug as well as the institution in which he works, for both institutional and personal characteristics have been shown to influence prescribing behaviour. In this case, he looks not at a structured sample, but at whole groups or institutions as such.

Case History and Social Context Observations: The chain of events which leads to a drug effect in a patient does not begin with the hospital itself, and the scholar interested in tracing the full sequence of symptom-defining, rôle-assuming, care-receiving, drug-taking and drug-impact finds himself looking at the individual in the whole community in work, family and peer-group settings.

Group Life: Many revealing studies have been made of natural groups which provide insight into how drug use and its effects are embedded in and consonant with other features of life, be that life in a primitive tribe, a peasant village, group of marijuana smokers or a neighbourhood group of heroin users.

Occupational Groups: It can be particularly helpful to look at what holders of particular rôles believe, do and experience when that occupation is of special importance in drug distribution or control. In this connection, studies have been made of, for example, the prescribing practices of physicians in relation to their own drug use and their beliefs about the power of pharmaceutical preparations, the attitudes of narcotics law enforcement officers, pharmacists, legislators responsible for drug laws, as well as illicit drug traffickers.

Studies on Control Impact: These studies should be of particular interest to policy-makers and systems operators. They include assessments of the effectiveness of law enforcement as studied through the operation of police departments and penal systems, as well as evaluations of different treatment modalities for drug users and the effectiveness of drug education programmes, although only a few of the latter are currently available.

Cross-Cultural Studies: These are conducted when someone wishes to compare several cultures to see if certain common conditions are associated with like behaviour in quite different settings. The term "cross-cultural" implies that the results of several cultural studies are examined within a common framework. Many such studies have been conducted and, as more information becomes available to such international organizations as the International Narcotics Control Board, even more cross-cultural analysis is possible. They can be particularly helpful both in predicting which groups are likely to engage in regular forms of new drug use and which groups are more vulnerable to problem use.

Country Studies: Under the press of public concern over youthful drug use, several nations have taken stock of their situations. Relying on a variety of data sources, being careful about methods employed and evaluating their laws and the impact of intervention programmes, these nations have set the stage for full-scale evaluation of where they stand and where their public policy should take them. Some such studies have been conducted in the United Kingdom, Canada, the United States and Sweden, among others. Under the encouragement of the United Nations Social Defence Research Institute in Rome, other nations are now initiating such studies. In addition to the value of the assessments that emerge from them, such studies also assist in the formulation of policy by both providing facts and introducing notions useful in measuring policies as they are applied.

THE BENEFIT-COST APPROACH TO THE EVALUATION OF DRUG CONTROL PROGRAMMES

Drug control policies share with many other areas of public policy two deficiencies: lack of knowledge of their costs, and lack of specified objectives. This is partly because of the uncertainty that surrounds both the appropriate means and the exact aims of such policies. It is also the result of the neglect of modern management techniques of structuring complex decisions so that despite many uncertainties the best use is made of available resources. We shall show that the techniques of decision analysis in evaluating their impact can be applied to drug control.

Drug Control and Scarcity

One basic economic premise is that since resources are never infinite a decision to spend money for one purpose is also a decision *not* to spend it on another. Another is that the wealthier a community is, the more it will be prepared to spend on public programmes. But these premises have important implications when we consider international programmes intended to be applied uniformly to countries with great disparities in per capita income.

The first premise implies that in allocating resources we need to consider which of several alternatives will achieve our objectives most economically. Thus, suppose our objective is simply to save life, and suppose an initial \$ 100,000 would save ten lives if spent on drug programmes but twenty-five if spent on highway improvement, then

clearly we would do better to allocate it to highways. According to the law of diminishing returns, an increase in expenditure on highway safety will decrease the number of lives saved per \$ 100,000 spent until, at some level of expenditure, an equal number could be saved by spending the same amount on drug control. This is the point at which we should consider drug control. The principle underlying this much simplified example is basic to the evaluation of public expenditure. How might it be actually implemented in evaluating drug control programmes?

The Benefit-Cost Approach

Basically, adopting a benefit-cost approach means weighing the desirable consequences (benefits) against the undesirable consequences (costs) of each alternative policy and choosing the one whose benefits most outweigh its costs. In principle, this is simple, if not obvious. In practice, however, it is both difficult and complex. For it requires that policy-makers first establish the actual costs (both direct and indirect) of their programmes and, secondly, explicitly identify the consequences to be expected from alternative programmes.

To make a benefit-cost approach work, three practical problems must be solved: 1) the measurement of benefits and costs; 2) the uncertainty of predicting results in the realm of public policy; 3) the fact that both costs and benefits are spread over time.

Identification of Objectives and Valuation of Benefits and Costs

The first step is to define objectives, and these objectives must be those that are valued for their own sake, i.e. the real ultimate objectives. Implicit assumptions about the effects of particular courses of action must be rigorously excluded. Mis-statement of objectives or the failure to

distinguish means from objectives can vitiate the entire evaluation of policy alternatives. For example, to take as an objective the increase of police drug squads, on the implicit assumption that this will reduce drug-related crime, would be doubly misleading. First it would bar from consideration alternative possible ways of achieving the real objective, a reduction in drug-related crime. Secondly, it precludes consideration of whether more enforcement will actually achieve this objective. (We shall show later that there may be circumstances in which it will do the reverse). Secondly, whenever possible, benefits and costs of achieving the objectives must be stated directly in quantitative terms or must be linked to some indicator that can be stated quantitatively. For example, the benefits accruing from the medical use of tranquillizers might be measured in terms of the numbers of persons requiring admission to mental hospitals, or released to re-employment. Some benefits and costs will nevertheless not be quantifiable directly or indirectly, and these must be described quantitatively with a clear indication of which qualities are valued.

Thirdly, the benefits and costs, which will have been stated in a variety of units (man-hours, crime rates, hospital-bed occupancy, etc.) and valued qualities (security from personal injury, etc.) must be valued in terms of a common unit, i.e., money, so that they can be weighed against the other. The conversion of quantitatively measured benefits and costs into monetary terms is comparatively straightforward. Money also provides a convenient way of valuing quantitatively-described benefits, for how much one values a quality can be measured by how much one is prepared to spend to obtain it.

Choosing between Alternatives

Once benefits and costs have been valued, it is theoretically simple to apply the benefit-cost criterion. The decision-maker assigns *his* values to the consequences of each alternative policy, and an analyst computes the net benefit or cost of each policy. But in the domain of public policy,

decision-makers (i.e. public officials) are often reluctant to state the values they place on various outcomes, either from fear of criticism or fear of limiting their options in political bargaining.

An alternative approach is to measure benefits and costs not by the values of the decision-maker but by the values of those affected by the decision. This is a highly attractive approach, at least in countries with a democratic tradition, since it means that unless a policy is perceived by the citizens it affects to benefit them more than it costs them, it is unjustified. Practically, it has drawbacks. First, it is not always possible to estimate a community's willingness to pay for a particular policy. Secondly, the policies derived from such classical benefit-cost analyses may be at variance with the political interests of the decision-maker; many well-founded benefit-cost studies have been ignored in the US, for example, for this reason.

A compromise that avoids many of the political difficulties of benefit-cost is the cost-effectiveness approach. Here the decision-maker is presented with a statement of the monetary cost of a programme or policy, the benefits and other costs in non-monetary units, and qualitative descriptions of non-quantifiable consequences. No attempt is made, however, to reduce all these factors to monetary terms and the decision-maker is thus given greater freedom in the weight he gives to one factor or another. What such a display of information enables him to do is to choose among alternative programmes that which provides the greatest effectiveness (as perceived by the decision-maker) for monetary unit spent. This kind of analysis has been illuminatingly applied to the evaluation of alternative methods of controlling heroin production and modes of treating opiate addicts.

Direct and Indirect Costs

Of exceptional importance in considering international co-operation in drug control legislation is the identification of individual costs and of who will bear them. Direct costs

are usually fairly simple to estimate and allocate. Indirect costs are as real and as important, but are not necessarily borne by the recipients of the benefits. Thus what provides a net benefit to a community may be a net cost to the state, and the indirect costs of a control system that benefits one nation may be borne, without corresponding benefit, by another.

Uncertainty

Up till now, we have assumed for the purpose of simplifying the presentation that costs, benefits, and effectiveness can be determined with certainty. In practice, this is usually not true. Any course of action may lead to a number of possible outcomes with different degrees of likelihood. Moreover, in the field of practical affairs, the assessment of the probability of any particular outcome remains wholly subjective, though knowledge, reason, and a careful statement of all the relevant factors do reduce the likelihood of error. Erroneous judgements are also less likely when decision-makers remember that they are choosing from among probabilities rather than certainties.

Time

A further complication is that benefits and costs of any programme are generally spread over time. It makes a difference whether the benefits are to be realized one or ten years hence, and whether the costs must be met now or later. The economist's approach to this problem is to assign monetary values to the benefits and costs and to discount them to their present value at a rate chosen by the decision-maker, usually the rate of return on other investments.

While this procedure is common commercial practice, it may not be obvious why it is appropriate in analysing public policy decisions. The reasons are twofold: first, by

treating expenditure on drug programmes as a form of investment, it enables the returns from such expenditure to be compared with the returns that might be obtained if the resources were used for other kinds of programmes or simply invested; secondly, it enables programmes with different time scales, where costs are incurred and benefits realized at different times, to be objectively compared.

Application to Problem of Drug Policy

The first step in the design and evaluation of drug control programmes and policies is the definition of explicit objectives. To plan, one must know what one wishes to achieve, and to evaluate one must know what the ultimate goal is. This may seem obvious, but it is in fact rarely undertaken in the field of drug control policies.

The next stage is to design alternative policies and programmes for the achievement of these objectives. The widest range of alternatives must be considered, and the tendency of public officials to think only in terms of their particular experience and expertise needs to be resisted, as does the temptation to reject possible policies because of apparent political or financial restraints. At this initial stage, no alternatives should be rejected out of hand. This is particularly important in the drug field, where in most countries a rational policy will combine legal treatment and other approaches, and there is an opportunity for using different approaches to complement each other.

In considering alternative policies, it is necessary to predict their outcomes. Though predictions can never be certain, the chances of accuracy can be increased. The first is by considering relevant data, and the second by using models of economic and social phenomena.

Prediction does not lend itself to general solutions, but it is often helpful to examine why some policies fail. Tasks may not be carried out. This may be because the responsible people simply do not do their job, or because the task is technically impossible (for example, the policing

of remote ill-defined frontiers to prevent the smuggling of drugs). However, tasks may be fulfilled well and yet not achieve the desired objectives. Here, economic analysis may often offer an explanation. For example, if our objective is to reduce drug-related crime (i.e. crime committed by drug users to get money with which to purchase drugs), the more effectively we enforce drug laws the less likely we are to achieve our objective. For reduction in the supply of illicit drugs will force up the price to the user, and he will therefore need to steal more to sustain his use. Studies have shown that the demand for heroin in the US, for example, is extremely inelastic, i.e. unresponsive to alterations in price; a reduction of 10 % in the supply would, it has been estimated, lead to a 100 % increase in price. An estimated \$ 500,000,000 worth of heroin is consumed annually in New York. If enforcement reduced the supply by 10%, the total amount spent would, because of the inelasticity of demand, increase by \$ 400,000,000 and drug-related crime would go up in proportion.

Similarly, economic analysis demonstrates that crop substitution programmes to eliminate opium cultivation are unlikely to succeed, and that the most pronounced effect of simple prevention of the diversion of legally produced drugs into illicit channels would be to stimulate illicit manufacture of these drugs, inferior in quality and higher in price.

Most drug controls can be analysed in terms of their effect on supply and demand, and it is surprising therefore that more use has not been made of economic methods of analysis.

The 1971 Convention on Psychotropic Substances

One might have illustrated the kind of benefit-cost analysis described by examining the Vienna Convention on Psychotropic Substances had the Commission specified the objectives of the Convention. Even so, the possible costs can be identified.

The Convention enjoins specific control and enforcement procedures on participating governments. The first cost is, therefore, the cost to governments (in personnel, resources, capital, etc.) of instituting these procedures. These costs will vary from country to country. In particular, they will be higher for producers of psychotropic substances than for non-producers.

The second set of costs will fall upon manufacturers and distributors for increased security, record-keeping, and so forth. It may be expected that some of these costs will be passed on to the consumer, and thus, in the case of exported pharmaceuticals, be borne by the consuming rather than the producing country.

A third source of costs arises from the prohibition of production and export of certain drugs, which may be imposed on certain countries. To the extent that this will mean the re-employment of resources at a lower level of productivity and the loss of foreign exchange, these costs could be substantial.

Lastly, ratification of the Convention may commit a country to unpredictable future costs. For example, a country may be required to cease the export of a psychotropic drug, with attendant enforcement and other costs, upon the initiative of another country that will itself bear no corresponding expense. It is not known how far those countries that have ratified or are considering ratifying the Convention have attempted to assess the costs to themselves, and the benefits they will enjoy. It is clear that costs and benefits will be inequitably distributed among the participants. Since the Convention contains no provisions for any compensation between countries to even out the benefits, it may be expected that some countries will find it in their interest not to participate. The advantages from non-participation could extend beyond merely avoiding the costs involved to actually enjoying the positive benefits derived from the inelasticity of demand for many psychotropic substances. For, as we have seen, effective law enforcement in the drugs field increases the potential profits of suppliers of some drugs. Some of these difficul-

ties might be overcome if the Convention could contain provisions for compensation between countries *, or for the imposition of sanctions on non-complying countries that could outweigh the benefits of non-compliance.

However, the purpose of this section is to demonstrate that many critical questions remain to be asked and answered. It is also intended as a plea that future decisions on national or international drug classification and control policies should be based on a more systematic analysis of benefits and costs and be addressed using the basic tools of modern management science.

* EDITOR'S NOTE: It might be argued that compensation should extend, if at all, to the benefits and costs arising from all of the drug treaties concluded since 1912. There are obvious difficulties, however, in obtaining reliable data for application of a benefit-cost model to negotiated international treaties which involve very complex clusters of economic, social and political costs and benefits.

THE CLASSIFICATION OF DRUGS FOR THE PURPOSE OF LEGAL CONTROL

When we attempt to classify drugs for the purpose of controlling them legally, we have to be concerned with not only the variables in the drug itself, but also with the complexities of the legal, social and political system of the society attempting to classify in this manner.

Models of Legal Treatment

Western society has already devised several types of legal treatment for dealing with some commonly-based drugs. Coffee, for example, may be freely sold and used in all nations, although in the past its use has been punishable by imprisonment or even death. Tobacco may be taxed heavily, its advertising restricted and its sale to minors forbidden. Considerable efforts are expended to convince users and others of its harmfulness, although it is still freely and legally available, at least to adults. In the case of alcohol, by contrast, specific legal restrictions are directed at both the supplier and user of the drug, although in most countries little is expended to warn the public about the dangers associated with its use.

Two other models of legal control have special application to drugs today. The first is the "vice model", by which the seller of a drug may be rendered guilty, but not the user. An example of this is found in the control of cyclamates in the United States. The other form of regulation is the "medical model", which is used for drugs which meet three criteria: they are medically useful; they

are capable of harming the user; they are not especially sought out by illegal users. The control of prescribing of antibiotics by the medical profession is an example of this type of regulation. If however, such drugs are obtained without a prescription, then the "vice model", applies, since the seller (pharmacist) is guilty of an offence, but not the purchaser.

Amphetamines and barbiturates resemble antibiotics in having medical uses and causing harm to some users. They differ, however, in that they are in substantial demand for non-medical use. The tendency is to regard the vice model as insufficient for such drugs, and to apply the threat of criminal penalties to unauthorized users.

Finally, there are drugs such as marijuana and heroin, which are subject to complete prohibition, at least in those countries where they have no recognized medical use. The medical model cannot thus apply, and the vice model is felt inadequate.

Several things should be noted about the model of legal treatment applied to those various drugs. First, these models are in no way all-embracing and do not preclude the creation of new models. There is, for instance, the "flower children model". By this model, all taint of commercialization would be removed by a law which permitted anyone to grow the drug for himself and use or give away as much as he wished. The only act that would be forbidden would be sale. This model bears some relation to the legal treatment of prostitution.

Second, the social system can in practice only make use of a limited number of the theoretically possible drug control models. For example, though there is nothing inconsistent in the vice model which forbids sale or production of a drug but not possession of it, a legal system which attempted to do the reverse would seem inconsistent.

Finally, although the assignment of drugs to various legal categories is to a certain extent influenced by the dangers of the drug in question, it also reflects many other factors. The assignment of models of control to drugs varies both from nation to nation and over time. Thus,

heroin is treated under the medical model in England today; alcohol was treated according to a combination of models in the United States some forty years ago.

The question is: how should a rational society allocate drugs among the different methods of legal treatment?

In deciding which variables should determine the legal classification suitable for a given drug, we must ask what social goals a society should have in mind in attempting such a classification. One answer might be that a legal classification should be devised on the theory that the law is essentially a moral system. The problems posed by this position are numerous. At the moment it can only be pointed out that the law is as much a means of social control as a moral scheme, that definitions of morality are often subject to dispute and that it is quite difficult to show why one drug should be intrinsically more moral than another.

The Utilitarian Approach

Accordingly the standard we will use here is a utilitarian one. From the benefits attributable to the drug under the control system, must be subtracted the harm attributable to the drug under that system and the social costs of the control system itself. This is only an approximation and there are other factors (such as side payments or threats from other nations — or even from non-utilitarians in one's own nation), which may rationally determine a nation's drug policies.

The Benefits of a Drug: Whether a given effect of a drug is a benefit or not is often a political matter itself. The benefits of using cyclamates as weight-reducing aids may appear minimal to one who simply believes fat people should eat less.

A second major point is that although one can imagine a legal control system actually designed to increase the good that a given drug would do over what it would do in the

absence of any control at all, in practice this is rarely the case. Fluoridation of water supplies is possibly one example. Of course, before one could reach a decision of whether fluoridation of the water supply was a sensible means of drug control, one would have to know, for example, whether fluoridation does any harm as well, and whether another control method could accomplish most of the good without so much harm and comparable social cost.

For the most part, however, a legal control apparatus will generally concern itself with not decreasing significantly the benefit of a drug while at the same time trying to reduce its harm.

The fact that a drug is seen to do considerable good as well as harm invites us to use the medical profession to authorize uses only under medical prescription and to forbid all other uses.

A further principle is involved when evaluating a drug, that is, that the good the drug might have done may very well exceed the harm prevented by its suppression. This is so particularly in the area of new drugs. Since we have turned over the evaluation to a bureaucracy we must remember that there is a constant and strong tendency for a bureaucrat to prefer invisible to visible errors.

It is even possible that this principle may have application to the cyclamates. There might be many people, for example, who should rationally take their chances on the relatively unlikely possibility of bladder cancer caused by cyclamates, rather than face the more certain health dangers of obesity.

The example of the cyclamates underlines another aspect of this problem. With the possible exception of some medical "wonder" drugs, the good that a drug does will tend to be more widespread, but far less dramatic, than the harm. In the case of marijuana, where the issue is subject to acrimonious debate, it is arguable that there may be people who avoid serious mental problems by relaxing and reducing anxiety with this drug.

If it is decided that complete prohibition is still the best social response, one would have to consider not only

the social and financial cost of making the prohibition work, but the restriction of beneficial use as well. It is here necessary to note that a prohibition may well discourage the beneficial use much more effectively than the harmful use.

One additional complexity is that the beneficial use of a drug may depend upon the legal treatment of other drugs. For instance, it is likely that were heroin the only available opiate, nations that currently forbid it altogether might make it available under a rigid prescription scheme, as generally is the case with morphine.

Harmfulness: It is important to note that on the subject of the harm the drug causes in a society, we lack a great deal of the necessary data. Even if we can pinpoint drug-caused harms, physical and psychological, to the individual and the society, we must consider that these harms depend upon other factors such as set, setting, and patterns of use in the society. It is possible that any one of these could make almost any drug quite harmful and a serious candidate for legal control.

The pattern of use of a drug is important not only in determining to what extent its use causes harm but in considering the complicated concept of contingent harm. It has been pointed out that once a drug is introduced into a society, there is a tendency for more concentrated and damaging forms of the drug to gain use. Under such a view, a widely used drug with a fairly benign use-pattern might nonetheless be regarded as dangerous, on the theory that, over time, the use pattern might grow more damaging. Moreover, the widespread benign use of a drug over a substantial period might make the application of otherwise desirable controls either impossible or simply impracticable because of citizen non-cooperation.

Social Costs: It is primarily when there is a sizeable amount of violation that the social cost of a drug control system becomes most significant.

Under this consideration we must include as costs the harm in arresting large numbers of citizens, especially the

youth of a nation. The great majority of those arrested for marijuana use, in the U.S. at least, would not, so far as we know, have been predicted to come into contact with the criminal system but for their marijuana use. In California alone approximately fifty million dollars in law enforcement resources are required simply to process marijuana cases each year.

If the law is violated quite widely, the problems of inhibiting a consensual traffic where no victim complains may force the police to adopt a whole range of practices which cause considerable resentment among the citizens, and governments to enact laws in response to the illegal drug traffic.

In addition, the existence of large profits in the trade, together with the absence of a complaining witness, may make police corruption a serious problem in the enforcement of drug laws.

Another significant cost of a prohibition on manufacture, sale or importation, is that it can call into existence a drug-dealing network which not only supplies the specific prohibited commodity but can supply other — perhaps more dangerous — commodities also.

Another social cost of drug control is crime. The heroin laws create a "crime tariff" which raises the price of the drug and it is this rather than addiction itself which requires addicts to turn to crime. Moreover, heroin produces "tolerance" and this gradually *socializes* the addict into criminality and makes sure that his need increases as he becomes a more experienced criminal.

Variables in Determining Control Models

An important factor in the success or failure of any method of drug control is the degree to which the users want the drug. This is one major reason why when the U.S. Government ordered cyclamates off the market they simply disappeared, whereas alcohol during prohibition, and marijuana more recently, did not.

A second important point is that the technology of drug production and consumption is a major factor in the success or failure of a drug control measure. Where the technology of drug production and distribution is not difficult, drug control will be very difficult; otherwise the control will be more effective.

Other variables concern the nature of the society which is attempting to control the drug use. For instance, is it one which is capable of coping with and enforcing a sizeable percentage of its criminal laws? Since drug control measures tend to produce the greatest social cost when they are inadequately enforced, the inability to enforce a law may be a good reason for not attempting a drug control measure beyond a nation's capabilities.

Another significant variable is whether the legal system of a nation is highly formal, with a relatively small amount of discretion accorded to the actors, or whether it operates to a sizeable degree informally with considerable amounts of flexibility. For instance, it is likely that the successes of the Japanese in controlling amphetamines and the Chinese in controlling opium were due in great part to the combination of a "hard" legal system with an informal one.

A further advantage of a relatively informal legal system is that it is conducive to experimentation without the need to mobilize political forces to change the law formally and errors in a drug control system can be more easily repaired.

International Drug Control

All the issues involving the appropriate classification of drugs for the purpose of national control apply with special complexity when the issue is international.

However, a utilitarian approach is difficult even when one considers only two countries. It is possible to conceive of an international drug control arrangement between two nations, each having identical ratios of the three variables

in the function. Insofar as the international drug control arrangement required a domestic law in each of the two nations, it would most certainly duplicate what the nations should do anyway. Where the two nations are in very different situations, however, an international drug arrangement which required both to enact a particular law might very well operate to the advantage of one and the disadvantage of the other. If only two nations were involved the matter could, and often is, settled by bilateral side-payments. In the case of a drug arrangement entered into by many countries it may be that a mechanism should be set up by those benefitting most from the control system to compensate those nations being hurt most by it.

ADMINISTRATIVE CONSIDERATIONS

Administrative measures created to classify and control psychoactive drugs are as much shaped by economic and practical constraints as by the ideals that have inspired attempts at control since the early 1900's.

The control of psychoactive drugs presents, in practical terms, great difficulties. First, it is rarely possible to identify the drugs with any certainty by their physical appearance. Secondly, the methods of production span the entire range of man's agricultural and industrial endeavours, from simple food-gathering to the most sophisticated technology. Thirdly, the fact that they are shapeless substances make psychoactive drugs not amenable to methods of control applicable to individually enumerable objects such as cars or firearms. A further complication is the ubiquity and variety of such drugs. They are used commonly in medicine and scientific research. In addition, not only do plants that produce psychoactive drugs also produce other useful non-psychoactive products (hemp rope from the cannabis plant, for instance) but many substances not commonly regarded as drugs can have psychoactive action in man (e.g. nutmeg, boot polish, paint thinners).

These difficulties inevitably affect the logical application of classification systems based, for example, on pharmacological properties or dangers of non-medical use, so that in practice legal classifications of drugs for the purpose of control rarely, if ever, apply a defined criterion with consistency.

Little or no information is available about the processes or criteria by which psychoactive substances are classified for control purposes in individual countries. The processes

and criteria by which substances are included in international legislation are, however, laid down in the 1961 Single Convention on Narcotic Drugs, and the 1971 Convention on Psychotropic Substances.

In order to provide an outline of the institutional framework within which the international classification system operates, the main bodies concerned will be briefly described.

The United Nations Economic and Social Council (ECOSOC) is ultimately responsible for many aspects of international control of drugs, including the drafting of international conventions. In 1946 it established the Commission on Narcotic Drugs to provide machinery for giving effect to international conventions on psychoactive substances and to provide a continuous process of review of international control. The Commission is composed of 30 states elected by ECOSOC for a term of four years and normally it meets every two years for about three weeks. Besides representatives of member states, the Commission's meetings are also attended by observers from numerous other countries and by representatives of other non-governmental international organizations concerned with drugs. Countries that are large producers of psychoactive substances are, by the requirements of the conventions, permanent members of the Commission and are represented by senior government officials with considerable administrative experience in the drugs field. Countries with little experience of drug problems may also be members and tend to be represented by individuals with general diplomatic experience. The Commission is responsible for the actual drafting of international conventions and for calling upon governments to take action. It has, like all the other international bodies in this field, no executive apparatus of its own. The Commission is serviced by the Division of Narcotic Drugs, which is part of the permanent secretariat of the United Nations.

The World Health Organization (WHO) is related to the U.N., but has a membership of its own which is not identical with that of the U.N. Within the WHO Division

of Pharmacology and Toxicology, the Drug Dependence Section is responsible for servicing the WHO Expert Committee on Drug Dependence. The members of this Commission are drawn from a world-wide panel of experts, and the committee's composition varies from meeting to meeting according to the subject matter of its agenda. On average, the Expert Committee meets in two years out of three. Its meetings last a week and both the agenda and the documentation are supplied by the WHO directorate. Members of the Committee are appointed in their personal capacity as experts and do not represent governments.

We come now to the machinery by which psychoactive drugs first come to be included in the Schedules of the Conventions, and, secondly, by which the schedules, once adopted, are amended.

The draft schedules presented to the conference called to agree on the final texts of the 1961 Conventions were prepared by WHO with the assistance of its Expert Committee on Drug Dependence. For the 1961 Convention, WHO introduced what was virtually a consolidated list of the substances controlled under previous international treaties. The Conference made no major alterations to the substances proposed for control. For the 1971 Convention, WHO put forward a draft allocating psychoactive drugs to one of four schedules, according to their medical usefulness and dependence-producing potential. This four-schedule structure was retained by the 1971 Conference; there were, however, a number of amendments to the list of drugs included in the "less dangerous" categories.

The procedure for amending its schedules is set out in article 3 of the 1961 Convention. The first step is the reception by the Division of Narcotic Drugs of a proposal to add, delete, or alter the scheduling of a psychoactive drug. In practice, the great majority of proposals have been for the addition of new drugs. Proposals may originate either from parties to the Single Convention or from WHO; however, in practice, WHO has not originated any

proposals relating to single drugs (as opposed to classes of drugs); they have all come from individual governments.

Proposals for the addition of individual new drugs usually have their origin with the pharmaceutical manufacturer responsible for its development. The notification received from a government by the Division of Narcotic Drugs will thus usually be based on information and supporting evidence from one source — the manufacturer.

The Division circulates the notification to all the parties to the Single Convention and to WHO. WHO places the proposal on the agenda of the next meeting of the Expert Committee on Drug Dependence. The Committee's recommendations are based on a consideration of the notification transmitted by the Division of Narcotic Drugs and of data prepared by the WHO secretariat from the evidence submitted with the notification and occasionally from other sources, sometimes accompanied by the views of an acknowledged expert. The Committee's rôle is confined to an expert consideration of the evidence submitted to it; neither the committee nor WHO have facilities for any kind of experimental investigation.

Proposals to free drugs from international control are uncommon. Only one, dextropropoxyphene, has been deleted from the schedule of the 1961 Convention.

The final stage in the process of classification is the consideration of the WHO recommendations by the Commission on Narcotic Drugs, which has the final authority for deciding whether a drug should be controlled under the 1961 Convention. This decision is made either at the Commission's session, or by a postal ballot of member governments of the Commission.

The Commission's power of decision is limited to accepting or rejecting the WHO recommendation; it may not amend it. The Commission cannot, for example, decide to place a drug in a different schedule, thus subjecting it to a degree of control different from that recommended by WHO.

In practice, the Commission has always accepted WHO's recommendations when they have been confined

to the allocation of individual drugs to particular schedules. When, however, a WHO recommendation strays beyond this and is in a form that could be interpreted as an amendment to the Convention rather than to its schedules, or could set a precedent affecting future classification decisions, the Commission has always either rejected the WHO recommendation totally or reduced it to a simple recommendation for the control of an individual substance. It is on these matters that the Commission will seek the advice of the UN Office of Legal Affairs to establish whether the WHO recommendation would constitute an amendment to the Convention rather than to its schedules.

When the Commission on Narcotic Drugs has decided whether or not to adopt the WHO's recommendations, the classification is in practice completed. For though the Single Convention does provide for an appeal to ECOSOC against a classification decision taken by the Commission, such an appeal has never been made.

The 1971 Convention has not yet come into force so any discussion of its machinery for classification must be theoretical. In general, the procedures laid down are similar to those of the 1961 Convention. The important differences are that the respective areas of competence of WHO and the Commission are spelt out in the 1971 Convention and that the wording gives the Commission much increased authority on matters of classification.

Though only the parties to the international treaties are bound to act on the Commission's classification decisions, in practice most nations treat any drug controlled under the international treaties as ipso facto in need of national control within their own jurisdictions. Indeed, countries with little non-medical use of drugs tend to have no separate classification process of their own. Thus, in the U.K., special legislation had to be introduced in 1964 to bring the misuse of drugs not covered by the Single Convention, such as amphetamines and LSD, under legal control.

The main effect of classification is to impose controls on licit manufacture and trade and to prevent leakage into the illicit market. So far as illicit production is concerned, international classification decisions do not seem to have great impact.

The criteria laid down in the Single Convention (Article 3) on the basis of which WHO is to make its classificatory recommendations are threefold: liability to abuse; production of ill-effects; and therapeutic usefulness. But close reading of Article 3 reveals that the substances WHO is asked to classify are a selected sample of psychoactive substances, and that WHO has not necessarily any influence over the criteria by which they are selected.

In actual fact, there are not one but two classification processes superordinate to the work of WHO. The first is virtually a selection made by national governments (often at the instance of the manufacturer responsible for its development) when they decide whether a drug should be notified to the UN as a possible candidate for international control; here potential commercial marketability may be a criterion. The other classification superordinate to WHO has much more profound implications and goes back to the genesis of the entire system of international control. Its existence is signalled in the Single Convention by a significant qualification of the criteria of liability to abuse and production of ill-effects: the abuse and the ill effects must be "similar" to those that attend substances *already* in the schedules of the Convention. It is this proviso that has prevented consideration of amphetamines and other psychotropic drugs for inclusion in the schedule of the Single Convention.

This means that WHO may only make classification decisions about the *kind* of psychoactive substances that the Single Convention is meant to cover. An examination of the Single Convention schedules shows that, apart from cannabis, all the drugs in it are derived from or related to opium and cocaine, which were listed in the first international treaty to deal with psychoactive substances in 1912. This original classification decision was not based on an

examination of statistical or scientific evidence, but on the kind of value judgements that go to the making of political decisions about social problems. In this instance, the determinants of this judgement are to be found in the 1912 climate of moral opinion and the complexities of international diplomacy and trade.

The 1971 Convention appears to give a freer hand to WHO. Besides the criteria of "similarity" to substances already covered by the Convention, an alternative set of criteria is laid down that would, on the face of it, appear to allow the inclusion of, for example, tobacco and alcohol in the schedules of the Convention. At the same time, however, the power of the Commission on Narcotic Drugs to enter into the classification process is substantially increased, and with it the opportunity for politically determined value judgements to override conclusions reached by the logical application of objective tests.

Until, and assuming that the 1971 Convention comes into force, it must remain a matter of speculation how far the pursuit of objective criteria in classification will be limited by the kind of pre-selection implicit in the 1961 Convention, and how far by decisions of the Commission, unsupported by sufficient evidence. Of these two constraints, the latter is to be preferred if only because it may enable the conflict between the conclusions arrived at by scientific endeavour and those reached by political judgements to be exposed and even fruitfully discussed.

Conflict is likely to be present in any attempt to use scientific methods in classifying drugs for legislative purposes. Such difficulties are not a peculiarity of the international system, which has been singled out for description because it has the virtue that its manner of working is capable of scrutiny and can serve to exemplify the dilemmas of classifying drugs for purposes of public policy.

ISSUES AND RECOMMENDATIONS

The complexity of the issues involved in devising drug classification schemes makes it abundantly clear that no simple and single approach can be anticipated. Some guidelines can be offered, however, which can go far to alleviate many of the difficulties that have plagued both nations and international bodies for decades.

In all drug classification, the first decision must be whether a substance is to be considered a drug. At the present time the drugs which command most legislative attention are those substances which affect the mind (psychoactive drugs). But it must not be forgotten that no classification scheme linked to a control system can effectively contain the distribution of all psychoactive substances. Many commonly available household and industrial solvents, for example, do not lend themselves to such controls, even though it is recognized that their use can and sometimes does give rise to problems.

The majority of psychoactive drugs constitute valuable and sometimes indispensable therapeutic agents. But the benefits of their legitimate medical administration must be weighed against possible risks arising from their non-medical use. A realistic assessment of that balance in relation to the objectives of control policies presupposes, however, the existence of appropriate criteria and adequate methods in order to estimate the nature and importance of these risks and benefits.

It follows, then, that, as new information emerges, new assessments will have to be made and, perhaps, new judgments based on the new data. Therefore, control efforts, classification schemes and, indeed, all forms of intervention

do well to be *permanently provisional*. They must have built-in mechanism for evaluation and revision. Likewise, programmes which are not intended to be evaluated should contain self-terminating mechanisms as part of their formal procedure.

Unfortunately, it must be said that little attention has been paid to the impact of existing treaties and regulations. This situation need not continue. There is general agreement that legislative and other social responses to drug use *can* be evaluated, and evaluated in ways by which we can learn something of the conditions which contribute to either effective or ineffective intervention. This process can also provide information about what corrective courses should be pursued. Laws without action are of little value. Likewise, laws and action without evaluation cannot provide a sound basis for drug control. *Continuous evaluation is essential*.

Classification schemes themselves are useful only insofar as they are designed for a specific purpose and attempt to rank substances according to defined criteria of concepts (e.g., chemical, biological, therapeutic or toxicological). But it must be kept in mind that *such classification cannot automatically be applied to social controls*. There are many ways to control the production, marketing and use of drugs - by prohibition or regulation, by taxing or issuing licenses or franchises, by punishing, educating or providing alternatives. *Do not* assume that one form of social response — criminal sanctions — is the only one deserving of national or international recommendation or requirement. Nor can one assume that the same response or intervention works equally well for each drug, user or setting, nor that a form of intervention will always succeed so long as one of these elements remains constant. The passage of time often introduces important changes which will alter the impact of that intervention.

It appears to be unfortunately true that national laws and international agreements have placed the emphasis on administrative and penal controls and administrators have rarely, if at all, conducted systematic analyses to determine

which models are appropriate to various national and local conditions. *In national laws and international agreements, the scope of all alternative courses must be considered if policies are to be comprehensive and flexible.*

Where are these alternatives to be found? While scientific methods and understanding of drug effects and drug use are still imprecise, nevertheless science can play an important rôle in the building of classification schemes and of the controls and other social responses linked to those schemes. It is true that scientists do not always agree on what are the best methods for studying drug uses and drug effects, nor on what data are the most appropriate and adequate for such studies. Nevertheless, there is unanimous agreement that many different factors influence the use of drugs. These include factors that are chemical, physiological, psychological, social and cultural.

One difficulty arises, of course, from the lack of standards to govern the kind and quantity of information which should be available to policy-makers before they classify drugs or devise control measures. They must, therefore, *set explicit standards* regarding this evidence. When it is insufficient they must establish procedures for obtaining it. They must devise methods for financing the required research, identify the pool or pools of scientists and scholars available for the studies, specify the settings in which they wish to have observations conducted and they must anticipate that their findings will have varying levels of probability.

The information upon which most existing classification schemes are based varies not only among schemes prepared by different agencies (e.g., national or international), but even among the classifications into subcategories within a single scheme. Although, for example, they may purport to be based on pharmacological principles, all too often they are incomplete, inconsistent or illogical, even within this limited framework. They seldom take account of well-known evidence that drug effects depend upon such factors as formulation, dose, frequency or route of administration and are subject to statistical (sampling) error. *The principles*

upon which any drug classification system is based should be explicitly stated and logically applied. If they are based on pharmacological principles they should explicitly take account of formulation, dose, frequency and route of administration. They should also state the permissible limits of tolerance (in a statistical sense), as do other internationally accepted measures for the estimation of drug concentration and purity (e.g., pharmacopoeial standards for antibiotics, hormones, vitamins).

It is also evident that the scope, vocabulary, sanctions, and logic of existing classification schemes and of the controls that are linked to the schemes are often inadequate. One need only consider the imprecision and ambiguity which arise from the use of such terms as "misuse", "risk", "benefits" or "efficacy".

Considering this multitude of complexities, and taking account of the serious shortcomings in present approaches, *the classification schemes currently employed for legislative purposes should be abandoned. New schemes must be developed which are suited to the goals of policy-makers.* These should deal explicitly with the array of criteria and assumptions which present themselves when policy-makers wish to achieve classificatory objectives for purposes of social control. However, before they adopt new schemes of classification, they should consider and systematically evaluate the many alternative methods and perspectives which are available to them. They must recognize the many factors that are implicit in all of this — pharmaceutical chemistry, pharmacodynamics, purposes of drug use, settings of drug use, the characteristics of the users, the different kinds of controls that might be employed as well as sanctions and other social response measures which are available. They must consider risks, benefits, costs of all kinds, feasibility of implementation and the likely impact of all the various policy approaches. *Again, they should not look for absolute and final solutions, but should keep in mind that probability rather than certainty is the proper language of estimation.*

Nor should it be forgotten that present drug classification and control schemes exclude some important, problem-

creating drugs. Because they have a history of social use that antedates international controls, we cannot ignore the problems posed by the use of such powerful drugs as alcohol and tobacco.

In a similar context, existing classification schemes are also prone to assume, without demonstration, the prevalence and severity of the problems which arise from the non-medical use of certain drugs. Inadequate though it may be, any and all information about the size of the problems created by the use of such drugs and the comparative success of the different measures that have been adopted to deal with the problem should be employed. This information can be used to create a quantitative basis on which model systems can be constructed which, in turn, can replace conjecture and unjustified assumptions about the prevalence, severity or outcomes of drug use.

Present schemes are also defective when they attribute observed drug effects solely to the pharmacological properties of the drug, ignoring profound modifications of behaviour which arise from variations in the responses of individuals to a drug. These modifications may arise from differences in the will, knowledge, expectations and the environment of both the person who receives the drug and the person who gives it. Therefore, *classification schemes should not be based solely upon pharmacological principles*. Because social and individual factors often modify responses to drugs as much as their chemical structure, these must also be taken into account. As a result of these factors, some groups may merit either exemption from controls or stricter control. In any event, the measures adopted should be sufficiently flexible to allow variation in either of these directions as well as modifications when changing circumstances require them.

Those responsible for classification must keep in mind that minor differences in the chemical structure of drugs may bring about different desirable or undesirable effects, giving rise to new and different social problems or degrees of problem. This requires special attention. Whatever control criteria are explicitly adopted to cope with this

factor, whether they be chemical, pharmacological, clinical or social, they should be *in sufficient detail to permit an appropriately differentiated control of substances* which may resemble each other in respect to one criterion, but not in respect to others. *The criteria should not, however, be so minutely descriptive as to result in a topheavy, uneconomic and unworkable administrative apparatus.*

Although explicitly based upon one set of criteria (e.g., pharmacological), some classification schemes may implicitly incorporate other concealed criteria. Some of these may concern, for example, whether the uses to which the substances are put are licit or illicit, or whether the control measures are workable in practice. Some measures may also, in fact, discriminate between the kinds of people who use drugs, or the kinds of places in which drugs are used. *Control measures should not seek to control or free from control groups of individuals for reasons that are not explicitly related to their actual use of drugs.*

Factors such as age, health and degree of maturation may modify individual responses to psychoactive drugs and the resulting risks. These and other factors may need to be considered in preparing classification and drug control measures. *Before they are used as a permanent basis for discriminatory measures, adequate information about their relevance should be obtained.*

We must also be aware of the danger that political leaders at times may act, in drug matters, under pressures that are unrelated, in fact, to drug-associated problems. They may, for example, associate drug use with crime, family disruption, youthful unrest or other social difficulties. If such complications are expressed in international policy they may very well inhibit effective intervention in genuine drug problems.

The type of control to be applied must depend not only on the effects of the drugs, but also on the effects of the control policies themselves. The outcome of these policies will vary according to national and even local conditions. Treaties and laws, therefore, should be flexible enough to permit the flexible application of policies.

The difficulties faced by policy-makers in devising classification schemes and control systems are further compounded by the rapid development of new psychoactive drugs, new means of administering them and new standards for both their medical and non-medical use. The expectation of such rapid change should be reflected not only in classification schemes, but also in information systems, methods of research, control measures or other social responses. Flexibility is absolutely essential. Personnel engaged in drug classification must have up-to-date information available to them so that fundamental revisions in the schemes, when needed, can be anticipated. Such revisions will affect, of course, the control systems linked to the classification schemes as well as other social responses. Essentially, it is a question of learning to anticipate the advent of new kinds of drugs, new standards of behavior, new expectations regarding both desired and undesired outcomes, new forms of non-medical drug use (both licit and illicit) and medical use and new mechanisms of action. In summary, they must expect new problems.

The virtually universal nature of drug use makes the formulation of international classification schemes having common objectives and policies which can be implemented extremely difficult. There are no cross-cultural or within-society agreements regarding preferences for forms of drug use, the propriety of drug use, or for the life styles that may be associated with drug use. For this reason it is highly unlikely that experiences (successes or failures) in one setting or country can be applied automatically in another setting or country, let alone find uniform application on an international scale.

At the international level, those planning classification schemes must consider what range of responses will be relevant to all those persons, communities, regions and nations which constitute the world community. They must determine which responses are capable of being facilitated by national or international action. They must know what *practical* steps must be taken. They must gather and interpret information about the operation and impact of each of

the various forms of response in order to estimate costs and benefits of various responses in specific populations in specific settings.

It must be kept in mind, too, that genetic and cultural factors modify responses to drugs to an extent that drug-related problems may differ substantially from one people to another.

History demonstrates that policy-makers have often been prone to recommend harsh sanctions to combat practices which are foreign to their own customs. Restraint should therefore be exercised in proposing interventions which are adverse to either non-represented groups or to disinterested parties. A golden rule in planning international drug policy might be: *discuss the classification and control of others' drugs as you would have them discuss the classification and control of yours.* Such an ethic might help to sensitize policy-makers to the inequities in control practices which are based on the drug customs of another culture.

Nor should it be forgotten that a variety of interest groups seek to influence the course of national and international drug programmes. These groups include users as well as commercial, religious and political institutions and experts in the various fields of intervention, to mention only a few. *Therefore, independent evaluations of international policies and operations are essential.* The alternative is to permit narrow interests to create policies which may not only fail to benefit but may bring harm to non-represented parties. Independent evaluations, on the other hand, can expedite the termination of ineffectual programmes and enhance workable ones. Evaluators should also be encouraged to study the interests which generate and oppose programmes, so that we may better understand the political, economic and social dynamics of drug policy development.

By failing to examine their own drug use and responses to it, for example, nations have tended not to formulate objectives in the national interest. The effects of this omission are compounded when they fail to assess how international collaboration may best serve national interests. Likewise, apathy or failure by governments to perceive the

utility of involving themselves from the beginning in treaty planning can give rise, at a later date, to international ineffectiveness or national discontent. This arises when parties which were formerly disinterested find themselves confronted with drug-related problems of their own, or when they discover that their own interests are affected by the control measures employed by parties outside their jurisdiction.

It cannot be denied that given the diversity of national interests any international scheme for control is likely to be in conflict with some national interests. It is also true that practices will exist within nations which, while not identified as a national interest, represent local customs or commerce which do not align themselves with uniform international policy. In consequence, international policies should be sufficiently broad to entertain *a diversity of national programmes*. In such situations, when local practices are antithetical to national and international objectives, methods can be devised to co-operate with the nation in question to influence or change local practices. One could consider, for example, steps by which those nations which are beneficiaries of international policies might compensate nations whose interests are compromised by those policies.

In addition, policy-makers should not forget that although precedent may provide a useful basis for achieving agreement among those trained in law and diplomacy, it may very well prove quite inadequate in anticipating drug-related problems or responses to those problems.

The administration of international drug programmes requires *a competent administrative apparatus*. It must be geared to gather, communicate and utilize new information in the drafting of classification schemes and the designing of control and intervention programmes. But one should not, in advance, assume the most desirable approach — centralized or decentralized administrative units, the finances that will be required, or the skills of the personnel that will be needed. These judgements should come only after a systems study which will take account of both present and anticipated programme objectives.

Obviously, however, a need exists for a resource pool or technical facility to serve international bodies by identifying drugs, outcomes, settings and users of special interest. This entity must have *clear channels of communication to policy-makers* and must have the capability to conduct or support needed research. It should routinely develop alternate classification schemes, identify all forms of social response to and intervention in drug problems, and ensure the evaluation of the various responses within the framework of drug, setting and population.

Once a systems study has indicated the appropriate structure and needs of this international entity, it can be formalized and its co-ordinating function can begin. But its endeavours should not be limited to those resources which are within the conventional framework of the United Nations and its affiliated institutions. *Other resources, international and national, should be utilized to meet national, regional or local needs.* The potential utility of all those human and technical resources which can be involved in drug response programmes should be considered. Essentially, a service-oriented network should be constructed through a process of search, registration, recruitment, co-ordination and dispatch. These resources (scientists, physicians, educators, administrators, police, etc.) need not be incorporated into the bureaucratic structure of either the United Nations or national governments. Maximum flexibility should be provided for their time and work and logistical-tactical support should be forthcoming from the co-ordinating agency.

At the present time, international bodies are strait-jacketed by the requirement that, with the exception of medical and laboratory data, their information must come from national governments. National governments, in turn, often tend to recognize only information emerging from within their own bureaucratic framework. As a consequence, when making decisions respecting classification and other responses, they have access only to data that are often incomplete and unreliable. At the same time, they are denied the use of more relevant data established by sound

research. *One solution would be for governments to encourage, with technical and financial assistance from the UN, if necessary, epidemiological and other studies to establish the nature and extent of drug use within their territories.* The annual reports of governments, as required by the international treaties, should incorporate findings from any reputedly conducted studies, whether carried out under governmental auspices or not. *The international bodies should also be authorized to collect and collate data on drug use from non-governmental sources.*

As has been already noted, new data about drug effects, drug use and the efficacy of control systems are accumulating continuously. However, little provision is made in the present international system for a continuing review of these new data or for adequate responses to change. *Therefore, international bodies should institute means whereby independent and expert advice — sociological, criminological, legal, economic, etc. — could be made available to them.* This might well be patterned on the system of expert panels and expert committees by which the World Health Organization has access to medical and pharmacological advice, independent of governments. The WHO expert committees and these proposed new sources of expert advice should be given the resources to enable them to gather relevant information and, when necessary, to sponsor special studies and research.

Though the United Nations does collect, translate and summarize drug laws enacted by individual countries, little information is available about the administration and practical application of these laws, or about their effectiveness in achieving their objectives. As much, if not more, attention should be paid to the administrative effectiveness as to the content of the laws themselves. Given the great disparity among countries in the resources available to them for administration of the laws, *the UN should take steps to acquire from governments information about the cost-effectiveness of their control and intervention systems.* This activity should be undertaken not with the aim of embarrassing or castigating governments whose programmes are ineffectual,

but rather of discovering examples of effective, low-cost programmes suitable for various economic and socio-cultural conditions. Assistance could then more easily be given to countries to enable them to introduce the most effective control methods appropriate to their individual situations.

But the improved flow of sound, objective information to international bodies will not obviate disagreements about the classification of individual drugs. At present, there is only a rudimentary system of appeal against classification decisions. This is available only to governments and has no practical apparatus for either reviewing the data on which a decision is based or for considering fresh evidence. *The Economic and Social Council should elaborate the apparatus by which it will deal with appeals from classification decisions made by the Commission on Narcotic Drugs.* This apparatus should include provision for review by a suitably qualified independent tribunal of the data on which the Commission based its decision and other relevant data not considered by or not available to the Commission.

One further broad consideration is in order. A principal objective of drug control in the past has been the protection of society as a whole from the consequences of certain individual or minority acts. But an equally important consideration has been neglected, bearing on the protection of individuals, minorities or, perhaps, the majority from governmental violation through the use of drugs. *Therefore, the development of international collaboration to protect individuals and society from the abuse of power through the use of pharmaceuticals is needed now and will be, in the future, an even more serious requirement.*

Given the opportunities for mistakes and failure when attempting to cope with broad social problems, there is a tendency for the public to lay the blame on individuals within national and international organizations, rather than on the difficulties under which they work in massive, complex and often un-coordinated bureaucracies. It is imperative, then, that *actions taken to create an international drug administration apparatus which can implement new approaches and programmes must be accompanied by a*

programme of public education about the complexities of international action. In this way the United Nations and other personnel can be relieved of the burden of false blame which arises from public misunderstanding.

To date, funds for the support of international efforts in the field of drugs have been extremely limited. Even with the advent of the United Nations Fund for Drug Abuse Control, there is no assurance that money for broad programmes will be forthcoming. In consequence, restrictive priorities are set and administrative machinery is necessarily limited. Under these conditions, expectations for performance cannot be grandiose. At the outset, participating nations and the world community must be made aware of this. These considerations, however, do not preclude much more sophisticated international endeavour or work attuned to realities rather than myths or self-serving interests. On the contrary, they emphasize the themes of the acceptance of uncertainty, the appreciation of alternatives and diversity, the need for evaluation of what is done and why it is done, and the need for knowledge as the basis for action.

ACKNOWLEDGEMENTS

Although many individuals and organizations were instrumental in making possible the publication of this book and the larger volume, *Controlling Drugs: International Handbook on Classification*, special mention must be made of the generous assistance provided to this group by both the Drug Abuse Council, Washington, D.C., and the Bureau of Narcotics and Dangerous Drugs of the U.S. Department of Justice.

In addition, we are grateful for the counsel and assistance provided by the following consulting editors: Sven Arndt, Peter Beedle, Philip Berger, T. H. Bewley, Dale C. Cameron, E. Carlini, H.O.J. Collier, Gerald A. Deneau, Ed Fujii, Silvio Garattini, Giuseppe Di Gennaro, Sir Harry Greenfield, Donald W. Goodman, Lars N. Gunne, David Hawks, Harris Isbell, Sanford Kadish, Harold and Oriana Kalant, P. Kielholz, Vladimir Kusevic, Gerald Le Dain, E. Leong Way, Jorge Mardones, W.H. McGlothlin, Patricia L. Murphy, M.J. Rand, N.H. Rathod, Walton T. Roth, Charles R. Schuster, Maurice Seevers, Reginald Smart, Walter P. von Wartburg, Tomoji Yanagita.

INTERNATIONAL RESEARCH GROUP ON DRUG LEGISLATION AND PROGRAMMES

The International Research Group on Drug Legislation and Programmes initiated its work programme in 1971. Its aim has been to conduct research into national and international legislation respecting psychoactive drug legislation with a particular emphasis on determining the consequences of the legislative policies currently employed. The individual members of the group do not necessarily represent institutions, countries or international bodies, but rather have agreed to consultation and co-operation with each other. Participants in the work of the group have been:

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7. 10. 1971

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