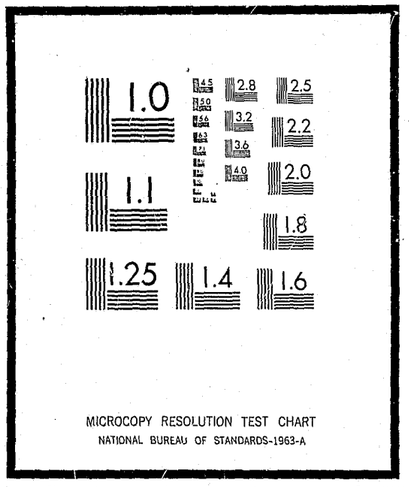

MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS-1963-A

PROCEEDINGS OF THE CONFERENCE ON DRUG RESEARCH IN PRISONS

PROCEEDINGS OF THE CONFERENCE ON DRUG RESEARCH IN PRISONS

AIRLIE, VIRGINIA
AUGUST, 1973

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

FOREWORD

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

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

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

C. Joseph Stetler
President, Pharmaceutical
Manufacturers Association

Milton G. Rector
President, National Council
on Crime and Delinquency

~~PROCEEDINGS OF THE~~ CONFERENCE
III

ON

DRUG RESEARCH IN PRISONS - Proceedings

Sponsored by

the

Pharmaceutical Manufacturers Association
and
National Council on Crime and Delinquency

August 6-8, 1973

Prepared

by

Research Center
National Council on Crime and Delinquency
Davis, California

A SUMMARY OF THE PROCEEDINGS
OF THE
CONFERENCE ON DRUG RESEARCH IN PRISONS

The following twenty-eight pages are a summary of the Proceedings of the August, 1973 Conference on Drug Research in Prisons which is available through the Pharmaceutical Manufacturers Association, 1155 Fifteenth Street, N.W., Washington, D. C. 20005, or the National Council on Crime and Delinquency Research Center, 609 Second Street, Suite D, Davis, California 95616. Following this summary, the Proceedings appear on the white pages.

PREFACE

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

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

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

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

ACKNOWLEDGEMENTS

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

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

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

TABLE OF CONTENTS

1. SUMMARY

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

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

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

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

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

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

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

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

2. WHAT THIS BOOK IS ABOUT

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

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

3. A CONFERENCE WAS HELD

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

4. SOME KEY ISSUES

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

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

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

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

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

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

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

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

5. THE NEED FOR THERAPEUTIC PROGRESS

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

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

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

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

6. A NATIONAL MISUNDERSTANDING

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

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

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

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

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

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

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

7. HOW DRUGS ARE TESTED

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

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

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

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

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

8. THE NEED FOR INMATES IN DRUG RESEARCH

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

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

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

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

9. THE NEED TO PROTECT THE INMATE'S RIGHTS

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

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

10. SOME CONCLUSIONS

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

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

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

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

11. WORK GROUP ON RESEARCH

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

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

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

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

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

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

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

12. WORK GROUP ON ETHICS, RIGHTS AND LAWS

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

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

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

The level of compensation for participation in Phase One testing was seen as an area for possible abuse. Wages are set by prison administration and are usually kept at the level of prison industry, which is much lower than "free-world" levels. It was agreed that wages for participation in research should not be in excess of the maximum wage available for other prison work, and alternate forms of remunerative work must exist, in order to minimize coercive financial aspects in

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

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

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

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

13. WORK GROUP ON CORRECTIONS

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

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

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

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

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

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

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

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

14. WORK GROUP ON PROCEDURES

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

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

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

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

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

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

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

15. FOR MORE INFORMATION

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

Proceedings of the Conference on Drug Research in Prisons

Available through:

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

For additional information the reader is encouraged to write to:

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

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

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

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

The American Correctional Association
4321 Hartwick Road, Suite L-208
College Park, Maryland 20740
(301) 864-1070

16. LIST OF ATTENDEES

1. ARNOLD, JOHN, M.D.
Harry S. Truman Research Laboratory
2322 Holmes Street
Kansas City, Missouri 64110
(816) 421-8048

2. AYD, FRANK, M.D.
912 Westlake Avenue
Baltimore, Maryland 21210
(301) 435-6562

3. BACKUS, ROBERT C., Ph.D.
Institutional Relations Branch
National Institutes of Health
5333 Westbard Avenue
Room 303
Westwood Building
Bethesda, Maryland 20014
(301) 496-7005

4. BURRELL, CRAIG D., M.D.
Vice President, External Affairs
Sandoz-Wander, Inc.
Route 10
East Hanover, New Jersey 07936
(201) 386-8230

5. CANNON, JOSEPH
Deputy Commissioner
Division of Youth Corrections
Minnesota Department of Corrections
310 State Office Building
St. Paul, Minnesota 55101
(612) 296-3553

6. CLARK, MERVIN, M.D.
Central State Griffin Memorial Hospital
P. O. Box 151
Norman, Oklahoma 73069
(405) 321-4880

7. CONNETT, ARCHIE V.
Western Behavioral Sciences Institute
1150 Silverado Street
La Jolla, California 92037
(714) 459-3811

8. COOPER, CLAIRE
Editor, ACLU Publications
American Civil Liberties Union
22 East 40th Street
New York, New York 10016
(212) 725-1222

9. COUGHLIN, JOSEPH
Assistant Director
Illinois Department of Corrections
201 Armory Building
Springfield, Illinois 62706
(312) 793-2964

10. CZERWINSKI, ANTHONY W., M.D.
Division of Clinical Pharmacology
V.A. Hospital
921 N.E. 13th Street
Oklahoma City, Okla. 73104
(405) CE5-9421, ext. 352

11. DIMPFL, LUDWIG
141 Crown Road
Kentfield, California 94904
(415) 461-5857

12. DUNN, PAUL
Director, Law Enforcement Council
National Council on Crime and Delinquency
Continental Plaza
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 488-0400

13. FINKEL, MARION, M.D.
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852
(202) 443-2894

14. FISH, ROBERT
838 Park Avenue, Apt. 3A
Baltimore, Maryland 21201
(301) 383-9137

15. HAND, RICHARD
American Bar Association
1705 DeSales Street, N.W.
Washington, D. C. 20036
(202) 293-1712

16. HENDERSON, VICTOR
American Public Health Association
1015-18th Street, N.W.
Washington, D. C. 20036
(202) 467-5040

17. HERRON, REX
Director, NewGate Project
c/o NCCD
Continental Plaza
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 488-0400

18. JACKSON, KEN
The Fortune Society
29 East 22nd Street
New York, New York 10010
(212) 677-4600

19. KELSEY, FRANCES, Ph.D., M.D.
Director
Division of Scientific Investigation
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852
(202) 443-1727

20. KIRKPATRICK, DON E., Ph.D.
Assistant Director for Treatment
Department of Corrections
Box 99
Huntsville, Texas 77340
(713) 295-6371, ext. 245

21. MCMAHON, F. GILBERT, M.D.
Head
Therapeutics Section
Department of Medicine
Tulane University, School of Medicine
1430 Tulane Avenue
New Orleans, Louisiana 70112
(504) 588-5319

22. MILLS, MICHAEL
Research Associate
Center for Studies in Criminal Justice
The Law School
University of Chicago
1111 East 60th Street
Chicago, Illinois 60637
(312) 753-2435

23. MORRIS, R. CRAWFORD
Senior Partner
Arter & Hadden
1144 Union Commerce Building
Cleveland, Ohio 44115
(216) 696-1144

24. NIXON, CONNOR
Director
Prisoners' Union
1317-18th Avenue
San Francisco, Calif. 94122
(415) 282-0918

25. PALLEY, CAROL STRUXNESS
275 Fairmount, Apt. 1
Oakland, Calif. 94611
(415) 836-0427

26. PELTIER, HUBERT C., M.D.
Vice President, Medical Affairs
Merck, Sharp & Dohme
Research Laboratory
West Point, Pennsylvania 19486
(215) 699-5311

27. PROUT, R. E., M.D.
Chief Medical Officer
California Medical Facility
Vacaville, California 95688
(707) 448-6841

28. RECTOR, MILTON
President
National Council on Crime and Delinquency
Continental Plaza
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 488-0400

29. SKOLER, DANIEL L.
Staff Director
American Bar Association
1705 DeSales Street, N.W.
Washington, D. C. 20036
(202) 223-1528

30. SMITH, BARRY
5447-16th Avenue, Apt. T-3
Hyattsville, Maryland 20782
(301) 559-6105

31. TROUT, MONROE E., M.D.
Vice President and Medical Director
Winthrop Laboratories
90 Park Avenue
New York, New York 10016
(212) 972-2612

32. TROWBRIDGE, JOHN PARKS
3548 Meadowbrook Lane
Cleveland Heights, Ohio 44118
(216) 321-8004

33. URBINO, RALPH
Solano Institute for Medical and Psychiatric Research
P. O. Box 386
Vacaville, Calif. 95688
(707) 448-0606

34. VARLEY, ALAN, M.D.
The Upjohn Company
7000 Portage Street
Kalamazoo, Michigan 49001
(616) 382-4000

35. WARD, FRED
Executive Vice President
National Council on Crime and Delinquency
Continental Plaza
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 488-0400

36. WELLER, HARRY, M.D.
Assistant Medical Director
Bureau of Prisons
U.S. Department of Justice
101 Indiana Avenue, N.W.
Washington, D. C. 20534
(202) 739-2261

37. WOODSON, ROBERT L.
Associate Director
National Urban League
55 East 52nd Street
New York, New York 10022
(212) 826-6340

* * * * * * * * * *

PHARMACEUTICAL MANUFACTURERS ASSOCIATION
1155 Fifteenth Street, N.W.
Washington, D. C. 20005
(202) 296-2440

C. Joseph Stetler
President

John Adams
Vice President
Scientific and Professional Relations

James B. Russo
Assistant Vice President
Public Relations Division

* * * * * * * * * * *

NATIONAL COUNCIL ON CRIME AND DELINQUENCY
Research Center
609 Second Street, Suite D
Davis, California 95616
(916) 756-0808

Robert L. Emrich, Ph.D.
Conference Chairman

Charmian D. Knowles
Conference Coordinator

PROCEEDINGS

OF THE

CONFERENCE ON DRUG RESEARCH IN PRISONS

ACKNOWLEDGEMENTS

When the concept of coordinating a conference on the subject of human experimentation in prisons was first presented to the conference staff, it was a new subject to them. Such prior experience as we had had with the subject led us to believe that it was an emotionally weighted subject with extreme diversity of opinion. The reading we pursued in the course of a literature survey revealed that most of the literature fell in one of two categories: Either it was so drily intellectual in its effect to escape the emotional overtones, or so emotional it failed all criteria of objectivity and common sense. By the time of the conference, the staff, bolstered by their reading, had given up any idea of consensus emerging from the conference.

By the end of the first day of the conference, the staff reached the conclusion that the conference had drawn together a group of vastly diverging opinions, but with great openness in their willingness to listen to each other, and awareness of the sensitive issues at stake. In point of fact, a remarkable group of participants came together, to whom go our heartfelt thanks. That the conference was intensely productive and rich in material and heart, is a tribute to all of the participants. It should be noted, too, that although there was no effort to draw a consensus from the conference, vast areas of communal interest were defined and agreed upon by the conferees.

No conference takes place with all of the detailed work and background development necessary without the devoted interest of a sponsor. In the case of the Conference on Drug Research in Prisons, the sponsorship was shared by the Pharmaceutical Manufacturers (PMA) and the National Council on Crime and Delinquency (NCCD).

It was they who, realizing the many problems which beset this field, decided to draw together the participants of this conference in order to lay a groundwork for the development of industry-wide guidelines. It was their openness and broadness of perspective which insisted on including those people with essential stakes in the process of research on human subjects, i.e., correctional administrators at different levels, and ex-offender organizations which acted as spokesmen for those still incarcerated. There is no question that it took courage to assume the sponsorship of this conference because of the sensitivity of the issues involved.

During the course of the conference, the burden of work was shared by eight people--the four chairmen of the work groups, Mr. Archie Connett, Mr. Rex Herron, Mr. R. Crawford Morris, and Mr. Fred Ward; and the four recorders, Mr. Robert Fish, Mr. Michael Mills, Ms. Carol Palley, and Mr. Barry Smith. On top of all the work they shared with the other participants, it is through them that we have the work group reports--Chapters IV, V, VI, and VII. These reports took many extra hours and so to them goes our deep appreciation for all the hard work which they put in.

As for the conference staff, since this was a new field to them, it presented a special challenge in becoming even a lay expert in a very short period of time. They found the subject, their contacts with the participants, both challenging and interesting and have enjoyed every moment of their work. Therefore, rather than be thanked, they would like to thank the Pharmaceutical Manufacturers Association and the National Council on Crime and Delinquency for the opportunity to broaden their horizons in their contacts with this group.

Last, but far from least, we would like to commend Airlie House in Airlie, Virginia. Certainly, there could exist no lovelier site for a conference, nor one which takes such great pains to provide both a quiet atmosphere and every comfort that the participants and staff of a conference might need. We commend Airlie House to all those who might be similarly involved in conference planning.

TABLE OF CONTENTS

* * * * * * * * * *

CHAPTER I

INTRODUCTION

In the early months of 1973, the Pharmaceutical Manufacturers Association approached the National Council on Crime and Delinquency with the suggestion that they jointly sponsor a conference on ethical standards for drug research on human subjects in prison. The conference, it was decided, would deal exclusively with Phase One research which is the type of research which takes place primarily in the correctional setting. It was decided that the conference would be coordinated by the National Council on Crime and Delinquency Research Center in Davis, California.

A group of 42 people were gathered together at Airlie House, Airlie, Virginia, on August 6-8, 1973. The participants at the conference were divided between researchers currently working with human subjects in prisons, researchers who were not conducting research in prisons, correctional administrators, the American Medical Association, young doctors just starting practice, medical students, the American Civil Liberties Union, lawyers who specialized in medical casework, and ex-inmates, along with representatives of the National Council on Crime and Delinquency and of the American Pharmaceutical Manufacturers Association, the Food and Drug Administration and the Department of Health, Education and Welfare.

The conference opened on the 6th of August with a keynote speech by Mr. Joseph Stetler, President of the Pharmaceutical Manufacturers Association (Chapter II, A.) and by Mr. Milton Rector, President of the National Council on Crime and Delinquency (Chapter II, B.). These were followed by four faculty addresses by Dr. F. Gilbert McMahon of the Research Work Group (Chapter III, A.), Mr. Ludwig Dimpfl of the Ethics, Rights and Laws Work

Group (Chapter III, B.), Mr. Joseph Coughlin of the Corrections Work Group (Chapter III, C.), and Dr. Don E. Kirkpatrick of the Procedures Work Group (Chapter III, D.).

Mr. Dimpfl focused on the need to review old guidelines and regulations and the regulatory bodies, and the need to eliminate redundancy and outmoded portions to make way for updated regulations in an area already over-regulated.

Dr. McMahon discussed the evolution of drug testing in the United States, and the current state-of-the-art. He posed the problem of setting high standards in the field.

Mr. Coughlin raised issues of inmate participation in the administration of drug testing such as in review boards, and discussed the need for credible sources of information for correctional administrators and wardens.

Dr. Kirkpatrick discussed the institutional responsibility toward the inmate involved in medical research. He also gave a summary of the approach to such experimentation within the Texas Department of Corrections. One major issue in his talk was that regardless of how high the gain expected from a particular experiment, the experiment might be turned down if in its execution there was any risk which might cause criticism for a correctional institution

Following the faculty speeches, the various participants at the conference gave a brief introduction of themselves, their concerns, and the background which they would bring to bear in the discussions. These introductions and comments are reproduced in the Appendix; they took up the remainder of the first day of the conference. The day terminated with the assigning of all the participants to the four work groups represented by the faculty addresses.

The second day of the conference was spent in the individual work groups. During the day the participants in each of the work groups counted off "A," "B," "A," "B," etc. In the evening all the "A" members of each work group met together as one group, and all the "B" members met together as one group, for an interfeed session. Each of the work groups had appointed one member

besides the recorder to make a brief summary presentation to the A/B groups, and each went to one of the two sessions to report.

The following morning, based on the interfeed session the night before, the individual work groups continued their discussions, having eliminated most of the redundancies, and finalized the reports of their work groups.

These reports were presented in the final plenary session of the conference and are reproduced with such modification as was indicated by the work groups upon their review of the original manuscripts received from the recorders. The Research Work Group report is to be found in Chapter IV; the Ethics, Rights and Laws Work Group report in Chapter V; Corrections Work Group report in Chapter VI; and the Procedures Work Group report is the final report and is located in Chapter VII.

A speech by Dr. Robert L. Emrich, Chairman of the conference wrapped up many of the concerns expressed from different participant sectors, and highlighted future action to be taken in the field. This summary speech has been reproduced in Chapter VIII.

II. KEYNOTE ADDRESSES

A. C. Joseph Stetler, President Pharmaceutical Manufacturers Association

It is my privilege to welcome you to this conference on behalf of the Pharmaceutical Manufacturers Association and our member firms. We are happy to have the opportunity to co-sponsor this important meeting with the National Council on Crime and Delinquency and we are grateful to all of you for sharing your time and your expertise with us.

Our purpose, as you know, is to explore one of the most delicate issues of law and ethics--the participation of prisoners, men and women, in the evaluation of drugs. Regardless of our backgrounds or present assignments, I am sure we are all here, at least in part, out of concern for both man and science.

Our subject would be difficult enough were it possible to study in isolation. In truth, drug testing in prisons is intertwined with a number of other, at least equally illusive problems. Among them: health care in prisons, which is said to vary from almost adequate to entirely absent; prisoners' rights, and the difficult, sometimes violent pursuit of them. The fact that drug company sponsors of prison tests are among the nation's most successful corporations is, for some, not readily divorced from the subject. Nor, for many, is the fact that science, all science, is the object of increasing doubt and suspicion. On the other side of that aspect of the problem is the fact that increasing sophistication in science and the demand for more and better data is accelerating the demand for controlled clinical studies which require homogeneous experimental populations.

As we visualize it, our prime objective should be to produce as full and complete a dialogue as we can on the ethical, scientific and legal questions surrounding

prison testing. To the extent that there is a consensus, we want to have it; but we do not want to force unanimous agreement on any point.

Our objective is to take your insights, your opinions and the facts, and hopefully put them to use in the development of a standard of conduct for sponsors of drug tests in prisons.

Whatever guidelines the PMA might draw up for our members will not govern the research of others, of course, nor will it have the force of law. At the same time, however, it is a fact that the pharmaceutical industry is a major sponsor of prison studies. Some of the physicians present here are directors of medical research for drug companies, and others are clinicians who have conducted studies for the industry and government as well. It seems clear, therefore, that any conclusions or recommendations developed out of your discussions could have major importance in the commercial sector, at least in terms of moral suasion.

But the effects of this meeting need not stop there. We were particularly pleased to join a sponsor, because we wanted many disciplines to focus on the subject at once. That meant bringing in not only experts in science, industry, correction, and civil rights, but also representatives from government, which is both sponsor and regulator of so much American research. We know, of course, that constituent agencies within HEW are actively seeking the improvement of guidelines and regulations concerned with clinical studies. We hope that in bringing together so diverse a group of experienced parties, we can contribute to the effective, sound resolution of the tasks which HEW and FDA face in this field.

I believe a particular word is in order for prison officials and former prison volunteers who have come to this meeting. Your presence here is most important. In my opinion, your experience and point of view are essential to any intelligent, balanced discussion of these issues.

The material circulated in advance of this meeting by Dr. Emrich was most interesting and inclusive. In reading it there were several items which I felt were of major importance--items which deserve, and I am sure will receive, extensive discussion.

One is the question of whether it is really essential that we have access to prison populations, for the purpose of testing drugs. We in the industry feel that the kinds of data needed and the quality demanded make it imperative that controlled populations be available. One can dispute, chicken vs. egg fashion, as to whether we test in institutions because it is possible to do good science there, or because FDA regulations make it impossible to proceed otherwise. Despite a tendency to be opposed to government regulation, I do not believe in this regard we can blame the regulations for our present practices and programs. On the contrary, I feel that prison populations are exceptionally suitable for the best of science. Still, the questions must be pursued: What alternative, acceptable populations are available? What would be the consequences of a national moratorium on prison testing? Could we take new drugs directly from the test animal to the sick patient? What are the ethical implications, if any, of that course?

A second area that interests many of us is, of course, the question of consent. Considerable debate has taken place over the aspects of "voluntary" and "informed" consent. Is it possible for someone who is being deprived of many of his civil freedoms, who may be poorly educated in science and health, to give a meaningful consent? I firmly believe that it is, but I also suspect that the attempt to inform is on occasion given little more than lip service.

A related area of concern is the prisoner's motivation to participate in research programs. Assuming that he is well informed of the risks and the purposes of the experiment, what motivates him? I have read some of the studies in this area, some of which were conducted by people in this audience. In all of them, it is clear that motivation is multifaceted. It is sometimes based on humanitarian concern, and apparently it is almost always influenced by the need for money.

This latter fact is not unique, since we are all motivated to some extent by money, and the need for it. But we need to be conscious of the possibility that prisoners frequently volunteer for test projects because there is no other way to earn money or a reasonable amount of money in that facility. In such circumstances, should tests be banned? Probably not; yet we must be uneasy about the situation as it is, and perhaps

the first step toward improvement is to look at it openly.

What would you do if you were the sponsor of a clinical trial, and you wanted to ensure that the research were properly conducted? I would encourage our friends from the academic, legal and government communities to try to give us some of their thoughts in that area. Certainly no drug company wishes to sponsor invalid or unethical research, in view of its own long-term interests, let alone the human values involved. But every drug firm that sponsors such studies must weigh its interest in being sure, for example, that adequate consent is obtained, against the possibility that it will interfere with the independence of the investigation. I think we can agree that the regulations now on paper are rather close to adequate on such matters. But there have been sufficient variances between what is on paper and actual practice to justify another look at what the sponsor's responsibilities are--what he should do to meet them, and how he can proceed without prejudicing either the experiment or the investigator.

Financial remuneration for prisoners as noted earlier is another area of real concern. Some firms have arranged to pay prisoners the same amounts they would pay for similar procedures on the outside; others, more commonly, pay less, the rates set by prison officials. Pharmaceutical houses are vulnerable either way, of course--in the first instance, it can be claimed that we are enticing the prisoner with a pay scale no other prison job can match; and in the second situation, of course, we are charged with using the overall prison wage scale to our advantage. We need your thoughts on what we can do to work for a constructive solution to the remuneration question.

The need for adequate review of the planned experiment is well recognized in the regulatory sense, but again, is not always honored. We can readily agree that no one should be asked to volunteer for an experiment poorly designed, or one that reasonable men, including laymen and fellow inmates, could not find justified. Yet it is said that review committees are far from routinely used, and that sometimes they exist more in form than fact. It is too easy to decry inadequate enforcement of regulations; we need to talk about what practical things may be done to encourage meaningful

representative review procedures.

A final area that I commend to your attention is the need to provide guidance on the sponsoring organization's responsibilities to the volunteer who is injured as a result of his participation in the experiment. It may still be possible to find institutions in which broad waivers are required of prisoners, and we want your view of the ethical and legal standing, if any, of this practice. But beyond that, what is your feeling about the sponsor's assumption of medical expenses and other losses associated with such an injury?

I have sought here only to highlight some of the specific concerns that I have in this area, but I certainly do not suggest that they are the only important elements for discussion. Your own deliberations will determine what the entire list should be. When we finish I hope we can reach one broad area of agreement: That under suitable protection and for reasonable purposes and compensation, a prisoner's rights should include the right to aid science. It is that protection and those purposes on which our discussions will focus.

Finally, I want to commend each of you for agreeing to rearrange schedules in order to come here for these three days. Looking over the list of participants, I also congratulate the conference staff on its success in bringing you all together. The two other members of the PMA staff who are here--John Adams and Jim Russo--and I look forward to spending these days with you, and to learning with you how we can improve the performance of our responsibilities to each other.

B. Milton Rector, President
National Council on Crime
and Delinquency

It was most appropriate that the targets of this conference be given by Joseph Stetler as President of the Pharmaceutical Manufacturers Association. I also appreciate having a few moments to talk about some of the perspectives of the conference from the viewpoint of the National Council on Crime and Delinquency.

First, my appreciation to my associates, Bob Emrich and Charmian Knowles, who have really engineered this meeting with the help of Joe Stetler and the PMA staff. They have sent to you considerable material in the form of abstracts and reprints. For some of you who knew as little about the problems of drug testing as I did--except that you had reason to be concerned about it--I hope that you found the advance reading materials selective and helpful.

The purpose of the conference, as set forth in the materials you received, is to help the pharmaceutical industry in setting and strengthening guidelines and to develop procedures and standards for the conduct of drug research. The purpose also is to help the NCCD in its current role as a national organization addressing all aspects of the criminal justice system, to help open up the correctional system to a greater extent than is done at the present. We seek to get other disciplines, other representatives of the citizenry in general, inside the system to help question, to help strengthen and to help improve corrections, so it can perform effectively.

A major purpose of the conference, then, would be also to develop guidelines which would help correctional administrators, which would help prisoners themselves as they are now striving, through their own organizations, to participate and to advise in the development

of correctional programs.

The NCCD is trying, as a national organization, to find ways in which the private sector can get involved in reducing the isolation of the criminal justice system, particularly corrections. One of our goals has been to find specific ways in which industry and organized labor can actually become participants in corrections work programs which will pay minimum wages to employed prisoners both in and outside of the institutions.

In terms of prison populations nationally, the administrators from corrections who are here, and the representatives of prisoners and ex-offender groups can tell you that we are in a new era in terms of prisoners' rights; it is an era that will have a permanent place in criminal justice in America.

As you examine the movement for the protection of prisoners' rights, you will see that it is based upon the principle of self-determination. This is an issue this conference is going to address as we examine the motivation for participation in medical research, and the prisoner's right to join in such research, or his right to decline participation in such research. These issues may parallel other correctional treatment questions about the right of the prisoner to treatment, and the right of the prisoner to decline treatment by not participating in rehabilitation or correctional programs which he has good reason to feel do not meet his particular need.

In the preparatory work on the NCCD's Model Act For the Protection of Rights of Prisoners, we found a great deal of question by correctional administrators as to whether or not the involvement of prisoners in drug testing is compatible with the goals of the correctional system. That, I guess, is a major issue to be addressed here, in which both the ex-offenders and the correctional administrators can offer some important input.

Another important issue relates to the makeup and functions of review committees for such research. How much responsibility should the correctional administrator have in the continuing monitoring of the research? How much of that responsibility can be delegated by the

corrections department to the individual superintendent or warden of the institution? To what extent should outside leadership and expertise be more heavily involved than correctional management, not only in the approval of research design, but in the actual monitoring of the research?

I was very grateful to Dan Skoler of the American Bar Association Committee on Corrections for seeing that each of you received in the mail a recommended protocol adopted at the mid-year Board meeting of the American Correctional Association. You also have the protocol recommended by the American Public Health Association. These two additional materials will give us a base from which to start our discussions at this meeting.

I join Joe Stetler and the Pharmaceutical Manufacturers Association in thanking each of you for taking the time on relatively short notice to attend this meeting. We deem it extremely important and valuable, not only to the NCCD and the Pharmaceutical Manufacturers Association, but to various medical schools, and certainly to correctional management throughout the country, and to the prisoners themselves, who are looking for such guidelines.

Thank you.

III. FACULTY ADDRESSES

A. Faculty Address--Research
F. Gilbert McMahon, M.D.

When I checked in yesterday at the desk, the desk clerk asked -- there are apparently two groups meeting here simultaneously -- "Are you with the crime or aging?" I didn't relish being identified with either one of them in particular, but I was glad to get Bob's [Emrich] invitation to come to such an important meeting.

I left my wife and four children with their backpacks and sleeping bags in the Santa Fe Mountains, and certainly the beds and accommodations are much more comfortable here.

Each of us brings with us to this meeting our own orientation and set of assumptions and biases. My bias is research, and I have been in research for about 25 years. I bring, among my assumptions and biases, a strong conviction that therapeutic progress is necessary. That seems sort of elemental, but not everybody believes it.

Back after World War II, in 1945, when you think of what medications the doctor had to take care of sick people with, he had very little in the way of active drugs as we know them now. We probably use only about 10 per cent of drugs which were available before 1945. In 1945 we had no antibiotics. Penicillin was still being developed. We had no treatment for T.B.; we had no psychopharmacological drugs, and mental hospitals were jammed, and really were bedlams.

In 1945 we had no vaccine against polio, measles, mumps, and rubella. We had no oral drugs for diabetes; we had no treatment for gout. We had no antihypertensive drugs at all that were effective, that are used today.

Doctors, indeed, were kind, gentlemanly people, who

made house calls and often gave large doses of reassurance, and were very strong on the art, but probably weak in the science of medicine.

And I am not being critical, but there were very few drugs available in 1945, and in 25 short years there has been a revolution, literally, in human treatment, treatment of sick people. I expect this same kind of revolution to go on in the next 25 years, so I am vitally interested in human research and in therapeutic progress.

My position at Tulane is to take care of sick people and teach young doctors, and to teach med students therapeutics. So I see sick people practically every day. Often we are able to help them, and often we are not able to help them. I think new drugs are going to come along in the next 25 years, and I hope America will continue to take leadership in the discovery of new drugs.

However, there is a shift going on now. More and more human research is being done in foreign countries. I resist this. I think that leadership for 25 years has been in America, and it ought to be able to continue in the United States.

I work in human experimentation, or clinical pharmacology, call it what you will, but anyhow, certainly the field is new.

I remember what Dr. Leo Hollister, President of the American Society of Clinical Pharmacology and Therapeutics said in our March, 1973 meeting, talking to 1,100 mostly physician researchers. He said, "All of us have done things twenty years ago that we wouldn't do today." It's kind of a candid observation, but the science, including the ethics and morality and techniques of human research, have all changed and are changing for the better.

And I think it is naive to criticize people who did research in 1935 or in the late 1800's by today's standards. Tomorrow's standards will be superior to today's, and I think it is by meetings such as this that we will raise standards.

I think human research is much more than a medical problem. It is a moral, ethical, and social problem. That is why I think each of us bringing our own expertise to a meeting like this is so important.

Because it will come up during the meeting, I would like to spend a minute just talking about the phases of human research.

Of course, all research begins in animals, and after a drug has shown good activity in animals, after it seems to lower blood pressure or lower blood sugar or help an animal in some way, and after elaborate toxicity testing has been done in a variety of species of animals, then it sooner or later has to go to man.

Who is going to take the first pill? That's a gutty question, because you don't know that it is going to be safe in man. You don't know that it is going to be effective in man just because it works in dozens of animals or dozens of species of animals.

In human research I think you ought to be willing, occasionally, to take that first pill yourself as an investigator. And I remember about 10 or 12 years ago, before we had such regulations which pretty much prohibit this, I took a half-gram of a new drug home one night, given me by a prominent Ph.D. researcher in anti-inflammatory disease. I put it in a teaspoon before my breakfast, and swallowed it, and ran around all day with a jug collecting my urine and told my wife after I took it, "If I act a little more bizarre than usual, it's due to the drug I just took." I also told my secretary the same thing.

Nothing happened all day, except I collected a lot of urine, and we at least found out the drug was absorbed.

Two years ago, again during this kind of holiday -- I am actually on my vacation now -- I came back from Santa Fe to New Orleans, because I was worried about something. I was supposed to give a new antidiabetic drug to med students. But in female mice, I believe it was, it was noted that they got jaundiced at four hours although they were back to normal in 24 hours.

I worry about hurting med students. I worry about hurting anyone. So I came back and took the dose myself, and had the technician draw my blood all day. I didn't get jaundiced, and so I went back and went on my holiday and relaxed, because I knew in a few weeks when the med students took the drug, they probably weren't going to get jaundiced.

I think an investigator should be willing to take an occasional new pill himself if he is, like I am, actively conducting human research. I don't work with prisoners myself, although I have in the past. There are other categories of healthy people. I have given pills to nuns, because they represent a homogeneous, honest group of healthy people. I knew they would collect their urine reliably. I gave them an anti-fertility drug, actually, I wasn't studying fertility, but the anticoagulation factors, I should hasten to add.

We sometimes give new drugs to medical students. I have, in my life, given them to military volunteers.

But I should like to make this plea, that when you go into man you have to have some orderly progression of information gathering, some scientific method.

And Phases One, Two, and Three are what we call the phases of human research. And if everything looks good as you gradually go into more and more people, it eventually gets on the market and every doctor can prescribe it, and that is called Phase Four.

Phase One is often conducted in healthy individuals, relatively normal people, and it is for the purpose of finding out: Is the pill absorbed? How is it metabolized? And, indeed, how is it tolerated?

One is not so interested, in Phase One, in finding out whether the drug works, but whether it gets into the body and whether you are causing side-effects. And therefore, in Phase One, prisoners are often utilized.

In Phase Two the question is efficacy: Does the drug indeed lower blood pressure by carefully controlled, often double-blind studies? Does the drug have human activity?

Phase Three is often called "clinical trials." In Phase Three the new drug is given to maybe 1,000-5,000 patients with the particular diseases, to assure yourself, to assure the company sponsor, to assure the Food and Drug Administration, that the average practicing doctor can safely and effectively use that drug before it is permitted to get on the market.

So we shall hear these terms, "Phase One," "Phase Two," and "Phase Three" during the meeting, perhaps, but

Phase One is where most of all prisoner studies are involved.

As I said, you could use other populations than prisoners. There have been some excellent studies reported in the *New England Journal of Medicine* involving Trappist monks. There have been excellent studies done in the military, and there are fine studies being done in military volunteers. As I said, we use med students and sick people and patients, so we are mostly active in Phase Two work.

If I gave a pretty polka-dot colored pill to everybody in this room and told you very sincerely that this was a new laxative, 33 percent of you would tell me tomorrow morning, "It is certainly working." This is known as a placebo reaction. If you gave an inert placebo to a group of 100 persons and told them, "This is a new antidiarrheal pill," 33 percent of the people would have constipation in the morning. If I gave a pill to 100 people who complained of headaches, 33 percent would be relieved beautifully.

In other words, there is something such as a placebo, an inert pill that appears to help.

Illnesses come and go. For years earnest, honest doctors used leeches to treat a large variety of illnesses. Not because their physicians were dumb, but because many people seemed to get better after they were bled by this method. They got better because nature is kind. It wasn't because the leech or bleeding benefitted them.

When my children are sick with colds, my wife takes them to our pediatrician. Most colds are caused by viruses. But many people, including my family, kind of insist on penicillin for sore throats. They often get penicillin for viral sore throats. Penicillin is an excellent drug, but doesn't have any anti-viral activity. In a few days my children's colds disappear, so my wife and children feel the penicillin made them better.

It is the old fallacy, "Post hoc, ergo propter hoc." You have a viral throat and get penicillin and get better and think it is the penicillin, but often it isn't.

But in clinical research it is our business *to prove* that the drugs we are studying aren't placebos, that indeed, they do something more than a placebo. So, indeed,

what we have to do is controlled, frequently double-blind studies. You and I want *active drugs* on the market. We don't want placebos out there; we want things that really have some horsepower, that do what they are supposed to do.

But since one-third of the population responds to a placebo, it's a very difficult job to prove drugs are actually doing something. Most drugs don't work in everybody. Very few drugs work in 100 percent of the people. Penicillin works in 100 percent of strep throats; oral contraceptives work in 100 percent of women; but most drugs work in only about 50 to 90 percent of people, and if a placebo works in 33 percent, we are working in that shady area of between 33 to 50 or 90 percent, so we have to do *controlled* studies or we cannot learn the truth about experimental drugs.

When one undertakes a controlled study, one often has three study groups: a placebo group, a test drug group, and thirdly, a standard drug group, if such exists.

You can't learn much in one person in human research. You have to have groups of people. There are too many genetic and environmental variables. You have to have statistical significance. This is not simply an FDA requirement; this is good medicine, good science, to have groups of people. And you often have 10 to 15 people in each of these groups in Phase One.

So human research, to be valid, has to have a bundle of people. And where do you find a bundle of people on whom you can collect their blood day and night, on whom you can collect all their urine day and night quantitatively, and follow their blood pressure and temperature and pulse and liver function and kidney function for days and weeks? Where do you find such a homogeneous group?

Well, you might find them in the military. You might find nuns, although they are harder to find now than ever before. You might find med students, but they run to class and can't be contained too readily.

A natural evolution since 1945 has been the greater and greater escalation of utilization of prisoners, because they are a relatively healthy young group of people in one place, often anxious, as we heard earlier, to earn some money, and I am sure some of them have

honest and humanitarian motives.

So the question to me as a researcher, and with my perspective, isn't whether or not prisoners will be utilized. The whole question to me is how they will be utilized.

I think there have been many abuses in the past, and I think that is the main concern. I think we have to start with new high standards of human research in prisoners. I think the problem of peer review, the problem of informed consent -- all of these are very real and all are very serious, of course -- the problem of treating prisoner-volunteers just as you would any other patient in a hospital, the problem of having emergency equipment available, having medical attention available continuously in the prison research unit -- these are things we have to concern ourselves with, in my opinion, and not so much whether or not prisoners will be utilized.

Thank you.

(Applause.)

B. Faculty Address--Ethics, Rights and Laws
Ludwig Dimpfl

About six weeks ago, Bob [Emrich] asked me if I would give the faculty address on Ethics, Rights, and Laws. It took me a while to get over my surprise. Although I am no newcomer to the field of research, none of my background is in medicine.

But as I got into the background reading material over these past few weeks for this conference, I began to see some advantages of getting a novice into the act. All this material was hitting me cold, and I found that I had very definite reactions to the subjects that were being discussed.

Now, a lot of what I have to say may strike you as incredibly naive. I don't make any apologies for that. It just happens to be a confession of where I am.

Bob Emrich sent out a list of ten basic topics, of which the work group on Ethics, Rights, and Laws will discuss five. I found I had opinions on all these, or, more correctly, reactions, and I suppose everyone in this group has his opinions and attitudes on these things. But I don't think it is proper at this forum for me to discuss those reactions. This is properly what is done in the work group. I would rather talk about the thing that jumped out at me as I read through this material. It's a kind of a thread that, to me, ran through all the material I read.

And it is in the form of a question which struck me as I read the background material. It is this: Is pharmaceutical research worthwhile continuing as an activity?

It took me a while to admit to myself that this was what I was reading. Mind you now, I am reading this cold. But I kept wondering: Isn't the pharmaceutical industry essential? Isn't this industry the successor to Pasteur, Lister, Walter Reed, and Ehrlich? Isn't this the industry that gave us vaccines and antibiotics and anesthetics, without which Western medicine could not function? You know, why are people attacking motherhood and endorsing sin?

But as soon as I formulated the thing in this way, the answer became apparent. Nothing, including motherhood is sacred today. Everybody and everything is subject to question and scrutiny. There is a widespread belief abroad today that increased scrutiny in itself is a good thing; and I think that maybe *that* ought to be looked at right now.

In my view, this is as good a time as any to scotch that assumption. Nothing in itself is so great that it doesn't have an exorbitant price if you do too much of it. Everything is a trade-off. Scrutiny, too, has to be scrutinized. Is more scrutiny worth the price?

Now, the positive function of scrutiny is not so much police control as it is review. The researcher is often so close to the problem on which he is concentrating that he overlooks things that stand in the way of his objective. It is a fact of the individual make-up of fallible, creative human beings. They have to be saved from themselves. This is the constructive side of scrutiny. No research can or should be without it.

The negative side of scrutiny is blame-sharing. Whenever something gets by the existing review system, the reviewer never attributes it to his own incompetence or lack of application. It is always that more review is needed.

Furthermore, the life of a reviewer is very dreary. All the things he approves that go right, nobody ever gives him any credit for. But Lord help him if he makes a mistake and approves something that he shouldn't have. No wonder there is so much incentive to increase the number of scrutinizers on the part of those who are in the review business. There is safety in numbers. I have seen cases of research progress come to a complete

standstill for years as the result of a review imposed in the wake of a rather small disaster.

All scientific progress is made by real people. Researchers make developments which they are anxious to see used in the real world. Reviewers who are conscientious try to avoid letting mistakes get by. Researchers get frustrated by having to go back for more tests, and all the attendant delays caused by review, although they will, for the most part, be pretty objective about fair objections. Reviewers will get more picky if they get scared, or if they get a lot of review themselves.

As researchers get discouraged from never getting anything approved by their reviewers, they naturally lower their sights and shoot for smaller departures from what has been done in the past, in the hopes of at least getting something through.

These are not theoretical generalizations. This is how the real world operates. If our society goes overboard on review, it gets less and less return for the development effort that is included in its medication cost. It is not just the dollars that are higher. The real progress, with attendant lessening of human misery, is less.

These effects are not small. Once creativity is disrupted, it is very difficult to get going again. The basic justification for being in the chemical drug development activity at all is likely to be crushed by its own burden of review. There is a point of no return. We may not be far from it.

Of course, the motivation to scrutinize the pharmaceutical industry's research efforts more intensely would not be there to the degree that it now is if the developments that are forthcoming were clearly needed. I am not talking as an expert in the field. I am talking about reactions from people in the public, of which I consider myself one.

No industry today can rest on its past laurels. Advertising and image-building cannot substitute for results. The large strides, vaccines and antibiotics, are getting rather far behind us. Speaking as a layman, I remember penicillin, sulfa, terramycin, and aureomycin.

I remember the vaccine for polio. But of things on the horizon along this line, there are only anticancer drugs that I can think of.

Since these last life-saving drugs, there have been a number of new developments which are very popular and presumably financially successful. I refer to birth control pills and attitude modifiers, tranquilizers, and the like. The question suggests itself: Is any risk to human life or health in drug development worth taking if the objective is a product in one of these last-named areas?

Now, the foregoing was just off the top of my head. I didn't research this. I just put it together from what I recollected having read in newspapers over the last few years, attitudes that I myself have collected.

For example, I still remember vividly having been disquieted by a spokesman for the pharmaceutical industry justifying the high degree of side effects from new drugs by saying that they are so much more effective than the drugs that we have had in the past. The thing that disquieted me was what he didn't say. He didn't say that developing drugs without these side effects was a present research objective.

Well, it is precisely this subjective type of summing up on the part of individuals that determines how zealous individuals will allow themselves to become in promoting their own cause at the expense of the pharmaceutical industry.

Let me illustrate what I mean by that.

Suppose my thing, or my bag, as they say today, is making sure that nothing like what happened in Nazi concentration camps by way of medical experiments can happen here in the U.S.A.

Just as an aside, let me point out that I consider this an impossible task. Isolated horrible examples will occur as long as there are incompetent or amoral people existing, and Nazi Germany did not have a monopoly on these.

If I want to draft a set of objective rules for conducting research in prisons that makes such a possibility not possible, I will so encumber the effort

with red tape that although I may forestall almost every possible mishap, I will, as a by-product, make it impossible for research ever to have any meaningful results again.

I will feel very virtuous in what I have accomplished if, among other things, I am convinced in my own mind that the pharmaceutical industry really wasn't doing such a hot development job, that all the important drugs have been developed, and that their research effort can well be sacrificed on the altar of my noble crusade.

You can apply this to anybody else's thing. Suppose I'm against the way our penal system works. Suppose I think the matter of legality of the agreement and full disclosure of risks is vital. Suppose I'm after more humane treatment of prisoners. I have a real incentive and opportunity to use the fact that the pharmaceutical industry needs to conduct research for its continuing existence to accomplish my ends.

And even if I am not one of those zealots, I would still like to make an observation. We all know people who hold some of the foregoing ideals. We know that all those who do hold such views hold them with some fervor. There is something inherently attractive about someone who believes in a principle. He attracts support.

Now let's compare those individuals with the pharmaceutical industry, though, this isn't the case with the pharmaceutical industry. The day is long past when a person working on, say, a smallpox vaccine took personal risks to the degree that was abroad when smallpox was a problem. People at that time had vivid memories of family and friends who died tragically or were scarred for life as a result of smallpox. At that time they worked on drugs with some fervor.

But the pharmaceutical industry is at a much higher level of development now, and we are much safer. So the natural need for fervor isn't there as it once was.

It seems to me that if we are going to be objective, we mustn't get carried away with issues simply because they are held with some fervor by their proponents. We must separate real hazards to individuals from theoretical wrongs of academic importance. In other words, I don't think we ought to consider whether to have a phar-

maceutical industry in this country or not as a matter for discussion at this conference. We need it. The quality of our medical care won't stay where it is if we don't have it.

Another thing to remember always is that it is a fact of life that the more review to which you subject a research effort, the less likely you are to get a meaningful advance. Review committees grow by Parkinson's Law, and they have a tendency to overwhelm real research. If review is allowed to grow unchecked, the researcher finds himself endlessly replowing old ground to satisfy the reviewers, for no purpose but their unwillingness to stick their necks out, with the unavoidable but inevitable result of drying up creativity.

There is no question that review is needed, but if an industry is worthwhile it must be presumed it is run preponderantly by worthy individuals. These individuals understand that their continuing to be worthwhile to the community depends on their policing themselves. And they are in a very good position to police themselves, because they know the ins and outs of their field. It is certainly to their interest to see to it that the work with human subjects is well done.

On the other hand, if we ever feel that the industry is not to be trusted, that assurance of their humaneness must be embodied in an objective and enforced code of conduct, then we are on the downward path. The encumbrance with which research must be saddled using such a set of assumptions can only result in a rapid decline of output at an ever-increasing cost. If that happens, we will have a pharmaceutical industry and a backup for our doctors which is much changed from what we know here today.

There is assembled here at this conference expertise enough to decide how much scrutiny is needed. I hope our recommendations serve to provide balanced guidelines, where we neither go overboard on control nor overboard on license.

That's how I see it.

Thank you very much.

(Applause.)

C. Faculty Address--Corrections
Joseph Coughlin

My first remark has to do with the issue of informed consent.

I talked to someone on the phone, and on the basis of that information, I consented to make some remarks. Later I discovered that I had consented to deliver a paper.

So I feel a little bit like the inmate who signed up for aspirin and ended up bitten by a malaria-ridden mosquito.

I hope by the end of this conference to be ready to write a paper. I suspect correctional administrators across the country are in a position similar to mine, having felt poorly prepared to struggle with the issue of medical research in correctional settings. I have had to place a lot of faith in the professionals who presented the proposed project, and have done a lot of soul-searching which has had to do with the welfare of the inmates, our responsibility to assure that appropriate research in the interest of humanity can occur, the weighing of insistence that the prison setting was the only place this research could occur, and so forth.

I have been involved in correctional settings where research has been carried on ranging from kind of a simple thing such as taking samples of sputum to the Malaria Project in Illinois, which you have read about. I do not now have responsibility for the institution in which that project is carried on, but did for a period of months earlier this year as an Acting Director of Corrections between administrations. And I have had to struggle with all of the issues about which you have read in the material and finally reached a conclusion several months ago, when I was Acting Director in Illinois, that there

would be no introduction of new medical research projects under programs within the purview of my office until I had some better guidelines. That happened just a couple of months before I received a request to participate in this meeting. For me it was very timely.

I think it is not timely in the sense that these kinds of meetings should have occurred many years ago, so that some of the tragedies that have happened would not have happened. I think we are all indebted to those who are responsible for putting this thing together.

I have come to several conclusions:

We in corrections, and those who work closely with us, are not competent to make judgments as to the technical aspects of the medical research project. I am enough concerned that I would not rely on the medical researcher coming to me from, say, a state university to provide me with objective information which would provide me with the necessary assurances as to the level of risk that inmates would be asked to involve themselves in.

I think we need some kind of an independent body, whether it is at a national level or regional level, of highly competent people in the medical research business, supported, perhaps, by people in the social sciences, or complemented by such people, to make a judgment about the project and to present it to the correctional administrator, to the prospective subjects and to any committees that the administrator relied on for further consultation -- a highly accurate picture of the kind of risks, particularly risks related to possible physical damage of a permanent nature, the kinds of physical discomfort, and so forth, to which subjects are going to be exposed.

Secondly, I think we should have an accurate assessment of the degree to which the scientist is, in fact, dependent upon a prison population for the completion of his research. Is it a fact that a prison population is the only population which can serve the project?

And I think we should have an accurate assessment of the level of possible benefit to the field of medicine, and therefore mankind, related to the risk that people are being asked to take.

What I am saying again is that, for these purposes, I do not think we should rely on those people immediately involved in the research, whose presentation to us may consciously or unconsciously be predicated on or influenced by their own enthusiasm for their own project and their own preconceived ideas. In addition, and again consciously or subconsciously, they may be influenced by their own attitudes about inmates as human beings, the degree to which inmates are entitled to the same protection or not entitled to the same protection that my son would be entitled to, for example.

We need also to consider the issue of the inmates' right to participate in research. I suspect that most of us around this table would accept the conclusion of the National Commission on Correctional Standards and Goals, that inmates should lose only those rights and freedoms which they must lose in order to carry out the mandate of their sentence. This would mean that, assuming the issues of risk and consent and so forth are dealt with adequately, an inmate has the right to participate in these activities as long as he can make a free decision to participate or to not participate.

Basically, the protection that he should be afforded is the same protection that would be afforded if we were recruiting subjects from the University of Illinois, or medical students or the sons and daughters of us sitting around the table.

From that, logically, the next major issue becomes: What are the differences in the setting in which a prisoner finds himself which have to be taken into account in order to provide him the same protection that we would provide for a citizen who is not a prisoner? And that is, in my mind, an extremely complicated kind of an issue, and it is one that has been dealt with by the many learned and conscientious people here today.

The Stateville project you have read about exemplifies my concern. And one of my first concerns early this year -- when there was a change of governors and I wound up in the position as Acting Director -- had to do with that malaria project. This is a project which has been scrutinized by people in the medical profession, by the newspapers, by social scientists, and really has been presented in many instances as kind of a model for medical research in a prison setting.

But at the moment that I walked into the prison and began to have some responsibility, the prison was in a state of extreme tension. Most of the inmates were locked up. Inmates were literally fearful for their lives. Most were locked in their cells 24 hours a day. They were out once a week for showers and canteen and so forth.

Whereas that project which has been under way since World War II, was instigated at a time when the situation in the prison was quite normal, and scrutinized at times when the prison was more normal -- it was inconceivable to me that a prisoner could, early this year, consent to being involved in a research activity with assurance that his decision could be regarded as a free decision.

I did issue an instruction that there were to be no additional projects considered until we had -- until I had, at least, as long as I was responsible -- some better basis for decision-making.

We face a real challenge in attempting to sort out where the right of an inmate to be a volunteer becomes compromised by his life situation as it affects his ability in that situation to freely consent. How do we weigh the kinds of pressures that relate to his comfort, the kind of food he is eating, the bed he sleeps in, freedom from fear, money compensation -- a whole gamut of things, all of which become compensation, which added together for an inmate in those circumstances, to me are just overwhelming beyond any reason.

I have concerns about any local committee having the competence to realistically evaluate a project and provide an adequate guide to the correctional administrator as to whether that project should be admitted to an institution. A cross-section of social scientists, of people in the medical profession, of inmates, can add something to the decision-making process, but that has to come after an assessment by a group of scientists at the national level or regional level, who really have the technical competence to know what the potential risks are.

I have reviewed, I think, all of the available suggested standards for medical research in corrections, and personally am not satisfied with any of them.

For example, I reject the idea that the only research

that should be done in prisons is that which cannot be done elsewhere. I think in the proper circumstances, if the risk level does not render it inappropriate, a medical research activity can be a valuable asset, e.g., in a prison situation where just the introduction of reasonable people with whom to carry on a conversation is an improvement. The opportunity for an inmate to feel he has made a contribution to the good of mankind, the opportunity for a break from the routine of the prison environment might make a project desirable if the risks are not inappropriate. Participation in medical research can be a helpful, positive experience for the inmate.

I am looking forward to these days with this group with great anticipation; I have already re-thought some of my own biases just listening to the men around this table in a very short time. I am sure by the time we are through we will produce something which will help correctional administrators across the country out of the dilemma such as I found myself in, and I am sure others have found themselves in in the past.

(Applause.)

D. Faculty Address--Procedures
Don. E. Kirkpatrick, Ph.D.

First, let me state at the outset that I come here with a high sense of ambivalence. As a behavioral scientist, I recognize and appreciate the value of the empirical research model, and appreciate that possibly there exists no better alternative in terms of experimental design than the controlled environment provided for by a prison setting.

I empathize with medical researchers and physicians in their efforts to work within any correctional setting today. Clearly, both institutions, medical research and corrections, whether justified or not, are evoking intense and, in the main, extreme reactions from many elements within our society.

And as an administrator in a major correctional system, I also recognize a few salient features of any medical experiment within a prison setting.

First, in the final analysis, it is the administrator, the administration, which is responsible for the institution -- and this means to me, for the men within the institution. It is not the principal investigator; it is not the pharmaceutical house; it is not NIH; not philosophers; and, paradoxically, it is not even the inmate himself. At least, in Texas with inmates who have been involved in medical experiments, most of these men feel that the Department bears the responsibility for their care, and not the medical school or medical scientists. Many of these men are aware that even the act of volunteering does not relieve the Department of this responsibility. I believe these men are right.

Perhaps the basis, I suppose, of this belief stems from the concept of medical care within an institution.

That is to say, the right to adequate -- or, more correctly, "quality" -- medical care within a prison seems to me no longer debatable, if it ever was. Men in prison in Texas know this, and they expect no less, whether involving prison or free world staff, whether involved in a therapeutic-type medical model or an experimental medical model.

Secondly -- and, I believe, relative to the first point -- is my belief that if this position of responsibility is accepted, then an obvious complement must also be accepted. That is in the form of the question: What is the cost of any medical experiment, relative to the threat or potential threat of danger to the inmate, compared to the benefit to that inmate?

Now, I want you to note that I said "benefit to the inmate" and not "to mankind," and not "to medicine." They may not be mutually exclusive; they may be.

The second factor, it seems to me, in this equation is one that must evaluate the threat or potential threat of danger to the institution, compared to the benefit to the institution. Again these may not be mutually exclusive.

If there is one thing that I do believe in, it is in reality. And anyone who does not believe that corrections today is under severe attack from all quarters, by all manner of groups and individuals, is simply denying that reality.

Given this condition, I personally have no wish, nor will I knowingly jeopardize the institution and the men within that institution by placing them in a vulnerable position by what could be construed or considered to be a dangerous or high-risk medical experiment. Frankly, gentlemen, we just can't afford it.

Thus, insofar, I believe, as the Texas Department of Corrections is concerned, I think I can state to you that our policy will continue to be one of guarded conservatism, in which we will support medical experiments and research which could be, I suppose, termed as benign in nature.

I would like to turn now to some specifics of our experience in Texas. Dr. Emrich informed me that I was to be on the Procedures Subcommittee, and I think, being

a neophyte, in corrections, and furthermore, a neophyte swimming in this sea of ambiguity, I would like to share with you briefly a little background on TDC [Texas Department of Corrections] and some of the elements we feel are critical in our experimental procedures.

The Department has the authority for confinement of all adult felons in Texas. It has no juvenile authority, nor does it have any authority in the matter of clemency or parole. It has no formal relationship with inmates in juvenile institutions. It is solely involved with adult felons.

To that degree, we had 16,659 men and women in prison as of yesterday in 14 separate units in the Department. The smallest unit houses approximately 700 men, and the largest approximately 2,000. Over 50 per cent of our population comes from four large urban counties in Texas.

In Texas, the median sentence of our inmates is approximately five years. However, due to the liberal good time laws in Texas, the time actually served in prison is less than 30 months.

Twelve per cent of our population are illiterate; 90 per cent are school drop-outs; 13 per cent are mentally retarded; and 34 per cent are under 25 years of age. We have approximately 8,000 men attending school and another 2,000 attending college within the Department.

These facts bear on "consent," and obviously what can be construed as "voluntary consent."

In terms of the medical aspects of the Department, we are fortunate in the state in having outstanding men on the medical staff of the Texas Department of Corrections. We have a medical officer on each unit. Typically these men -- and I am sure it is like any other state -- on the unit are retired Navy Corps men. We have a medical director, six physicians, two psychiatrists. In terms of the overall medical picture, we provide basically one physician for every 1,600 men.

I think in terms of medical research, the Department has an excellent relationship with the medical schools that we are involved with, namely, the University of Texas Medical School, and Baylor University College of Medicine. We began our sojourn, if you will, in medical experimentation in 1967, and to date we have had about

2,200 men involved in medical research.

In terms of the specifics of our procedures, rather than detailing those procedures I would like to share with you some of the more salient elements of those procedures:

First, the Department will not entertain any proposal for a medical experiment unless it comes from a major medical school. I have defined that as the University of Texas and Baylor.

All protocols must be approved by the human experimentation board at the medical school.

Generally, we are in accord with the American Correctional Association protocol for medical experiments, since the Department was fortunate enough to have our medical director serve on that subcommittee which drafted these procedures.

All medical experiments must be approved by our Board of Corrections, which is appointed by the Governor and essentially functions as a governing body to the Department.

All medical experiments must be on a voluntary basis.

Any remuneration of the inmates is recommended by the administration to our board for final action.

All medical experiments, and individuals involved in those experiments, are under the jurisdiction of the Department.

We insist on and have constant monitoring of our experiments by Department personnel, including both the medical and paramedical staff.

All medical experiments must be approved in terms of sequence by, first, the medical director, and then by myself, and then the director, and then our Board of Corrections.

Volunteer criteria are open in terms of age, race, and offense. Generally, of those inmates participating, about a third are Mexican-American, a third white, and a third black. We have no restrictions on age unless it is demanded by the protocol.

As to offense, we run the full gamut, of theft over $50 to murder -- as I say, the whole gamut.

No employee of the department will receive any additional remuneration by any pharmaceutical house or medical school. If we commit to support medical experiments or research, we then support them.

I would like to think that this would provide some of the tone and some of the background of what medical experimentation and research is, at least in Texas, and to give you some insight into our philosophy and some of the mechanics of our procedures.

Clearly, we are concerned about the area of medical research in prisons, and I don't believe anyone would deny that the easiest solution would be simply to get out of this area. I believe, however, in the long run the seemingly conflicting goals, the ones that are going to be discussed here, can be resolved. I think we in Texas feel an obligation to be part of, and to make a contribution to, the solution of this problem.

Thank you.

(Applause)

IV. REPORT OF RESEARCH WORK GROUP
Barry Smith

This work group was asked to address its issues from the perspective of clinical research and to consider the implications of the following five topics, primarily in terms of their impact upon the quality of research.

1. *The Moral Fitness of Researchers*--What is best to ensure moral responsibility on the part of researchers without interfering with the ability to do effective research?

2. *Monitoring Research Plans and Practices*--What are the requirements for monitoring? What should be monitored? Who should do the monitoring? What are the shortcomings of existing provisions for the monitoring, inspection, and control of clinical research in prisons?

3. *Risk, Safety, and Treatment*--How adequate are the provisions for handling serious side effects in prison treatment facilities? Are there limits on how much risk should be taken in prison experiments? What should be done to maximize safety and availability of treatment capability?

4. *The Prisoner as a "Normal" Volunteer*--Are prisoners a good source of normal, healthy volunteers for all kinds of Phase One testing? Are prisoners adequately reliable as subjects? Do some drugs such as narcotics and mood-altering drugs present special problems?

5. *The Importance of Prisoners as Volunteers*--What would be the impact on drug research should prisons no longer be available as a major source of vol-

unteers? What are the pros and cons of attempting to find alternate sources of "normal" volunteers for Phase One testing?

One of the first objectives of this group was to establish an agenda based on the above topics. It was the unanimous opinion of the group members that these topics be reordered in terms of priorities. To that end the topics were assigned the following priority from most important to least important:

Topic I--The Importance of Prisoners as Volunteers and The Prisoner as a "Normal" Volunteer

Topic II--Monitoring Research Plans and Practices and The Moral Fitness of Researchers

Topic III--Risk, Safety, and Treatment

Preamble

The chairman took the prerogative to assign the above four areas to various group members. This division of labor aided considerably in formulating a final report from this work group, not of course, without much discussion back and forth.

The following is the report from the Research Work Group:

Preamble

In order to assure therapeutic progress and the continued discovery and development of new and better medications for the prevention/treatment of human disease, it is essential that drug research in humans be encouraged. Recognizing that some abuses of human rights have occurred in the past, it is imperative that ethical guidelines be established and implemented to safeguard the dignity, rights, and health of human subjects involved in such research.

Human experimentation involves a broad field of complex, interrelated considerations. Preliminary testing in basic human pharmacology (Phase One of

studies of drugs) frequently occurs in prisons. While this symposium addresses itself to the specific concerns of ethical standards for drug research in prisons, there is nevertheless an awareness that several of these issues are fundamental to all other areas of human research. In essence, any study--whether therapeutic or strictly investigative, whether involving drugs or other modalities--must consider underlying obligations to the individuals at risk.

These obligations are even more compelling when the persons involved are disadvantaged or captive groups or other individuals with limited access or ability to appreciate and assure their basic welfare and civil liberties. These groups include children, and the unborn, the mentally incompetent, and those in custodial situations--as well as prison populations that are directly the concern of this conference. Each study, each modality of experimentation, each population involves special features which in summation has as its ultimate goal the achievement of the humane conduct of all human experimentation.

Although the abuse or misuse of some older drugs in common use, i.e., opiates, antibiotics or sleeping pills, frequently result in serious harm or even death, the record to date indicates that immediate effects adverse to the health of the subjects involved in well-planned and adequately supervised Phase One studies have been minimal. This includes those studies conducted within or outside prisons.

With a high standard of investigator integrity, institutional review and continuous monitoring of studies, the possibility of serious short term adverse reactions should continue to be minimal.

Topic I: The Importance of Prisoners as Volunteers and The Prisoner as a "Normal" Volunteer

In this area, much time and discussion was spent in answering the questions originally proposed. The definition of "normal" consumed considerable time. In the end an operational definition was agreed upon. Whether prisoners are reliable as volunteers was not settled as an issue. However, it was generally agreed that prisons provide controlled conditions that

may in some tests be especially appropriate for the information sought. The conditions that make prisons unique as research resources and the kinds of tests that should be conducted in prisons deserve additional attention and development.

The system of drug evaluation continuing to evolve in this country has emphasized a gradual stepwise development of basic drug knowledge in Phase One and Phase Two. An important function of these stages is to provide valid basic pharmacological data of drug effects, toxicity, absorption and metabolism. Phase One studies must be done in "normal" subjects--defined as relatively healthy individuals, appropriately free of measurable pathology as determined by pre-study physical examination, laboratory screening, and special tests and evaluations where indicated. Many different subject populations have participated in such studies, including students, employees, civic groups and prisoners. No such selected population is ideal.

In general, the longer the study, the more complex the procedures, or the closer the observations required, the less suitable non-inmate populations become, and the more useful prisoner populations are for the optimal Phase One studies of many new drugs.

Granting that expanded new drug research is definitely a desirable goal, it is believed that inmate populations can continue to perform an important service in the new drug discovery and development system in this country. Indeed, exclusion of prisoner participation would require major changes and readjustment in the procedures for the drug industry to obtain the data for satisfying Phase One regulatory requirements. For this reason, it is proposed that prisoner drug experimentation be permitted only when conducted in strict adherence to a broad set of special guidelines. Because of the unique punitive and captive nature of the prison environment, these guidelines must include requirements for assuring, controlling and monitoring the general health and safety of participants; for identifying and minimizing all forms of coercion; and for paying close attention to basic humanitarian principles.

Topic II: Monitoring Research Plans and Practices and The Moral Fitness of Researchers

Responsibility for protecting the rights and welfare of prisoners who participate as investigational new drug research subjects resides at five identifiable levels. The cooperation of all persons involved at these levels is required to assure full implementation of appropriate principles, policies and procedures that have been devised for the purpose. Those involved at these five interrelated levels are:

1. The Investigator
2. The Implementation Committee
3. State Authority
4. The Sponsoring Company or Agency
5. The Food and Drug Administration

The investigator is responsible to the subject for protection of his dignity and well being during the drug tests including full implementation of all procedures prescribed for this purpose. The investigator is accountable to and expected to work cooperatively with the designated authority in charge of the prison, to the implementation committee, to the sponsor and to the FDA and other governmental agencies with regulatory power or functions.

The implementation committee is responsible for objectively reviewing all procedures and conditions for the purpose of assuring that the best interests of the prisoners are fully represented and all appropriate means are implemented for his protection during or as a consequence of his participation as a research subject. The implementation committee is accountable to the investigator for accessibility for advice and counsel. This committee is accountable to prison authority for maintaining appropriate committee records, keeping the prison authority informed of the development of any conditions that may adversely affect the health of prisoners as a consequence of their participation as drug research subjects. The implementation committee is also responsible and accountable to the FDA and other regulatory governmental agencies for implementation of governmental policy and regulations.

State authority having custodial responsibility for prisoners must bear the full burden of any decision or tacit approval permitting the use of prisoners as human subjects in any given project or activity. In the past there has been little demonstrated sensitivity of prison officials or higher state authority to such issues as the ability of prisoners to give informed consent especially in the light of such adverse factors as undue inducement, the coercive effect of even small payments and the expectation of momentary relief from prison routine by participants, the vulnerability of prisoners to group pressures, and the incapability of many prisoners to make objective decisions for themselves.

State authorities have often failed to require those who have been granted access to prisoners for experimental or commercial testing or research studies to abide by the now well established principles enunciated in the Resolution of Helsinki or the Nuremberg Code.

From the view point of state authority, implementation committee actions favoring the use of prisoners as subjects should be considered as only advisory opinions that may require further review and even rejection. Unfavorable decisions or restrictions imposed by the implementation committee on project directors proposing to use prisoners as human subjects should always be reinforced by state authority. State authority should be familiar at all times with the status of studies or activities involving prisoners as human subjects, including the effectiveness of committee continuing review, attitudes of investigators, and the provisions made for adequate professional attention and facilities for the protection of prisoners whose well being may be at risk during or as a consequence of their participation in a study.

Care should be taken to ensure that proper records are kept and that any adverse reactions are immediately reported to appropriate state and federal offices.

The sponsoring company or agency is responsible to the investigator and through him to the implementation committee and prison authority, for providing all

records and information available to it, including the results of animal tests, other tests in man and all relevant pre-clinical information pertaining to the specific materials to be tested. The sponsoring company or agency is also responsible to the investigator for making available to him all of its expertise for consultation and additional research for any purpose that would serve to protect the health and welfare of prisoners during or as a consequence of his participation as a subject and during or after his term in prison.

The Food and Drug Administration, as the primary federal agency charged with the enforcement of regulations for the protection of human subjects and investigational new drugs, is responsible for acting on all information that comes to its attention pertaining to improper use of prisoners as human subjects for investigational purposes. As the agency accountable to the American people, the FDA bears ultimate responsibility for the full implementation of its regulations. It is recommended that the FDA regulations be revised to specify the composition of the implementation committee,i.e., the local Institutional Review Committee for prisoners serving as subjects on investigational new drug studies. Implementation committees should include as a specific minimum two licensed physicians, one licensed lawyer, one minister or social worker, two inmates of the prison and one ex-offender not on parole. The implementation committee members will be appointed and recognized by the governor or as delegated to appropriate state authority. The manner of selection of members and the chairman of the committee will be such as to ensure optimal objectivity and will be subject to periodic review and acceptance by state authority and the FDA.

Some concern was expressed over inmate membership on the implementation committees. It was felt by some that such membership could constitute a power base for a particular inmate clique and lead to the selling of influence. Adequate protection against such a situation should be provided, making certain that the inmates themselves desire inmate participation on the committee, i.e.,would they prefer the research to remain totally independent of the corrections system to the point that they themselves have no decision-making power?

Topic III: Risk, Safety, and Treatment

Studies should only be undertaken in prisons if facilities are adequate for handling risks attendant to the particular study.

Generally speaking, an emergency cart containing drugs and oxygen, together with monitoring and defibrillating equipment, in a setting providing 24 hour physician coverage and unit personnel trained in emergency care and having immediate access to a fully equipped hospital could be considered minimal in a unit where a broad range of studies are to be undertaken. However, in units in which presumably innocuous studies such as testing toothpastes or antiperspirants take place, less elaborate precautions would be necessary.

Essential also is a good system of record keeping that permits prompt access to details concerning the drug under study and procedures that subjects may have been exposed to during the course of the clinical trial.

The researcher also has the responsibility of ensuring the security and accountability of the drug. He also has the responsibility of seeing that the drug is taken by the subject. Failure to take the drug will invalidate the study and perhaps create a possible hazard to other inmates should they instead take it.

There are definite limits to risks to which subjects in the study may be exposed. No drug should be administered to the subjects if animal experiments indicate severe toxicity. Such drugs, deemed to have possible value, may enter clinical trial at Phase Two level. No drug related to a known narcotic, hallucinogen, or other drugs subject to abuse, should enter Phase One trials in a prison setting. Specialized institutions such as Lexington may be excepted. Wherever use of radioactive isotopes is contemplated, strict adherence to the Atomic Energy Commission methods and regulations is mandatory, and approval by a competent group of technically qualified reviewers is essential.

No studies should be undertaken unless adequate

provisions are made for appropriate follow-up to ensure the safety and well being of the subjects.

No drug studies should be initiated until adequate screening procedures have been done, including histories, physical examinations, laboratory screens, and special procedures such as slit-lamp studies, EKG's,etc., where indicated, have been completed and the results known.

Care of the subject should not be delegated to fellow inmates. Reliance should be placed on frequent observation by physicians and para-medical personnel and laboratory results to evaluate drug toxicity rather than on subjective complaints alone.

Laboratory tests should be completed and evaluated pre-, during, and post-study as often as necessary for patient safety. Unusual findings should be reported rather than dismissed as "laboratory errors." Laboratory studies should only be done by competent staff working in adequately equipped laboratories. Attending physicians should be able to converse with the subjects--there should be no language barriers.

The committee is urged to go on record as recommending that some form of "no-fault" insurance be available to clinical investigators. One such system, developed by a private group, is apparently working well in the state of Washington.

This report from the Research Work Group does not by any stretch of the imagination represent a unanimity of opinion but rather a compromise and synthesis of many ideas.

V. REPORT OF ETHICS, RIGHTS AND LAWS WORK GROUP

Michael Mills and Ludwig Dimpfl

The Summary of Work Group Two's discussions is a task for a reporter more than a recorder, because literal transmission of a complex ethical debate would be too much to compress into these few pages. I shall attempt, then, to communicate the substance of our discussions on Ethics, Rights, and Laws without being as discursive as we necessarily and properly were.

Most of the participants in this conference have in three days discussed the underlying ethical issue of drug testing in prisons with great care in work groups, in the informal sessions, and casually in the course of the conference. Because our work group was specifically charged with an examination of the ethics of this testing, we thought that part of our responsibility was to lay out the full dimensions of the issues, for ourselves and for others here.

We talked about the inevitable coercion that exists in a prison: no matter how modern an institution, no matter how humanely run, no prison in America today exists in which the quality of prison life does not make participation in drug research a very attractive alternative. Although there were large areas of agreement, our discussion did not reach unanimity on all points. We ended up saying that the ethical problem is not resolved in committee, is perhaps never resolvable, but we did, I think, agree to disagree--amicably, with some heat but with a good deal of light as well. The value of this conference lies as much in the exposure and the discussion of the ethical problems as in the resolution that we have not achieved.

With that preface, these are some of the elements of the ethical conflict that we considered. First, we

learned (and I emphasize *learned* because this insight was, I believe, somewhat new to most of us) that the opportunity to participate in drug research and testing offers the prisoner a rare and important thing: the chance to make a real, effective decision about some matter affecting his life in prison. When clothing, daily life, movement, sound and sometimes communication are under the control of someone else--the prison institution--even the seemingly small choice of whether or not to sign up for a new drug test is an important one. In one view of the prison experience, what the prisoner most needs is the opportunity to make decisions that require him to take responsibility for his own actions and their consequences. Drug testing is one such opportunity.

We next discussed the advantages to the prison and to the correctional reform movement of the involvement of drug companies in prison life. These advantages--or disadvantages--have a number of aspects. First, the presence of testing projects, and particularly of the professionally talented personnel who usually conduct them, has improved the quality of medical care in the prisons. The base line from which improvement is measured is of course very low, but such things as physical screening of large numbers of prisoners, provision of pharmacy service, gifts of equipment and drugs, or volunteered services by physicians, have contributed to better health for the prisoners who are fortunate enough to be so exposed.

Second, largely under the tutelage of Milton Rector we discussed the idea that the presence of private industry, of non-correctional people, without a stake in the existing corrections system, was necessarily a disclosing, illuminating presence, one that could be the beginning of much wider public involvement in the correctional system. The primary focus of this involvement will be industrial: the establishment and operation of factories or meaningful work programs, together with the requisite training. If prisoners are to be returned to the free world with marketable skills, then private industry must go into the prison to provide the needed experience. In addition, however, the presence of pharmaceutical manufacturers and others in industry can extend the base of political and social concern upon which correctional reform stands. Just as a few socially conscious and responsible corporations have been effective in job training and hiring programs for

minorities, so could they be effective in restructuring corrections.

Our next major topic was the financial benefit to prisoners who participate in drug testing. For those who have joined in this conference, it may not be necessary to repeat the arguments about whether financial reward in the prison setting is inherently coercive. Nonetheless, certain facets of the argument deserve special attention. Prisoners do, it is clear, like and want the money they get and, indeed, are sometimes dependent on testing as their only source of income.

Some members of our group thought that the financial reward and the other qualities of prison life make it imperative to discontinue drug testing in prisons until the conditions of prison life are improved, until there are alternative forms of remunerative work, until the wage level that can be paid for drug testing is equal to that of a minimum wage or a free wage.

We discussed the inevitable conflict between the needs of a public institution and a private corporation. The experience of some drug companies has been that their test programs are viewed as an interference with the proper rehabilitative goals of the prison, or at least as disrupting the orderly flow of prison life. Contrarily, some viewed the testing as a program equally legitimate, participation in which was very likely just as productive as joining most ostensibly rehabilitative programs. Although an analogy to the Southern chain gang was made, none in the group was willing to accept as universally true the charge that the prison system was crassly leasing its prisoners, contracting them out for private gain.

I think these concerns really boiled down for us to the degree of responsibility that we thought drug manufacturers working in prisons ought to accept for the correctional system. All are agreed, of course, that the testers have an obligation to be sure that the research they do is not harmful to prisoners, that it is scientifically sound and conducted in circumstances that ensure proper medical supervision and care for the subjects.

Phase One testing, as done in prisons, is about as

safe to the inmate as it can be made--so much so that the representative of the Fortune Society stated flatly that he has never had a complaint about Phase One testing from an inmate. However, prisoners do object to experimental mind altering drugs administered forcibly in the name of psychological research. Morally, the work group considered the latter as deplorable. Phase One testing or experimentation is in an entirely different league. It is considered to be well conducted and the protocols are well reviewed--hence, no damage to volunteers results, and volunteering for such tests is generally a coveted privilege in most institutions where they are conducted.

What appeared to me the majority view was that the manufacturers, in addition to their scientific responsibilities, should take an active interest in the correctional system--an active interest like that all citizens should take, but as peculiarly well-informed and perhaps influential citizens.

During the course of this conference, the drug companies were made more aware of the poor moral conditions in prisons. They will, as a result, take even more interest now, just as any good citizen. There was, however, an undercurrent saying that the pharmaceutical companies owed it to the prisoners to reform the prison system. The drug companies took justifiable umbrage at such a suggestion, feeling perhaps that it was not up to them to impose their will on a situation which is properly within the purview of the corrections system, the prisoners and the general citizenry, and that they might properly be criticized if they attempted to do so. Also, the work group felt that since pharmaceutical companies, in essence, do not need research in the USA to survive since they can move such research to Europe, there was little to be gained, and much to be lost to the prisoners by pursuing such a course of action in insisting on their position of reform.

We ended the ethical discussion there. The majority of the group (I use the phrase not to indicate that we took votes on all these issues, but only to differentiate what appeared to me to be a dominating view from that of an articulate other group) then went on to say that there are improvements that can be made, there are changes we think should be made to improve the prison conditions and civil rights of prisoners in prisons,

and that these changes would contribute in a positive way to the environment where drug studies take place.

By the time the work group got around to the morality review of protocol, we were tackling a subject without a feeling of need to add anything. We all really knew that today's protocol review is adequate as it stands. Nobody wants to go on record as saying "no improvement is possible" but, as a practical matter, protocol review is in so much better shape than, say, approval for attitude modifying drugs for psychological experiments on prisoners that, truly, the ethicist felt he could not fault it. It was generally agreed that participation in the review of protocols by a representative of an independent ex-inmate or inmate organization would help. However, custodial personnel might prefer not to have Phase One research conducted in the prison.

Some, however, said in effect "We think the ethical question is still open and has not been answered satisfactorily, but assuming for the moment that it has been, we agree with the need for these changes."

We dismissed quickly the signing of waivers on consent forms. They are forbidden by Department of Health, Education and Welfare regulations, they are without legal effect, and they may intimidate the subjects who sign them. They should be banned.

We then dealt with the problem of the research review committee. Although it was the feeling of our group that other groups could suggest more pointed improvements in the scientific and technical aspects of research review, we examined at some length the issue of what the committee's composition should be.

The committee should include lay people (those not scientists) and, most importantly, inmates and former inmates of the prison in which the testing is being carried on.

The selection process for the inmate members and ex-inmate members is a difficult problem, but we have reason to believe that, increasingly, prisons have real internal political processes, whether recognized by the administration or not, for the selection and designation of spokesmen. It is important that the inmate

member of the committee have genuine legitimacy with his constituents in the prison, and demands a selection process free from influence by the prison administration.

Although we did not resolve that the committee should proceed unanimously, so that any single member could in effect exercise a veto, strong sentiment for that procedure was evident. I understand that many existing research review committees in fact proceed this way, whether their rules require it or not. Particular circumstances might, of course, arise in which the unanimity rule was unwise.

Just who the laymen on the committee should be was not clear: clergymen and lawyers are the customary selections, but the group was not particularly impressed with their utility.

We conclude and recommend that the review committees take an active responsibility for supervision of the projects they have earlier approved. Review of the protocol and checking of the investigator's credentials are not sufficient. The committee's membership must be known to the subjects (perhaps by inclusion in the consent form), must be available to the subjects, must visit the site of the testing, and must be closely aware of the conduct of the project. They must ensure that the scientific work is being carried out as approved and in proper fashion but most important, from our point of view, is that the subjects are being treated correctly.

We charged the research review committee with the review of consent procedures, to be sure that the information given and the language in which it is phrased are suitable for the subject population. The test of each consent form to be used must be approved and the prisoner must receive a copy of the form he signs.

Informed consent is not handled badly now, considering two things: a) the risk is minimal, and b) saying too much affects the results. It was pointed out that it is essential for a prisoner to have contact with "outside" people in order to rehabilitate him. This he gets with researchers who are trying to do a conscientious job. Researchers in Phase One do not try to pull "fast ones."

We then turned to the issue of disclosure. Drawing upon thin threads in our discussion, I think that there was a consensus that the manufacturer and the department of corrections--and perhaps the Pharmaceutical Manufacturers Association--are obliged to disclose, to make known, the contribution of prisoners to medical research. As California minimally does, each department should publish the name of the investigator, the nature of the study, how many men were involved, the number of days they participated, and the compensation they received. The role of prisoners in drug testing is not well known and widespread publicity for the enormously beneficial contribution prisoners make would be helpful to the cause of correctional reform, the work of ex-offender organizations, and the self-esteem of the prisoners themselves.

We turned then, with some trepidation, to the problem of informed consent. The consent half of that is intimately tied up with the fundamental ethical question of whether it is possible for a prisoner to make a truly free choice in a prison, and the failure to resolve the ethical issue underlies our failure to resolve the informed consent issue.

Leaving aside the "consent," we focused on "informed," preferring the phrase "the duty to inform" to that of "informed consent." This duty falls upon the investigator, the department of corrections, the research review committee, and the sponsor. Maximum possible disclosure of the nature of the experiment, the risks to be expected, and the benefits that may flow from the drug's success must be made. Consent forms must be written individually for each protocol; blanket consents to vague studies are unacceptable. Further, by contrast with the waiver provisions occasionally found now, the consent form might contain an explicit assumption of the obligation of care in the event of test-caused harm to the subject.

We discussed at great length, without I think much success, the task of finding alternative populations on which to conduct drug tests. The resistance to even attempting to devise mechanisms for attracting and utilizing free-world volunteers was impressive.

We discussed, finally, compensation, realizing that the issue is really two. First is the payment

question. We concluded that the proper level of payment for participation was not much in excess of the maximum wage available for other work in the prison. Some recommend that something in excess of the wage paid be contributed to a fund to be applied for the benefit of the prisoners. This might be an existing inmate welfare fund or it might be specially established, perhaps with a narrower purpose like the improvement of medical care. Such a fund, including all interest on it, should, in any case, be controlled by the inmates, without interference from the prison administration.

We did not settle precisely how much should be contributed. Two logical measures were the difference between the amount paid and the statutory minimum wage, or the difference between the amount paid and something calculated as what it would cost to get a free volunteer.

We learned that the drug companies do not object to paying a reasonable wage. Wages, however, are set by the prison administration, and are purposely low to minimize the coercive financial aspects in testing. They are, in fact, kept at the level of any other prison industry, or slightly below them.

We learned that pharmaceutical companies like using prisoners because they meet the Phase One requirements of the Food and Drug Administration, such as no contact with women during testing (when the effect of the drug on a foetus is unknown), and control over diet, etc. The expense of developing a new suitable reservoir of Phase One subjects outside of prisons is so great that it would simply mean moving research for new drugs outside of the United States. This is really well underway under existing FDA rules. The pharmaceutical companies have made developments ready to go to Phase One which they are holding back simply because they doubt they can afford 14 years to get through Phases One, Two, and Three. The competition comes from Europe in this form: a pharmaceutical house (e.g., Geigy in Switzerland) finds a new drug, and slowly introduces it to humans via private doctors (after screening only in animals), in one country after another. Each year they apply to FDA for approval for USA marketing as the Phase Three evidence builds up in country after country. This does not take 14 years to get USA approval. The European subsidizing

route for research is already cheaper. We may, therefore, be arguing a dead issue in debating the problems of Phase One testing in the prisons of the United States.

The other half of the compensation issue, and the one for which the term should properly be reserved, is taking care of those who are injured in the event of mishap in an experiment. We realized that the risk of injury is very small in the kind of Phase One testing with which this conference has dealt, but some risk does exist. The moral obligation to provide assurance that injuries will not go unaided does not vary with the probability of harm.

We spoke of a no-fault insurance system, to be provided either on the model of Workmen's Compensation or by a special system. If private insurance companies were unwilling to assume the task, perhaps because they considered the risks too unpredictable for the making of financially sound actuarial decisions, then a government insurance system will have to be considered.

There are two things that still go on which are morally reprehensible, and the conferees were unanimous as to what should be done about them. These are: a) blanket waivers (which are illegal, and represent the wrong approach to the problem of which they are the symptom), and b) no-fault insurance in case of harm to the subject. At present, the prisoner has to prove a fault in the protocol to collect. Because there is no history of insurance experience, no-fault premiums would at first be high. But, if present experience continued, the premiums would come down in cost rapidly.

VI. REPORT OF CORRECTIONS WORK GROUP
Robert Fish and Charmian Knowles

Introductory Note

The Corrections Work Group felt it would be pertinent to the reader to have a small statement on corrections from the administrator's perspective. Mr. Joseph Coughlin, Assistant Director, of the Juvenile Division of the Department of Corrections in Illinois was kind enough to provide the following statement regarding the role of superintendent on down to the custody officer in correctional institutions in terms of the word "rehabilitation":

> Our first responsibility is to the community as a whole. I regard the inmates as a part of the community. We have a responsibility to assure that if an inmate is an immediate threat to the community because of overt aggressive activities, we have to hold him in custody until we can somehow conclude it is safe to send him out. I think confinement of any kind is punishment.

The Work Group on Corrections looked at the problem of drug research in prisons with special emphasis on the prison environment. In the two days of discussions, the topics which we covered included:

1. Federal policies concerning drug research;
2. Monitoring research plans and practices;
3. Informed Consent;
4. Risk, Safety, and Treatment; and

5. Compensation for participation and for injury.

A. The Nature of Phase One Testing and Its Regulation

There is confusion in many people's minds between Phase One drug testing and other more dangerous types of experimentation. If Phase One drug testing is to continue, it is necessary that this distinction be made known to the public as well as the administrators and prisoners. Serious risks to prisoners do not occur in Phase One drug testing. However, there was much concern expressed regarding other types of drug testing and other types of research. It was recognized that most of the research about which there has been concern and criticism has been done by persons other than those associated with the pharmaceutical industry. We addressed the issue of how to do Phase One research in a way which would not be too much of a problem for the correctional institution, would not be psychologically offensive to the prisoners, and would not add to the rumors which circulate among prison inmates and the public about the horrors of prison experiments. Such rumors have existed because of unethical or questionable research which has gone on in the past, and still goes on in fields other than Phase One testing.

In 1952 there were almost no Federal regulations regarding drug research. Since that time more and more laws and regulations have been enacted and adopted to secure the safety of the consumer. The FDA is concerned with drugs to be used on humans, and they regulate animal studies leading to human studies and all human tests. Anytime a research group wants to test out a new drug on humans or study a new therapeutic use for an existing drug, they must first file with the FDA. The results of their animal studies must then meet FDA standards before being allowed to proceed to the first of the four phases of testing of drugs on humans.

Convicts are involved in Phase One studies because you need healthy subjects. In Phase One you are just trying to establish safety of the drug, and to take measurements regarding its absorption and metabolism. In this type of testing you are using only up to a certain dosage level which is a small percentage

of what was considered safe in animals. A Phase One study rarely extends more than 30 days and is usually concluded in 14 days. FDA regulations are very effective, and if anything they are more conservative than the drug companies like; thus, they are the protectors of the prisoners.

With regard to the question of whether prison is an ideal place for Phase One research, it was stated that while it is possible to do Phase One studies in a hospital environment and it might be safer in certain cases, at this time, for most drugs, the prisons are the best places for conducting such studies.

Highly toxic drugs are used in humans only to treat highly lethal diseases like cancer. The initial testing of these drugs is done on the sick patients, which is in effect proceeding directly to Phase Two, and is not carried out in prisons. As far as prison testing is concerned, it is estimated that 90 percent of it involves essentially no risk and concerns such materials as pollen testing, and skin lotions. In fact, a greater risk is involved in the later phases of drug testing, which are not carried out in prisons, when the dosage levels are increased to the range of therapeutic effectiveness.

New drug studies begin with the filing of an Investigational New Drug (IND) application with the FDA. The research is permitted to begin within 30 days of filing, if the applicant has not heard to the contrary from the FDA. However, the investigator would be most naive to start a project at this point without positive notification. Pharmaceutical companies have representatives in Washington who trace IND's through the FDA and know where they are in process.

B. Monitoring

There are four positive results which effective monitoring should accomplish. One of the big problems with prison research is the prevailing belief that prisoners are used as guinea pigs for dangerous experimentation. This misconception could be cleared up and any abuse of prison research could be uncovered and eliminated through national monitoring. On a state or institutional level, monitoring would have two aspects:

It would ensure that the design of an experiment is scientifically sound, and it would assure appropriate concern about sociological, psychological, and ethical issues. Institutional monitoring might help improve prison life by giving some of the prisoners the opportunity to serve on the review committee, which would provide among other things, a channel of interpretation to the prison population.

1. Monitoring at the National Level

Extensive work is now being done in the area of monitoring prison research. Mention was often made of the Research Advisory Committee of Connecticut which was written up in a recent article in the *American Journal of Correction* and used as a source paper for the conference. In addition, there was mention that plans are being formulated for the establishment of a temporary moratorium on drug research while the issue is being investigated more thoroughly.

Barring any unethical practices there is not much likelihood of extreme physical danger to the prisoners at least where research under drug manufacturers' auspices is concerned. However, there exists both within the prison system and also in the public a bad image with regard to prison research. Prisoners have a distorted point of view, as does the lay public on the degree of risk involved in Phase One testing because they do not differentiate between this and other forms of experimentation and treatment involving psychosurgery. This is not of such great concern with regard to the public at large, but this could be psychologically very detrimental to the prisoners. There exists in prisons a "rumor mill." As a result of this "rumor mill," prisoners are made to feel that dangerous experimentation is going on inside the prisons. In addition to the effect on morale, these rumors leave room for deceptions to crop up. The example was given of a convict who came out of jail with heroin tracts on his arm, claiming that it was scar tissue from prison testing. Although FDA regulations ensure drug research, there are other types of research being done in prisons which are in part responsible for the existing image; examples being psychosurgery and behavior modification.

It would be helpful if facts about research (keep-

ing in mind that trade names and formulas must of necessity be kept secret) are released to the public. In fact, some of the pharmaceutical companies are already making plans to publish written reports of their prison research. Also, it would be helpful if the FDA released their information about prison research.

There is a need for adequate full disclosure on the part of not only pharmaceutical companies, but on the part of corrections as well, as to what types of experiments are being conducted in institutions. This should be an active release of information, and not just a reluctant provision of information when someone hunts for it hard enough. This information should be in keeping with the necessary confidentiality for such experimentation. For instance, while it might not be necessary to know the names of experimental subjects, or the chemical breakdown of drugs utilized, it would be perhaps necessary to know something of the effects of the drugs being administered, e.g., is it a massive sedative, a skin lotion test, etc. The lack of such information lies at the root of the rumor mill, and has caused much of the distress of those trying to deal seriously with issues involved in experimentation.

While the suggestion of revealing FDA protocols was made, much of the information involved in protocols could be quite frightening to those with inadequate background to understand them, and they could be used in an alarmist fashion to frighten the public.

The view was expressed that such information as it was decided was proper, should be released publicly and actively, but that there are problems in doing this. Corrections and pharmaceutical companies both have trouble getting the confidence of prisoners. While both should make input, they should process the information through a source that has the confidence of the prisoners and public alike.

2. A National Conference on Research in Prisons

Wishing to follow through on the issue of national monitoring, we found that making the drug research available still left another part of the rumor problem unsolved, because we had not considered the effect which non-drug type prison research might be having on

the public image. Recognizing that it was beyond the scope of this conference to handle that question, our work group formulated the following resolution:

> The Corrections Work Group recognizes that the best interests and the rights and well-being of the inmates are paramount. We further recognize that biomedical research is essential to serve the health and well-being of the community-at-large, and, further, that the rights and well-being of one should not compromise the rights and well-being of the other.
>
> The Corrections Work Group recommends that the scope of inquiry into experimental research in prisons be extended to include all biomedical research being planned and conducted in all correctional institutions within the United States and Puerto Rico. We recommend that further exploration of biomedical research in prisons be done with possible formation of a coordinating agency to inform the local organizations and government of research conducted.
>
> In carrying out the inquiry, it is recommended that the National Council on Crime and Delinquency and others convene another conference with other institutions and organizations, both public and private, conducting biomedical research in prisons.
>
> At the conclusion of such a conference, it is recommended that the National Council on Crime and Delinquency explore with others the establishment of a body of people representing a cross-section of the national community which should include groups as the American Medical Association, American Correctional Association, American Public Health Association, National Urban League, National Council on Crime and Delinquency, prisoners' and ex-offender organizations, biomedical researchers and physicians. This body will take the responsibility for collecting information on present biomedical research and experimentation on inmates, the nature of such studies, comment on the impact of such studies, and make recommendations to the inmate groups, correctional systems and others, provide testimony on existing and proposed legislation, and take any appropriate action to eliminate injurious or improper biomedical practices.

This resolution would call for a similar meeting to this one representing all those who are involved in biomedical research in correctional institutions. Following that and growing out of that might be a national--call it watch-dog--committee, which would have the responsibility for informing itself on those matters nation-wide, and through communication with the various principals involved, of assuring that abuses do not occur and helping to assure that there are standards which become disseminated nation-wide; that lessons learned in one situation are carried over to another situation. Three major sources for research information would be the FDA, the pharmaceutical companies, and the state and local review boards.

Our concerns were that the methods chosen would provide safety and consideration for the prisoners and at the same time keep the research from being too troublesome for the overburdened correctional officials. In addition, too many rules and regulations would make it difficult for the research to be carried out at all.

The other three aspects of monitoring dealt with monitoring on a local level.

3. The Scientific and Ethical Review of Protocols

There are three issues remaining with regard to monitoring, two of which involve the present day protocol, (such as the American Correctional Association's "Protocol for Medical Experimentation and Pharmaceutical Testing") which call for both a scientific and an ethical review of experiments. The scientific review looks at the overall research design, the medicines being used, the questions being asked and considers whether the ex-

periment is scientifically sound. In addition, it attempts to come up with some sort of risk benefit ratio. The ethical or lay review considers such questions as safety of the prisoners and appropriateness of the correctional setting for the experimentation.

These two types of reviews should be carried out by two separate committees and the scientific group should report their findings to the lay committee. However, an arrangement such as they have in Connecticut, where the scientific committee is a sub-committee of the institutional board, would be adequate.

The important point about the scientific aspect of reviewing is that the reviewers should be objective and, of course, honest in their decision making. Scientists from a nearby university could meet this need. None of these scientists should be in any way affiliated with the research project.

The Institutional (or lay) Review Committee which acts as an advocate of the human rights of prisoners as opposed to the Scientific Review Committee may be predominately composed of non-medically trained individuals. While the researchers of the A/B work groups expressed resentment of some of the implications that they were not capable of protecting the rights of their subjects, and possibly were not as concerned about their welfare as they might be, the others felt that it was not so surprising to see researchers strong in the belief that they were sincerely and devotedly interested in the human rights of subjects in their studies. The point that the group tried to get across, however, was that unless one eliminates an obviously biased enthusiasm for a particular study from review committees, the committee will be tempted, from enthusiasm and good will --not as a malicious or malevolent factor--to let the rights of individuals be compromised.

The monitoring committee should not only be responsible for approval of a research project but should follow each and every step of the project. For example, they should inspect selection of the subjects, scheduling of the subjects' time (to make sure the research does not conflict with other necessary activities), treatment of side effects and other aspects of the experimentation.

4. The Assessment of Risk and Its Relationship to the Institution

One of the first questions which the lay board should consider is the risk involved to the prisoners, based on the predicted side-effects of the drugs. Because certain factors predispose prisoners to volunteer, some high risk experiments should not take place at all in the prison system.

An important question to consider is whether the institution where the research is being carried out has adequate facilities to handle the risk. The difficulty in attempting to answer this question is that it is hard for the scientists to give an accurate description of the risk involved. One possible tool to assist those considering medical research in corrections would be a chart relating the degree of risk involved in the medical research with the degree to which the correctional facility meets the requirements for an ideal correctional setting in which medical research might occur. A sample chart is shown in Figure One.

RISK	1	2	3	4	5
A	?	X	X	X	X
B			X	X	X
C				X	X
D					X
E					?

PRISON CONDITIONS

FIGURE ONE: RELATIONSHIP BETWEEN RISK AND PRISON CONDITIONS

The horizontal scale of the chart would rate institutions from one through five. "One" would not meet the minimum requirements. "Five" would meet the ideal

requirements. The vertical scale would rate the experiment on the basis of risk to the subjects: A--would involve no risk of either discomfort or danger to health, such as the evaluation of different taste attitudes toward cough medicine; B--would involve some inconvenience and possibility of some irritation; C--minor discomfort; D--major discomfort; E--chance of side effects. An experiment with a risk of E, then, could only be undertaken in a correctional setting with a rating of 5 or ideal correctional setting for medical research. The ideal setting would have to, among other things, provide alternatives to subjects such as paid work opportunities. It would have to have available adequate medical facilities both to work with the subject in the process of the experiment, and to immediately meet the subject's needs in the event of unanticipated severe reactions. All elements of opportunity for free decision would have to be present, etc.

The best recruiters for medical experimentation have been found to be subjects who are happy in their experiences with a program.

5. The Composition of the Institutional Review Committee

Still unresolved questions were, who should pick, pay or serve on the Institutional Review Committee, and whether there should be many institutional committees, or one state or state-wide committee with institutional reporting sub-committees. However, several guiding principles were developed.

In order to secure diverse viewpoints, such people as lawyers, sociologists, correctional officials, clergy, prisoners and ex-prisoners, as well as doctors and clinical pharmacologists should be chosen to serve on the committee. They should not be connected with the project under consideration.

A majority of prisons are located in areas where many of the local citizens are in some way connected with the institution. In such a situation, it is possible that the Institutional Review Committee being sympathetic to the prison administrators, might tend to overlook some of the inadequacies of the prison for housing a proposed research plan. Two suggestions were made for solving this problem. First one or more non-

local representatives could be picked to serve on the review board, and second, the local board could be put under the jurisdiction of a state board.

It is difficult if not impossible for laymen from the community at large to understand the mentality of the prisoners involved in the research. Without that knowledge, it is often difficult to make meaningful decisions. This would be true especially of the later stages of monitoring where the committee is trying to ensure that a project does not hamper prison life. To combat this problem a number of review boards such as the Research Advisory Committee in Connecticut have asked prisoners and ex-prisoners to join the committee. Although we were unable to come to a consensus with regard to the number of prisoner representatives, we all agreed very strongly that prisoners should be included on the Institutional Review Committee. Suggestions for numbers of prisoners on the committee ranged from two up to one third, and most agreed that a ratio such as 1/20 would be too low.

It was felt the committee positions opened to prisoner representatives should be divided between inmates and ex-inmates, because prisoners serving on a committee with correctional officials might be hesitant to express their viewpoint whereas an ex-convict would feel freer to do so. While convict and ex-convict participation would be relevant to the committee on institutional review, which deals with sociological and psychological issues in terms of the prisoner's rights, their experience would be unlikely to qualify them to participate in the committee which deals with scientific and medical review.

The composition of the Institutional Review Committee shall include representatives of both the subject population and outside groups designated by members of the subject population to serve in this capacity. Perhaps representatives of ex-prisoner groups should be chosen to serve. Because of their familiarity with prison problems and understanding of the many difficulties prisoners face, they can make valuable contributions.

D. Informed Consent

A primary concern in the area of informed consent

was whether a prisoner who is conditioned to having every decision of life made for him is capable of deciding whether or not he will participate in a research experiment. The initial form in which this question was posed was, "Can a prisoner give informed consent in high risk experiments?"

1. The Provision of Information

One major problem with informed consent is that too much information definitely biases an experiment. Reference was made to the placebo effect, e.g., when you list a whole series of symptoms or reactions to a person, such as vomiting (which frequently occurs with dogs in drug trials because of their extreme sensitivity to drugs, but is seldom recapitulated in human subjects) as a possible consequence of taking a trial drug, a substantial percentage of those so informed report those symptoms. In a group not so informed, the amount of such reports drops off sharply. So, there is no doubt but that this prior knowledge biases tests. The problem which has been raised many times before remains as one of "how much information is a necessary and good thing."

We all agreed, that in the legal sense of the word all prisoners are given the right of informed consent. In other words they are duly informed of the nature of the experiment and risks involved as well as their right to pull out at any time.

2. Coercion and Informed Consent

The real problem is the possibility that the prisoners are being forced or unfairly induced to participate by rewards which are not commensurate with the prison setting. The question then is whether or not prisoners are free to volunteer in the prison setting.

Several major obstacles to free volunteerism on the part of the convicts are: (1) the belief that participation might help obtain early release; (2) the promise of high pay (in relation to the regular prison pay scale) for relatively light work; and (3) the lack of other work alternatives. We realized the prisoners are not in a position to make a completely free decision and hence are not free to volunteer, but this in itself is not reason to discontinue the research.

The first problem is the promise of parole. We agreed with the current opinion held by most people in the field that early parole should never be used as an inducement for participation in research. In spite of published guidelines to the contrary, most prisoners still believe that their participation will help obtain parole. To combat this we recommend increased effort be made to inform prisoners before they are allowed to sign up for a project.

The next obstacle to free volunteerism is money. Money is a powerful inducement for work among prisoners, because it not only buys much needed supplies but also obtains privileges within the prison society. It was generally agreed upon by the group members that the best way to get around this problem is to pay wages for the experimentation which are commensurate with the minimum prison wages. This means that in a prison where there are no paying jobs, any research would not be able to compensate the prisoners monetarily.

The third obstacle to free volunteerism is the lack of other work opportunities in certain prisons. The majority of the work group felt that no research should be carried out in this situation. However, a minority of the group members felt that research in this situation would provide a healthy opportunity for prisoners to keep active and to have physical examinations and contact with outsiders to the prison, and so it should be permitted, keeping in mind that there would be no pay for the work and the extra care necessary to a free decision.

To summarize our suggestions for maximizing free volunteerism:

(1) No parole should be offered for participation--care should be taken to avoid any suggestion of favorable parole consideration as a reward;

(2) Pay scales should be equal to the minimum[1] prison wages in the prison system and no payment should be made where no other

[1] One participant specified instead of "equal to the minimum prison wages," "no more than prison wages."

paying jobs are available;

(3) No research should be conducted in prisons where there are no other work opportunities. (With a minority feeling that with appropriate care research is acceptable in this situation.)

In instances where correctional institutions institute work programs for prisoners, and where there are also medical research projects in process, these work projects, whether they are book binderies or any other type of workshop, should be arranged so that they employ enough people overall to give all of the men or women in the institution the option of working within them in contrast to becoming involved in the medical experimentation.

3. The Consent Form

In addition to other suggestions designed to guarantee the informed consent of prisoner participants in drug research, members of the Corrections Work Group agreed that:

(1) The consent form should include the name of the project sponsor and the use, as far as is known, to which results will be applied (a prisoner who might be willing to participate in a study to find a cure for disease might not be willing to participate in a study for germ warfare by the Army); and

(2) A prisoner should be allowed to keep a copy of the consent form signed.

Recognizing that these guidelines could not make volunteering entirely free, we felt nevertheless, that they were sufficient to warrant the continuation of prison research. We also came up with other suggestions for facilitating informed consent. First of all, the names of the members of the Institutional Review Committee as well as some information about whose sponsoring project should be published on the consent form. This would enable the volunteers to keep in touch with the monitoring committee in case they have any questions. Secondly, the monitoring committee should make

some assessment of the motives of individual volunteers and keep track of how many times a prisoner volunteers. In this way they can avoid having prisoners in more than one study at the same time, and screen out individuals compulsively volunteering for every prison study. The protocol should state that prior recent experience of any extended period of time would exclude the person from the opportunity to participate again, since all of the inmates should have equal opportunity.

E. The Benefits of Phase One Testing in Prisons

1. Benefits to Inmate Volunteers

From the practical point of view, all volunteers are required to go through a complete physical before testing begins. Due to existing inadequacies in prison medical care, this is often the first physical which the prisoners have had in years. Doctors have diagnosed such illnesses as diabetes, cancer, and brain tumors. Having research programs allows outside doctors access to the prisons and to raise questions about treatment and what goes on in the name of treatment. Secondly, participation in research gives the prisoners an opportunity to have contact with people outside the prison system. In addition, it gives prisoners an opportunity to learn something about the research taking place. Some prisoners, for example, have gone into science occupations after release in part based upon their exposure to the prison research. And finally, participating in the research is an opportunity for the prisoner to feel that he is doing something worthwhile and useful.

2. Benefits to the Institution and to the Inmate Population

Besides these benefits which come from the personal experience of participating in the research; benefits might also come from the pharmaceutical companies. In some cases for instance, the pharmaceutical companies doing the research have made substantial improvements on the prison facilities which were left standing after the research was finished. Granted that these instances are not that common, there is still another possibility where, as in Connecticut, the participating companies pay a certain sum proportional

to the size of the research which goes into the local prisoners welfare fund. All in our group were in favor of this idea with the reservation that in cases where the companies are aware that the money from the prisoners' welfare fund does not go to the prisoners, then they should not contribute the money. One possibility which might be looked into, where the prisoners' welfare fund is used improperly, is to contribute money into an outside trust for use of the prisoners after they are released. Programs, above and beyond the pay scale for research projects, sometimes contribute to such welfare funds on the theory that only a certain number of prisoners can be used on research, and that because the spots are limited, the other prisoners should derive some benefit also from the program. Therefore, this money is put into the general welfare fund, to purchase recreational equipment, etc.

F. What the Work Group Participants Took Away From the Discussion

All those concerned with helping the prisoners--actually this included not only the prisoner representatives but everyone in the work group--took away the feeling that our suggestions for monitoring and conducting prison research will help to eliminate those elements of the research which might be hindering prisoner rehabilitation. Furthermore, those who work with prisoner groups can help allay some of the fears and rumors regarding research insofar as pharmaceutical experimentation is concerned.

Correctional officials took away a clearer picture of some of the guidelines which Institutional Review Committees should use in deciding whether or not to allow research at their institutions. One member at the closing session remarked that after being at the conference, he would pay particular attention to seeing that prison facilities are adequate for the involved risk.

> In the Juvenile Division of the Department of Corrections in Illinois, all of the institutions are small, and all of them are programmed to the hilt. They are running into the problem where they

> are looking for time. If you have a new program, where do you plug it in?

The involvement of research activities in correctional institutions is an additional substantial burden to the correctional administrator. Correctional administrators are going to be increasingly concerned about what they will allow to happen at their institutions. They are moving away from the old fashioned, traditionally oriented, tight-fisted approach to a more professional approach to corrections. So, administrators will be concerned for two reasons. The second is that they are being increasingly held accountable in regard to legal challenge as to what happens in a correctional setting. The faculty protocol developed by ACA reflects the increasing concern of correction administrators about these kinds of issues. One correctional administrator felt it was hard to listen to the same kinds of allegations directed at correctional administrators which had been expressed by others about doctors and biomedical researchers, i.e., that a lot of correctional administrators are unthinking, unkind, unconcerned, and willing to let inmates get hurt. He felt that certainly some of those kind of people are around us just as there are doctors in corrections who have slid into corrections because they have slid out of anything else, but that nevertheless we have many excellent men across the United States who are practicing in corrections.

A member stated that he, through the ACA, will be able to bring the suggestions and ideas of the Corrections Work Group to other corrections officials, and maybe next year when another decision along these lines comes his way, he will be in a better position to cope with it.

Finally, the pharmaceutical manufacturers can be confident that any new guidelines or committees that may be set up along the lines which the Corrections Work Group have advocated, are not meant to hinder their research, but, if anything, to facilitate it and help to ensure that it will be done in a responsible way.

VII. REPORT OF PROCEDURES WORK GROUP
Carol Palley

The Ethical Fitness of Investigators

The problem of how best to assure the ethical fitness of a researcher was the first raised in the Procedures Work Group.

The group considered whether investigators should be licensed as means of ensuring their ethical and scientific qualifications. The discussion led to description of an existing system of licensing in Europe, where the practice is open to abuse. Perhaps a detailed and careful licensing system could avoid such abuses, but the consensus of the group was that the ethical fitness of an investigator could not be assured by licensing.

The Food and Drug Administration (FDA) has regulations to ensure the scientific qualifications of the investigator, evaluating both experience and expertise. Their system is flexible enough to ensure that the investigator is qualified for the particular research he or she is conducting. However, the FDA can by no reasonable means accomplish the task of weighing the ethical fitness of the researcher. This task is better given to a local review committee.

To aid the local review committee in its task of assessing the ethical fitness of an investigator, he or she should appear personally before the committee, either to make a presentation, or to answer questions posed by the committee. No procedure can assure removal of all unethical researchers, but at least by exposing the investigator to the committee, there will be opportunity to assess the person and determine whether he or she should be participating in research.

Appointment of the Review Committee

Discussion then turned to the problem of appointment to the local review committee. In the appointment of a committee it is necessary to avoid collusion between the review committee and investigators, and to ensure credibility; there is also need to avoid the appearance of collusion. The appointment of the committee is closely tied with the problem of the legitimacy of the committee. Is the system of appointment such that fair and reasonable assessment of the study in all its aspects can be assured? The committee must be beyond the coercion of investigators and pharmaceutical companies alike in order to have credibility in the public eye.

Currently the appointment of a local review committee varies from area to area. In some cases where the study comes out of a university, the president or dean of that university will appoint a committee from among members of the university. In some areas prison authorities review proposed research projects.

Perhaps in a situation where investigators are not going through a university the review committee should be set up by the Board of Corrections. They could be responsible for finding a group qualified to serve on a review committee. At one point it was even suggested that the Board of Corrections could be responsible for reviewing any proposed new drug research in their prisons. The problem stated with this suggestion is that this responsibility is really outside the expertise of most Boards of Corrections. The question then was raised: Should all pharmaceutical company research be involved with a university and thereby have all review committees come out of a university? This proposal would lead to a university monopoly on new drug research, which would be unjust since many good scientific investigations can be based in hospitals or medical schools.

The problem of the legitimacy of the committee still has not been solved. Yet, should this group dictate how a local committee is appointed? Isn't it the responsibility of the local people and the local institutions to choose a committee appropriate to local conditions? In this forum it is impossible to solve all these problems. If we try to appoint

someone to monitor the appointment of committees, the number of monitors and controls could be endless. The regulations do specify that members of the committee should be qualified to serve, and beyond that it is really the responsibility of the local people to determine how the committee will be chosen. This study group can make suggestions about the proper considerations when choosing a review committee, but cannot presume to outline how it shall be done and expect to include all the varying circumstances throughout the country.

Review Committee or Committees

Discussion of the problem of appointment of the committee made it clear that in some investigations there is not one review committee, but two, or more. For example, in a university-based study, the university may set up a review committee, but before the study enters a prison the prison officials may also set up a committee to review the project. In this case there are two distinct problems handled by two committees. The first group tackles the problem of the validity and ethicalness of the scientific study and the second group handles the problem of how the study can fit into the confines of a particular prison.

The main concern expressed with having two committees is that it is then difficult to assign responsibility for the project to either committee. If something goes wrong someone has to assume responsibility for the error and do their best to ensure it does not happen again. It has been known that in the event of a mishap each committee will place the blame on the other, feeling it was the other's responsibility to stop the study from continuing.

Thus, it is necessary to have at least one committee bear prime responsibility. This does not rule out the possibility of having other committees to review special aspects of the research project (i.e., a prison board may review the feasibility of the study within their institution). The committee which bears prime responsibility need not be isolated from other resources. It can and should get input from any appropriate source, including other committees.

The committees reviewing new drug research have been commonly called "Peer Review Committee" or "Institutional Review Committee." Neither of these names seemed appropriate to the Procedures Work Group. "Peer Review" is not accurate since the committee is not intended to be made up of a group of peers. "Institutional Review" also seemed inadequate because one of the recommendations to come out of this work group is that some of the members of the committee be chosen from outside the institution. We settled on the name "Research Review Committee."

Composition of the Committee

FDA regulations offer suggestions for the composition of a review committee. To their list of physicians, or other scientists, and lawyers, clergymen or laymen, our group would like to add nurses and inmates or ex-inmates. Some of the members of the Research Review Committee should come from outside of the institution conducting the research. Private and public institutions are under scrutiny everywhere and it is necessary that they be opened up in order to gain credibility in the public eye. Opening up of the review committee can be gained by having some of its members come from outside the institution.

Nurses are appropriate members for the committee because they are very much concerned with the care of the patient. Some physicians may have a special interest in the pursuit of research, but nurses do not generally have such an interest. A nurse on the review board could serve particularly as an advocate for the patient.

It is also desirable to have an inmate or an ex-inmate on the committee. It was felt that he had a unique perspective to offer the review committee in sensitizing the group to conditions in a prison.

The feasibility of having inmates on the review committee will vary from state to state, but nonetheless it is desirable to attempt to have their viewpoint represented. The use of prisoners in positions of influence often depends on whether the warden understands how best to utilize them. They can be misused and thereby may endanger the function of the

whole prison, or their input can be used to the benefit of the whole prison population.

In the course of this discussion it was brought up that in an existing institution the general inmate population was asked how they felt about being represented on the review committee. The response was that the prisoners did not want representation. They felt that a fellow inmate might misuse the power delegated to him in such a situation. He might use his position for his own personal needs, against the interest of the general population. Anyone without power will try to gain it and may exploit it.

Also brought out in the discussion was the point that where prisoners do currently serve on review committees they often act more like a shop manager than a man looking out for the safety of his fellows. Thus far they tend to bargain for wages more than any other activity.

The conclusion reached was that inspite of the fact some prisoners do not want to be represented and inspite of the fact that representation may be fraught with difficulties, it is desirable to include an inmate, or an ex-inmate on the Research Review Committee. We chose not to make an across-the-board recommendation because in some institutions this still may be impossible to implement.

There is a danger of misunderstanding why a prisoner or an ex-prisoner is included in the committee. Our formulation of why the inmate population should be represented has been more poorly stated than the resolution that inmate representation is desirable. There is a need to clearly state why it is desirable to have an inmate representative. After one day of work groups it became clear in the evening combined session that each group, though in various ways, agreed that the inmate population should be represented on the Research Review Committee. One group stated the spokesman should be an ex-inmate rather than an inmate, since he could act with more freedom. Another group felt the representative should be a member of a prisoners' union. A third group said that one third of the review committee should be composed of inmates. All groups struggled with the idea of how to properly represent the prison population.

If it is recognized that an inmate on the committee cannot act as a true representative of the inmate population, but that he can still perform the important function of educating the other members of the committee to the conditions of prison life we can come to a clearer statement of why it is desirable to have him on the committee. A big pitfall we can fall into is assuming that a prisoner is speaking as a representative of the entire prison population. His needs and ideas may not correspond and do not need to correspond with those of his fellow inmates, but he can speak to the conditions of prison life.

He does not speak for all other inmates, he simply offers a point of view invaluable to the review committee. Indeed, this can be said for any member of the committee, though it now may seem to apply more specially to prisoners since they are new to this forum. A physician or scientist on the committee cannot represent his entire profession, only a point of view. The inmate's case is special, since he brings the point of view of the subjects of the research and in that sense he has more personal concern--if the drug is harmful inmates will be the ones to suffer.

The review committee is not a forum for collective bargaining. The proper function of a Research Review Committee is to consider and monitor proposed research projects, and not to debate reforms that should take place in a prison.

The Research Review Committee has plenty to do without getting sidetracked from the main issue. So, in discussing additions to the review committee it is important to emphasize that all members must concern themselves with the business of the committee. Particularly, each must adhere to topics of discussion within the five functions of the committee that are outlined below. Internal prison problems are not the problems of the committee and it is beyond the scope of the committee to try and solve these difficulties.

It is a relatively new phenomenon that inmates are being given a legitimate voice. When they are given that voice a lot will come out of inmates, some of it inappropriate for discussion by the Research Review Committee. The committee has to restrict itself if it ever hopes to accomplish its task. If

the committee fails to restrict itself it may be used as a forum for discussion of every failing of prisons.

It may be a proper function of the committee to consider whether existing conditions indicate that no studies should take place in a particular prison. Beyond that the committee should not burden itself too heavily with the issues of prison reform.

To have an inmate serve on the committee will necessarily involve controversy, but he has a legitimate point of view to offer, and one which should be examined by the committee.

There was total agreement on the issue of having prisoner representation within the review committee. Discussion from that point revolved around the question of "just how representative" this person would really be. Some feeling of consensus was achieved in making a distinction between being able to speak for the conditions of being incarcerated and being able to speak for inmates generally. The latter, it was felt, would be an unrealistic (and perhaps dangerous) expectation of any inmate member of the review committee.

Recognizing the possibility that the Research Review Committee could be overwhelmed with participants' personal agendas that have little direct implication for the business of reviewing protocols and research processes, the functions of the committee were made explicit as stated below. Under these functions the inmate would not be expected to represent the inmates' "point of view" or to raise the consciousness of the committee to issues which are loaded with institution politics, but, rather, simply to offer a valuable perspective on the predicted consequences of any proposed drug research program.

Functions of the Research Review Committee

Many of the currently existing review committees are confused about where their responsibilities lie. They have rarely been told distinctly what are their areas of concern. If a set of guidelines could be resolved most would probably be grateful and would do their utmost to fulfill responsibilities therein outlined. There seems to be no doubt that most committees would do a better job if they were told their areas of responsibility.

The Procedures Work Group endeavored to work out a set of guidelines and arrived at five principal functions for the Research Review Committee:

1. First, the committee should assess the ethical fitness of the researchers. The FDA ensures that investigators are qualified as scientists, but has no means of assessing their ethical fitness. This task is more easily accomplished by a local committee. In order to aid the committee in its assessment the investigator should appear personally before the committee, either to make a presentation of the proposed project, or to answer questions of the committee.

2. Second, the committee should review the protocol to ensure the study design is appropriate for a sound scientific evaluation. Protocols should be reviewed in open meetings. Some committees have had communication concerning protocols only through the mails and this method was felt to be improper. Protocols can be distributed to committee members before meetings for their private perusal, but they should also be discussed in open meetings. Time lmmitation would prohibit discussion of any protocol point-by-point in open meeting, but nevertheless general review of the protocol is necessary before approval is granted for the project.

3. The third task the Research Review Committee should undertake is to examine the known and foreseeable hazards of the experiment. Once these have been reviewed then the possible benefits gained from conducting the experiment should be weighed with the risks and a decision made as to whether the benefits justify the risks taken.

4. The fourth function of the committee is to provide for continued monitoring of the study. Each major modification of the protocol will need to be reviewed. Any on-going project will need to be reviewed periodically. Discussion brought out the fact that some long-range projects, once begun might continue indefinitely. It was felt that these projects should continue to be examined. The conclusion of

the work group was that continuing projects should be reviewed at least annually.

5. The fifth and final function of the Research Review Committee should be to ensure that prison conditions are appropriate for the study to be pursued. Some prisons may have inadequate facilities for some experimental procedures. Also, some drug research may not be appropriately done in a prison environment. For example, it was generally felt that hallucinogenic and narcotic drugs should not be tested in a prison.

This concludes the tasks outlined by the Procedures Work Group for the Research Review Committee.

Overview of Research Review Committees

Supervision of Research Review Committees on the national level would meet two needs discussed by the Procedures Work Group. First, there would be some assurance that the review committees were doing their job. A pilot study done recently by the FDA revealed that some committees have no records, making it unclear if they have ever functioned. The second need is the need for public information concerning drug research in prisons. Currently no one seems to know what the general picture looks like and only a few examples can be gleaned of what research is being done in prisons.

The overview of review boards needs to be outside the institution conducting the research. Several possibilities were raised: the Pharmaceutical Manufacturers Association, the Food and Drug Administration, and the Department of Health, Education and Welfare. The importance of having the overview at a national level brought the elimination of the governing boards of institutions or Departments of Corrections. It was felt that PMA was not set up to handle such a responsibility at this point in time. It was also agreed that a supervisory body should have some distance from the pharmaceutical companies, and therefore PMA might not be the appropriate agency to supervise the Research Review Committees. Finally the FDA or HEW seem the ideal candidates for a supervisory agency.

Most of the discussion in the group centered around the FDA as the supervisory agency, though it was never clearly decided that the FDA should definitely be the agency to perform that function. However, because of later discussion, the following comments will refer to the FDA as the agency to provide national supervision of Research Review Committees.

The FDA could monitor the review committee activities by receiving annual summary reports. The amount of detail required could be determined by the FDA, but should give some indication that review is actually going on.

If national supervision involved receiving annual summary reports rather than on-the-spot inspection the FDA could conceivably handle the task. With current resources the FDA could not possibly conduct on-the-spot inspection of every review committee.

In the role of supervisor the FDA could serve as a clearinghouse for public information on drug research in prisons.

A member of another work group raised the idea of organizing a new agency to serve as a clearinghouse for all biomedical research going on in prisons. The rumor mill is churning now with stories of medical atrocities in our prisons. The information is there to substantiate or refute these accusations, but it is not available to the public. Community groups are concerned and want to know how they can prevent mistreatment of the prisoners.

Community groups, among them the Urban League, have tried to get at this information and have thus far been unsuccessful. If they had access to information then they could judge for themselves whether projects are immoral or injurious to inmates. Some of these groups feel the need for one central clearinghouse to explain the studies taking place in prisons.

This issue brought up the question of confidentiality. How much of a study is confidential? How much can be released to the public? Certainly the name of the drug is confidential. How much of the progress of the study can be revealed before confidentiality has been breached? Access to FDA files on new drug research is currently limited to Congress.

The discussion of rumored and actual atrocities in prisons brought up the point that medical practice abuses within a prison will occur regardless of any controls that may be placed on experimentation. In fact, experimentation could be abolished and abuses would continue. It was agreed that there needs to be a beginning to answering questions and perhaps this beginning lies in new drug research itself. The research is under good supervision and is carefully screened. Then these other practices would stand out in sharp contrast. Otherwise they might go undetected. Research in prisons could act as a ray of light on the practices under suspicion.

If the FDA could centralize the experimental drug information about prisons it would be a beginning. Later public information can hopefully be available about all biomedical research occuring in prisons.

Actually the interest of concerned community groups and the interests of the investigator are the same. Until the community is satisfied, the investigator is in trouble and will be less able to carry out his work.

Would the Department of Corrections allow community groups such as the Urban League access to their files so they could ascertain information about biomedical studies? They may try to cooperate with such groups, but certainly could not indiscriminately allow them to come in and examine everything in the department.

A possible organization for a clearinghouse could be the American Correctional Association (ACA). They are certainly concerned with what goes on in prisons and the organization represents all fifty states and all the correctional institutions in the country. The ACA might be a good place to begin gleaning information about drug research in prisons. Credibility of ACA as a clearinghouse for information on drug research in prisons might be doubted because it is a part of the prison system, but this may be too hasty a judgment. A little background given on the ACA indicated they are open to changes within the penal system and have been critical of education in prisons as well as the medical treatment in prisons. This organization may in fact be a good place to plant a

seed of questioning current medical practices.

Here discussion had to be discontinued due to the press of time.

Informed Consent or Duty to Inform

All groups had been asked to consider the question of what is a volunteer and whether or not a man in prison can truly volunteer. Rather than long discussion we settled on a practical definition: A volunteer is one who consents, that is, one who signs the consent form.

When gathering volunteers the investigator is usually concerned with the motivation of the volunteers. Some prisoners volunteering may have perverted motivations. The investigator tries to screen out mental aberrants since inclusion of such volunteers can bias a study.

Discussion of the purpose of a consent form brought out some interesting points. The original purpose of the consent form was to protect the investigator--so that he could prove consent had been given. Now the purpose has expanded. If a subject knows what he is taking part in and understands the risks from the beginning he is less likely to withdraw. A well-written consent form can develop trust between the volunteer and the investigator. Both are advantages from the point of view of the researcher. The consent form now is taking on the quality of protecting the subject also. Hopefully he will be allowed to keep a copy of the form, and if he has questions can consult the form, or refer to the investigators therein listed.

The written form should include: (1) the nature of the study (i.e., why the study is being done, or possibly who is actually conducting the study); (2) the known and foreseeable risks involved, including both risks from the drug and risks from the procedures involved, and whether or not the drug has previously been given to man; (3) the right to withdraw at any point in the experiment.

Discussion of what should be on the form brought

up the question of whether the form should include a statement of the purpose of the experiment and who was conducting it. It is possible someone might be willing to take all the risks involved, but if he knew the sponsoring agency he might not be willing to cooperate at all. Perhaps participants in an experiment should be allowed that decision. However, it was pointed out by one member of the group that this matter is usually examined by the review committee and that may be the most effective means for controlling this aspect of the experiment.

Those drawing up the consent form should be guided by the knowledge of special communications problems. They may be addressing themselves to a heterogeneous population that includes retarded, illiterate, or foreign speaking persons. The form should not be so long that it confuses. Its purpose is to enlighten. It is not expected that the subject will gain great insight from the form, nor is he expected to be able to carry on an intellectual discussion of the experiment, but the subject should have at least a general idea of what is involved in the study.

Discussion turned to the issue of whether the existence of a review body should be stated on the form. A prisoner often finds himself in a communication desert and may not even know of the existence of a review committee. All agreed that prison volunteers should know of this committee and that there should be some way for them to communicate with the committee.

If those selected to participate in the experiment are allowed some form of communication with the Research Review Committee we have to consider those not permitted to join the experiment after the preliminary physical indicated some physical condition making them unsuitable for the study. Many of these men will not believe they were turned down for some real physical reason. Should they be allowed to bring their complaints to the review committee? However, it is undesirable to burden the committee with too much minutia. Where can the line be drawn? This issue was not clearly resolved, though it was pointed out that there may be some mechanism set up to carefully inform prisoners why they were not accepted to participate in a particular study. This could perhaps

be done by the investigators themselves, or by the medical staff of the prison, assuring them, if it be the case, that their physical abnormality is not necessarily detrimental to their health, merely out of the range of "normals" needed for the study. A public list was suggested which would include the name and reason for exclusion from the study. One problem with this procedure is it may be violating the confidence between physician and patient. An individual might not want his physical ailments publicized throughout the prison.

Leaving the issue of whether "rejects" from the study should have access to the review committee the group moved on to discuss the mode of communication with the committee. Direct access through uncensored mail was first suggested. Currently in many prisons, inmates can write uninspected and uncensored letters to government officials such as governors or heads of agencies, and prison administrators. Perhaps this privilege could be extended to cover uncensored letters to the review committee. Some members of the group felt this procedure might press too far up against security aspects of the prison. Some men serving time in prisons have been heavily involved in organized crime and are not allowed to write uncensored letters to anyone except certain public officials. Even their lawyers are not above suspicion of dealing with contraband, and cannot receive uncensored letters.

It was suggested at one point that an ombudsman could serve on the committee or serve as a contact for the committee. It was then pointed out that in order to remain within the concept of an ombudsman he must remain outside of the committee, he necessarily must be looking from the outside. The use of ombudsmen is not now a widely spread practice in the prison systems and therefore may not generally be the best means for communication between volunteers and the review committee.

In some prisons, the men's advisory council, made up of inmates, has gained more credibility than it had in the past and perhaps this group could receive complaints or inquiries to be addressed to the Research Review Committee.

The grievance procedures currently available in

prisons are actively used by the inmate population. We need not underestimate the prison inmate. He will use every available means to make his complaints known. Witness the current flow of inmate complaints and demands which are putting stress on prison systems today.

The conclusion reached by the group was that we could recommend that those prisoners involved in a new drug experiment have access to the review committee. The channel of communication set up should not compete with the prison system and its existing channels of communication. It should be stated on the consent form that there is a body that reviews the experiment in which they will be participating, and that they can communicate with the committee if something about the study disturbs them. It should be made clear that any questions about details of the experiment should first be asked of the investigators, since they will probably be able to answer most questions.

At one point it was suggested that it should be a requirement that the investigator's name appear on the consent form. The investigator should bear some of the responsibility for the experiment he conducts on other humans. As remarked earlier the consent form now works two ways, both for the protection of the investigator and for the protection of the subject of the experiment. The subject needs a route of redress in case the investigator harms him. Often the name of the organization conducting the experiment appears on the form, but more rarely the names of the people actually conducting the experiment. Personalities rather than institutions need to be identified.

Not identifying individuals can prove to be a problem, especially when a principal investigator delegates his authority and has others actually performing the experimental procedures. Some investigators do not really know what is going on in the experiment. This situation can occur when he or she is overworked, in charge of too many projects, or combining a heavy teaching schedule with research. If authority is delegated to other investigators, their names should also appear on the form. One member of the group dissented from this position, feeling it was adequate that the organization be identified.

The problem of the overloaded investigator should perhaps be explored by the Research Review Committee. To date this aspect of the fitness of the investigator is not examined.

The final decision reached by this work group was that it is desirable for an inmate to keep a copy of the consent form he has signed. It was felt he should be able to keep a document he has signed. He may want to refer to it during or after the experiment. In some institutions, they may not allow inmates to keep documents, so this procedure cannot always be implemented. However, where possible, it is desirable.

The Procedures Work Group ended its sessions with the hope that the changes and controls discussed at this conference will make for more credible and productive new drug research.

VIII. CONCLUDING REMARKS--ROBERT L. EMRICH, Ph.D.

What I am about to say does not attempt to suggest a consensus. I wouldn't be surprised if every one of you feels in disagreement with something that I am about to say, and maybe some of you with a great deal of it.

I am speaking for myself, as an observer. I have no special expertise in any of these areas. My observations are based on what I have heard while moving in and out of the sessions, as well as in informal comments over dinner, over lunch, and so on.

This conference has had an interesting, almost paradoxical quality, in that the area we are looking at, that is, the area of Phase One drug research in prisons, is not characterized by having any really serious problems. This was characteristic of the four work group reports which we have just heard, i.e., that they have offered some modifications and some important ideas and suggestions to an ongoing process. But I think it is a consensus, if there is a consensus here, that the Phase One research in prisons is not in bad shape, that it is being well attended to. Yet, at the same time our area resides in a Pandora's box that is full of problems, which keep spilling over and making this a very tricky area.

For example, all the problems of corrections have been dredged up here because they do spill over into our topic. Corrections is at a turning point. It is receiving much public attention. It has developed an internal consciousness that it did not have a decade ago. It is trying to become more professional. There is a great struggle internally between those who want to make corrections more professional and those who want to retain the custody orientation.

Phase One testing suffers from the general problems of medical research in prisons. We have all seen Jessica Mitford's article.[1] Phase One drug research in prison exists in the shadow of many other kinds of research going on in prisons--medical, behavioral, etc. These other areas of research cast quite a shadow of horror stories and disasters over Phase One testing, a relatively tame and risk-free area.

Phase One testing shares in the problems of the FDA. In every work group session I have heard participants discussing the success of the FDA regulations and the responsible job that the FDA is doing. However, we have an agency that has a perennial lack of funds, of sufficient staff, and of well-qualified staff, and that can't seem to find any way out of its poverty. Everyone knows that the FDA is in trouble, but where are its friends when it comes time to ask for more money?

Phase One testing shares in the problems of the industrial drug researcher, who is suffering from the pressures of the current wave of conservatism. He is suffering from the problems of increasing costs, increasing time required, and a decreasing expected return that makes venturesome research in the drug industry decreasingly attractive. There is also the problem which the research directors of the industry are having in convincing their corporations to undertake significant venturesome drug research.

Phase One testing shares with the problems of the clinicians, who I have frequently heard groaning that almost the whole weight of the new increased controls which we are proposing falls on their backs in terms of regulations and additional people to oversee their work, with regard to constant inspections, and new procedures, especially the way they deal with their subjects. Therefore, much of what has been proposed at this conference, if implemented, would increase the already tremendous burden on the clinical researcher.

Finally, our consideration of Phase One testing has raised the problems of the inmates. They are a

---

[1]Mitford, Jessica, "Experiments Behind Bars," *Atlantic Monthly*, 231(1):64-73, January, 1973.

little understood group, unless you happen to be one of them, and they have had little participation in this process. They have little hope. One of the most tragic observations of the conference is that the opportunity to say whether you want to be a participant in a skin-patch experiment is one of the few decisions you ever get to make during one's stay in an institution.

These are problems which confront us. The following are some of the threads which ran through the discussion as these problems were considered by the work groups.

One thread which impressed me and which was not discussed, is the thread of youth versus age at the conference. We have a number of young people, and frequently, during the discussions, the young people were on one side of the issue and the older people on the other side. We experienced something that is going on throughout the country. We sometimes call it a generation gap. A new kind of consciousness is arising in our nation. It spilled over in this conference. I am certain that we couldn't have held a real conference without it.

The youth look around, and they are not drawn into the establishment with a commitment to the traditional stakes as the older ones. The youth, for example, were continually keeping at the center of their focus the horror of conditions in prisons, and the fact that no one really wants to take cognizance of these conditions and pay for that reform and rehabilitation of the prisons that is drastically needed. The young look everywhere for someone to enlist as an ally. It was the following theme which they brought to this conference: How can the pharmaceutical industry and the clinical researchers who make use of the prisons become more responsible for doing something about prison conditions? How can they continue to work in prisons without being more responsible to the horrors of the situation?

On the other hand, the older people were responding to the need to try to do the job of Phase One testing in prisons as ethically as possible, continually policing the problem for abuses, while trying to do things a little bit better if we can--while remaining wary of attempts to totally reform the prison situation.

I think this conflict is a healthy one, and I am grateful that the youth have brought it to the attention of the conference.

The most important accomplishment of the conference, as I reflect on it, is an increase in mutual understanding. We are going to leave the conference with all kinds of new impressions, that we were not anticipating when we came here. These impressions are very valuable commodities, and I don't think we can say where or when they are going to come into play. It could be weeks or months or years hence that we will find ourselves utilizing experiences that we acquired here. I encourage you to actively seek opportunities to employ the understanding that you gained here.

I observed the following dynamic which was seldom explicitly talked about, and I feel that it was an important undercurrent of the discussions. I have called it, "the search for sympathy."

We have come together pretty much as strangers to each other. We have come from our own different worlds, and each major group represented here has been looking for a particular kind of sympathy.

The clinical researchers have felt that they have been bearing a tremendous burden of regulations, and that people have been willing to dump more and more on them without much consideration of the burden that they already bear, so that it is getting less and less attractive to do research on new drugs. I think there are some people who are just about "at the end of their ropes," and that may be true to some of the most creative clinical researchers.

The pharmaceutical company officials who have attended this conference are pragmatic. They have to think in terms of the economic realities that face all industries. They are concerned that research is becoming a more marginal operation every day. We hear about the pharmaceutical manufacturers that have ceased to do research in the last decade. We hear that, with increasing frequency, drug research is being done overseas, which means that the United States must wait years, until the preponderance of clinical investigation overseas finally forces a drug market in this country. As a result, there is a definite change in the atmosphere in the pharmaceutical industry, that makes it unlikely

that we are going to experience in the next 25 years the major accomplishments of drug research which has characterized the past 25 years, as Dr. McMahon emphasized in his opening remarks.

The people who represent the legal profession, particularly the young ones with their focus on civil liberties, are concerned that people will not face the unethical state of prison squarely, and are not willing to share the indignation that they feel at the conditions in prisons.

The initial reaction of the more militant ex-inmates here to the correctional officials who sit across the table is, "There is the enemy." The four correctional officials who have joined us all have a "treatment and rehabilitation" orientation, as opposed to the "custodial" orientation, making them a unique group. I think many of us ought to realize there are some tough, hardline prison officials out there.

The administrators of prisons who advocate a professional approach are caught in cross-fire from many sides. They have their conservative colleagues to deal with. They have penurious governors and legislators who find it particularly unattractive to spend increasing sums of money on prisons. It seldom pays off as a way to attract votes. They have the guards and the prison force that actively and effectively have on occasion, opposed prison reforms. They have some inmates who have vested interests in the state of affairs and work actively against prison reform. And they sometimes even have to work against our own organization, NCCD, who is working towards a sharp decline in the use of prisons. Correctional officials are surrounded with problems.

The ex-inmates represent still another group. Of all the groups here, they are the one group that everybody has tried to sympathize with. The irony is that we have the least ability to sympathize with the prison group, because we haven't known anything like the prison experience. Effective sympathy depends on having had a similar experience. I don't think anyone who has not been in prison or in that kind of an enforced confinement can share sympathy with prison inmates. I have spent some time in prisons as an observer, and that has only pointed up more clearly my lack of capacity for effective sympathy.

Lacking the sharing of that experience, it makes it difficult for us to communicate. I admire the ex-inmates here who have tried to communicate with us, and I suspect they have experienced a tremendous amount of frustration.

I finally would like to sum up my remarks with a question. I asked myself: "Should we get together again to have another conference?"

If the second conference were simply to go over some more details of regulations, to concern ourselves with the possibility of further guidelines, it probably would not be very profitable. I don't think people would like to get together to just rehash pretty much the kinds of things we have gone over here. We are fortunate that we have an assembly which consists primarily of busy people, who do not spend their time going to conferences for lack of anything better to do. What would make another conference of this kind attractive and useful?

The thing that would make it most attractive and most useful is if we can make some changes in our own way of doing things over the course, let's say, of the coming year, and come back with the perspective of having struggled with these problems in a somewhat new way. If we are willing to grapple with the issues that have come up here, willing to experiment with the suggestions that have come up here, then a new conference to share those experiences and to discuss the practicalities and impracticalities of the propositions we have put forth here might be very valuable.

There is no question in my mind--and I am not speaking for anyone else--that we need safe, challenging drug research, and that we should be doing Phase One research where it is appropriate, primarily in prisons.

I think we should, as a group--and I am now asking you, not reflecting you--make a commitment to keep Phase One research in prisons, and to make it a better kind of operation than it is now.

We should strive to treat the prisoners more as partners in Phase One research; given, as Connor Nixon, Ken Jackson, and others have pointed out, all the difficulties that we are faced with in trying to provide an opportunity for inmates to exercise greater respon-

sibility in an atmosphere where everything works against it. Such a change could provide a great deal of benefit for the interests of everyone here, i.e., medicine, the drug industry, or corrections or the prisoners themselves.

We must try to use the ideas that have been developed in this conference from the point of view of: "What can we get out of it for ourselves?"

I recommend to the FDA that they consider some of the suggestions here as possible new regulations. However, I would like to make this recommendation in a context suggested by a man I used to work for, Dr. Ralph Siu.[1] He once said that the United States has too many laws, and we ought not to enact a new law without getting rid of one that is on the books. The FDA may have too many regulations, not only for the drug industry and the clinical researchers, but also for their own good. As a result, we need a new sense of priorities. Taking the new perspectives that have been developed here, let us eliminate a few regulations and adopt a few regulations, thereby altering the priorities, with an eye towards sustaining Phase One research in prisons.

As far as the pharmaceutical manufacturers are concerned--I don't think anyone can rightly ask you to bring about prison reform single-handedly--it is not your business. In fact, it is hard enough in many drug companies to keep venturesome drug research going, which is your business. On the other hand, there are small reasonable contributions that can be made by pharmaceutical manufacturers that can improve the situation in prisons, and that may be a reasonable request.

One thing that would not only help prisons and prisoners but would also help the industry, would be to develop a greater public understanding of Phase One research and of the role of prisoners and prisons in Phase One research.

Today when one drives by a prison, one's feelings, as a member of the general public, are mostly negative,

[1]Formerly Associate Administrator, Law Enforcement Assistance Administration, U.S. Department of Justice.

and when meeting someone who has been a prisoner, most people react negatively. Here we have a very positive and important social contribution that prisoners are making. Few of us, before this conference, realized the extent and the importance of that contribution. The pharmaceutical industry therefore, can help give a positive image to the inmate and to the ex-inmate.

I think that drug companies can opt to work in those prisons that fit the qualifications which the corrections work group talked about--that is, where there is less economic coercion because there are more job alternatives. Perhaps you can even give some kind of economic "carrot" to the prisons in which you do Phase One testing, so that this will be an incentive to other prisons to seek out drug research, and to rise to the standards of job opportunities that would make them qualified for drug research.

Finally, addressing the concern that brought us together, from the perspective of the Pharmaceutical Manufacturers Association, i.e., the need for guidelines in the area, pharmaceutical companies can cooperate with the Association in the developing of new guidelines incorporating the findings of the conference.

The clinical investigators can do more to contact the prisoners on a partnership basis. Your very presence, as minimal as it may be in some instances, enriches the life in the prison. And the more you can do to enrich that terribly empty and dull life, the better it will be. If you can leave behind you an understanding of the kind of research you are doing, if you can leave behind a little understanding of the role the subject is playing and how the Phase One research of the particular research study contributes, I think that might help.

I ask the clinical researchers to be patient with the entire conference--and that's a big order. Because I know that in some respects we have been pushing you around, and you haven't objected very loudly. What we are asking is that you try to experiment with some of the ideas presented here, and hopefully the FDA might shift the nature of your regulatory burden, rather than just increase your burden, if possible.

Most of all, I ask the clinical researcher to see

this conference and its findings as an opportunity to increase the scope of your service to humanity. This perspective could make the findings and suggestions a welcome rather than an unwelcome burden.

I address myself to the two young people who have come here to present a civil liberties perspective. It is very important that you continue working for prison reform. It is very important that you know people in the Prisoners Union and the Fortune Society and similar up-front, ex-prisoner and prisoner societies, to help you target your thrust in areas where it will not only increase civil liberties, which is your primary concern, but where it will also help to relieve human suffering and improve the human condition. I am not saying that your interest in reforms in this area and in seeking a halt to the testing of drugs in prisons necessarily should be set aside; but, as you realize, there are a tremendous number of civil liberties problems associated with the prisons, and this is only one of them. Perhaps you should put in priority order the topics you intend to attack in the area of prison reform, and then start by focusing your efforts on the ones that will do the greatest good for the people who are suffering under these oppressive conditions of our prisons.

The prison officials who are here can help others to achieve a greater understanding of Phase One drug research. There is no question but that they have achieved a greater understanding themselves, and this is an indication that the majority of prison administrators have little understanding of this area. Once you have that understanding, you can become effective partners in Phase One research and help its presence, rather than wanting to eliminate it. It is important for prison officials to cooperate with pharmaceutical companies, clinical investigators, offenders, and ex-offenders in trying to develop a better format for carrying out Phase One research.

Prison administrators are especially concerned about having adequate assurances of the safety and soundness of the research which they introduce into their prisons. It is important that they be able to discriminate between research which has a low risk from research which has a very great risk. Certain prison administrators have been misled by clinical investigators in the past. The FDA, the industry, the

researchers, and the review committees must be satisfied that the research being undertaken is sound and safe, and they must cooperate to ensure that the prison administrators are also satisfied on this point.

The prison administrators who are seeking reforms, who are concerned with the professionalism of corrections, can utilize the presence of Phase One research as a tool for opening up the prisons, for making them more visible to an intelligent and concerned public. Therefore, correctional leaders can look upon Phase One research as a valuable asset, to be encouraged.

More inmate decision-making leads to greater inmate responsibility. This is a step in helping to develop inmates who, to quote one ex-inmate, will not have to say, "When I got to New York, I didn't know which way to turn." We need people who are able to make decisions for themselves when they return to the free world, and prison administrators should capitalize on whatever potential exists in Phase One research for providing more opportunities for inmate decision-making.

The ex-offender organizations can play an important role. Several of the work groups recommended participation of ex-offenders on review committees. Your organizations supply ex-offenders who have credibility within the prisons. It is important that you be known to and be able to work with the pharmaceutical industry, the FDA, and others who will formulate and carry out recommendations based on the work of the conference.

The ex-offender organizations have shown a considerable ability to gain access to public opinion and to legislatures. If you see value in this kind of research, you can be a helpful force in maintaining it, assuming that it can be done in the positive manner that has been described in work group reports.

As you well know, two of the ex-offenders came here with hatchet-in-hand, ready to knock the psychosurgeons over the head--however, that is not what this conference is about. Your initial misunderstandings are widely shared. There is a great need in the ex-offender community, in the offender community, in the general public, for an increased ability to discriminate the different kinds of research that go on in prisons.

It was a very valuable suggestion of the corrections work group that there ought to be a conference of some sort to clarify the general picture, putting the total picture of research in prisons in proper perspective, i.e., Phase One research, medical research on physiological topics and on various new procedures, various kinds of psychosurgery and biomedical research on aggression, and behavior modification research which attempts to deal with the rehabilitation of the offender. If we have had trouble in sorting it out, certainly the public does.

Let us consider carefully, during the coming year, what was done here, and approach your part of the problem with enthusiasm. If we do look into our own lives and into our own particular situations, for the opportunities we have; and if we do find in those opportunities that we are able to make some changes in our thinking, in the thinking of our colleagues, and in our own actions, then it might be worthwhile getting together again.

I invite you to leave here challenged, and to look upon this conference as offering you a new sense of opportunity, new areas for service, new areas to accept responsibility. Thank you all for coming.

APPENDIX:

STATEMENTS FROM CONFEREES

WITH BIOGRAPHIES

DR. EMRICH: We have an unfortunate competition at this conference. We are competing with the American Bar Association, which is meeting in Washington at the present time, and as a result we have not been able to have Dan Skoler's presence, but Mr. [Richard] Hand comes from the same group and represents that point of view.

Also, I received a note this morning in my box that Joseph Cannon is not able to attend.

Everybody else on the list, except for Cannon and Skoler, is at the conference at the present time. So I think we have done very well, and I appreciate the faithfulness with which people have held to their commitments.

We have had a very good beginning this morning. We heard a lot of issues, but I think anyone who is cognizant of the dynamics of a conference realizes that we haven't heard from about half the people here at all.

I think it is important that we as a group get to know each other, so I would like to start out this afternoon by going around the room with each person introducing himself. And I think we will hold any discussion until after we have heard from everyone.

What we would like to hear is who you are, what background you represent, what thoughts you have, and finally, what you would like to get out of the conference.

I would like to ask the faculty members and people who have given talks to join in on this, be-

cause we may have heard your talk but we may not know where you are coming from and what your background and interests are.

We will go around the table starting with Mr. Hand.

REMARKS -- RICHARD HAND

My name is Richard Hand. I am an attorney and I have spent most of my professional career working in O.E.O. legal services programs. I worked for two legal aid programs in Louisiana for approximately two and a half years. During that time, one of my primary areas of concern and involvement related to issues concerning the legal rights of prisoners. I served as counsel in several lawsuits brought against both the men's and women's state penal facilities. I am presently employed by a legal services back-up center which provides technical assistance and support to legal services attorneys and others involved in the area of prisoners' rights. Although the Center is sponsored, though not funded, by the American Bar Association, I am not here as a representative of that body nor do the views which I express necessarily reflect those of the A.B.A. Rather, I come here today as a private individual and speak from my concern over the difficult issues which form the substance of this conference and the implications they have to the legal rights of the confined.

My remarks are going to be short. I had one very basic reaction this morning when a gentleman from over on this side of the table commented about why it was good to have prisoners involved in drug testing. Well, from the viewpoint of the people who are doing the experimenting, I, too, can think of a number of reasons why prisoners, as a group, present many advantages. Among these are that prisoners are captive (and thus easily monitored), cheap and willing; the last because in most prisons there is usually no better alternative form of activity, and prisoners recognize that the treatment (including medical treatment), and food, received at a medical clinic are likely to be far better than that which they receive as part of the general

prisoner population. However, from another viewpoint, I can think of an equal number of reasons, which to my mind are far more persuasive, why prisoners are a very unsatisfactory group with which to experiment. I will try briefly to list some of these, and I think that before such things as standards and procedures for the regulation of drug testing in prisons can be discussed, these issues, basic to prison systems as they exist today, must first be recognized and addressed since they should ultimately determine whether we should have drug testing in prisons.

One such issue which I mentioned earlier this morning is the simple and obvious fact that prisoners are involuntarily confined--that is, their legal status is distinguishable from that of the free-world citizen. Prisoners are people who have passed through a judicial process which has found them guilty of some wrongdoing and as punishment has placed them against their will in an institutional setting. The involuntariness of this confinement casts some doubt on their ability to voluntarily enter into a program that, at one and the same time, offers incentive to escape from the boredom and sometimes brutal reality of prison life but yet can involve great risk.

Second would be the fact that the totality of conditions that characterize prison confinement would, in and of themselves, constitute duress upon the prisoner and dramatically affect his or her ability to freely consent to participation in an experimental drug program. The fact that either the pay scales are so low in other prison jobs or that there simply *are* no other prison jobs makes a prisoner's decision to participate in a drug testing program, one that is inalterably affected by the lack of viable alternative programs; similarly the poor living conditions, often including a lack of adequate medical care, contribute an inevitable element of coercion. The failures and unfairness of the parole system, combined with the fear in the mind of the prisoner that refusal to participate in a drug testing program might adversely affect parole eligibility, once again raise the specter of coercion.

Another issue that must be recognized has to do with the make-up of the prison population--that an inordinate number of prisoners are poor and/or illiterate, and many are mentally retarded. These factors alone would seem to me to cast grave doubt upon the ability

of the researchers to get truly informed and voluntary consent from those who participate in experimental drug testing programs. Another issue, and one which I had not previously given much consideration to, is that many prisoners do not have a good sense of what their medical backgrounds are and would have difficulty in providing any guidance or documentation. Further, how will the released prisoner be protected if later adverse side effects from the drug were discovered?

One last thought I would have--I am not sure exactly how it will fit into these discussions, yet I am uneasy about it and hope to have some discussion and development of it during the workshops--is how does the issue of a prisoner's ability to participate, or not participate, in experimental drug programs affect his ability to participate, or not participate, in correctional programs designed for "treatment." Since there has been much discussion about certain of these "treatment" programs which are geared toward modifying human behavior, drug aversion therapy and psychosurgery among them, it seems to me that what we say and do here in the next few days may have broader implications for future trends in corrections. If a prisoner can freely consent to participate in a privately-sponsored program involving a degree of risk, does this in any way comment on that person's ability to consent to "treatment" programs made available by correctional officials who may soon be acting under a constitutionally mandated duty to "rehabilitate" prisoners?

Finally, the assertion that prisoners should not be deprived of the "right" to participate in drug testing programs strikes me as a particularly specious line of argument when the exercise of other, more basic constitutional rights have yet to become a reality behind the prison walls.

Biography

Received a B.A. from Holy Cross College (1962-1966) and a J.D. from Georgetown University Law Center (1966-1969). Upon graduation from Law School he joined Legal VISTA and served as managing attorney at the Desire office (Desire Housing Project, New Orleans, Louisiana) of the New Orleans Legal Assistance Corporation. In September, 1970, he accepted a Reginald Heber Smith

Community Law Fellowship with the Legal Aid Society of Baton Rouge. While in Baton Rouge he concentrated his efforts in the areas of juveniles' and prisoners' rights and was involved in litigation in both state and federal courts. In January, 1972, he accepted a position with the A.B.A. Commission on Correctional Facilities and Services and is now with a Commission sponsored legal services back-up center which provides technical assistance in the area of prisoners' rights to legal services programs and others interested in the reform of prisons.

REMARKS -- MILTON RECTOR

For those who are not familiar with the National Council on Crime and Delinquency, you should know that the NCCD evolved from the national correctional field as the National Probation and Parole Association. Our principal thrust from our founding in 1907 was to promote the juvenile court movement in America, and systems of community correctional systems, first probation and later parole, to replace confinement as much as possible. In 1959, we became the NCCD with a much broadened program, to address all aspects of juvenile and criminal justice as well as crime and delinquency prevention.

I have had the privilege of being a member of the NCCD staff for some 27 years; travelling the United States and abroad, with an opportunity to look at many kinds of systems; working on survey teams, assessing courts, police, sentencing, correctional programming; working with staff in development of model laws and national guidelines for improvement of practice and procedure. Increasingly, the NCCD is becoming an advocacy type of organization. We have a strong enough base of non-governmental support from voluntary contributions to permit us to monitor the public systems and to serve a viable role as a constructive critic of public services, offering alternatives for existing programs, practices and statutes which do not represent the best attainable standards.

One of the NCCD program priorities is to promote better protection for the rights of prisoners, including the right to minimum wages. As this concept gains acceptance in corrections systems we shall see private industry and organized labor operating inside the institutions for the training and employment of prisoners who will produce for the open market and receive full wages.

When the wage break-through comes, whether it is in terms of prisoner participation in scientific research or whether it is replacement of the present exploitive prison industry system with a modern, private enterprise system, it will at the outset create temporary problems of imbalance. Maintenance workers, and others essential to the daily operation of a prison, such as those working in the kitchen and laundry, will have to be paid. This will escalate the cost of confinement but also should have the benefit of forcing greater care and certainty in the justice process of determining who should be confined. Cost effectiveness is practically unknown in the criminal justice system.

This is pertinent to our consideration at this meeting of the issue of prisoner volunteers and coercion in relation to volunteering if the payment of minimum wage scales were to be the policy of the correctional system. I sincerely believe that payment of prisoners for all work performed is just around the corner.

I hope to take from the conference some specific help for correctional managers who are addressing the matter of Phase I drug testing with prisoner populations. This is a problem to many correctional systems and the guidelines and controls recommended by this conference will be of immediate and practical help to them.

Also Phase I drug testing, if it can be done safely and well in correctional institutions, can bring another outside leadership force representing the drug industry and medical profession who are not aware of what destructive devices prisons truly are. They can thus become another outside force to help us reduce dramatically the amount to which the justice system and the public rely upon such confinement.

Biography

Has been President of the National Council on Crime and Delinquency since 1972, having served as its Executive Director from 1959-72, and NCCD Western Consultant and Assistant Director from 1946-59. He has been appointed by Presidents Kennedy, Johnson, and Nixon as delegate, United Nations, World Congresses on Prevention of Crime and Treatment of Offenders, attending

Congress sessions in London, 1960; Stockholm, 1965; Kyoto, Japan, 1970. He has recently been reappointed to this post. He is the U.S. representative to the Social Defense Section, United Nations, and a Member of the New York City Coordinating Council for Criminal Justice. In addition, he was a member of the President's Advisory Council on Juvenile Delinquency 1960-66; consultant to the President's Crime Commission, 1966-68; member of the Advisory Committee, National Commission on Reform of Federal Criminal Laws, 1969-70; and Chairman, Board of Directors, Joint Commission on Correctional Manpower and Training, 1966-71.

REMARKS -- DR. FRANCES KELSEY

I am Frances Kelsey with the Food and Drug Administration. I am basically a pharmacologist.

Since 1967 I have been directing a small group, the Scientific Investigation Staff. Our main responsibility is to visit sponsors and see that they are monitoring the clinical investigators and to visit clinical investigators and see that they are following the investigational drug regulations.

In the course of this work we have visited a number of prisons, and also many other institutions and private investigators. We have found a number of problem areas. Some of these are obviously not in the spirit of the regulations, and therefore we can take corrective measures. There are other problems that we have encountered, and questions which have been raised to us, however, for which there seemed no very good guidelines, and hopefully this conference will supply some of these.

I would like to emphasize, however, that these shortcomings apply not only to prisons, which are the subject of this conference, but also to other institutions.

We are concerned about the qualifications of the investigators, and not only them, but persons to whom they frequently delegate the work.

We are concerned about the quality of the records, and the protection that is not given to subjects when such records are poor. This particularly applies to the possibility of late, unrecognized hazards, or hazards not recognized until later, and follow-up studies are indicated.

We are concerned with the nature of the patient consent, and we are also concerned and in fact, have a special program directed towards surveying the operations of Institutional Research Committees. These committees are a recent requirement, and our work in this area has just begun.

We are concerned about such ethical problems as what drugs should be tested in what type populations, in prisoners and children, for example, and other particularly sensitive areas.

We are naturally concerned, too, with the alternatives to prison testing, if this should have to, for some reason or other, be curtailed, or if the burden of work gets so great that present prison facilities cannot handle it.

As you can see, therefore, practically every item in the program will be of direct interest to us, and I hope it will help to solve some of our problems and give us guidelines for future studies.

Biography

Born July 24, 1914, Cobble Hill, Vancouver Island, British Columbia, Canada. She received a B.S. and an M.S. from McGill University in Montreal, and her Ph.D. (1938) and M.D. (1950) from the University of Chicago. She has served as an instructor and an Assistant Professor at the University of Chicago, 1938-50; and as Associate Professor of Pharmacology at the University of South Dakota, 1954-57. After receiving her M.D. she interned at the Sacred Heart Hospital in Yankton, South Dakota, 1953-54; and had a private practice as a general practitioner in Vermillion, South Dakota, 1957-60. She joined the Food and Drug Administration in 1960 where she has served as: Medical Officer, Bureau of Medicine, 1960-63; Chief, Investigational Drug Branch, Division of New Drugs, Bureau of Medicine, 1963-66; Director, Division of Oncology and Radiopharmaceuticals, Office of New Drugs, Bureau of Medicine; Assistant to the Director for Scientific Investigations, Bureau of Medicine, 1967-68; Director, Division of Scientific Investigations, Office of Medical Support, Bureau of Medicine, 1968-71; and Director, Scientific Investigations Staff, Office of Scientific Evaluation, Bureau of

Drugs, 1971-present. She also is a member of several professional and scientific societies, has held several awards in education and government service, and has published extensively.

REMARKS -- DR. F. GILBERT MCMAHON

Well, I certainly spoke enough this morning, but I am a physician at Tulane Medical School in New Orleans. I didn't mention this morning something I would like to say now, and that is, there is an old slogan, "Primum non nocere," "Above all, do no harm."

If that is the philosophy of anyone in this room, I would like to debate with you, because if you intend to do no harm, you should never practice medicine, let alone research, because all treatment is experimental. There is no drug that is not capable of being toxic. There is a dose of water that could kill any one of us. I think if you didn't want to take any chances, you wouldn't practice medicine. All medicines are potentially toxic. Good medicines, like penicillin, are abused every day. People die of misuse of aspirin or of consuming good drugs in the wrong dose or for the wrong diagnosis.

Anyhow, I would like to say there is a certain benefit/risk expected out of new drugs, and that is what we try to evaluate in Phases One, Two, and Three. Even in Phase Four you have to watch for toxicity of drugs, because the incidence of toxicity might be extremely low and might not be evident until a couple hundred thousand people have taken the drug.

So I think that is all I would like to say.

What I would like to get out of the meeting is guidelines. By coincidence, we have a new Governor of Louisiana in the last year or so, and he has a new Commissioner of Health, and he has asked me to assist in writing guidelines for the conduct of human research in state-funded institutions. And that's a tough job, but I hope to be able to bring your ideas

back and incorporate them into the Louisiana guidelines.

I think if human research is to go on in Louisiana prisons--and there is practically none now--there has to be substantial gain for the prisoner, and hopefully improvement in his routine medical care, as someone else said earlier this morning, and not just benefit to the research subject. But probably the standard of medical practice in Louisiana prisons would benefit from the proper conduct of drug research within our prisons. We don't even have enough money to hire full-time doctors in some Louisiana prisons. That is why I think the money ought to spill over and help medical care inside of the prison.

Biography

Currently Professor of Medicine and Head, Therapeutic Section, Department of Medicine, Tulane University School of Medicine, his education includes: B.S., Chemistry, 1945, University of Notre Dame; M.S., Pharmacology, University of Michigan, 1949; M.D., University of Michigan, 1953. He did his residency in internal medicine at the University of Wisconsin Hospitals and Lackland Air Force Base Hospital, San Antonio, 1953-56. He has taught at the University of Detroit, University of Wisconsin, and Louisiana State University School of Medicine, and has practiced medicine at several hospitals in New Orleans. In addition, he has held the following positions with the pharmaceutical industry: Director of Clinical Research, The Upjohn Company, Kalamazoo, Michigan, 1960-64; Vice President in charge of Medical Research, Ciba Pharmaceutical Company, Summit, New Jersey, 1964-67; Executive Director in charge of Clinical Research, Merck, Sharp and Dohme, West Point, Pennsylvania, 1967-68. He holds several honors and has served on numerous committees and has written many articles for publication.

REMARKS -- DR. ANTHONY W. CZERWINSKI

I am Dr. Czerwinski from the University of Oklahoma College of Medicine.

I am here primarily because we manage a Phase One unit at the Oklahoma State Penitentiary. I speak primarily as a medical scientist, and I regard prison inmates as I regard anyone else--as human beings subjected to study. But I think one of the important things we must remember is the potential risks and benefits.

Who is responsible for making this assessment? We have review committees, but I think ultimately the investigator is responsible for assessing the risk-to-benefit ratio. I think that the investigator has a much greater role when you are talking about normal people, because very little risk should be taken in normal people since the study, at least in Phase One studies, seldom benefits the person who is taking the risk.

Now, what do I wish from this conference? I really wish that we could define the problems that corrections people have in prisons, the problems that we cause corrections people; try to answer, if possible, some of their uneasiness about using normal people; and try to develop guidelines which may be useful for corrections people.

As far as the inmate population, I think the inmate is like the public. The inmates need to be aware of investigation; they need to be aware of the value of investigation, however, they should be treated the same as anyone else who you might use in a study.

Biography

Born February 10, 1934, St. Louis, Missouri. Educated at St. Louis University: received his B.S. in 1955 and his M.D. in 1959. He served his internship and residency at the University of Oklahoma Medical School and held fellowships in renal medicine at the V.A. Hospital in Boston, Massachusetts, and at the University of North Carolina. At the University of Oklahoma School of Medicine, he was an Assistant Professor of Medicine from 1969-72. He is now an Associate Professor of Medicine at the University of Oklahoma Health Sciences Center, where he has been since 1972. He is a member of several honorary societies and professional organizations, and has published numerous articles.

REMARKS -- DR. MERVIN CLARK

I am Mervin Clark, and I am with the University of Oklahoma also. Dr. Czerwinski and I are co-workers at the university and at the unit at McAlester.

Needless to say, we share all of the same concerns, and I would like to get out of this conference essentially what Dr. Czerwinski has stated.

There are, however, one or two additional specific questions that come to mind. Recently, in working with the group at McAlester we have had some important questions arise, one of which concerns our responsibility regarding follow-up studies on prisoners, particularly when chronic toxicity studies years later show that there may be possible harm from drugs that prisoners received years before as subjects of an experiment.

Often it is very difficult to follow up people who have been discharged from prison. And the question comes up: How far do we go? How far do we invade the privacy of citizens, now, who are out of prison and are no longer involved?

The studies are done with subjects identified only by prison numbers. These prison numbers (i.e., history) may or may not follow people into society. For follow-up we then have to identify the subjects by name. What is the balance here? How far do we go "invading the privacy" of a citizen who has participated in the study in the past, who may not want to be followed up and reminded of his past history at this particular time?

The other question I have in mind I would like to hear discussed by others is something that concerns all of us in this field: How do we meet our respon-

sibility for any harm that may come to any subject participating in an investigation?

I am thinking in terms of adequate medical care or adequate compensation should anything occur that might prohibit a subject from, say, supporting himself or supporting his family as a result of participating in a study. Just what provision should be made by us as investigators? Or by the espousers of the study?

And it applies not only to prisoners, but to any subject in any clinical research project.

These, then, are two things that I am particularly concerned about.

One additional comment: I am not so much concerned about my consideration of the rights of the prisoners as I am concerned about how the rights of the prisoner might be abrogated by fellow prisoners, who might be more influential in the prison society as it exists.

This became a concern in talking to some of the prisoners about whether or not they wanted representation or a protocol review committee, and I found that a significant number were quite ambivalent, for fear that whoever would represent them might take advantage of it and them.

This is a possibility that needs to be considered in further discussions about prisoner representation on review committees.

Of course we are all concerned about the right to participate, the right to not participate, and the existence of coercion as a function of poor prison conditions. But I think perhaps we should keep separate, as best we can, those problems that belong to the Corrections Department and those problems that concern research per se.

Biography

Born May 18, 1921. Received a degree in Chemistry from the Virginia Polytechnic Institute in 1942 and his

M.D. from Northwestern University School of Medicine in 1948. He has served on the faculty of the University of Oklahoma College of Medicine, Department of Medicine, from 1956-present (Assistant Professor through Professor); as the Chief, Medical Service, Central State Griffin Memorial Hospital (mental institution) from 1956-present; as Principal Investigator, Psychopharmacology Research Unit at CSGMH from 1958-present; and as Acting Director, Division of Clinical Pharmacology, Department of Medicine, University of Oklahoma College of Medicine from 1969-present. In these capacities he has conducted Phase One and Two drug testing in prisons and mental institutions.

REMARKS -- DR. ALAN VARLEY

I am Alan Varley. I am a physician, and I am presently the Director of Medical Affairs at The Upjohn Company in Kalamazoo.

As I mentioned this morning, a little over nine years ago we entered into an arrangement or program with the medical schools in the State of Michigan, and the Department of Corrections, to build a research facility within the walls of the largest prison in our state. I don't think this was the first use of prisoners in research that the industry has sponsored, but I think it was the first rather large-scale program that was under direct industry supervision.

In developing this program I feel that we wrestled with many of the questions that we discussed this morning. To address the question of "what I am interested in getting out of the conference," I am curious to see how we did in answering these questions almost ten years ago.

It is hard to boil down one's concerns in a subject as broad as this, but perhaps I have two.

There seem to be people who feel that use of prisoners in research is an invention of the pharmaceutical industry, and I think it is important to realize it is part of a much, much larger program. In this country we have moved the study of new drugs in a different way than has been done in Europe in that we spend a lot more time carefully documenting things other than just efficacy. Pharmacology, tolerance, metabolism, excretion, bioavailability, all of these are documented to a much greater degree in our system in this country than abroad. We are also putting a much greater premium on statistical validation. This in turn requires

larger numbers, and a more controlled environment, and has led to the involvement of prisoners in research studies. I would urge at the outset that we realize that if we are going to change or limit the present investigation system, we will also have to change simultaneously the approval system for drugs in this country and the quality and quantity of the non-efficacy data that now is considered essential.

The last concern I have relates to the rights of volunteers. Over the last few years we have all been greatly concerned about prisoners' rights. We have been concerned that prisoners be treated the same as other volunteers. This emphasis is essential, but I am beginning to get a feeling of concern for the non-prisoner volunteer. In our discussion I hope people will stop to consider that other potential non-prisoner volunteers have rights the same as prisoners, and what is deemed right for prisoners should be applied to others as well. I refer specifically to informed consent. If it is categorically not possible to elicit "informed consent" from prisoners, is it possible to elicit it from non-prisoners? If prisoners are coerced by their environment, are non-prisoners equally coerced by theirs? If standards set for prisoners are applied to all volunteers and consent becomes impossible and coercion generalized, general research in non-diseased population will become impossible.

I think this is a consideration this conference must also keep in focus.

Biography

Dr. Varley graduated from Baylor University in Houston, Texas. After a residency program in surgery, he practiced privately and joined the Upjohn Company about 15 years ago. He has held several positions within the company, and is presently Director of Medical Affairs. His interests are in clinical pharmacology and ethics, and legality of ethics with prisoners. He has written a number of papers on these subjects as well as on the

bioequivalent of drugs. About ten years ago he had responsibility for developing a model research unit in a prison in Jackson, Michigan involving the pharmaceutical industry, the corrections department and the academic world showing that such a combination of resources can work together and do a good job.

REMARKS -- DR. FRANK AYD

I am Dr. Frank Ayd of Baltimore. I am in the private practice of psychiatry. I am also Director of Professional Education and Research at Taylor Manor Hospital.

I have been involved for twenty years now in testing psychopharmaceuticals. I just recently celebrated the twentieth anniversary of the first day on which I gave chlorpromazine to a patient.

I took time from what I consider a busy schedule at this particular time to come here because I am concerned about many of the issues to which we should address ourselves at this conference.

I would start with the premise that we all are ethical people interested in implementing, as much as we can, the highest ethical standards in the work we do. In addition, I believe that we have enough compassion and humane consideration for those for whom we are going to work or with whom we will work that we are vitally interested in protecting their rights as much as possible.

To me the crucial point is to devise adequate guidelines that, hopefully, all of us will judge acceptable. I also hope that these will protect the rights of the experimental subject, be he prisoner or non-prisoner.

To achieve this there are certain things that I consider essential. One is that we do not confuse the issues. The inequities and the injustices and all the other bad things that we can say about the penal system and correctional system is one problem which I consider, quite frankly, independent of the purpose of our being

here.

Likewise, I think the inadequate delivery of health care within our penal system certainly needs to be improved, but to me this is also separate from the problem we are here to consider.

I think we also have to separate legitimate drug research from a research treatment program. For example, the use of psychosurgery has been mentioned this morning. In one sense this is experimental and in another sense it has a very specific therapeutic objective, namely, to offer treatment to a patient who, because of the nature of his disability, is in need of treatment. Another example would be aversive therapy, but no one knows for certain whether this is beneficial therapy or not. These are different from using someone as an experimental subject to learn something about the pharmacology of drugs, and so forth.

Finally, let me stress that I believe we have assembled here people with enough expertise and goodwill that we ought to be able to reach some kind of a rapprochement.

Thank you very much.

Biography

Dr. Frank J. Ayd, Jr., M.D., F.A.P.A., (Director of Professional Education and Research, at Taylor Manor Hospital), has been actively engaged in the practice of psychiatry and in clinical research since 1951. He has lectured in Europe, Asia, Africa, the Orient, Australia, New Zealand, and North America. He is a member of numerous national and international medical societies, and of the Fellow American Psychiatric Association, the American Academy of Psychosomatic Medicine, the American Geriatric Society, and is a Fellow and Founder of the American College of Neuropsychopharmacology. He is a member of the Royal College of Psychiatrics (England).

Dr. Ayd has published over 200 scientific articles and is a contributor to over 30 books. He is editor of

numerous professional and scientific newsletters and journals and author of *Recognizing the Depressed Patient* (Grune and Stratton). He is a member of the National Association of Science Writers, Inc. Dr. Ayd is listed in *Leaders in American Science*, *American Men of Medicine*, and *American Catholics Who's Who*. In 1962, Dr. Ayd began broadcasting over the Vatican Radio on a program called "Religion and Science," and in 1963 was honored by being the first American layman to be appointed to the faculty of the Pontifical Gregorian University in Rome.

In recognition of his achievements, Dr. Ayd has received many honors including four honorary Doctor of Law Degrees and an honorary Doctorate of Science Degree. He has been the recipient of numerous awards for outstanding contributions to the community, to religion and psychiatry, and to biological psychiatry.

REMARKS -- DR. JOHN ARNOLD

Dr. John Arnold, Professor of Medicine at the University of Missouri, and Director of the Harry S. Truman Research Laboratory.

I have been in experimental drug research for 27 years, using human volunteers, many of them prisoners. I come out of that period with a couple of notions, several of which I would like to share with you.

In the first place, I believe very profoundly in the need for the Food and Drug Administration requirements for careful tolerance and toxicity studies done in normal volunteers. Our files are filled with the dead bones of drugs that failed this test, and consequently, tests were never imposed on ill patients to ascertain this information.

Many of the public controversies that now surround drug safety might have been averted had we, in an earlier age, had these same rigorous requirements; and, secondly, had we developed the professionalism that I think we are now in the process of developing to find adverse drug effects and hazards not only from drugs but other chemicals as well.

So the need for normal human testing, I think, is really without much argument. Where this should be done--meaning the question of alternate populations--is a matter of some argument. The data before us are very limited. In our studies of this question, it would appear that normal, free-living individuals, for reasons of time commitment alone, probably will not provide willingly the population groups in which this work needs to be carried out. I could envision that the solution thereto might have to be a kind of national selective service, to pick from the population

at random those people who are to take this selected risk--a thing not unlike that of jury selection.

I am quite serious in this proposal, because all the evidence at my disposal suggests that it is the only alternative to the use of a large number of people within prisons.

That is the first problem.

The second problem is that institutions, under the rubric of prisons, vary enormously in the quality of life. Consequently, the conditions under which these experiments are carried out vary enormously. It is against this background of the institution that we determine many of the ethical problems.

Mr. Coughlin has pointed out--and I worked in Stateville many years ago--that conditions within that one institution have evolved over a span of 20 years, so that the ethical problems 20 years ago are not the same ethical, operational, and moral problems that exist today. There are quite a lot of differences within a given prison as well as between institutions.

So I urge everyone to look at this question of diversity in formulating ideas about prison research.

The last problem I would like to speak about is what I want out of this conference.

I have worried for a couple of decades about the moral and ethical implications of prison research and I have been very aware of the public response, the political needs and emotional reactions that are likely to be generated by a meeting of this sort. In fact, we went through such a period in the late 1940's, but except for the Ivy Committee appointed by Governor Green of Illinois, it has not evolved very far.

I think if we had had this meeting a decade ago, and it had been a constructive one, as I fully expect this one to be, this problem would now have been laid to rest and we would be getting on with the job.

I reinforce, then, Mr. Coughlin's appeal that the job for this meeting is related to the construction of some kind of guidelines. I have examined what I think are the deficiencies within our own present

system. I think there are deficiencies and they need correction. They could get correction from this group.

First, the peer review system as set up by the NIH [National Institutes of Health] and FDA [Food and Drug Administration] is inherently a very effective way to manage many, perhaps most, of the moral and ethical problems surrounding human medical trials. I suspect, however, it is not operating as it ought to be. As I talk to our own peer review group and look at our own problem, I have several suggestions to make.

First of all, the peer review group, being made up not really of peers--they are non-peer reviews--are confused in large part about what they are to do. Perhaps that is the major problem. If suggestions were made on a national basis about what these local non-peer review groups are expected to do, I think a great many of the difficulties would be resolved. For instance, have they visited the facilities in question? Have they considered the backdrop of the prison conditions? Have they really looked at this thing that they are reviewing?

And lastly, I would make one appeal to you. This comes from my own peer review committee. If you take away the major responsibility from the local peer review group, that committee will atrophy. It is difficult enough today to get their attention. If they do not have a major role in this review, they will disappear.

Biography

Born May 4, 1922, Bradford, Ohio. Educated at the University of Chicago; received B.S. in 1943, M.D. in 1946. At the University of Chicago, Department of Medicine, he served as: Research Assistant and Research Associate, 1947-53, Assistant Professor and Associate Professor, 1953-63. In 1963, he joined the University of Missouri School of Medicine, where he served as Professor of Medicine. He has also served as Chief of Medicine, Kansas City General Hospital and Medical Center, and Chairman of Medicine, University of Missouri School of Medicine at Kansas City. He is

currently the Director of the Harry S. Truman Research Laboratory and Professor of Medicine at the University of Missouri School of Medicine at Kansas City. For 25 years, he has been involved with human experimentation in prison facilities and the testing of a wide variety of pharmaceutical compounds. He has received numerous awards, has published many articles, and has contributed to many scientific exhibits.

REMARKS -- JAMES B. RUSSO

I am Jim Russo. I am with the Pharmaceutical Manufacturers Association.

I bring to this meeting almost complete ignorance. I am neither a scientist nor a lawyer. I am a journalist by training, and any of you who know journalists know that journalists have a solution for everyone's problems.

I hope to have a part in drafting the guidelines for the drug industry, if indeed that is indicated as a recommendation at the end of this meeting.

I really hadn't focused on the prisoner issue at all eight or nine months ago. I have learned a good deal in that interim, and a good deal of that is unsettling.

It seems to me the problems that should be considered at this session include, as many people have already said, the possibility that perhaps we ought not to do testing with prisoners at all. I think sometimes it is hard to document the validity or the need for testing in prisons. I think the existence of regulations and guidelines at the FDA level, particularly, seem adequate on paper, but I have heard enough stories of the inadequacy of enforcement that I think we ought to focus hard on the existing guidelines and what is being done or being missed in their observance.

I think the monitoring problems for the sponsor of the drug studies are particularly acute with respect to prisons. The companies need some guidance there.

Perhaps the monetary issue we talked about may be the knottiest of all. We are kind of caught in both

directions. If you pay what you would pay on the outside that amounts to intimidation. If you pay what you pay, that amounts to coercion. We have to get at this issue in some way.

Finally, I think the whole idea of this conference is very healthy. I think the whole movement of prisoners' rights is something that has been long overdue and will not go away. I think that PMA is interested in improving and defining the role that the drug industry can play to improve the situation in prison testing, and may itself lead the industry into finding its role without waiting for federal legislation or regulatory action to take place.

I guess in the process of describing my concerns I have also described most of the things I want to get out of the meeting, namely, the wherewithall with which to draft some guidelines.

Biography

James Russo graduated in 1956 from the Temple University in Philadelphia, with a B.S. in Journalism. After spending about five years in the Navy, as a Public Information Officer, he joined PMA in 1960. Positions he has held with PMA are Director of Public Information and Director of Special Studies in the Research and Planning Department. He has held the position of Assistant Vice President of Public Relations for the past two years. His duties include the preparation of testimonies for use in Congressional hearings, writing speeches, the preparation of booklets and leaflets on subjects of interest to the pharmaceutical industry, and advertising on behalf of the drug companies.

REMARKS -- DR. DON E. KIRKPATRICK

My name is Don Kirkpatrick, and I am from Texas. First I would like to, in all deference to Mr. Rector, clarify at least in my mind a couple of points he made, one concerning the movement to pay inmates in prison.

I don't disagree with that philosophically, but I also don't see that as really being "around the corner" as he says it is, at least in my state. People in Texas, in terms of appropriations, spend about $4.50 a day for a man in prison. I don't see that the economic impact of paying inmates for all jobs in prisons at the same rate as the general population, being a "live option" politically.

The second point I would just like to briefly touch upon is the concept of some kind of goal to reduce or eliminate all correctional institutions. I believe when you look in the society and look in the general population--I assume we are talking about some of these alternatives to corrections--I don't really believe they exist. We write about them, we allude to them, we hope that they are there, but in the main when you go into the community to try to seek them out or construct them, they are not there.

I think this is important because it tends to indict all correctional systems, and this is in relation to Dr. Arnold's point, while there is tremendous disparity in some systems because of their location and because of the particular society they are in. I think obviously there is a tremendous difference in the way they are meeting their missions and goals.

In terms of this conference, I think I come here with a tremendous concern in terms of medical experimentation and medical research in a correctional setting,

specifically my own, and I think what I really look for in this conference--I came to see the kind of men and the kind of leadership that is being evidenced in the private sector with the Pharmaceutical Manufacturers Association, so that I can better make determinations within my own institution. I think the kind of interchange between correctional people and people around the country involved in this work is a critical element in this equation.

Biography

Born April 12, 1938. He received the following degrees from the University of Houston: B.S. in Psychology, 1964; M.S. in Experimental Psychology, 1969; Ph.D. in Experimental Psychology, 1971. His work experience includes: Research Assistant-University of Houston, National Aeronautics and Space Administration, Manned Spacecraft Center, Houston, Texas, 1964-65; Research Psychologist-NASA, Manned Spacecraft Center, Houston, 1965-68; Associate Director of Biomedical Communications, Baylor College of Medicine, Houston, 1968-69; Research Associate, University of Houston, Department of Psychology, Houston, 1969-70; Assistant Professor, Sam Houston State University, Institute of Contemporary Corrections and the Behavioral Sciences, Huntsville, and Research Coordinator, Texas Department of Mental Health/Mental Retardation, 1970-72; Assistant Director for Treatment, Texas Department of Corrections, and Assistant Professor, Sam Houston State University, Institute of Contemporary Corrections and the Behavioral Sciences, 1972-present. He is also a member of several professional organizations and has presented numerous papers.

REMARKS -- DR. R. E. PROUT

My name is Gene Prout. My background is clinical medicine and correctional administration. I am Chief Medical Officer in the California Medical Facility in Vacaville, which is about a 1,900-man institution, primarily a psychiatric hospital.

My involvement in research has been over the past ten years there, occasionally as an active clinician in the research, but most often as a non-participant and as a member of the Institutional Research Committee.

Our Institutional Research Committee there consists of four physicians and psychiatrists on the staff, including the superintendent, who is a physician and psychiatrist; also the institutional chaplain; and one inmate, who is the Chairman of the Men's Advisory Council.

I have no particular vested interest in seeing that a protocol is either approved or denied. Actually, my primary goal is the protection of the health of the inmates, and in that sense I think of myself as representing the inmates on the committee.

Our experience at Vacaville in the years I have been there has been mostly one of a happy symbiosis with the coexistence of research in an institution. There have been some administrative problems. Fortunately, we have not had any serious medical complications out of our research.

But we have enjoyed a lot of intangible benefits from the coexistence of research. There is an educational and cultural one. I think it has a humanizing influence on an institution. The inmates--it's a very intangible thing, but the experience in our insti-

tution is that our inmates like it. They want to see it continued. Any people on the outside who are "trying to help them" by shutting down research, they would be very unhappy with.

So this briefly gives you just a little bit of an idea of the situation in Vacaville.

I came to this conference really as an alternate for our superintendent, Dr. Clannon. I hope to see what the trends and what the standards are in different parts of the country, and also hope to benefit from hearing from other states about their experiences.

Biography

Born February 27, 1933, Los Angeles, California. He received his A.B. from La Sierra College, Arlington, California, 1953; and his M.D. from the Loma Linda University School of Medicine, 1957. After doing residency in Internal Medicine and Psychiatry, he practiced privately from 1961-63. In 1963, he joined the staff of the California Medical Facility at Vacaville as an Internist. In 1968, he became Chief Medical Officer and still holds that position. At Vacaville, he has participated in research projects with NASA and the University of California Medical Center Research physicians. In addition, he has taught at Loma Linda University School of Medicine, 1965-66, and is a member of a number of professional and civic associations.

REMARKS -- RALPH URBINO

My name is Ralph Urbino. I am the Administrative Director of the Solano Institute for Medical and Psychiatric Research located within the California Medical Facility at Vacaville.

The psychiatric part of our title is a misnomer, because to date we have not participated in any type of psychiatric research.

Vacaville is the only institution in the California State Prison System with an ongoing research program. The participation involved is approximately 2 percent of the entire state's prison population. But the fact is that it's the only game in town, and as a result, opponents of prison research have no other target except Vacaville.

And of late they have borne down very hard. I just read an article in the *Atlantic Monthly*, for example. Ironically, it has had a dual effect. A second and closer look at all procedures and policies has been taken, and some improvement was found necessary. The effect has been an increase in reviewing of protocols.

A protocol must first be reviewed by the University Human Research Committee, then by the Review Committee within the Solano Institute, and then by the Institutional Research Review Committee at the medical facility, and lastly through the Research Review Committee at the central office of the Department of Corrections.

---

[1]Mitford, Jessica, "Experiments Behind Bars," *Atlantic Monthly*, 231(1):64-73, January, 1973.

rections.

On the other side--I said "dual"--it has created "over-caution," though I hesitate to use that term. I have noticed, of late, a reluctance to approve Phase One proposals.

And that brings me to my last point, that I hope to be able to go back to Vacaville with some kind of an idea from our discussions here as to how we can strengthen the need for Phase I studies.

Another thing that I hope to take back to Vacaville is the establishment of a pay schedule that would be applicable nationwide.

Thank you.

Biography

Ralph Urbino is the Coordinator of Research between the Solano Institute for Medical and Psychiatric Research and the California Medical Facility at Vacaville, California. He came to CMF after spending more than 20 years in the United States Air Force as a military aviator and general administrator. His duties with the Solano Institute are purely administrative; he has been there for the past 11 years. The Institute has enjoyed success with the academic community as well as with corrections; it is very popular with the inmates. The Institute handles the settings for the investigators from the universities. His role is strictly a lay role, the investigators themselves provide the professional services under the guidance and supervision of the physicians at CMF.

Up until the time of the conference, he did not really know that the problems they were having were problems being felt throughout the country, and welcomed the chance to talk about some of these problems with other people at the conference. He found some of the items that were being proposed were actually procedures already in progress at CMF, probably because CMF was a prototype when it was orginally set up.

REMARKS -- DR. ROBERT C. BACKUS

I am Bob Backus of the Institutional Relations Branch of the Division of Research Grants, National Institutes of Health. And I hope before this is over you won't be calling me, "Big Brother Bob Backus," but if you don't recognize the title I have just given you --Institutional Relations Branch--it's because you are not in an institution that is subject to DHEW [Department of Health, Education, and Welfare] policy.

We do administer the DHEW policy on protection of human subjects from this office and, as you probably know, those of you who have been familiar with it, the policy has been through quite an evolutionary process in the last five years.

I might mention in passing that the documentary information you have received does not include the DHEW policy as it now exists. The information you have is obsolete. It is the old Public Health Service policy. The new DHEW policy has been in effect a little over two years. It is the one most of you are familiar with, however, because it ties in with the investigational new drug requirements of the FDA.

The policy we administer follows the federal dollars into the grantee or contracting institution. We are only indirectly involved with any prison population, because funds for pharmaceutical research go into medical institutions around the country, and as far as prison populations are concerned, funds would probably go through a university. So there is only a secondary relationship.

We have felt the same pressures you have out in Vacaville, and we are reacting to them in our own way.

We expect, in this continuing evolution of the policy, to go from here to something that will cover all institutions as sources of human subjects, and we expect to have to apply the policy wherever the federal dollar can be followed, no matter where that institution is.

And I might also add that there is a possibility--and you might as well brace yourself for it, that we are moving toward a federal policy.

I might put in one disclaimer. While I am here at this conference I am not going to be speaking as much for the Department of Health, Education, and Welfare as I am speaking for myself when we get into issues of a controversial nature. The policy is very clear, and if you wish to raise a question concerning that policy, we can handle that when you want to raise it, and I will speak officially when I can. But, providing you with that disclaimer, I would like to get into this a little bit myself.

DR. EMRICH: I think that should be a blanket disclaimer for all of us, that unless someone says something to the contrary, we are all speaking as individuals.

DR. BACKUS: I came up through the NIH system, and if there is any one motivation--there are several, but the one I will allude to is quality of research. We are very quality conscious for the kind of research we want to see done.

I just pose one question in that regard, and that is whether prisoners necessarily represent the best kind of subjects for the quality of research you want to do. There may be occasions when the prisoners do not represent the best source of human subjects.

And in exploring this whole issue with you, I hope we can discuss the possibility of going to other sources. I don't think that has received enough attention--I know it hasn't in the discussion we have had so far--but I think it is a subject that needs a lot more attention.

I know of one or two instances outside of the prison systems where excellent research has been done on non-captive subjects, if you think of prisoners as

captive in the usual custodial sense. One I can mention and that most of you will recognize is the Salisbury Laboratory in England, where they conducted studies on the common cold. This is a very ingenious method, and I think we may have to tax our ingenuity in the future on obtaining suitable subjects for research.

We have to consider what the best subjects are for the research we want to get done, whether they are prisoners or somebody else. And it may very well turn out we will have to devise some additional methodology and impose some additional constraints on other people if we all want to reap the benefits of medical research.

I think someone mentioned at one time here that we need an educational campaign. If that is the case, let's get with it.

If any of you have any suggestions, directly or indirectly, that might apply to DHEW policy development, I would appreciate hearing from you individually or in any other way.

Biography

Born August 25, 1913, Carroll, Iowa. Received his B.S. from Dakota Wesleyan University in 1937; his M.S. from the University of Michigan in 1944, and his Ph.D. in Bacterial Immunology in 1951. He has worked as a virologist, 1945-46, and as a research associate in biophysics, 1947-50, at the University of Michigan; and as an assistant research biophysicist at the virus lab at the University of California at Berkeley, 1950-56. He has also served as a research grants administrator for the American Cancer Society from 1956-57. Since 1958 he has been with the National Institutes of Health in the Institutional Relations Branch.

REMARKS -- VICTOR HENDERSON

I am Victor Henderson, a medical student at Johns Hopkins, and am working this summer for the Medical Care Section of the American Public Health Association in Washington.

The APHA will soon be drafting policy concerning use of captive populations in general as subjects of medical experimentation. In the late mailing, I believe all of you received a copy of an APHA resolution and a draft policy statement in this area, but in view of the fact there is to be a new task force that will be considering this again, I would like to caution that these are probably not the final positions of APHA.

Speaking only for myself, I would like to see this conference address itself not only to what guidelines could be formulated governing the use of prisoners as subjects for testing of new drugs, but also to a more basic question, one mentioned earlier by others here, whether prisoners ought to be used in the first place as subjects for drug evaluations or for any other kind of medical experimentations.

The fact that this is a convenient population for one's experimental design doesn't answer this question. Is anyone in a prison environment today free from or can he be made free from a significant amount of coercion? Does one who has most of his decisions made for him in the routine of his daily life retain the competency to consent to participation in an experiment involving potential hazards to himself? Should one who has had so many rights removed from him by law still retain the right to consent to a procedure not for his own benefit but for the benefit of somebody else?

I think questions like these need to be addressed first, before the issue of guidelines is considered.

Biography

Currently a medical student in the Year III Class at the Johns Hopkins School of Medicine in Baltimore, Maryland, he has a particular interest in the area of medical ethics. Born on August 20, 1951, Mr. Henderson makes his home in Augusta, Georgia. He attended the University of Georgia in Athens, Georgia, on a National Merit Scholarship. Majoring in psychology, he received the B.S. degree with General Honors in 1972, graduating *summa cum laude* and was elected to membership in Phi Beta Kappa. He is presently working as a summer intern for the Medical Care Section of the American Public Health Association in Washington, D. C. Here, his activities include assisting an APHA Program Development Board task force to draft APHA policy concerning the use of members of captive populations as subjects for biomedical experimentation.

REMARKS -- PAUL DUNN

I am Paul Dunn of the NCCD. I am on the staff of the Law Enforcement Council of the agency. Before that, I worked in Iowa for reform in the whole justice system there.

In line with Bob's [Emrich] direction to us this morning, I will try to follow the goal that he labeled as credibility--which is a risky word to use in this day and age, Bob. His understanding of that word is for openness and honesty and interchange of communication. I think he used the word "flexibility," which means I should be able to change my mind if I want.

Since this conference was on the drawing board, I have changed my mind about a dozen times. I was going to say, "I have come here with a closed mind and I hope during the next two or three days you can open parts of it."

There are a lot of cosmic issues floating around, and I find it difficult to put my hand on all of them.

I was interested that Jessica Mitford was already mentioned here. I knew of her, as some of you did, when she wrote another book that must have caused as much consternation in the hearts of association general directors and general managers, called *The High Cost of Dying*. She laid out chapter and verse, with all kinds of gruesome anecdotes, the funeral directors' industry and the league it had with the legislatures. And if you look back, you will see the funeral industry is still in business and still doing quite well.

There was a by-product, though, and that was the increase in the use of and the flourishing of memorial societies for cooperative cremation of deceased people. So it had a small effect.

Another book I am reminded of is Rachel Carson's book, *The Silent Spring*. It caused a great deal of pain and discomfort to chemical manufacturers. It caused them to re-examine some of their products and activities. Without question, Miss Carson's book had a much greater effect than did Jessica Mitford's earlier book.

I don't know how much effect Jessica Mitford's current book, *Kind and Usual Punishment*, will have on corrections in this country. But I think it is fair to suggest that her book will probably have a greater impact than much of what we discuss and conclude here, because she has an audience that does not want to be informed in the great detail that we care to be, and which reacts with gut instincts that I tend to react with sometimes.

What I would like to get out of this conference, though, are the answers to some of the questions that I have put. Yet the questions keep changing.

The first set of questions has to do with some of the legal terms of art: the privilege as against rights; coercion and duress as against voluntariness. I think these have to do with power, which is an unstated part of those equations.

At the present time, the departments of corrections and the administrators of the prisons have the power, and the prisoners don't. The option to participate in or not participate in research activities is filtered to the prisoners through the administration. And I think only when that power is passed directly by the drug research operatives to the prisoners can we then begin talking about voluntariness.

That may or may not be so. I think we can get an answer to that question in the next three days, though.

I have another question, and that is whether this power that pharmaceutical testing has, when passed on to the prisoners, can be used for other purposes, other leverages, to effect change or reform within the system, whether it is a fair wage rate or whether it is a different manufacturing process within the prison or new employment opportunities.

I am asking--and I don't think this question will

be answered--whether pharmaceutical research would permit itself to be used as an agent of reform in corrections. I don't think we will answer that.

Another question I have is really whether captive populations, prisoners in the United States, are a solid population as a test base for long-term continued research. Our agency, and many in the American Correctional Association, some even in the State of Texas, think that there are alternatives to prisons, and that in the long run we will see a disestablishment of prisons. In any case, we will probably see a shrinking of the prisoner base in that the state prison populations will get smaller and county jail populations will get larger, resulting in a shift in population. So in the long term, you may have built models on shifting sands. We won't answer that question in the next few days, however.

Dr. Arnold raised another question about national priorities, which I have thought about a bit, in finding a test population. He suggested a national selective service or jury service type of selection. I can think of using the draft or the lottery or some form of conscription of research subjects, as legitimate and as constitutional. If Congress or the nation feels that its priority for seeking therapeutic cures is great enough, there is certainly power in the government to create that.

It may be debated.

My last question, the one I came to the whole subject with last winter, is: How important, really, is progress?

This is a simplistic approach. Have we not gone far enough with air-conditioned cars and filtered cigarettes in which we are quite well advanced? I think more and more people will be asking the question: Do we need new therapeutic drugs?

The other part of it is: Is the research such as to not violate the commandment, "Do not mess over some other human being"?

I think Dr. McMahon may have to discuss this, where he says the medical precept is to do no harm and yet you have to do harm to eventually do some good.

I think we can find an answer to that question in the guidelines and standards we are looking at here. There may be some way of judging that question.

Biography

Paul F. Dunn (Director, Law Enforcement Council, National Council on Crime and Delinquency, Hackensack, New Jersey) is the staff support for the 24-member council since its inception in 1971. The Council develops standards, programs and guides addressed to both public and private law enforcement issues. He was State Director of the Iowa Council of NCCD, from 1969-1971, where he administered the Des Moines Community Corrections Project for NCCD and worked to develop regional corrections centers in the state. From 1967-1969 he was coordinator of the Washington State Attorney General's Citizens' Committee on Crime, writing the OLEA comprehensive criminal justice state plan. A law graduate, he has worked for Legal Services Centers in Seattle-King County, Washington, and for private insurance companies in Seattle and Detroit. He was a board member of the Iowa Civil Liberties Union, and a founding director of the Washington Consumer Interest Committee. He has written on welfare law and procedure, consumer education, police policies. While on the staff of NCCD he has contributed to surveys on police education, probation reporting, and has taken part in numerous criminal justice training and evaluation efforts.

REMARKS -- MS. CLAIRE COOPER

I am Claire Cooper of the American Civil Liberties Union.

I think I should tell you first what my purpose is, and then tell you the rest of what I have to say.

My purpose is to refine or destroy my own premises, the premises I came here with, and to hope that you will be open to having your premises refined or destroyed by anything I may have to say.

I always hope that any solutions that are formulated will respect the civil liberties of any individuals who may be involved. I'm most concerned that civil liberties be protected, but how you go about doing that, I'm not sure.

I will go on to tell you briefly what my premises are. There is nothing that hasn't been said in this room, but I'll tell you how I put it together at this point in this conference.

I think that medical advances are all to the good of civil liberties, because they enhance an individual's opportunities to exercise his or her civil liberties. However, I think that the prison system at present is so defective that the prison environment is inherently and pervasively coercive. Therefore, prisoners' free and informed consent to participate in drug experimentation at present is impossible.

I don't think that these defects in the present prison system are the fault of the drug industry or the universities. I think that the defects are the fault of the prison system and of the larger society. But I do think that the drug industry and the universities

can help perpetuate the present defects by taking advantage of them.

To be more specific about that, all of the benefits, so-called benefits, I have heard spoken of, benefits to the prisoner population as the result of medical experimentation, would not be benefits if the prison system worked correctly. If peonage or near-peonage were ended, then prisoners would not so-called "benefit" by getting money by offering themselves as experimental subjects.

If there were objective and stated criteria for parole, prisoners would not try to earn good points by subjecting themselves to experimentation.

If a clinic were not a better environment than a cell, prisoners would not want to go into clinics rather than cells.

And there are subtler kinds of coercion that exist in prisons that should not exist.

Biography

Claire Cooper, Information Director at the American Civil Liberties Union, was formerly a freelance writer, Senior Editor of Prentice-Hall, and a journalist. She is a graduate of the University of Florida and New York University and an author of numerous articles on a variety of social issues.

REMARKS -- DR. MONROE E. TROUT

I am Monroe Trout. I am a physician and attorney. At the present time I am Medical Director for Sterling Drug, and I also am serving a term as President of the American College of Legal Medicine.

We have a committee which has been working for over a year now on this very issue, and related issues, and I have to say that at our last convention we had a very long, heated, emotion-filled discussion from the floor, and came to no resolution. So the committee is back to the drawing board.

I am here to hopefully learn, and I am delighted to participate, to be exposed to viewpoints that frankly I am not exposed to on a daily, weekly, or monthly basis.

I am deeply concerned about the whole area, because there has been a lot of rhetoric; politics has become involved; there has been sensationalism. Events have occurred, some of which have nothing whatsoever to do with clinical research, but which are being used by those who want to sensationalize the areas as though they were episodes of clinical research.

I believe that what we do and say with regard to research with prisoners will be applicable to other population groups, and I think we should at least keep this in the back of our minds.

I refer to the pregnant woman, who has a foetus that cannot give informed consent. I refer to the mentally ill, who cannot give informed consent. I refer to children, who cannot give informed consent. And I really also refer to students, because I believe that students are in the same category as prisoners

since there is that coercive idea of grades from the professor.

But I am also deeply concerned that if we ban research as far as prisoners are concerned, we are going to ban research from all of these other groups. We will have no therapeutic agents for children; we will find no cures for mental illness; we will make therapeutic orphans out of pregnant women.

So I think whatever we do with regard to prisoners will have a carry-over. And I think in the long run, if it becomes sensational enough, if it is filled with enough emotion--and I have heard this expressed on several occasions within the past week--we will have a national moratorium on all research.

And I think that if this occurs, then only society is going to suffer. Your children and my children will suffer. And some of the great illnesses for which there is no cure at the present time will have no cure found, at least in the United States.

I hope that we can reason and be reasonable, and that we can let the emotion and politics be behind us. I think that we should concern ourselves with some of the incidents that have occurred, but we should also remember that there are built-in mechanisms already to take care of some of the violators of ethics and morals, and I really don't believe that we can legislate morals. But we have licenses, more or less, for physicians; we have FDA regulations; we have, now, a 30-day waiting period before Phase One; we have peer review.

These mechanisms are built into the system. I think what we need now are really guts to use them.

I think that as far as prison research is concerned, or, in fact, any research, there is a duty to inform--and I don't like the term "informed consent," but I think there is a duty to inform. I think that whoever the recipient of the research is, he should be free from as much coercion and seduction as humanly possible. And, of course, in any type of research one must always balance the benefits to risks.

I don't believe that the industry can take on all the burdens of prisoners and all of the peripheral issues, but I think that the industry should be responsive to the areas of concern in research. I think that we need to look at the various phases of research, as the FDA has said. I don't think they are sacramental; I don't think they should be. I think there are many drugs in the United States that could go into Phase Two or even Phase Three and skip Phases One and Two.

I am thinking of drugs which are already on the market in such countries as England and France. I am thinking of drugs where it would be actually unethical or immoral to go into Phase One, drugs such as those that are used in the therapy of cancer.

So I don't think that the FDA phases are sacramental. I think we need to take a very close look at them. I am not sure we need the large numbers of patients that are used before new drug approval is received.

I would hope to get from this conference some areas of agreement, certainly identification of the areas of disagreement; if possible, some pluralistic guidelines, but I am not sure that is going to be possible; and hopefully to learn more about some of the problems that the corrections people have, that prisoners have, that the academicians have, so that when I make my decisions as far as new drug research is concerned, I will be better informed, and hopefully make better decisions.

Thank you.

Biography

Received his A.B. and M.D. degrees from the University of Pennsylvania and his LL.B. and J.D. degrees from Dickinson School of Law. He is currently Medical Director of the Sterling Drug Inc. and President of the American College of Legal Medicine. In addition, he is Trustee, Cleveland Clinic and Dickinson School of Law, lecturer in Legal Medicine at Dickinson School of Law, and Associate Professor at Brooklyn College of Pharmacy. He is a member of the Board of Editors on Forensic Science; Journal of Legal Medicine; and Hospital Formulary Management; the Secretary's (HEW) Commission on Medical Malpractice; and the Sterling-Winthrop Research Board.

REMARKS -- DR. MARION FINKEL

I am Marion Finkel. I am a physician and currently Deputy Director of the Bureau of Drugs in the Food and Drug Administration.

Dr. Kelsey has expressed our interest in research and the use of normal volunteers, so I won't reiterate that.

I would like to make a comment with respect to what Dr. Arnold said. I was about to agree with him that there is no real alternative to the use of prisoner volunteers if we are going to get the same kind of safe, detailed research that we want in this country and have come to expect, until I remembered what Dr. McMahon from Tulane said.

Dr. McMahon, of course, not only uses students, as he mentioned this morning, but he also uses hospitalized patients who are not very ill, and who are able to be used for Phase One types of studies. They are volunteering for studies of drugs which they don't even need.

I suppose it is possible to set up more experiments of this type and go away from the use of prisoners, but I think that is irrelevant. Dr. McMahon's concerns are the same as the concerns of any investigator who uses normal volunteers, namely, patient safety and patient consent.

Also, I would submit that if one did not use prisoners and simply went to other closed environments, such as hospitals, that instead of this group sitting here today, there would be a group with different faces who would be involved in devising guidelines for the use of hospitalized patients as volunteers for investi-

gational studies with drugs from which they could not be expected to immediately benefit.

What do I hope to get out of this meeting? What a number of other people have expressed, namely, some guidelines which will hopefully give us the best use of normal volunteers that we can have.

Biography

Born November 2, 1929. Educated at Long Island University 1945-48, received M.D. from Chicago Medical School, June 1952. Has privately practiced her specialty in internal medicine in New York City and New Jersey. Has served as a clinical instructor at the New York University Post-Graduate Medical School, 1955-61; and at the Georgetown University School of Medicine, 1963-present. Hospital appointments include: Head of a IV Medical Division Diabetes Clinic, Bellevue Hospital, 1958-61; Attending, Medical Clinic, Georgetown University Hospital 1963-64, Diabetes Research Clinic 1964-67; Assistant Visiting Physician, Bellevue Hospital, 1956-61; Adjunct Attending in Medicine, Paterson General Hospital, 1962-63; Associate in Medicine, Valley Hospital, Ridgewood, New Jersey, 1962-63. She has held several positions with the Food and Drug Administration: Medical Officer, Bureau of Medicine, 1963-66; Director, Division of Metabolism and Endocrine Drugs, Office of New Drugs, Bureau of Medicine, 1966-70; Deputy Director, Bureau of Drugs, 1970-71; Director, Office of Scientific Evaluation, Bureau of Drugs, 1971-72; and Deputy Director, Bureau of Drugs, 1972-present. She has also held several honors and has published various articles and papers.

REMARKS -- REX HERRON

I am Rex Herron. I direct a project for NCCD called the NewGate Resource Center. We are in the business of providing information and technical assistance nationwide to corrections agencies and/or universities who are modifying, or developing programs of post-secondary education for offenders. Our approach is to encourage replication of the NewGate model program, a program now operating in seven states.

My interest in the criminal justice system has developed through my association with NCCD and graduate experience in criminal justice administration. In 1971 I finished seven years experience in corrections as a recipient of justice. As an ex-offender participant in this conference I would like to make an important distinction in what the ex-offender role implies. That is, I cannot and will not attempt to speak for or represent the collective voice of inmates. What I do feel I can offer is another personal perspective to the issues that will be debated at this conference. I feel competent to speak on the *conditions* of incarceration, but not on the many thousands of inmates' subjective feelings toward being incarcerated.

I am pleased that there appears to be a great deal of concern over the "coercion" issue. I don't think we can overdo attempts to really understand the many effects and connotations of this issue. Many elements of institution coercion are so subtle that they are lost to the awareness of inmates. That's how "institutionalization" or "prisonization" occurs. The coercion issue is inseparable as an inverse relationship to voluntariness which, as I understand, is a major concern confronting our interest in drug research with prisoners.

Recalling my prison experience and the many choices I felt were made freely and voluntarily I can see now how freedom of choice is relative--and contingent upon environmental conditions. And if we are attempting to establish guidelines for drug research which reflect concern for high ethics, I suggest that while a prison inmate may have legitimate opinions in this regard his opinions, at the same time, must be heard in the context of his situation. An inmate, for example, may not see monetary incentive as coercive. And I believe it is. The point here to me is not that we consider coercion unethical but that we accept it as an unalterable fact of institutional conditions.

I am anticipating three benefits of this conference. The first is personal in that this is my first experience at publicly identifying myself as an ex-offender. If the discomfort I feel at this moment eases, I will consider some kind of personal growth has taken place. Secondly, this conference should be educational. I do not understand what Phase One research is, and am interested in how the degree of subject-risk is determined. Third, I am interested in how it might be determined at this conference to utilize offenders or ex-offenders as participants in policy making.

Additionally, I would see some of the same issues and concerns of this conference applying to other aspects of correctional treatment--perhaps at some more enlightened point in time, but as an example, we may some day question the whole aspect of institutions as treatment facilities.

Other than that I am pleased to be here and excited about the potential results coming from such a broad range of professional people as are gathered here.

Biography

Rex Herron is Director of the National Council on Crime and Delinquency NewGate Resource Center, Hackensack, New Jersey, a national project whose special function it is to provide information and technical

assistance in the development, modification or expansion of post-secondary education programs for offenders. Mr. Herron received a Bachelor of Science degree in psychology from the University of Oregon, Eugene, Oregon, in June 1971, where he was named Woodrow Wilson Designate. In June 1973 he was awarded a Master of Arts degree in criminal justice administration by the School of Criminal Justice of the State University of New York at Albany where he was a Ford Foundation Fellow. Mr. Herron received his undergraduate degree as an inmate and school-release student while serving an eleven year sentence at the Oregon State Penitentiary, Salem, Oregon.

REMARKS -- KEN JACKSON

My name is Ken Jackson, and I represent the Fortune Society at this conference. My main purpose in attending this conference is to gain some insight into this facet of the prison system to be better able to answer questions from those who write to the Fortune Society who are being considered for one of your research programs.

The Fortune Society is an organization, New York based, of ex-convicts and other interested people. Eight years ago I received a phone call from an attorney friend of mine who asked me to get in contact with a fellow who had gone out of his mind, who felt that he could bring about a change in the prison system in this country.

I saw no need for that change, because I had solved the crime problem in my own home. I had two locks on every door; I had a dog to eat people if they came near my home; I put an alarm on my car, and didn't allow my wife and children out after dark.

But in meeting with him, I found he wanted to offer something that hadn't been offered before. I, too, believe there is no alternative presently to prison, so I think we have to create an alternative to crime. I think one of the ways we can do that is by not exploiting people as we have in the past, and by setting up guidelines where people who feel they are being exploited might rid themselves of that feeling.

I came to this conference hoping to hear discussions regarding behavior modification but I learned since arriving that that is for another conference.

Biography

Mr. Ken Jackson, President, of the Fortune Society, joined the Society when it was formulated in 1966. He is a member of New York City's Board of Corrections, having been appointed by Mayor John V. Lindsay and a member of the New York Criminal Justice Coordinating Council, which is under the direction of the Mayor. He is also on the Executive Board of the National Alliance for Shaping Safer Cities. Educationally, Mr. Jackson claims to be a "grammar school throwout" with no degrees, but as an ex-convict he teaches a course in criminology at the Adult School, Greatneck, Long Island. He is married with two children. His concern with behavioral modification and psychosurgery as serious abuses of prisoner's rights brought him to the conference.

REMARKS -- CONNOR NIXON

My name is Connor Nixon, and I am with the Prisoners' Union in San Francisco.

I would like to give you just a little background on the basis of the Prisoners' Union. We have been in operation for approximately two years. We are formed and composed of--the original group--a series of convicts and ex-convicts, basically out of Soledad, Folsom, and San Quentin, who attempted while in the institutions to create a manner in which the convicts would have a voice and a say-so in what happened inside of those institutions in a manner that did not necessarily have to reflect in terms of violence.

During the original stages, we decided on the structure of the union.

We felt, number one, the union concept, being pragmatic, was that was a weak point inside the correctional departments and penitentiary systems in the United States, and when you look at the prison systems you recognize that although we have a difference in terminology on who runs the system, the convicts in fact do run the system, and once organized into a peaceful body they would play a role similar to labor unions on the outside.

During this time we have gained a membership of 13,000. We are now in 11 states. The specific goals of the union are:

First, not only a minimum wage, but a decent wage, a comparable wage to the outside work that is done by free people.

Second, a full restoration of human and civil

rights, with the possible exception of freedom of travel inside of those institutions.

Third, an end to the indeterminate sentencing system which we are presently forced to live under in California and in those states that do not have a determinate sentencing system, a modification in a real sense, a change in the sentencing systems that are presently in existence.

Fourth, an enlarging of the educational and vocational facilities inside a prison, so they realistically prepare a person when he is eventually returned to society.

Overall, with those four goals, the way we intend to implement those goals is through collective bargaining as equals on the inside of penitentiaries.

As Kenny [Jackson] just stated to me a few minutes ago, talking about the difference between change and reform, our concept is not reform in the penitentiaries. I do not believe you can reform an institution, an organization that is permeated with cancer. And that is the view that we hold as ex-convicts and convicts.

As to the goals, the ideas which we hope to get out of this conference and in the near future, the key goals that I think our membership inside the prison walls would like to accomplish in this conference in the near future is the removal of any corrections department control over any medical research or health-care delivery inside of prisons.

Dr. Ayd suggested that we separate those into health care versus therapy versus research. For this conference that may be very important, but as the convicts see them, there is very little difference, and they are coupled together in terms of the corrections department.

It is our firm belief and conviction that the corrections departments in all of the fifty states in the United States and the federal institutions have lost all moral rights, due to the neglect and the outright misuse of the medical community and of the convicts to have any degree of control over or any say-so concerning the health care or research on convicts. We advocate a cooperative control over the medical delivery

and research between the recipient of the medical delivery and the local medical communities, without any intervention whatsoever of the corrections department.

Biography

Member, Board of Directors, Prisoners' Union , he has a B.A. in Political History. Although he passed his bar examination in law, he was not admitted to the bar due to a marijuana charge against him. Conner joined the Prisoners' Union about six months after it was founded. The Union at that time was comprised of one chapter and 500 members. Since then it has grown to encompass some four Union offices and 20,000 members in four states. Since the time of the conference, Conner has left the Prisoners' Union to take up a new career, in which we wish him the best of luck and all success.

REMARKS -- R. CRAWFORD MORRIS

I am Crawford Morris from Cleveland, Ohio, and I am a medical malpractice defense trial lawyer. I have defended the Academy of Medicine in the Sabin oral vaccine experiment in which four people got or claimed to have gotten poliomyelitis. We went through the whole bit of differential diagnosis and Coxsackie virus and Echo; we worked out a lot of those things and settled it and took a lot of testimony from doctors all over the country. It was a very interesting experience, and there was some feeling from some very high people in my community that the people had been over-sold on the safety of the vaccine.

My second case involved 11 Thalidomide cases, of which three were experimental in the Ohio area. We finally got those worked out. I am back in the Thalidomide game in a class action on behalf of all the remaining children in Canada. The drug was on the market in Canada, so it was not experimental. But I have defended other experimental cases in court.

Then I was asked to be on the Clinical Research Committee of Case Western Reserve. We pass on all medical experimentation on human beings done there, and that has been a most interesting experience.

I must confess to you that with all this experience I have no expertise on the criminal side, either on the in-patient or out-patient side, and I say that with some humility. I know nothing about prisons. All of the research and experimentation I have seen pass through our committee has not as yet involved prisoners.

I would like to make a contribution to you along this line. I would like to play the devil's advocate for a very brief moment, and rise to meet this problem

which confronts me as I have listened so far.

I hear so much talk of prisoners. Prisoners of what? Of life? I put it to you that we are all prisoners of life. There is nobody in this room, man or woman, who is a free agent. We are all prisoners, one way or another, of our economic background, of whatever company store we owe our soul to.

I am certainly a prisoner. I am a prisoner in an institution. It has bars and it has rocks, and they are invisible and intangible, but they are real. As a senior partner in a conservative law firm, I am required to lead a conservative life. I would not be allowed to grow a beard, and I see men wearing beards, and I am not free to.

So I pay a price, and I am a prisoner.

And every one of you is a prisoner. As close as I can come is a little baby, one day old, born of extremely wealthy parents, who has his life ahead of him--and at age six he is a prisoner; he has been programmed by his childhood conditioning.

If you have read Jonas Salk's new book, *Man Unfolding*, you will realize all of us live our lives having to live out the programming our parents gave us. It's too damned bad. At 21 you ought to be a free agent. You never are.

The point I make here is when we talk about prisoners in institutions, I don't want to differentiate us from them. We are prisoners of life as they are prisoners of the bricks and mortar institution. And we have our problems, and they have theirs.

To me, they are no different in kind from us. They are different in degree, as there are different circumstances, and I am sure some of them need correction badly. But they are no different in kind.

My plea is that we treat the prisoners in this discussion just as the Oklahoma people want to, and as Dr. Trout talked about, as human beings. They have gotten themselves into a situation not of their own choosing, as I may have slipped into the profession of law not of my choosing. Some things are coercive to them, and some are not. I may have had a dream to be an architect.

I can't; I'm stuck. I have children in medical school. It's too late for me to change.

I envy them. While they are there, they have that precious commodity, time, and I have none of it. Neither does any other professional man or woman. But they have the time to train themselves.

I cite you the example of some prisoners who have become lawyers and gone out and practiced law. Malcolm X was a very bright man who had never had a chance, and in seven years in prison he educated himself beautifully and became very religious, and unfortunately was destroyed by his own people.

I am trying to make the point as briefly as I can that we are all part of the human race, and I think we should treat the prisoners and their problems as part of our problems. And I think we should not deprive them of the freedom to enter research if they want to enter it.

I think we want to make sure that the people who speak for them really speak for them, and they really do want it. But if they want it, I think they should have it. I don't think they should be entitled to any advantages we are not entitled to, just because they happen to be prisoners of life in an institution while we are prisoners of life outside an institution.

But I think they are entitled to every safeguard we are, informed consent, peer review, decency and integrity, subject to the limitations of the correction they are required to go through.

That is my plea, and that is what I hope comes out of this conference.

Biography

Born October 29, 1916, Columbus, Ohio. Educational background includes: A.B. from Princeton University in 1938; LL.B. from Harvard Law School in 1941. He is currently a partner and a senior trial lawyer of Arter & Hadden, Cleveland, Ohio, a law firm specializing in

the defense of medical malpractice and products liability cases. He has defended in 32 years of practice such companies (products liability) as Proctor & Gamble, The Upjohn Company, Richardson-Merrell, Inc., Parke Davis & Co., Johnson & Johnson, Merck, Sharp & Dohme, Smith, Kline & French Laboratories, and Brown & Williamson Tobacco Company, as well as numerous doctors and hospitals. He is presently chairman of the Malpractice and Professional Liability Committee of the International Association of Insurance Counsel and served as a member of the Legal Issues Advisory Panel to the Secretary's (HEW) Commission on Medical Malpractice, 1972. He is a recipient of numerous awards, a member of several professional societies, and has published extensively.

REMARKS -- JOHN TROWBRIDGE

I am John Trowbridge, a student of medicine at Case Western Reserve University in Cleveland, representing the Student Medical Association at this conference.

At our recent national meeting, there was active floor debate concerning human experimentation. The result of the debate was a resolution which urged that national uniform standards be applied across the board for some kind of review of ethical practices and scientific protocol for human experimentation, *if* it were to proceed at all. Basically, the Association is concerned with finding out what goes on at this meeting, and how we can best implement the action our body has taken.

My background in humanities leads me to feel we have to remember that life pretty much blurs across a spectrum--a gamut that usually is critically examined, *only* in the area of what is often called a thin line that one can cross between right and wrong or black and white, or whatever.

For example, many blades are sharp, but some of these are relatively dull; and many blades are dull, but some of those are relatively sharp. And the critical question focuses on the very thin line of distinction between the sharpest *dull* blade and the dullest *sharp* blade, for here is where categories are assigned, where something is declared to be "this" or "that."

And this line is the distinction between those of us who are free-living individuals and those of us who are captive, in the sense of being confined to an institution. At some point, some decision was made whereby a person crossed that line on whatever basis,

whether selected by judges or by juries or by physicians or by Fate, some persons have been separated from others in terms of relative freedom. A person can become a captive in a mental institution or custodial center or prison, and these captives have limited abilities, and access to methods, to protect their own civil liberties. The task to assure that those civil liberties are protected is *ours*. It remains absolutely the responsibility of those of us who are free-living and who *do* have free access, to employ various methods to protect civil liberties of those in compromised settings.

All of us are human beings, not S's, as subjects are referred to in reports on experiments. We have to remember the thin line of distinction between S's and human beings. It is easy to slide that line, to depersonalize human beings when they are replaceable units in a research program. Because one person participates in experiments and another does not, does not reduce one to being an S, while the other remains a human being. "There, but for the grace of God, go I," is really the fundamental standard by which human experimentation should be conducted.

The decisions that will be reached in the work committees here could affect what is going on in a good many areas of human experimentation, but they just as likely could result in a lot of hot air. The recommendations of policy, I would hope, could be founded upon such *compelling* bases that they will be accepted by all organizations that are involved with captive populations, not just correctional but other custodial situations as well.

If we don't face this problem, it is likely that we could remain *eloquent but impotent*, and our work and efforts relegated to the same obscurity as many past presidential commissions that have failed to justify the expectations of the Chief Executive. So I would hope we could consider mechanisms by which we could convey our results to people in useful ways, so that they could *use* them in the work that they are doing or considering.

Biography

He was graduated from Stanford University with an A.B. degree in Biological Sciences in 1969. An emphasis in studies in the humanities has led to continuing efforts to stimulate consideration of the ethical overtones in the many concerns of science and medicine. His research interests have centered mainly in immunology and congenital heart disease. He received advanced training in clinical laboratory technology and authored a limited-circulation text on laboratory methods in blood clotting. A native Californian, he is currently living in Cleveland, where he is a second-year student in the School of Medicine, Case Western Reserve University.

REMARKS -- LUDWIG DIMPFL

I am Ludwig Dimpfl. I am by profession a research chemist, and in the petroleum business with the Chevron Research Company in Richmond, California.

I have never had anything to do with medical research, and from what I have seen since I have come to the conference, I think I am fortunate that I never got into the medical field.

I think I would go mad.

I know what I would wind up doing. If I developed a drug that I had adequately tested in animals, the next thing I would do would be to take it myself before I went through these interminable delays of protocols. I would probably get so impatient I would wind up doing that with every drug until I finally made a mistake and wound up damaging myself permanently in some way and putting myself out of business.

The other thing I see is that the level of concern of this group here is sensitivity to the general public pressure for more of the kind of review that would already drive me up the wall.

So, talking in terms of what I would hope to see here, it is some recognition of the fact that you can't ignore what the purpose of this research is in the first place. The purpose of this research is to do something that will do humanity some good. With the amount of encumberance that is already put on this kind of research, I don't see how anybody of a creative nature maintains his sanity in the business.

This is a pre-impression that I have and, as you can see, it has to be a very superficial impression,

because I have only been exposed to people in this business for today.

But I went into the chemical profession with a view to doing something for humanity. I wanted to have the world somewhat of a better place to live as a result of my having been in chemistry. And I think that I have managed to accomplish this in my career with the oil business.

It has taken me many places. I spent three years in the Middle East training Iranian nationals in how to run their own research business, and I think I helped them a great deal so they could help themselves, where they couldn't before in the colonial days.

When you look back on things that you have accomplished, when you are through with them, you get better at accomplishing more; you are able to accomplish more.

Of course, medical research is a completely different field from the kind of thing that I am in. The time scale has to be slower because mistakes are more serious. But someplace along the line you have to be able to put something through to a result that is meaningful. And I don't know how you get into that situation without mistakes, without accidents happening. Good Lord, I certainly learned from my mistakes. And most of the people that I see that are not creative are the people who are so careful that they are afraid to make a mistake, and they spend their lives spinning their wheels.

The thing that I am looking for is either to find out that my assessment up to this point of pharmaceutical research is mistaken, or some hope that some progress can some way be made to increase the results of medical research progress by releasing it from the very heavy load that it is dragging along now--not in terms of taking unnecessary risks, but just in terms of recognizing that every worthwhile human activity has risks connected with it that can't be avoided.

Biography

Received his B.S. in Chemistry from the University of California at Berkeley in 1940. Since then he has been engaged in industrial chemistry and chemical engineering research, most of it in the petroleum field. His developments include test methods, chemical additives, and refining procedures to prevent fuel system deposits (i.e., filter plugging) in jet aircraft and home heating systems; asphalts of improved durability for highway paving; and computerized refinery control of asphalt manufacture. He trained Peace Corps volunteers, and in 1964 went to Iran to demonstrate a practical way in which villagers could use asphalt to waterproof their mud houses. From 1960-62, he was employed by the Iranian Oil Refining Company at Abadan, Iran, where he organized a development laboratory staffed entirely by Iranian nationals. He is currently Senior Research Associate, Chevron Research Company, Richmond, California.

REMARKS -- CAROL PALLEY

My name is Carol Palley, I am the recorder for the Procedures Work Group. I plan to attend medical school, although I am not currently enrolled.

The field of research in prisons is new to me, and already I am learning a great deal. I hope that in the next few days I will have the opportunity to learn a lot more.

One concern I do have, which may be somewhat peripheral to the topic of this conference, is about the abuse of drugs. My husband and I both work with young people, primarily teenagers, a good number of whom are now abusing drugs manufactured by our pharmaceutical companies. The damage I see done to these young people makes me wonder: Are these drugs, in fact, beneficial enough to the greater part of our society that we should be marketing them? The drugs I am referring to here are mostly the tranquilizers and mood-altering drugs.

This subject is, as I say, somewhat peripheral to the main topic of discussion here, but I am concerned with the primary research of these drugs. For me the problem of the ethics of drug research includes the problem of whether the benefit gained from many of these drugs is enough to risk losing more of our young people to their abuse. There needs to be some kind of control of these drugs. Should it be on the research level?

Biography

A 1972 graduate of the University of California, Berkeley, her major field of study was Geography, though she also completed a pre-med program. She plans a career in medicine and hopes to attend medical school in the near future. She has worked in the field of drug abuse prevention with the Committee on Alternatives to Drugs in Berkeley, California, and with Karma House, Inc. in Rockville, Maryland.

REMARKS -- MICHAEL MILLS

I am Michael Mills. I am at the Center for Studies in Criminal Justice at the University of Chicago Law School. I am a law student and in the course of this past year I have been doing some work with prisons. As a result, I have tended to divide the world into law students and prisoners, and it is something of a pleasure to discover that there are other people around. Doctors, at least, have been added to my world.

I have a couple of general observations, a couple of specific ones, which may, as is inevitable when so many of us have been talking about the same issues, be slightly repetitive.

I have been troubled with the thought in the beginning of this discussion that the issues of the quality of prison life could somehow be separated from those of human research. I think this conference exists because they cannot be separated. If it were possible to isolate human research in prisons from the character of prison life, then the NIH could solve its problems without any input from people who have experience in prisons.

So I would hope that although we do not place the burden of solving prison problems on the pharmaceutical industry or the academic research community, we would not forget those two issues are, for our purposes, anyway, inevitably related.

The second general remark is that although I am not sure I agree with Milton Rector that these changes are around the corner, it is nonetheless true that there are two major changes in correctional policy which I think will begin to have substantial effect on the kind

of research that can and will be conducted in prisons.

The first of those is the experiment now about to be tried in the federal system with the full wages prison, in which prisoners will be paid a going market rate for their work. It is true that the federal system is much advanced over any of the state systems in this respect, but if that experiment is successful, as it has been in a number of European countries, particularly in Denmark and Sweden, it may spread.

I think the implications of that are obvious. If a man is being paid $3.50 an hour to assemble beds in California or to work in a bakery in a prison, then he is going to have to be paid an equal amount, at least, if he is to be attracted into a medical research project. That, I think, will have some influence on how we look at coercion.

A second change in the economic situation in prison is, as Milton [Rector] suggested, the increased involvement of private industry in prison industry. The Federal Prison Industries, Inc. is an independent corporation which does contract and subcontract work for private corporations. That idea, I think, will gradually be extended to state prison systems. It is probably a desirable thing, because it means that prisoners are, in fact, being trained in and working in occupations that are more useful than those of making mailbags or license plates or keeping the warden's garden weeded.

I think that just incidentally we should be a little cautious about proceeding in that direction. For years the chain gangs in the South, and perhaps elsewhere in the country but mostly in the South, were contracted out at great benefit to the warden and no great benefit to the members of the chain gang, to do labor on private farms. So we should be cautious about selling the prisons to private industry, but I think we should be open to the idea that private industry, provided the prisoners are properly paid, can make a contribution.

Such a change in corrections is what I guess is loosely and generally called the move to community corrections. I can give you a simple example of that. I was talking last week to the warden of a prison who said, "Yes, we used to have a medical research project here, a diabetes project, but the State of Vermont is closing down its general penitentiary and distributing

prisoners around the state closer to their work and homes, in centers with an average population of 30 or 35 men. As a result, the size of the population pool of the state penitentiary is no longer large enough to support a research project."

How rapidly and widely that is going to happen, I don't know, but certainly most people in corrections think that kind of change is a desirable one: first, that fewer people be institutionalized, that more people be on probation or other kinds of independent release; and second, that if there are institutions they be much smaller ones.

And if one can only get 20 percent of the prisoners in a prison to volunteer, 20 percent of 150 is very different from 20 percent of 3,000, and it may be increasingly more difficult for prisons to be used for research.

I would like to make a couple of comments about coercion.

I am not an ex-convict, and like Crawford Morris I don't have real experience or expertise in prisons. I have, in the course of doing some work on medical research in prisons, visited a number of prison research clinics, and it is very clear to me that although the monetary payment is the key--"seduction," as Dr. Trout said, may be a better word than "coercion"--there are, nonetheless, real qualities of prison life that make the clinical setting a very attractive one.

At Stateville, the Illinois penitentiary where the malaria project has been conducted for many years, the research participants are in a separate, air-conditioned ward in the prison hospital. I was there recently on a July day when it was 95 degrees outside, and these prisoners were the only ones living in air-conditioned comfort. They said they ate better food, food the guards ate, rather than what the prisoners ate. So the circumstances of life itself are vastly more attractive in a patient clinical research operation.

Secondly, the issue that Bob Woodson and Connor Nixon raised about parole, whether or not the prisoner is, in fact, released earlier because he has participated in a medical research project, really doesn't make any difference. The question is what he *believes*.

Nathan Leopold of Leopold and Loeb was a participant in the malaria project at Stateville, and he said, "We were specifically told we would not be released early because we had been involved in the malaria project but it was a chance we couldn't possibly not take. The most important thing in our life was to get out of prison, and anything we thought would influence that decision, no matter how marginally, we would be willing to do."

A comment about money. Illinois has a relatively better prison industry and prison pay system than most. Prisoners in the malaria project are paid something in excess of $1.50 a day, plus specific amounts each time they are infected with malaria, which is about as high as the prison wage scale goes. The attraction of money, aside from toothpaste and cigarettes, in prison is, as one prisoner said to me recently, "When I get out of prison I'll get $50 from the prison system, that's enough to buy a Saturday night special and a couple of bullets, which will serve as a stake to generate a little money," which he can then use to regenerate himself. Fifty dollars doesn't go very far on the street these days.

The prisoner who told me that had been involved in the malaria project for three months, and expected to be on the project for another six months, until his discharge, at which time he would have earned a couple hundred dollars which he thought would get him over the period required to establish himself in the community. He had a wife and a kid and wasn't willing to take the risk of buying a Saturday night special and sticking up a gas station again. He thought the malaria project, in addition to being a better way to spend life in prison, was a way to earn money. That is an additional seduction.

An additional thing is although I think the drug companies are not responsible for the quality of medical care in prisons any more than the universities who are conducting research there are, it seems to me, a prerequisite for the conducting of research in prisons is that the medical care available to any subject in prison be as good as the medical care that would be available if he were in Gilbert McMahon's teaching hospital or somebody else's private hospital anywhere in the country.

The drug companies cannot solve that, but I think those people in government or corrections, or those here who have some policy-making authority, need to understand that.

I think that conducting research where first-class medical facilities are not available is inherently irresponsible and unethical from the medical point of view.

I would like to say something about alternate populations. I will borrow a line from Jessica Mitford testifying before the Kennedy Committee earlier this year. She said the most appropriate people to volunteer were the stockholders of drug companies. I am not sure that is true, but perhaps because I have been trained at the University of Chicago where we have a 19th century view of economics, thanks to Milton Friedman and a number of other people, we believe if you pay enough you can get people to do anything.

But it seems to me we should not be willing to say we cannot have alternative populations. We should consider hiring people to spend three months in a hospital. There are plenty of people around unemployed.

I am uncomfortable with the idea of drafting people. In some circumstances I might be willing to consider that. If there were 5,000 people dying of typhoid in the United States, we might have an interest comparable to the military one.

Biography

Michael Mills received a degree in Political Science from Reed College and is presently completing a law degree at the University of Chicago. He is a research associate of the Center for Studies in Criminal Justice and has done work in the areas of prison history, victimless crime, plea bargaining, and corrections. He has assisted the Advisory Board of the Illinois Department of Corrections in drafting policies for the participation of prisoners in medical research.

REMARKS -- ROBERT WOODSON

My name is Robert Woodson, and I am with the National Urban League, a human rights, human service delivery organization, established well over 60 years ago, with a history of service to the community in general and the black community specifically.

And we are trying, at the Urban League, to accomplish something that seems impossible for mankind to accomplish, and that is to benefit from our own history. And our own history indicates to us that while some of us have managed to overcome life's little inconveniences like poverty, racism, and exploitation, and made positive contributions to society, we have benefited very little from some of the results of this sacrifice.

For instance, we are aware that a man by the name of Dr. Hale Williams was one of the first to experiment with open heart surgery. Yet many black people or poor people in this country do not have the benefit of surgical kinds of related medical treatment.

We are aware that Dr. Charles Drew, another black physician, developed blood plasma. Yet he died for want of his own invention.

And we are aware that the majority of prison poplations are made up of black people, even though we are only a small percentage of the total population, and therefore any time you are talking about a prison population, you have to be talking about black people.

And we know we are large participants in experiments throughout this country, and here we are talking about assistance to mankind as one of the primary motivations for our participating in experiments. Well, it is difficult for us, I think, to comprehend that, in

light of the fact that again we benefit very little from those experiments that have already proven beneficial to mankind, when we look at the health delivery system in this country. In other words, there are experiments that have already proven to be effective, and there are drugs available, yet in terms of delivery we don't have these.

Our death rate is still very high, our health remains very poor, and therefore our motivation, I think, would be low.

And also I come to this conference with the organization's having participated in the review of investigation of the Tuskegee experiment, and also we were asked to give testimony in the whole matter of sterilization that occurred. I am not so sure it is by accident that the people who were victimized by those experiments were black people.

And any time in the past that groups have raised the issue of abuses in experimentation throughout this country, we have been told that the abuses, first of all, don't exist, and then when they are uncovered, we are told they are just isolated circumstances, and then when it is discovered that it is widespread, we are told it is only a function of government.

So we are very sensitive to the whole issue of experimentation, and we are pleased that we have an opportunity to sit down beforehand and deliberate with people like yourselves, so we can gain more information and knowledge; and so we can make intelligent decisions as to what experiments are harmful or helpful to our people, so we can inform our constituency.

And I hope to get more information. Usually we are called in after a tragedy has been uncovered, to investigate the results of it. We are looking for an opportunity to participate in some of the policy formulations and some of the practices that we are asked to prevent to keep some of these problems from occurring.

I am pleased to be here, and look forward to deliberating.

Biography

Born and raised in Philadelphia, Pennsylvania. Educated at Cheyney State College, Cheyney, Pa., B.S. in Mathematics. While completing his undergraduate studies he worked as a youth counselor at a correctional center. As a result of this experience he attended the University of Pennsylvania School of Social Work earning an M.S.W. Has had advance training in Child Therapy and has worked in a psychiatric clinic. Is currently working for a doctorate degree in Public Administration. Was an organizer in the civil rights movement in the early sixties; assisted in a successful campaign to appoint the first black councilman in 100 years in Westchester, Pa. He designed and developed a comprehensive, bail, legal service program which later became a model for national and local organizations. Has held a faculty position at the Experimental Graduate Program at the Martin Luther King School for Social Change in Chester, Pa. He held the position of Director of U.S. Programs for an international service organization. At present, he is the Associate Director of the Administration of Justice Division and the Division of Consumer Protection for the National Urban League, Inc. He is also chairman of the Chester, Pa., Community Health Corporation, Advisory Committee on Criminal Justice for National Urban Coalition, board member of the International New World Coalition, and former chairman of the U.S. Projects Committee for the American Friends Service Committee.

REMARKS -- BARRY SMITH

My name is Barry Smith. I am a medical student at Howard University. I am here as a recorder for the Research group.

I think my remarks would simply echo what Mr. Woodson has already said, and I won't go into that again, because he has voiced my sentiments.

But I would like to repeat a couple of things that have been said time and time again around the table. I come here with many questions in my mind because I have not looked at this problem before in any detail. But the questions I have are such as these:

Is the prison population the best population for doing pharmaceutical research? When you look at the fact of the type of person incarcerated in prisons, their attitude towards medical research usually isn't why they are volunteering for such research.

Second, I am asking whether medical research is compatible with the goals of the correctional systems, and what are the responsibilities of these research institutions as far as medical research and as far as the institutions are concerned?

I would like to also have the question answered as to a person making a decision who is incarcerated in a correctional institution: Can he make that decision, deciding, "I would like to volunteer for this type of experiment"? Should he be allowed to make those decisions at all?

Thirdly, again, as I said before, I would like to know the responsibilities of the research institution,

and also exactly what does a volunteer in a prison or a correctional institution expect to get out of participating in medical experiments.

If I can get some of these questions answered in any way, I will be very happy.

Biography

Mr. Barry Smith, a junior medical student at Howard University College of Medicine, hopes to eventually specialize in family practice. He is interested in community work, particularly with young people. He worked at one time as a field representative for Abbott Laboratories in New York City. Mr. Smith was the recorder for the Research Work Group at the Conference. His hobbies include raising house plants, of which he has a tremendous collection and the breeding of tropical fish.

REMARKS -- JOSEPH COUGHLIN

I am Joe Coughlin, Assistant Director, Illinois Department of Corrections, responsible for the Juvenile Division. I would be disinclined to approve a project that used children as research subjects on the premise that anyone who is going to be asked to make that decision should have reached a point of maturity, judgment and information where he can make a decision for himself.

Every man should have the opportunity to make decisions which affect his own life in a substantial way, with full information, so long as we stay within some reasonable kind of limits. By that I mean limits which have to do with his ability to make a reasonable decision where issues of mental competence and public well-being are involved.

As I listen to the group, I hear a tendency to over-generalize and, at the same time, to over-differentiate. By over-differentiate, I am talking about the tendency to see inmates as quite different from non-inmates insofar as their ability to give informed consent is concerned. In my opinion, inmates in reasonable circumstances--and, by that I do not mean those circumstances which I described at Stateville--are not that different from you and me in their ability to make good judgments. As someone else said, "There, but for the grace of God, could I have gone." We know that crime occurs in all segments of society. We also know that society differentiates as to who is committed to prison. Thus, I do not think we should tend to see prisoners quite as differently as we do.

We tend to over-generalize in the sense that we see correctional institutions in the light of the worst.

Wisconsin Department of Public Welfare for 17 years, serving successively as caseworker for juvenile offenders, as probation and parole agent, as supervisor of social services in the State prison, as Vice-Chairman and Administrator of the State Parole Board and Juvenile Review Board, and as chief of administrative services for the Division of Corrections. In 1965, he went to Iowa as Director of the State Division of Corrections and was named Deputy Commissioner of the newly organized Department of Social Services in 1968. While an undergraduate student at the University of Wisconsin, he worked full time as a Madison police officer. He holds an M.S.W. from the University of Wisconsin at Milwaukee.

There are many correctional institutions where--while I would not recommend them as appropriate places for any but the most threatening offenders--living circumstances are quite reasonable. Life at Vienna, one of the prisons in Illinois, for example, is grossly different from life at Stateville. The grounds at Vienna look like a college campus and the programs include a broad range of personal growth opportunities. Included are college courses taught on campus, with outside students coming in to participate in the courses, and inmates leaving the institution to attend courses on the regular college campus.

As we consider these medical research projects, we must have an accurate assessment of the level of risk involved and develop elements of care to assure an informed decision giving full consideration to the circumstances in which the inmate finds himself. There has to be some relationship between level of risk and the real opportunity a man has to make a reasonably free decision recognizing that, as someone else has said, no human being ever makes a decision completely without some elements of compulsion to make that decision.

Biography

Formerly Executive Director of the Illinois Youth Commission, he serves the Illinois Department of Corrections as Assistant Director in charge of the Juvenile Division. The Department, which came into being on January 1, 1970, combines the services of the former Illinois Youth Commission with the adult correctional functions of the Department of Public Safety. He has responsibility for all operations of the Juvenile Division, including 18 correctional facilities as well as delinquency prevention and after-care services. Prior to his appointment to the Illinois Youth Commission in 1969, he was Deputy Commissioner in the Department of Social Services for the State of Iowa, supervising the administration of State programs for mental health, retardation, corrections, family and children's services, and public assistance. He entered the social service field in 1948 as Guidance Officer in the Wisconsin State Prison. He was with the

REMARKS -- DR. CRAIG BURRELL

I am Craig Burrell and I am a physician with Sandoz Pharmaceuticals. Compared with most of you I am somewhat of a mongrel! I was born in England of Scottish parents and educated in New Zealand, and graduated in medicine there in 1951. I did my graduate work in London, England, at the Royal Postgraduate Medical School and then moved to the hospital of the University of Wales Medical School, Cardiff, Wales.

In both these places I was an investigator, but in London I was also an investigational subject, on four occasions being the first human to receive a new drug that was under development by the government.

When I came to Cornell University Medical School in 1960 I was again an investigator. Since joining Sandoz in 1961 I have been involved, among other activities, in monitoring.

It is appropriate, I believe, for me to say that I am active as a layman in the United Presbyterian Church, and that my religious views certainly color my concerns in this area of ethics, civil liberties, and human rights.

As about 30 people have already spoken, most of what I would want to say has been much better said than I could put it. I would, however, like to associate myself with Crawford Morris' comments on who is a prisoner, or rather, who is not a prisoner.

I can summarize my own concerns quite simply. Somebody has to be the first person to get a new drug. Phase One studies are necessary, and they will have to be done somewhere if any further new drugs are to be made available.

So I hope in this meeting to get answers to at least three questions:

First, if it is shown that the prison environment provides one of the best situations in which these necessary studies can be done, can we ensure that prison studies are conducted under the highest possible ethical standards, with the greatest concern for human rights?

Second, even given the above, is it reasonable to continue studies in prisons?

And third, are there any viable alternatives to the use of prisoners in the United States within the current regulatory framework?

In somewhat of an aside, may I say that despite our varied backgrounds and the already very obvious fact that we do have trouble in communicating even our basic ideas, I think it would be fair to claim that at least we are all united in our concern for good. I probably shouldn't say the common good or the public good, because we are often concerned about specific individuals' good.

I am not debating Gil McMahon at this stage, on his contention that it isn't possible to operate under "Primum non nocere," although I believe we should always attempt to avoid harm where possible.

But perhaps the motto of the Airlie Foundation that you see up on the wall is an appropriate meeting ground for all of us, "Omnia pro bono," "All for good." Surely you could say we are all desiring to reach good as a result of this conference.

And then, as a final postscript, could I modify for Mr. Dimpfl an old truism in medicine that applies to his suggestion that were he in research he would try out all the new drugs on himself, doubtless to his ultimate harm. The saying is, "The physician who treats himself has a fool for a physician." You see, you can't maintain the objectivity that is needed to treat a patient with wisdom and safety if you treat yourself. In similar fashion I would suspect that "The investigator who uses himself for a subject has a fool for an investigator."

Biography

Craig D. Burrell, M.D., is a graduate of the Otago University Medical School, University of New Zealand. He received his specialist training in endocrinology at the Royal Postgraduate Medical School in London. On coming to the United States, his post was that of Assistant Professor of Medicine and of Medicine in Psychiatry, Cornell University Medical School, with an appointment to the Endocrinology Clinic of New York Hospital, where he was in charge of the Metabolic Unit of Payne Whitney Psychiatric Clinic. He joined Sandoz Pharmaceuticals in July, 1961 and shortly became Vice-President, Medical Affairs, in which capacity he directed Clinical Research, Phases III and IV, and Drug Regulatory Affairs. Since the first of this year he has been Vice-President and Director of External Affairs.

REMARKS -- DR. HUBERT PELTIER

I am Bert Peltier, and I am with Merck, Sharp & Dohme.

I have been involved for the greater part of the last 20 years in clinical research in the pharmaceutical industry, being with a couple of other organizations before coming to Merck.

And I have also been involved on both the local and the national scale with the problems of clinical research and its relationship to our industry.

I have worked with our colleagues at the Food and Drug Administration over the years. It seems as if any panel I am on anymore, and every meeting I go to, I see my friend Dr. Finkel sitting across the table. We have worked with our regulatory colleagues to help ourselves understand better what our needs are.

I don't believe it is possible for us to sit around this table and disassociate the problems of clinical research and the regulation of it, as it applies to the use of volunteer subjects whether prisoners or otherwise.

It is almost to the point where I think the one precedes the other. One could almost say that you would only allow clinical research to go on in the environmental settings where everything is perfect, and that probably would be limited to a very few prisons in the whole United States.

But I don't think there are that many places we could say that "This is an environment where all the things we are concerned about can be properly enforced."

Dr. Trout says he is pleased with the laws that are on the books, but they are not being enforced. Maybe we can come up with recommendations as to how we as a group, and particularly the pharmaceutical industry, can document our monitoring processes, assuring the rights of the individuals involved in these studies.

But I feel we may be putting the cart before the horse, as I said earlier, and it seems to me that we do have to consider the over-all set-up of prisons and go on from there.

What disturbs me--in my present position with responsibility for the clinical research that is carried on by Merck physicians throughout the world--is that the United States is the only country in the world where prisoners are even allowed to be used as subjects. It makes it difficult for me to understand how researchers have come to the conclusion that prisoners are not proper subjects for research in all other countries.

Being a pediatrician before I went into industry, I want to comment on one other thing.

Mr. Coughlin mentioned the concerns that he has about anyone who can grant permission for a child to participate in research. I am totally sympathetic with the difficulty of knowing who can permit a child to participate. There are clear cut needs for children to participate in certain types of research. The development of virus vaccines for measles, polio, and rubella are examples where such participation is essential.

How do we obtain such permission is another challenge in this whole area of experimentation on humans. We need to study children who have not been exposed to disease, who do not have anti-body titers, and can be maintained for a period of time free from external exposure to contact with the natural virus after they have received a dose of a vaccine.

This is another complicated area we need to discuss.

Biography

After having received his M.D. from the Indiana University School of Medicine in 1948, and having been in the private practice of pediatrics from 1952-56, he hss held various positions with pharmaceutical companies. He worked with The Upjohn Company, from 1956-64 as Research Physician (1956-59), Chief, Clinical Development (1959-62), and Manager, Clinical Research (1962-64). From 1964-68, he was Vice President and Medical Director for Bristol Laboratories. From 1968 to the present, he has worked with Merck, Sharp & Dohme Research Laboratories as Senior Director, Medical Research-Domestic (1968-70), Executive Director for Medical Affairs Area, Domestic (1970-71), and Vice President for Medical Affairs (1971-present). He is also affiliated with several professional organizations.

REMARKS -- DR. HARRY WELLER

My name is Dr. Harry Weller, I am presently assigned to the Federal Bureau of Prisons as Deputy Medical Director, on detail from the United States Public Health Service. I was previously the Chief Medical Officer at the U.S. Penitentiary, Lewisburg, Pennsylvania for two years.

It has been interesting to me today to hear the many points of view, especially those about the system for which I am working. On the one hand, a comment was made about abolishing the Bureau of Prisons, on the other hand, it was cited as an example of a system with a good prison industry, and in between, we need to improve the health care.

I come to this meeting as a pinch-hitter, and will try to represent the situation as it is in the Bureau of Prisons during the conference work groups. My boss, Dr. Brutsche, as well as Dr. Gray from Texas and others, helped develop the ACA [American Correctional Association] experimentation guidelines that were approved last August, so we have an interest in further discussion of them, as I understand others of you do, too.

It is difficult, this late in the comments to avoid redundancy, but I would like to reemphasize several points.

Since I am relatively new to the prison game, one of the things that I still remember as an institutional physician is the non-homogeneity and transiency of the prisoner population. I think those of you who have mentioned that researchers need to assume that the population has homogeneity in captivity are in for a disappointment. For example, of the 22,000 inmates who are incarcerated at any moment in the federal system,

14,000 of them come and go every year. This creates problems for researchers.

Someone earlier mentioned the difficulties encountered in obtaining adequate follow-up information after the individuals are released from the institution, and the problem of avoiding the impression of "Big Brother" watching over you. We are concerned about knowing the effects of the correctional programs that are being used, including follow-up after they leave the institution, but yet avoiding this "Big Brother" stigma.

I have been impressed with the action and response of the federal system in shaping and responding to the public's expectations, especially as reflected through the Congress and the news media. Public accountability for our actions and results is an important force to be considered in our deliberations.

I hope to leave this conference with better insight into a solution for the problems creating this cloud that is over prison research, especially regarding implied or specific coercion.

I also hope that we will expand upon the ACA guidelines, and that we will come to a better understanding of the precise conditions under which human experimentation in prisons might take place. Many of you have already spoken about this in various terms.

Lastly, I would emphasize again the importance of the interest and activity of the courts in corrections. We need to police our own system; we need to supervise, monitor and evaluate what we are doing, not only in research, but in all correctional programs, and not wait for the courts to make our decisions for us.

Biography

Educated at Pennsylvania State University, B.S., June 1950; Jefferson Medical College of Philadelphia, M.D., June 1954; Johns Hopkins University, School of Hygiene of Public Health, M.P.H., 1967-68. Served two years with the Peace Corps, Washington, D. C., 1961-63 and at various USPHS Clinics and Hospitals

(Washington, D. C.; Detroit; Baltimore; New Orleans; Seattle]. Was Chief Medical Officer, U.S. Penitentiary, Lewisburg, Pennsylvania, 1965-67. Has been assigned to the Bureau of Prisons, Central Office as Deputy Medical Director from 1968-present. He holds a rank of Medical Director, U.S. Public Health Service.

REMARKS -- FRED WARD

Mr. Chairman, I have been impressed not only with the expertise, but the fact that we have a very verbal group. As No. 34 on the list, I must say that there isn't very much left to be said, and in deference to a couple of gentlemen who are yet to speak, I will try not to take all of my alloted time.

But apropos of something that was said earlier about all of us being captives, I would submit some of us are more captive than others.

In the context of the NCCD where I have been working for the past 26 years, we have been working at the entire system of criminal justice, of which the field of corrections is an important part, and which, is the focus of this particular conference.

At NCCD we have been looking at how to improve the system, how to open up institutions to the light and bring in outside influences in the interest of constructive change. We have been looking at ways to make the criminal justice system more effective, more humane. While at the same time we emphasize alternatives to institutionalization, we are also interested in what happens to the individual who is in an institution. Whether or not rehabilitation or treatment can really be expected under the circumstances that we see today in many of our penal institutions is a question.

The architecture of institutions really hasn't changed in a few hundred years.

For those of you who may wonder about the status of prisons, it is estimated that some $3 billion of prison construction is currently being planned within the next five years. If these $3 billion are spent for

construction, it will cost some $600 million a year to operate and maintain these institutions.

This is one of the reasons why NCCD has been interested in bringing to the public's attention the problem that we face in continuing to build institutions. How much better it would be to take not only the capital investment, but also the operating funds, and apply these to meeting other human needs--housing, education, welfare, and research.

But I wonder if we really know whether especially pharmaceutical research in prisons is increasing or decreasing. Some states have at least temporarily stopped drug testing programs in their institutions. I believe Oregon has abolished the practice. I think the Bureau of Prisons has deemphasized such testing and there is practically none going on now in federal institutions.

In Pennsylvania all drug testing programs have been stopped until the matter can be examined. We have been in contact with officials of that state and they are very interested in what happens at this meeting.

I hope that out of this conference we can find ways of serving the needs of research, the welfare of prisoners, as well as the administrators of institutions.

Also, I think that we should examine why current guidelines, of which there are many, aren't working.

A person called me the other day who had hoped to be at this meeting, but who had a conflict that made it impossible, and introduced himself by saying that he has written at least 20 sets of guidelines for various institutions around the country, and he says none of them work. He says there has to be a willingness and a spirit to implement these guidelines before ever getting started.

And so this may be the flaw.

What can we do, as a group, to recommend a set of guidelines that can be implemented? What is the guideline for implementation prior to, let's say, the guide-

line which sets out the procedures and controls.

What can we do to ensure their application? Is there a role for third-party monitoring?

How are present review committees appointed? Current guidelines are silent on this. Perhaps we need more guidelines on this point.

Perhaps there needs to be a totally new and more objective way of looking at and monitoring research, perhaps not in the interest of each and every individual project, but in periodically reviewing the whole process and feeding back information to people who should be making decisions about this.

But I would hope that in a group like this, which is probably the largest interdisciplinary group that has ever addressed these issues, most of which have been very well identified and described by others up to this point, that if we can reach a kind of collective objectivity, we may really be able to make a contribution that hasn't been made before.

Most previous efforts of this sort have been within individual professions. The correctional people have looked at the problem from their point of view. Researchers have looked at it from theirs and the medical profession has looked at it from its point of view. Lawyers have struggled with the problem from their perspective.

But I would hope that collectively we may be able to come out with something that is practical, and workable, and that would give some confidence to prisoners, researchers, correctional administrators, and the public.

Biography

Completed undergraduate work in social sciences at the University of Houston; did graduate work there and at the University of London, and the New York School of Social Work at Columbia University. He has been Director of Probation in Houston, Texas, and later

Chief Probation Officer and Supervisor of County Institutions in Dallas, Texas. He is currently Executive Vice President of the National Council on Crime and Delinquency and Director of the Division of Professional Services. He joined the staff of NCCD 26 years ago and has served as Field Consultant, Southern Regional Director, National Survey Director, and Director of the Division of Research and Special Services before being appointed to his present position, which includes responsibility for the Information Center and Library, Research Center, Training Center, Legal Department, Editorial and Publications Department, Youth Development Center, staff specialists in law enforcement, courts, corrections, and demonstration projects. He has served as advisor and consultant to government of all levels on all aspects of criminal justice. He has directed more than 50 surveys throughout the U.S. and he designed and directed Correction in the United States, a nation-wide survey for the President's Crime Commission. He is the author of numerous articles and reports. He is a charter member of the Association of Certified Social Workers and serves on a number of professional boards and committees.

REMARKS -- ARCHIE CONNETT

Fred [Ward], I indeed agree with you that some of us have been more imprisoned or are more imprisoned than others.

First off, though, my name is Archie Connett, and that is who I am. That is my name.

I want to distinguish that from things that have happened to me and things that I have done, and perhaps things that I hope to do.

I kind of grew up as the All-American boy. I was an excellent student and a good athlete, president of my student body in high school. In university, I became president of three organizations, made Phi Beta Kappa, three other honoraries. I became a naval officer, a teacher, a coach.

But in 1952, in December, after an estrangement from my wife and my children, and being joined with them again temporarily, a thing happened and I wound up killing all three of my children and attempting to kill my wife and myself.

I think sometimes in introducing ourselves we tend to be very abstract and very impersonal, and I liked what Gil [McMahon] had to say about himself this morning. I thought he sort of reached in and pulled out a couple of personal things.

I think that introductions tend to be meaningless if they are couched in terms of titles, and maybe merely accomplishments or what we have done.

I went to prison, and on June 30, 1968 I was released on parole, after serving 15 years in five different institutions. Shortly after my release, I went

to work at the Western Behavioral Sciences Institute as a coder. They originally thought of using me as an interviewer but decided that if I were to go out as an interviewer, I might, in view of the fact that I was an ex-con, get into it in conservative San Diego with some little old lady, and it might reflect discredit on the Institute. They hadn't seen me, of course, when they made up their minds to this.

Since I have been out, for five years, I have been quite often called upon to bring my perspective, the perspective of an ex-offender--by the way, I never bought that "offender," "convict," "inmate," "patient," whatever label. I fought tooth and toenail all 15 years I was in prison to maintain my identity.

And I think that one of the things that could happen here with your medical research is that this could be an opportunity for the offender to contribute something, something that was meaningful and significant. I think that it is extremely important that we open up avenues of this type, and that you folks in medical research are in a pretty good spot to begin crossing the frontier and breaking the ground in this respect. I hope you will do more and more of this, because more and more of it is needed.

Connor Nixon has his way, Herron has his way, and in my small way I have been attempting to do a number of things. I want to mention some of these--not for ego purposes, but to illustrate something.

I have been utilized as a resource, as a research associate, at Western Behavioral Sciences Institute. I have published seven times. In fact, I have a couple or three things here I was going to distribute, but I think I will not do that now in view of the lateness of the hour and the tiredness of everyone.

I have taught the prison community, which I think I am sort of familiar with--I am familiar with both the formal and the informal structure of the prison community--and at San Diego State College.

I have been a counselor for San Diego County Department of Honor Camps. That is a Civil Service job. I qualified through the Civil Service procedure, qualified, as a matter of fact, in the number one spot, and was hired the next day and worked there a couple of

years and became acting assistant superintendent and superintendent in that system at one time or another.

I have spoken before all kinds of bodies, including the State Department of Rehabilitation, the Criminal Law Section of the local chapter of the California Bar Association, been a member of three committees in corrections, a member of the board of directors of three organizations, including the California Parole, Probation, and Correctional Association--that would be the local chapter there in San Diego.

I realize that I am not the typical person who goes to prison, but I think I experienced some common-denominator experiences while I was there. I think I have some understanding of what it means to run naked down the street, stripped of the props that we ordinarily travel out of, you know, such as your family, your children, your friends, your licenses, your credentials, your property, everything that you can think of. You run naked down the street, and you have an opportunity to see who you are, find out whether you are a man or not, among other things.

Talk about whether or not people in this kind of predicament should be allowed to participate in medical research, should have the opportunity--I just think that they should have every kind of opportunity. Participating in medical research is a minor opportunity that they should have. We have got to open up things the way that Milt [Rector] was talking about, the way that Connor [Nixon] was talking about, and give people a chance to become participants, to get in the ball game.

To be in the ball game means for each person to have the opportunity to present his perspective now, at whatever level, of whatever quality it might be. If, in medical research, in addition to just being a volunteer, a subject in your research, the offender shows he has research skills, certainly use him in every way you can. I think we have a moral and ethical obligation to do this.

And I don't think there is any limit to these things.

On the other hand, I don't think that being an ex-offender and offender is anything special. That doesn't qualify you for anything, particularly. In fact, they

say that California puts out the best prisoners in the world. The only trouble is there is no demand for prisoners.

So anyway, I guess the kind of thing that I really have to say to you people--and I am sure that I am not following your standard format here, but I say to you: Let's utilize the perspective and the efforts of the ex-offender and the offender in every way that we can. We have to get him into the ball game. Until you make him a participant, you have no hope of rescuing him from his predicament.

Biography

Born March 13, 1914, Bird City, Kansas. Received a B.S. in Sociology from the University of Colorado, 1941, and an M.A. in Education from Stanford University, 1950. He is a member of Phi Beta Kappa and other honorary societies. He has served as a teacher of English and Social Studies; as a coach of gymnastics and track; and as a naval officer with teaching and administrative duties. In 1953, Mr. Connett was arrested, convicted, and sent to California State Prison at San Quentin. In 1968, he was released on parole after serving 15 years in five California penal institutions. On August 24, 1970, he was released from parole. The day after his release from prison he began work at the Western Behavioral Sciences Institute in La Jolla, California. Over the past five years, he has been called upon many times to bring the perspective of the ex-offender to bear upon the problems of the criminal justice system. He has been an expert witness in the penalty phase of three first-degree murder trials and contributed "The Perspective of an Ex-Offender" to the symposium, The Purpose of Corrections--Directions for Improvement, published in the University of San Francisco Law Review, October 1971. Mr. Connett is President of Ex-Offenders Resources, Inc., founded in 1970 to influence the ex-offender community to contribute to society. Currently, he is executive director of a WBSI project, "Utilizing Ex-Offenders in Rehabilitation," funded by federal, state, and local agencies. He will in the near future be the subject of a television documentary.

REMARKS -- ROBERT FISH

I am Robert Fish, a medical student at the University of Maryland in Baltimore, and I'll be a recorder for group three. From the point of view of a medical student I'll be looking forward to learning about drug research from those directly involved in the field. I'll also be interested in the discussion as to when drug research is applicable or when it might be subjecting the prisoners to too much risk compared to the possible value of the research.

I am also hopeful that the conference will be able to set up guidelines for the research that will lead to practical applications which can be of help in the rehabilitation of the convict, because as the last speaker mentioned it is important to see this issue from the point of view of the convict as well as the other points of view.

Biography

Robert Fish is a second year medical student at the University of Maryland School of Medicine in Baltimore. He completed his undergraduate work in Zoology at the College Park Campus of the University of Maryland. His participation in the Conference at Airlie House came at the end of a summer program run by the Medical School in which students were able to observe and to some extent assist a doctor at work in his office setting. As yet he has no definite plans as to the type of medicine he will take up, but he expects to go into active practice as opposed to teaching or research.

REMARKS -- ROBERT L. EMRICH, PH.D.

I think in closing I would like to say a couple of words myself.

I have been with NCCD Research Center several years. My background is in criminology by practice, although I was trained as a cultural anthropologist. This conference is presenting a very new field to me, but I find it very exciting. I think I have an advantage, that Mr. Dimpfl also mentioned, and that is that I know so little about the subject. As such, I feel it is much harder, in a way, for some of you who have spent ten or fifteen or twenty years grappling with the subject to step back from it.

I was reminded of a Zen story as I listened to Claire Cooper's comments, of a philosopher who visited a Zen master in Japan and said, "I would like you to teach me some Zen."

He said, "Fine. Would you like a cup of tea?"

And the man said, "Yes."

So the Zen master walked over to the tea caddy and poured off a cup of tea. He poured and the tea filled the cup and flowed all over the floor. Finally the Western philosopher got so upset he said, "You have to stop pouring. What are you doing that for?"

The Zen master said, "This teacup is like your mind. You have come in with it totally filled, and where can I put the tea?"

I think that is our greatest challenge here today.

I was also struck by the very different kinds of

issues that are being raised. We have some almost metaphysical issues: the nature of freedom and coercion, the nature of rights and liberty. We have issues on the social level: what society needs in the way of research, and what risks have to be taken, and the fact that we must continually take risks. Medicine has come where it has today because we have continued to take risks, and unless we continue to take risks, we cannot advance.

We have people who work in prisons or who have been the customers, so to speak, of that situation, talking about it from the human experiential level. There is something about being a human being in that situation, no matter which side you are on.

We have heard of the social inequities that exist: that people who have to take the risks aren't always the people who get to receive the benefits of those advances.

There are a lot of issues here, and the answers have to be found by working with all those issues--and that is a tremendous challenge. It is hard to force the discourse into any one single box and get anywhere today, I think.

I must say, therefore, that I strongly argue the point Dr. Ayd made--and I am only beating a dead horse, since it has been argued several times--but I am making it as a kind of recommendation to the conference. Please be patient. Don't rule anybody out of order because of where he carries the discourse. We have to probe a lot of different concerns and a lot of different areas, and I think it is much better, if we are going to get some answers, to take the risk of probing a few blind alleys in the next couple of days.

I think the answers we are looking for are going to be very different, if we do any good at all in this conference, from the cliches and the pat answers that we have brought with us. I hope most of us can come away with very new ways of thinking about this problem. In a sense today we have mostly rehearsed the choreographies we have been used to over the last ten years. I hope by Wednesday we will have learned some new choreography.

Biography

Robert L. Emrich, Senior Research Associate, has been with NCCD since the middle of 1971 and has conducted several conferences during those two and one half years. An expert in evaluation, he has served as principal consultant on evaluation to the California Council on Criminal Justice, as well as conducting evaluation studies for NCCD. From 1968-69, he was Chief of the Research Planning and Evaluation Staff, National Institute of Law Enforcement and Criminal Justice, and from 1966-68, he was Grant Program Manager for Science and Technology, Office of Law Enforcement Assistance. He was a staff member of the President's Commission on Law Enforcement and Administration of Justice from January 1966-December 1966, and Technical Analyst with the Technical Analysis Office of Hughes Aircraft Company from May 1965-March 1966. Though he has worked in the criminal justice field extensively, his educational background includes an A.B. in Liberal Arts, 1955, and an M.A. in Anthropology, 1958 from the University of Chicago, and a Ph.D. in Anthropology, 1962 from the University of Oregon.

END