

PART III. ACTIVITIES OF THE COMMISSION

Chapter 5. Site Visits to Prisons

The Commission made a site visit to the State Prison of Southern Michigan at Jackson on November 14, 1975. In addition, groups of Commission members visited Washington State Penitentiary in Walla Walla, the Michigan Intensive Program Center at Marquette, and the California Medical Facility at Vacaville. Prior to the visits, Commission members were briefed by a former prison administrator, a former prisoner, and a director of research from a pharmaceutical manufacturing firm, regarding conditions to look for and questions that might be asked.

The State Prison of Southern Michigan at Jackson is the largest penitentiary in the United States, housing over 5000 residents. It is also the site of one of the largest nontherapeutic biomedical research operations, with special buildings on the grounds constructed by two pharmaceutical manufacturers (Parke-Davis and Upjohn) specifically to conduct phase I drug studies.

Commission members toured the prison facilities, including regular and honor cellblocks, prison industries, the prison infirmary, and the research buildings. They discussed prison procedures with the deputy warden, and research procedures with the vice-chairman of the committee that reviews each research protocol and with members of the research teams. Most of their visit was devoted to discussion of prison conditions and the research program with prisoners.

According to materials made available to the Commission, the research conducted at Jackson is primarily phase 1 drug testing, although some phase 2 studies and device testing are also performed. Research protocols must be reviewed and approved by the Protocol Review and Protection Committee (composed of five physicians in the community and at Michigan medical schools, two lawyers and a third lay member) and by the Director of the Department of Corrections. Annual reports of research performed are made to the Review and Protection Committee and the Department; any adverse reactions that occur are reported to the Committee immediately.

Information about the research program is included in the packet of information an inmate receives upon entering the prison; there is no additional recruitment or contact with the prisoners by the research personnel unless he requests information about participation. Then the program is described to him in a group meeting, and if he wishes to be considered for research he undergoes a physical examination and laboratory screening tests. Eligibility is contingent upon approval of the prison authorities and passing the screening tests; in addition, subjects must have an IQ of at least 70.

Those who qualify enter a common subject pool maintained for the two companies on a card file. When a new protocol is initiated, prisoners' cards are pulled from the front of the file, and the specific protocol is described to them. If they decline to enter the study, they reenter the pool. The studies are about equally divided between inpatient and outpatient trials. Pay is based on the procedures involved, according to a schedule devised by the Protection Committee and approved by the Department of Corrections, and is comparable to pay received in prison industries. Of the 5200 prisoners at Jackson,

approximately 800 are in the research subject pool. The Commission was advised that medical supervision is close, that a physician is present or on call in the immediate vicinity at all times, that a prisoner can discontinue participation in a project at any time,* and that no notation of his participation in research is made in his official prison record, so that the parole board is not advised of it.

Commission members talked with a representative sample of 80 prisoners both individually and in groups. The sample was selected by Commission staff from the master list of all prison residents, and included both research participants and nonparticipants who responded to an invitation to meet with the Commission. In addition, prisoners suggested by other inmates were interviewed in a group setting. Overall impressions from this experience were that prisoner-participants valued the research opportunity. In general, they felt that they were free to volunteer for or withdraw from the program at will and were given adequate information about research protocols. Nonparticipants expressed various reasons why research was not for them, but did not object to its being available for others.

Participants gave many reasons for volunteering for research, including better living conditions, need for a good medical evaluation, and desire to perform a worthwhile service to others, but it was clear that the overriding motivation was the money they received for participating. In fact, their strongest objection was that the pay for participation in research was held

* A consent form provided as a sample for review contained a contrary implication. The drug company representatives readily acknowledged that this was a mistake, however, and they gave assurances that the form would be corrected.

down to levels comparable to prison industries. Other complaints focused on limitations to participation rather than on research excesses: if a prisoner stayed on an inpatient study for more than a week, he would lose his prison job seniority; prison officials were said to exclude certain prisoners arbitrarily; some prisoners did not seem to get called to participate in research as often as others. They generally rejected the notion that they were coerced into participating in research, and stated that they knew their participation would not be revealed to the parole board.

The major complaints of the participants were directed toward the prison system, not the research program. When asked if research in prisons should be stopped, the prisoners interviewed unanimously said no. They urged correction of what they viewed as inequities (e.g., that pay be increased, that authorities be forbidden arbitrarily to withhold permission to participate), but asked that biomedical research programs in prisons be allowed to continue.

As a follow-up to the visit to Jackson, the Commission staff compared the characteristics of the 792 men in the drug-testing pool on November 27, 1975 with a randomly selected control sample of similar size. Data came from a computer print-out of the prison's daily roster. Subjects were disproportionately white; although blacks comprise almost 68% of the nonsubject prison population, they are only about 31% of the subject pool. (Data furnished to the Commission by Dr. William Woodward of the University of Maryland showed a similar inverted racial pattern in the biomedical research program at the Maryland House of Corrections at Jessup.) At Jackson, subjects tended to be older than nonsubjects, to have been in prison much longer (an average of almost two years, compared to one year for nonsubjects), and to have been sentenced to Jackson more times (2.1

times compared to 1.8 times for nonsubjects). There was also a striking overrepresentation among the subjects of men housed in the prison's two honor blocks.

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In order to observe behavioral programs operating in a prison setting, groups of Commission members visited a unit of the Washington State Penitentiary at Walla Walla and the Michigan Intensive Program Center at Marquette. Neither program is conducted as research, and the Commission is not aware of a behavior modification program in a state or federal prison that is so conducted at present.

The program at Walla Walla utilized a therapeutic community approach, and dealt with the state's most difficult-to-manage prisoners, who were sent to the unit generally because of unacceptable conduct in the regular system. The unit is operated almost entirely by the prisoners themselves, who serve as the therapeutic community, establishing and enforcing rules of conduct. On entering the program, a prisoner is placed in an isolation cell. His only contacts are visits by the director and other prisoners on the unit, who explain the rules to him and urge him to conduct himself in such a way as to be able to join them. When he is willing to conform, he is released from his cell to the open ward. There, the main emphasis becomes retraining in appropriate patterns of social interaction, using such mechanisms as group discussions of current events, recreational programs, and group therapy. Swearing, use of jargon, and fighting are among the numerous forbidden behaviors; violations are punished by a return to the isolation cell, with the group serving as enforcer of the rules and determining when the violator can return to the ward.

The primary purpose of the Walla Walla program is to encourage learning of socially acceptable behavior rather than specifically to prepare the prisoners for return to the outside world or the regular prison system. Most men remain on the unit for long terms. Those who have been released outside the prison are said to have done remarkably well, with recidivism a rare event (follow-up records are apparently not maintained). Return to the regular prison system would be dangerous, since those in the program gain reputations as informers. Interviews with prisoners in the program yielded only the highest praise for it. Prisoners admitted initial resentment of the isolation treatment, but claimed that it was the only way they had ever been made to think seriously about themselves and their behavior, and that it provided the necessary impetus for their behavior change.

The Michigan Intensive Program Center (MIPC) at Marquette is a maximum security facility housing difficult-to-manage prisoners who have been transferred from other facilities in the state. The behavioral program there is based on a six-level token economy. Privileges and comforts increase as a resident earns enough tokens to progress from the lower to the higher levels. Tokens are earned for correct behavior (making the bed, cleaning the cell, attending educational activities, not fighting, etc.) and are awarded at frequent intervals throughout the day. The purpose of the program is to improve the prisoner's behavior sufficiently to enable him to return to the regular prison system and be manageable there.

Interviews with prisoners at the MIPC indicated no enthusiasm for the program. The prisoners seemed to tolerate it grudgingly and submit to the process in order to get back into regular prison life, but with the determination that nothing done

to them in the program was really going to change their behavior. They generally viewed the program as "just another lock-up," no better or worse than the segregation blocks to which they might have been assigned alternatively. Their major objection was the arbitrariness by which the prison system could decide to send them to the MIPC. No figures were available on recidivism, nor was there any other means to document the effectiveness of the program.

Commission members also visited the California Medical Facility at Vacaville, which houses approximately 1400 inmates. Most of the prisoners are referred to Vacaville for medical or psychiatric reasons, and one-fourth of the population is excluded from participation in research for security reasons. Those who wish to volunteer sign a roster at the research office, and selection of subjects is made in numerical order from this list.

Research conducted at Vacaville includes a large program of skin-testing for hypersensitivity, as well as internal administration of experimental drugs. New volunteers begin with a skin-test study before advancing to higher paying pharmaceutical studies.

Other paying prison jobs are available, and at the time of the visit there were unfilled slots for reasons that were unclear but possibly had to do with disparity in pay or difficulty of the work as compared with participation in research. Legal counseling is available from law students who visit the prison weekly. Educational programs range from elementary school through a baccalaureate degree. There is spot censorship of mail. Telephones are available, but the inmates must pay to use them.

The inmates' council reviews all research projects and can veto any protocol. Most of the active protocols have also been reviewed by Institutional Review Boards of outside institutions. Informed consent is obtained in writing, and the prisoner receives a copy of the signed form. Examination of a card file indicated a significant dropout rate from studies; apparently prisoners feel free to withdraw, even though they know that if they do so frequently, their chances of being invited to participate in future studies will be reduced.

Chapter 6. National Minority Conference on Human Experimentation

In order to assure that minority viewpoints would be heard, the Commission contracted with the National Urban Coalition to organize a conference on human experimentation. The conference was held on January 6-8, 1976, at the Sheraton Conference Center, Reston, Virginia. Attended by over 200 representatives, it provided a format for presentations of papers and workshop discussions from which a set of recommendations emerged. The papers and the recommendations relevant to prison research are summarized below.

Joyce Mitchell Cook, Ph.D. Dr. Cook suggests that ethically acceptable research may be assured by a principle of equality (i.e., that researchers not propose experiments which they or members of their family would not participate in). She argues that the term "informed consent" is ambiguous, since it wrongly places the emphasis upon process and information rather than on voluntariness. Dr. Cook adopts the position that volunteering is genuine only if the end to be pursued is one to which the volunteer is devoted. Because of the extraneous motives of prisoners, she concludes that they are volunteers in name only. She recommends that behavioral research be permitted only if it directly benefits the participants and can be conducted on hospital wards rather than in prisons. Dr. Cook concludes that experimentation on prisoners ought to be abolished and that the risks of experimentation should be distributed more equally among members of the free-living world.

Larry I. Palmer, J.D. Mr. Palmer begins with the premise that the ethical problems posed by prison experimentation derive from racial, religious and

nationalist conflicts and that the issues of prisoners and race are merged. He recommends guidelines to encourage scrutiny of: (1) the appropriateness of using prisoners in a particular protocol, (2) the societal priorities associated with the research, and (3) the potential risks and procedures to minimize such risks. He suggests that research involving prisoners might be regulated by state officials, with additional monitoring and scientific evaluation by professionals and some supervision of the consent process. All decisions and consequences regarding experimentation in prisons should be open to public scrutiny. Mr. Palmer sees little justification for a ban on all research in prisons; rather, he advocates a "scrutiny of values," through a statement of the nature, purposes and risks of each protocol in relation to the interests of the prison population.

L. Alex Swan, Ph.D., LL.B. Dr. Swan argues that behavioral research is aimed at quelling dissident prisoners who view their incarceration in political and economic terms. He suggests that such research ought instead to promote "human liberation" by exposing oppressive conditions in prison. He advocates self-determination for prisoners, particularly with regard to the goals of social and behavioral research, and challenges social and behavioral scientists to accept responsibility for the possible misuse of their research findings. Dr. Swan asserts that scientific manipulation of prisoners to conform to the will of the state is unethical, just as it is unethical to use scientific techniques for disciplinary or punitive purposes. He further states that experimentation on the brain to alter behavior violates the inmate's independence and right to free speech, that the prison system is so inherently coercive that informed and voluntary consent is impossible, that labeling of prisoners as aggress-

sive or violent for research purposes is dishonest and repressive, and that civil liberties are endangered by behavior modification techniques in prisons because of the closed nature of such institutions.

Recommendations of Minority Conference workshops on research involving prisoners. Two workshops were devoted to the topic of research involving prisoners. The first of these recommended a moratorium on all nontherapeutic biomedical research in prisons until a comprehensive evaluation of human experimentation has been made. This evaluation should include consideration of the purpose of research involving prisoners, criteria for selection of subjects, assessment of risks, government responsibility for regulating research in prisons, responsibility of professional organizations regarding such research, the role of prisoners in the supervision of the research, the fixing of financial responsibility including compensation for harm resulting from research, and access of prisoners to official bodies outside the prison. The workshop also recommended that behavioral research be redirected from a focus on the individual prisoner to the goal of understanding the nature of prisons and their effects on individual prisoners. Recommendations were not proposed regarding informed consent because of doubts that it is possible to obtain informed consent in our prisons.

The second workshop recommended the establishment of a permanent commission to regulate human experimentation, a ban on biomedical research and psychosurgery in prisons, establishment of a human subjects review committee with prisoner representation, and the provision of technical and legal resources to prisoners who are potential subjects of human experimentation.

Chapter 7. Public Hearing

On January 9, 1976, the Commission conducted a public hearing on the issue of research involving prisoners. Summaries of the presentations that were made to the Commission follow.

Gabe Kaimowitz (Senior Staff Attorney, Michigan Legal Services) suggested that researchers assume that there is informed consent, and that they often fail to use adequate control subjects, particularly in behavioral research. Further, investigators may limit public access to information about prison research projects. He stated that they often use captive populations without considering the availability of community volunteers, and too often apply medical or psychological models inappropriate to economic and social problems. Prisoners are in an inherently coercive environment, and their consent to research is always suspect. Mr. Kaimowitz is not opposed to therapeutic biomedical or behavioral research when the prisoners themselves request its implementation. In such situations a review committee should examine the conditions that caused the prisoners to make such a request.

Matthew L. Myers (National Prison Project of the American Civil Liberties Union Foundation) stated that informed consent is not feasible in the prison environment. Regardless of prison policy concerning participation in research and parole, prisoners may believe that involvement contributes to early release. They may also participate to escape from the routine of prison life or to earn money for necessities. Mr. Myers said that most medical experimentation is conducted in medium or maximum security facilities in which conditions are

oppressive, alternatives are few, and there is a potential for abuse due to the closed, isolated and coercive nature of the prisons.

William R. Martin, M.D. (Director, Addiction Research Center, National Institute on Drug Abuse, DHEW) stated that addiction research is important and necessary both for society and for the prisoners. Limiting such research will retard development of therapy for addicts and will prohibit the evaluation of the addictive properties of new analgesics. Research participation is beneficial to most prisoners, he said, in that it is generally a safe and constructive experience, often improves health, and is a source of pride. Dr. Martin has been unable to identify any other population in which such studies can be done as validly and safely as in prisoners. He feels that prisoner participation may be altruistic, and therefore society should compensate participants for their involvement and for any injuries that may occur. There is empirical evidence that prisoners can and do make informed judgments, and are equally knowledgeable about research programs as other subjects. Practical measures can be taken to minimize the seductiveness of the research setting compared to the prison environment.

Theodore Francis (Occupational Drug Use Program, New York State Office of Drug Abuse Services) urged that biomedical and behavioral research in prisons continue, but that more attention be paid to compensation, the level of health care provided to subjects, and review of behavioral research. Participation of prisoners should be judged an acceptable means of earning money, and inmates should be reimbursed according to discomforts and risks incurred. Money earned should be held in escrow for prisoners until release

or paid to their families. A national board should review all behavior modification research for efficacy, validity, and risks to individuals and to the community. This board would issue public notices in lay language, describing dates and place of the research, as well as the reimbursement provisions.

Michael S. Lottman (Commission on the Mentally Disabled, American Bar Association, and the National Association for Retarded Citizens) urged that special care be given to protecting the rights of mentally disabled prisoners. Thereafter, testifying as an individual, he opposed nontherapeutic biomedical research on prisoners which exposes them to risk of discomfort, pain or incapacity. He stated that the coercive and oppressive nature of penal institutions precludes obtaining voluntary informed consent. Prisoners are not physiologically unique and therefore provide no information which cannot be gained from a free population. Research on prisoners benefits drug companies and researchers, he said. If research is to continue in prisons, particular care should be given to protecting the rights of mentally retarded prisoners, and an independent body should certify that each subject can and has given informed consent. Mr. Lottman is not opposed to therapeutic biomedical research in a prison setting, provided there are proper controls and consent procedures.

Joseph Stetler (President, Pharmaceutical Manufacturers Association) stated that to the best of his knowledge no prisoner has died or been permanently injured from research sponsored by drug companies. He advocated continuation of drug research in prisons provided that: (1) researchers are qualified, (2) facilities are adequate, (3) participation is voluntary and informed, (4) research is monitored, and (5) prisoners are compensated fairly. He stated that prisons

are practical and safe for drug testing, and that discontinuance of such research might delay development of new drugs. He estimated that 85% of all phase I drug testing is done on prisoners, and that the rate of compensation could increase substantially and still be insignificant relative to the total cost of new drug development. Prisoner testing of cosmetics or over-the-counter drugs is minimal relative to research involving prescription medications. A 1975 policy statement of PMA on the conduct of clinical research was summarized.

Allan H. Lawson (Executive Director, Prisoners' Rights Council of Pennsylvania) held that prisoners should be permitted to participate in experimentation only if the decision is absolutely voluntary. This is impossible in today's prisons, he said, because of economic pressures, forced idleness and inhuman conditions. In his view, research programs provide an excuse to prison administrators to neglect responsibilities such as housing, medical care and job programs. Because of the reality of economic pressures, the Prisoners' Rights Council would permit some research in prisons provided safeguards are instituted, until other means of earning money are available. However, the Council would ban research which involves exposure to incurable diseases or is otherwise dangerous or unnecessary. Mr. Lawson urged that medical care and compensation be provided for inmates injured during research.

The Reverend Americus Roy (Prisoners Aid Association of Maryland, Inc.) testified against medical experimentation in prisons based on personal experience at the Maryland House of Corrections. Prisoners participate in research, he said, because of economic deprivation and as a temporary escape from inhuman conditions.

Use of prisoners is exploitative of the economically depressed. Risks of research should be widely distributed, especially among those who are likely to benefit.