Medical and Psychological Experimentation on California Prisoners

I. INTRODUCTION

Our prisons are a two hundred year old experiment in crime control. The data are now in; prison administrators and reformists agree that the experiment has failed. Yet within this larger experimental design, prisoners continue to serve as subjects in specific medical and psychological experiments. Some of these experiments continue the search for effective penology and crime control, while others are not at all related to correctional goals.

California prisoners participate in drug tests for pharmaceutical companies, in medical research for university research teams, and in psychological experiments for Department of Corrections personnel. Research has shown that these experiments are often subject to abuse. Certain characteristics of the prison system tend to mitigate consent, obscure professional responsibility, and lessen concern for the physical and psychological well-being of the inmate subject.

These experiments have raised several serious questions. A central issue has been the free and informed consent of all human experi-

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2See, e.g., AFSC, supra note 1, at 91; interview with Warden Louis Nelson, San Quentin, Wall Street Journal, April 9, 1968 at 1, col. 1; speech by Director of Corrections Raymond K. Procurier, Davis Human Relations Council, December 1973; Calif. Assem. Comm. on Crim. Proc., Deterrent Effects of Criminal Sanctions (1968). In this report, the committee found that:
(a) The amount of time served has no viable effect on crime among released convicts (at 33);
(b) Time served can be reduced without increasing recidivism (at 31);
(c) Incarceration, especially when lengthy, does not benefit the public safety (at 34).
3Department of Corrections, Annual Research Review (1972) [hereinafter cited as Research Review].
4Id., see especially projects at 75, 57 and 47.
5In Cobbs v. Grant, 8 Cal. 3d 229, 243, 104 Cal. Rptr. 505, 514, 502 P.2d 1, 10 (1972), the court held that a physician has "a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each." Section 1 of the Nuremberg Code (discussed infra page 368) sets out the following requirements to establish volun-
mental subjects. Since most of the activities in an inmate's life are ultimately involuntary, it is doubtful that an adequate standard of free and informed consent can be maintained within prison walls. Questions of tort liability for injuries in experimentation raise special problems for the prisoner because of civil disability and governmental immunity statutes. Finally, the unique isolation of prisoners and staff behind prison walls can conceal experiments of questionable quality from public scrutiny and control.

A broad spectrum of experiments on prisoners will be examined in this article to illustrate the range of problems to be addressed by limited legal remedies. Some abusive practices in other states will be noted; examples from these states may indicate the direction of future experimentation in California prisons.

This article is not intended as a condemnation of all medical and psychological experiments in prisons. It focuses instead on abuses that do exist and on the weaknesses in present review procedures that allow these abuses to exist. The article surveys controls on experimentation as they currently operate in California prisons and analyzes legal and extra-legal remedies currently available to a prisoner who is an unwilling subject or who has suffered injury in a prison experiment.

II. THE EXPERIMENTS

Experiments conducted in prisons can be divided into three types: commercial tests, medical research and psychological studies. Commercial and medical research are similar in many respects. Both involve agreements between the prison authorities and an outside corporation or university. Both are subject to established review procedures which are discussed infra.

Commercial tests are usually initiated by a pharmaceutical or cosmetic company. The tests are conducted to comply with Food and Drug Administration (FDA) regulations which require extensive testing on human subjects prior to the release of a new drug on the market.

Medical research projects are generally initiated by teams of uni-

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7These regulations are discussed infra p. 370.
versity scientists. These experiments are often funded by government agencies under the Department of Health, Education and Welfare (HEW). The experiments seek data on the progress of diseases, the metabolism of certain substances and other characteristics of the human body.

Inmates are paid for participation in commercial and medical experiments. The necessity for specific financial arrangements with the institution and the governmental requirement of review procedures in commercial and medical experimentation make these studies potentially subject to public control. The fact that abuses persist indicates a need for closer scrutiny of the review procedures and other controls on experimentation.

The third type of experimentation is initiated by Department of Corrections personnel within the institutions. These experiments range from statistical observation of inmate behavior to behavior modification involving the use of strong tranquilizers. Often these experiments are not visible to an observer of prison activities; they are seldom identified as experiments by corrections personnel. The experiments are frequently regarded by the corrections staff as a part of an inmate's treatment plan within the rehabilitative scheme. Inmates are not paid for participation in these experiments; indeed, inmates are sometimes required to participate against their will. These treatments or experiments will be discussed as experiments here because they frequently involve methods or drugs that have not been approved by the medical and psychiatric professions for general use. These treatments or experiments are usually novel approaches to old problems; sometimes, however, they employ methods which are

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8Hearing of the Assembly Committee on Criminal Justice on the Subject of Prison Volunteers in Medical Experimentation, at San Francisco, October 23, 1973 [hereinafter cited as Hearing on Prison Experimentation]. The transcript of this hearing is not yet ready for publication; the rough draft is located in the office of California Assemblyman Alan Sieroty in Sacramento. (Testimony of Dr. William Erenfeld, Committee on Human Experimentation, University of California at San Francisco).


10See, e.g., Research Review, supra note 3, at 85.

11See, e.g., Mackey v. Procnier, 477 F.2d 877 (9th Cir. 1973).

12The Research Review, supra note 3, does not report the examples of psychological experimentation which are questioned in this article on ethical grounds.

13Hearing on Prison Experimentation, supra note 8 (Testimony of Dr. Thomas L. Clanon, Superintendent of California Medical Facility (CMF) at Vacaville); interview with Dr. Charles Jew, Director of Research Evaluation, CMF at Vacaville, February 26, 1974.

14See McNeil v. Director, Patuxent Institution, 407 U.S. 245 (1972); Mackey v. Procnier, 477 F.2d 877 (9th Cir. 1973); McCray v. Maryland, 456 F.2d 1 (4th Cir. 1972).
considered risky by psychiatric professionals.\textsuperscript{15} The fact that these treatments or experiments are often administered by para-professional or lay personnel within the prison increases the risk of injury to the inmate.

A. COMMERCIAL AND MEDICAL EXPERIMENTS AND ABUSES

1. COMMERCIAL EXPERIMENTS

Commercial experiments in prisons follow a well established procedure. Pharmaceutical houses are required by the 1963 Amendments to the Food, Drug and Cosmetic Act to satisfy certain testing requirements before releasing a drug on the market.\textsuperscript{16} Prior to any testing in humans, the pharmaceutical houses conduct extensive laboratory tests, comparisons with prototype drugs, and testing in small animals. The drug tests involving humans are then done in three phases.\textsuperscript{17} Phase I is the first introduction of the drug to humans. The drug is administered to healthy, normal subjects to discover possible toxic properties. In spite of the precautions taken, Phase I presents the greatest risk a human subject will face in drug testing. If the drug and the subject survive Phase I, a Phase II study will be run to determine minimum and maximum dosages. In Phase III, the drug is administered to hospital patients to determine its efficacy as a remedy for illness. Most of the tests done in prisons are Phase I toxicity studies.\textsuperscript{18}

Commercial experiments are usually conducted in special wards of university hospitals near prisons.\textsuperscript{19} At a few prisons, laboratory facilities have been built on the prison grounds for the express purpose of experimentation on prisoners. Three such facilities are: a privately owned laboratory built on the grounds of the State Prison of Southern Michigan,\textsuperscript{20} a university-owned laboratory at the Montana State Prison,\textsuperscript{21} and a state-owned laboratory at the California Medical Facility at Vacaville.\textsuperscript{22}

\textsuperscript{15}Hearing on Prison Experimentation, supra note 8 (Testimony of Dr. Philip Shapiro, a psychiatrist representing the Medical Committee for Human Rights).
\textsuperscript{16}21 C.F.R. § 130.1 et seq. (1973).
\textsuperscript{17}Blackwell, For the First Time in Man, 13 CLIN. PHARMACOL. THER. 812 (1971) [hereinafter cited as Blackwell].
\textsuperscript{18}Id.
\textsuperscript{19}See, e.g., the experiments described in Blackwell, supra note 17; Hodges and Bean, The Use of Prisoners for Medical Research, 202 J.A.M.A. 513 (1967) [hereinafter cited as Hodges and Bean].
\textsuperscript{20}Drug Tests Behind Bars: Jackson (Mich.) Prison, BUSINESS WEEK, June 27, 1964, at 58 [hereinafter cited as Drug Tests].
\textsuperscript{21}Moore, The Deer Lodge Unit, 13 CLIN. PHARMACOL. THER. 833 (1971).
\textsuperscript{22}Hearing on Prison Experimentation, supra note 8 (Testimony of Dr. Clanon, Superintendent of CMF at Vacaville).
The commercial experiments require varying degrees of participation by the inmate-subjects. In some Phases, the tests require that the inmate be hospitalized for constant observation. Other tests require only that the inmate be seen by the medical staff less than once a day.

"Skin patch" tests are perhaps the most common type of commercial testing. In these tests, a medication or cosmetic preparation is applied to the forearm of the inmate-subject; the arm is then bandaged. The inmate is instructed to wear the bandage for a certain period of time and to report back to the laboratory at specified intervals to allow the staff to record observations. For these experiments inmates are paid up to $15 per month.

Commercial drug tests are reviewed by a committee within the institution, pursuant to FDA requirements. At the California Medical Facility at Vacaville, for example, the institutional review committee is composed of the superintendent, the assistant superintendent, the chaplain, one inmate from the men's advisory council, and the chief medical officer. This committee reviews the proposed tests for safety factors, protection of the subject, and adequate compensation. This type of committee, with similar membership, is common to all prisons in which inmates participate in commercial experimentation.

Financial arrangements must be made for the use of institutional facilities after the experiment has been approved by the institutional review committee. At the California Medical Facility at Vacaville these arrangements are made through the Solano Institute for Medical and Psychiatric Research (SIMPR). SIMPR is a non-profit corporation, organized by doctors doing research at Vacaville, for the purpose of receiving and distributing grant monies. SIMPR maintains a laboratory facility on prison grounds. Faculty members from nearby University of California medical schools arrange for research grants from large pharmaceutical houses and then place the funds in

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23 Hearing on Prison Experimentation, supra note 8 (Testimony of Ralph Urbino, Administrator of Solano Institute for Medical and Psychiatric Research).
24 An example of more intensive participation by inmate-subjects can be found at the State Prison in Southern Michigan. Upjohn and Parke-Davis have built a $500,000 laboratory on prison grounds. Part of this facility is a ten-bed metabolic ward in which all bodily functions of a subject can be monitored and analyzed as his body metabolizes a new drug. Drug Tests, supra note 20, at 58, 62.
26 Hearings on Prison Experimentation, supra note 8 (Testimony of Dr. Thomas L. Clanon, Superintendent of CFM at Vacaville).
27 Id.
28 Hearings on Prison Experimentation, supra note 8 (Testimony of Ralph Urbino, Administrator of Solano Institute for Medical and Psychiatric Research).
29 Id. Until a few years ago, the space was donated by the State of California; currently, SIMPR pays $1000 per month in rent.
SIMPR accounts. The administrator of SIMPR assists the researcher in determining the costs of the experiment, including salaries of the extra guards, salaries for technicians and assistants, and pay for the subjects. The amount to be paid to the subjects for a given experiment is determined by the SIMPR administrator in collaboration with the researcher. SIMPR then acts as a conduit for the grant funds and as a coordinator of facilities and personnel. The experiment and arrangements are reviewed by the SIMPR board, which is composed of a researcher, two physicians, a pharmacist, a veterinarian, a banker, a lawyer and a former inmate. This board examines the experiment for feasibility, scientific merit, and availability of appropriate facilities.30

2. MEDICAL EXPERIMENTS

Researchers doing medical experimentation on university, government or private grants follow similar procedures. Teams of university scientists arrange with prison authorities to conduct medical experimentation using inmates as subjects.31 The controlled environment of the prison makes the inmate a very attractive subject for medical experimentation.32 The inmate is readily available for check-ups at appointed times. He is accustomed to constant supervision, so he can be checked more easily than a free person for ingestion of the proper drugs and food. Large numbers of potential subjects are available at a single prison, allowing for the efficient use of the researcher’s time.

The institutional review process for medical research is similar to the review process for commercial drug tests. A typical process has been described by a doctor from the University of Iowa who conducted experiments at Iowa State Prison.33 Under this process, the researcher proposes a project to the research committee at the university medical school. If approved by the university the proposal is then sent to the Director of Penal Institutions who sits on the Board of Control. The Board of Control, which consists of three persons appointed by the governor to direct state institutions, reviews all such proposals.34 Arrangements are then made by the researcher with the prison to recruit subjects for the project. The prison authorities screen the subjects, disqualifying those who are emotionally ill, unreliable or otherwise unsuited for the project. The research team

30 Id.
31 Id.
32 Drug Tests, supra note 20, at 62.
33 Hodges and Bean, supra note 19, at 514, 515.
34 The function of the Board of Control is now served by the newly-created Department of Social Services in Iowa. The process of review is essentially the same. 11 IOWA CODES ANN. § 217.1 et seq. (West Supp. 1973).
then explains the experiment, obtains consent, conducts physical
examinations, and further screens the subjects. Upon completion of
the experiment, a letter of appreciation for the inmate’s cooperation
is sent to the prison warden to be placed in the prisoner’s file for the
attention of the parole board.35

3. ABUSIVE PRACTICES IN COMMERCIAL AND MEDICAL
EXPERIMENTATION

At times, these review procedures have failed to screen out abusive
research. Sometimes the approval of the university review commit-
tee, or of the research team itself, is substituted for the required
review by the institutional committee.36 Such careless review pro-
dcedures have resulted in experiments such as one conducted by Dr.
Robert Hodges at Iowa State Prison in 1969.37 To prove that a lack
of ascorbic acid causes scurvy, which was common medical knowl-
gedge at the time, Dr. Hodges induced severe cases of scurvy in five
inmate subjects.38 The experiment was very painful and was criti-
cized by Dr. Hodges’ colleagues as “a senseless piece of cruelty.”39
Dr. Ephraim Kahn of the California Department of Public Health
censured Dr. Hodges’ experiment as a “totally pointless study.”40
He predicted that the injuries sustained by the subjects in the experi-
ments would be permanent; these included heart damage, loss of
hair, damage to teeth, and hemorrhage into femoral nerve sheaths.

In other cases, the required review procedure has been totally
ineffective. A series of injurious experiments conducted by Dr.
Austin R. Stough at Alabama State Prison in 1969 resulted in an
epidemic of viral hepatitis.41 Dr. Stough was collecting blood plasma
from inmates for sale to hospitals and blood banks, and was simulta-
neously testing new drugs for pharmaceutical houses and HEW

35 Hodges and Bean, supra note 19, at 515.
36 Hearing on Prison Experimentation, supra note 8 (Testimony of Dr. Thomas L.
Clanon, Superintendent of CMF at Vacaville).
37 Hodges et al., Clinical Manifestations of Ascorbic Acid Deficiency in Man, 24
AM. J. CLIN. NUTR. 432 (1971) [hereinafter cited as Hodges et al].
38 Id. The inmates were fed a liquid formula devoid of ascorbic acid via a stomach
tube for 84 to 97 days. They were exposed to temperatures approximating a
cold climate for four hours a day, and had enough blood withdrawn to cause
mild anemia in each subject.
39J. MITFORD, KIND AND USUAL PUNISHMENT 147-149 (1973) [hereinafter
cited as MITFORD]. In addition, Dr. Kahn criticized the incompetence of Dr.
Hodges and his researchers, evidenced by the fact that a mineral supplement rec-
ommended by the National Research Council “was inadvertently omitted from
the diets during the first 34 days of the depletion period.”
40 Id. at 149.
41 Walter J. Rugaber, Prison Drug and Plasma Projects Leave Fatal Trail, N.Y.
Times, July 29, 1969 at 1, col. 5 et seq. [hereinafter cited as Rugaber]. At least
500 cases of hepatitis came to the attention of the Public Health Service, and the
epidemic caused at least 6 deaths. The inmates were paid a dollar a day.
agencies. Though more than one federal agency and a number of pharmaceutical houses were aware of the gross contamination and dangerous practices involved in Dr. Stough's experiments, no action was taken against him. Both private and public funds continued.\textsuperscript{42} When news of the hepatitis epidemic was brought to the attention of the FDA, only a single physician was employed by the agency to investigate questionable research practices. That investigator visited Dr. Stough's laboratory twice and suggested that there be more careful medical supervision in the experiments, but no changes were required.\textsuperscript{43} These experiments and others\textsuperscript{44} indicate a need for careful and objective review of research projects by institutional and governmental personnel.

According to ethical standards discussed \textit{infra}, some experiments reviewed by institutional and governmental committees should be rejected because they cause excessive pain or create an unwarranted risk of injury.\textsuperscript{45} One such experiment was conducted by Dr. William Epstein at Vacaville in 1962 with funds from Lederle, a pharmaceutical company.\textsuperscript{46} The experiment was called a "pain tolerance test" by Dr. Epstein. The test involved the injection of an enzyme, Varidase, into the subjects' muscles. All subjects suffered extreme pain, fever and chills. The inmates were paid $4 each for this experiment.\textsuperscript{47}

These examples are limited to abusive practices in medical and commercial research. Most of the abuses that occur in this area could be apprehended and corrected by adequate review procedures. Research indicates that failure to obtain consent from the subject is uncommon in medical and commercial research.\textsuperscript{48} The quality of that consent, however, is open to question and is discussed further \textit{infra}. In contrast, abuses in psychological experiments involve a failure to obtain informed consent as often as they involve unethical

\textsuperscript{42}Id. at 20.
\textsuperscript{43}The agency (FDA) frowns on insufficient supervision, but under present policies, there are no specific minimum standards. In the gray area that results, frowning is about the limit. \textit{Id.} at 21.
\textsuperscript{44}See, \textit{e.g.}, Rugaber, \textit{supra} note 41, at 20. (Whooping cough experiment results in death from whooping cough vaccination).
\textsuperscript{45}Declaration at Helsinki, § I-3; Nuremberg Code § § 4, 5 and 6. It is not clear from HEW and FDA regulations, discussed \textit{infra}, whether review committees are authorized or expected to reject proposals for ethically unacceptable experiments.
\textsuperscript{46}Mitford, \textit{supra} note 39, at 158.
\textsuperscript{47}Id. One subject, who later sued the experimenter, developed a nearly fatal disease of the muscles during which his weight dropped from 140 to 75 pounds.
\textsuperscript{48}Blackwell, \textit{supra} note 17, at 935.
practices in the experiments themselves.

B. PSYCHOLOGICAL EXPERIMENTS AND ABUSES

The California prison system is often praised for its treatment programs which are "closer to the rehabilitative level than any other correctional system in the United States."\textsuperscript{49} Some of the treatment programs are innovative approaches to perennial problems. In most of the California institutions various types of group therapy are available, patterned on theories as divergent as psychotherapy, Synanon techniques and transactional analysis.\textsuperscript{50}

Innovative techniques however imply trials and risks. Some programs described in this section have gone beyond the level of risk normally endorsed by the psychiatric professional community for private patients.\textsuperscript{51} The correctional staff identifies these programs as treatments rather than research projects. The programs are initiated by staff and are subject to review only within the institution.\textsuperscript{52}

Abusive practices in psychological programs have included the use of non-approved drugs, the misuse of approved drugs, the administration of drugs and therapy by unqualified personnel, and the involvement of inmates in high-risk and intensive programs without consent.

\textsuperscript{49} AFSC, \textit{supra} note 1, at 83; speech by Raymond K. Prouncier, \textit{supra} note 2.
\textsuperscript{50} Interview with Charles Jew, Director of Psychiatric Research Evaluation, California Medical Facility at Vacaville, February 26, 1974. Several of these innovative psychological programs involve the application of behavior modification theory. Behavior modification theory is based on the idea that all behavior can be divided into units. Behavior is learned in units by the simultaneous occurrence of an action (a response) with a reward or punishment (a positive or aversive stimulus). Behavior can be changed by making the occurrence of a new positive or aversive stimulus contingent on the occurrence of a desired or unacceptable unit of behavior. According to the theory, when a subject is rewarded (receives a positive stimulus) he tends to repeat the behavior he associates with the reward. When a subject is punished (receives an aversive stimulus) he tends to avoid or completely eliminate the behavior he associates with the punishment. Behavior modification theory is based on the work of B.F. Skinner. For an explanation of the theoretical model see B.F. Skinner, \textit{Contingencies of Reinforcement, A Theoretical Analysis} (1969) [hereinafter cited as B.F. Skinner]. For an application of the theory to a social model see B.F. Skinner, \textit{Beyond Freedom and Dignity} (1971) and J.H. Wheeler, \textit{Beyond the Punitive Society} (1973).
\textsuperscript{51} \textit{Hearing on Prison Experimentation, supra} note 8 (Testimony of Dr. Philip Shapiro, a psychiatrist representing the Medical Committee for Human Rights).
\textsuperscript{52} \textit{Hearing on Prison Experimentation, supra} note 8 (Testimony of Dr. Thomas Clanon, Superintendent of CMF at Vacaville). Interview with Dr. Charles Jew, \textit{supra} note 50. In some cases, even this in-house review is not required. According to Dr. Clanon, staff initiated experimental treatments or studies are reviewed by the Special Treatment Board of which he is a member. However, research reveals that this Special Treatment Board has not met to discuss the Anectine experiments, the Lithium program, the use of Prolixin or the development of intensive psychological programs. Indeed, Dr. Charles Jew (in interview, \textit{supra} note 50) was unable to recall whether the Special Treatment Board had met within the last several years.
(1) Use of non-approved drugs. A drug called anecine has been used at the California Medical Facility and at the California Institute for Women as an aversive stimulus (a punishment) in a behavior modification program.\(^53\) In 1970, the drug was approved for use on unconscious patients during surgery or electro-shock therapy.\(^54\) However, since 1967 the inmates have been given injections of anecine while fully conscious.\(^55\) The psychological effect of the drug on a fully conscious person is to cause a desperate feeling of drowning and dying.\(^56\) The physical effect is to paralyze the subject’s muscles, particularly the breathing apparatus.\(^57\) Inmates have been selected for anecine aversion therapy for a variety of offenses, including frequent fights, verbal threatening, deviant sexual behavior, stealing, and unresponsiveness to group therapy.\(^58\)

(2) The misuse of approved drugs. Lithium carbonate, a drug used for the treatment of manic-depressives, was discovered to have a leveling effect on the moods of inmates not diagnosed as manic-depressive.\(^59\) Before the drug was approved by the FDA, it was administered to selected inmates as an experiment.\(^60\) Since that time, the drug has been approved for use on diagnosed manic-depressives; but it is now administered as a treatment for non-manic-depressive inmates whose disruptive behavior comes to the attention of prison authorities.\(^61\)

Prolixin, a strong tranquilizer, is used at the California Medical Facility at Vacaville.\(^62\) In heavy doses Prolixin does not calm the subject. Instead it produces a condition called “akathisia,” an irresistible urge to maintain purposeless, driven motion.\(^63\) This side effect can be relieved by daily doses of a drug called Artane.\(^64\) According to the deposition of an inmate at Vacaville, no attempt is made to relieve this side effect; the drug is used as a punishment

\(^53\) Hearing on Prison Experimentation, supra note 8 (Testimony of Dr. Thomas Clanon, Superintendent of CMF at Vacaville); Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973); Note, Conditioning and Other Technologies, 45 S. Cal. L. Rev. 616, 633-40 (1972) [hereinafter cited as Note].


\(^55\) Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973); Bowers, Prisoners’ Rights in Prison Medical Experimentation Programs, 6 CLEARING. REV. 319, 320 (1972) [hereinafter cited as Bowers]; Note, supra note 53, at 633.

\(^56\) Note, supra note 53, at 633.

\(^57\) Id.

\(^58\) Mitford, supra note 39, at 128.

\(^59\) Hearing on Prison Experimentation, supra note 8 (Testimony of Dr. Thomas Clanon, Superintendent of CMF at Vacaville).

\(^60\) Id.

\(^61\) Id.

\(^62\) Bowers, supra note 55, at 320. Prolixin is fifty times stronger than the more commonly known tranquilizer, Thorazine. One dose usually lasts two weeks. Id.

\(^63\) Id.

\(^64\) Artane is currently used in conjunction with Prolixin at Atascadero State Hospital.
rather than as a tranquilizer.\textsuperscript{65}

(3) Administration of drugs and therapy by unqualified personnel. According to testimony of inmates, many psychological programs are administered by para-medical or lay personnel within the prison. The anectine injections were often administered by other inmates under orders and supervision of non-medical staff.\textsuperscript{66} Prolixin injections were given by "three prison helpers, one guard, and a prison employee called a medical technical assistant."\textsuperscript{67} At the Federal Prison at Lompoc, California, graduate students entering the Department of Educational Psychology at the University of California are introduced to the practice of counseling by conducting intake interviews and group therapy sessions.\textsuperscript{68} The decisions that must be made in these experimental therapies are sometimes critical; when the therapy includes the injection of a drug, medical supervision seems to be indicated. Such decisions are even more critical in behavior modification programs, where it is essential to the effectiveness of the technique that the subject be rewarded and punished in strict adherence to the theoretical model. Misapplication of the theory can have a more damaging effect on the inmate's behavior than no treatment at all.\textsuperscript{69}

(4) Involvement of inmates in high-risk and intensive programs without consent. At the California Medical Facility at Vacaville, a Maximum Psychiatric Diagnostic Unit (MPDU) was developed as a center for intensive psychological treatment of seriously disturbed inmates who requested this specialized program.\textsuperscript{70} According to Mr. Jim Kane, the director of the Northern Reception Guidance Center at the California Medical Facility, the MPDU operated very successfully while it offered its services to voluntary patients. Now, how-

\textsuperscript{65}Bowers, supra note 55, at 320:
About a month ago I was given Prolixin, a punishment drug at Vacaville . . . coerced by the presence of three prison helpers, one guard, and a prison employee called a medical technical assistant. The drug stays in your system for two weeks . . . I had a Parkinson reaction to it — couldn't sleep — couldn't think — couldn't get comfortable — couldn't walk normally and my tongue thrust between my teeth. Prolixin is torture. It is called liquid shock therapy by the prisoners.

\textsuperscript{66}Bowers, supra note 55, at 320.

\textsuperscript{67}Bowers, supra note 55, at 320 (quoted supra note 65).

\textsuperscript{68}Interview with Stef Sisman, former counselor-intern in prison counseling program.

\textsuperscript{69}B.F. SKINNER, supra note 50.

\textsuperscript{70}Interview with Jim Kane, Director of Northern Reception Guidance Center at CMF Vacaville, who was involved in the planning and development of the MPDU. One of the intensive programs planned for the MPDU was the development of a Violence Prone Expectancy Scale, by which inmates could be identified as potential candidates for psychosurgery, discussed infra. Interview with Dr. Ned Opton and Dr. George Bachritya, in British Broadcasting Company film entitled The Surgery of Violence, produced by Allan Segal.
ever, the unit is filled with inmates who could not be handled at other institutions. These inmates did not request and do not respond to psychological programming.\textsuperscript{71}

A high-risk form of therapy, called “attack therapy” is being used in an intensive program at the California Institute for Women (CIW).\textsuperscript{72} Several inmates from CIW have corresponded with the Prisoners’ Union and with a psychiatrist, Dr. Frank Ervin, complaining that women had been included in the intensive program against their will.\textsuperscript{73} In the intensive program, selected inmates are isolated into a living unit which is segregated from the main population. They are required to sign a “contingency contract” through which they can earn their way back to the main population and normal privileges. Six hours a day are spent in “attack grouping” which consists of verbal attack on any statement made by a selected inmate until the inmate breaks under the stress. Although the attacks are supposed to be verbal rather than physical, further investigation by the Prisoners’ Union has revealed that one very young inmate required hospitalization for lacerations and bruises following her day in attack therapy.\textsuperscript{74}

Perhaps the highest risk to which an inmate could be exposed is the possibility that the prison authorities could permanently alter his personality through brain surgery. Department of Corrections personnel report that there has never been a case of psychsurgery performed within the California prison system.\textsuperscript{75} Department offi-

\textsuperscript{71} Interview with Jim Kane, supra note 70. Other intensive treatment units developed in other states include:

(a) Project START at the U.S. Medical Center at Springfield, Missouri. START, an acronym for Special Treatment and Rehabilitative Training, was developed as a behavior modification unit for “hard core unmanageable inmates”. A suit brought by the ACLU has resulted in a termination of the program as of March 1974 on grounds of cruel and unusual punishment. CONG. REC. (daily ed. October 10, 1973).

(b) The Patuxent Institution. The institution operates as a total program in behavior modification. A new inmate is deprived of all normal privileges when he enters the institution; these can be earned back by cooperation in psychological and rehabilitation programs. The operations of this institution have been limited by McCray v. Maryland, 456 F.2d 1 (4th Cir. 1972), and McNeil v. Director, Patuxent Institution, 407 U.S. 245 (1972), which is discussed \textit{infra} p. \textsuperscript{76} MITFORD, supra note 39, at 104-118.

(c) The Federal Prison at Marion, Illinois. There, the Asklepius Society has been established as an intensive psychological program based on Transactional Analysis and Synanon-style group therapy. CONG. REC. (daily ed. October 10, 1973).

\textsuperscript{72} Hearing on Prison Experimentation, supra note 8 (Testimony of Stephanie Riegel, Prisoners’ Union, and Dr. Frank Ervin, Professor of Psychiatry in Residence at U.C.L.A.). Letter published in 18 Berkeley Barb No. 12, at 1.

\textsuperscript{73} Id.

\textsuperscript{74} Id.

\textsuperscript{75} Hearing on Prison Experimentation, supra note 8 (Testimony of Dr. Thomas Clanon, Superintendent of CMF at Vacaville).
cials distinguish three lobotomies (removal of the frontal lobe of the brain) which were performed in 1968 on three inmates, as medically indicated treatments for epilepsy. 76 These greatly publicized operations were not intended as neurosurgery for the purpose of behavior modification. However it must be noted that the Department of Corrections is not opposed to the use of psychosurgery to control the behavior of aggressive, non-epileptic inmates. In 1971 the California Department of Corrections applied to the California Council on Criminal Justice (CCCJ) for $48,000 to perform psychosurgery on aggressive inmates. 77 CCCJ rejected the proposal as an “undeveloped concept.” Unexpected publicity of these plans brought a shocked response from the public; the department eventually shelved its plans for psychosurgery in response to public pressure. 78

Psychological experiments intrude on the mental processes of the inmate. These intrusions carry as much potential for injury as do medical and commercial research. And yet review procedures are more relaxed, sometimes even non-existent. Information on these programs is actively protected from public view. The confidentiality that shrouds the inmate’s treatment plan can also obscure inept and unethical practices by correctional staff. In view of the strong potential for injury in psychological experiments, one would expect that careful attention would be given to the practice of obtaining informed consent from all participants. But as illustrated in some of the above examples, experiments initiated by Department of Corrections personnel often include individuals against their will. 79 When consent is given, the quality of that consent is open to question.

III. THE PROBLEM OF CONSENT

It has been asserted that a prisoner, because of the coercive nature of his environment, cannot truly be said to give informed con-

76 Id.
77 Mitford, supra note 39, at 129. Mitford quotes from a letter from Raymond Procuiner, Director of Corrections, to the California Council of Criminal Justice: The problem of treating the aggressive destructive inmate has long been a problem in all correctional systems. This letter of intent is to alert you to the development of a proposal to seek funding for a program involving a complex neurosurgical evaluation and treatment program for the violent inmate . . . . Surgical and diagnostic procedures would be performed to locate . . . . centers in the brain which could serve as the focus for episodes of violent behavior. If these centers were . . . . verified . . . . [as] the sources of aggressive behavior, neurosurgery would be performed.
78 Id.
79 See, e.g., Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973); Bowers, supra note 55; Note, supra note 53; Hearings on Prison Experimentation, supra note 8 (Testimony of Stephanie Riegel).
sent to his own injury in an experiment. If an inmate can consent to be an experimental subject, there remains the difficult problem of monitoring the quality and completeness of the information he was given, and the further task of determining that the inmate's consent was voluntarily given. Sometimes no attempt is made to obtain the inmate's consent before requiring his participation in a psychological experiment; in such cases, the inmate's refusal to participate has received the protection of the court.

Several factors in the life of an inmate can induce him to consent to an experiment that he would never consider outside prison walls. These factors include the pay, the opportunity to relate to free persons, and the indeterminate sentence.

(1) **Pay.** Prison jobs pay as little as a few cents an hour. Inmates usually have very limited outside sources of income; they must depend on families and friends who usually have little to spare. Yet the prison is set up to create a need for income in order to encourage inmates to work at prison jobs. Researchers pay relatively little for the use of inmate-subjects in experiments, but within the prison context, pay as low as $1 a day will attract a large number of recruits.

(2) **The opportunity to relate to free persons.** Most researchers have little contact with inmates; they are not accustomed to dealing with inmates as anything other than human beings. Such treatment can be a luxury to an inmate. In addition, some experiments involve a move to a more comfortable physical setting, with better food and more privileges. One researcher reports, "A prisoner who volunteers and is accepted for the research project moves into the special

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80 For a definition of informed consent, see supra note 5.
81 In May 1973, the Northern California Psychiatric Society officially declared its belief that "prisoners are unable to give fully free and truly informed consent for experimental procedures . . . " *Hearings on Prison Experimentation*, supra note 8 (Testimony of Dr. Philip Shapiro). *See also* Declaration at Helsinki, discussed infra.
82 Discussed *infra* p. 366 et seq.
83 *CAL. PEN. CODE* § 2700 (West 1970). Prison jobs start at 2¢ an hour. The statutory limit is 35¢ an hour; jobs paying the limit are rare.
84 The prison does not supply necessities such as toilet articles, or tools, books or supplies for various educational and recreational activities. The inmate must purchase these items through the canteen (family and friends are not permitted to send in the items). The inmate must pay cost and shipping plus a 10% surcharge to the inmate welfare fund. *Mitford*, supra note 39, at 203.
85 Dr. Robert Batters, a researcher, was given an estimate by a SIMPR official on the cost of using inmate-subjects in an experiment requiring a weekly blood sample. Cost: $15 a month per inmate. For the same experiment, using divinity students from a local college, Dr. Batters would pay over $100 per subject. *Mitford*, supra note 39, at 144.
86 *Id.*
project area. This area differs from other parts of the jail because the volunteers are treated more like members of a free society.  

(3) The indeterminate sentence. The California inmate lives in a vacuum of uncertainty regarding the contingencies of his release. In California, the legislature attaches minimum and maximum terms to each criminal offense. Judges sentence convicted persons to state prison “for the term prescribed by law” rather than for a specified number of years. The inmate’s sentence is then set by a nine-man panel appointed by the governor — the Adult Authority. The inmate appears before an Adult Authority panel approximately once a year. At these hearings the inmate is told the date when he should return for another hearing (a “nine-month denial,” a “year denial”), or the date when he will be released on parole, and/or the date when his sentence will terminate. All three of these dates can be changed at will by the Adult Authority.

Ideally, this system allows for the individualized treatment of each offender. The intent of the proponents of indeterminate sentences was to allow the inmate to be released “at the earliest time within the limits fixed which his personal situation indicates.” However, the result of indeterminate sentencing is that the median time served by California prisoners is the longest in the country.

The Adult Authority panels consider several factors when determining the length of an inmate’s sentence, many of which have nothing to do with the inmate’s efforts toward rehabilitation. The inmate does not have an opportunity to examine the reports that the Adult Authority will consider at the hearing. He does not know which crimes, offenses or infractions will displease the panel, or which programs, achievements or recommendations will impress them. It is, therefore, reasonable to expect that the inmate would

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88 Id.
89 See CAL. PEN. CODE generally. The most common term set by the legislature is one to fifteen years. AFSC, supra note 1, at 92.
90 CAL. PEN. CODE § 1168 (West 1970).
91 CAL. PEN. CODE §§ 5075, 3020 and 3023 (West 1970).
92 CAL. PEN. CODE § 3020 (West 1970).
93 AFSC, supra note 1, at 34-47, 84; MITFORD, supra note 39, at 80.
94 MITFORD, supra note 39, at 81, quoting RAMSEY CLARK, CRIME IN AMERICA 222 (1970).
95 AFSC, supra note 1, at 91.
96 Id. at 94.
97 Id.; MITFORD, supra note 39, at 90-93. In considering the inmate’s psychological adjustment, the Adult Authority also considers psychological problems unrelated to the inmate’s offense. Thus a forger on a sentence of one to fourteen years may serve several years beyond the median sentence for that crime if he is a homosexual or if he has an alcohol problem. Bowers, supra note 55, at 321.
98 MITFORD, supra note 39, at 89. But see In re Prewitt, 8 Cal. 3d 470, 475-76, 105 Cal. Rptr. 318, 323, 503 P.2d 1382, 1387 (1972) (recognizing limited right to disclosure of documents to be considered at an Adult Authority hearing).
attempt to load his file with reports of good conduct and cooperation. If there is a possibility that the board would look favorably on a participant in a medical or commercial experiment, or that the researchers would submit a letter to the board commending the inmate's attitude, such a possibility can be a stronger inducement than money for an inmate seeking release.

Participation in an experimental psychological program can be doubly attractive under indeterminate sentencing. First, the board may be impressed with the inmate's cooperative attitude toward the staff-initiated experiment; the board may infer that the inmate is indeed motivated to seek rehabilitation through this new program. Second, there is the possibility that the program will be effective in bringing about behavior changes, which will be evident in numerous staff reports to the board (not the least of which would be the recommendation of the staff researcher himself).

The factors that may induce an inmate to participate in an experiment may also induce him to continue when the experiment should be terminated. The inmate may tell an experimenter that he is feeling well, when in fact he is experiencing side effects. The inmate's desire to stay in the experiment, for whatever reasons, can seriously distort the results of the study and may result in the placing of an unsafe drug on the market. 99

In some cases, correctional officials have failed to obtain the consent of an inmate included in an experimental program. 100 Although such failures to obtain consent are infrequent in commercial and medical research, 101 there has been some dispute over the necessity of obtaining an inmate's consent before requiring participation in a psychological program. 102 This dispute has reached the court in several recent cases; the court has protected an inmate's right to refuse treatment. In Mackey v. Procunier, 103 a federal district court

addition to the inmate's behavior and attitude within the prison, the Adult Authority considers the seriousness of his crime, past offenses (whether acquitted or convicted), the amount of time served, the opinion of the District Attorney who prosecuted him, and current public opinion about the crimes on the inmate's record.

99 Rugaber, supra note 41, at 20.
100 See examples given supra note 79.
101 Blackwell, supra note 17, at 935.
102 Recent cases on the treatment of the mentally ill have found a duty to treat in spite of the patient's refusal, Whitree v. State, 290 N.Y.S.2d 486, 56 M.2d 693 (1968), and no right for a patient to refuse drug therapy on religious grounds, Winters v. Miller, 306 F. Supp. 1158 (E.D.N.Y. 1969). Relying on similar reasoning, Department of Corrections officials have expressed the opinion that they have a duty to treat inmates for psychological problems, and that this duty is inconsistent with an inmate's right to refuse to participate in psychological programs. Hearings on Prison Experimentation, supra note 8 (Testimony of Dr. Thomas Clanon, Superintendent of CMF at Vacaville).
103 Mackey v. Procunier, 447 F.2d 877 (9th Cir. 1973).
of appeals recognized a cause of action for an inmate who had been included in an anecine program against his will. In *McNeil v. Director, Patuxent Institution*,\(^{104}\) the United States Supreme Court held that the Maryland State Prison at Patuxent had violated an inmate’s due process rights in that the prison had confined the inmate beyond his sentenced term because he refused to participate in treatment programs. The *McNeil* decision supported an earlier federal district court decision in Maryland, *McCray v. Maryland*,\(^{105}\) in which the district court found a violation of the constitutional protection against cruel and unusual punishment when prison authorities placed “recalcitrant” prisoners in solitary confinement for refusal to participate in psychological treatment programs.

Although no statutes in California address this point directly, analogous statutes applying to mental patients recognize their right to refuse certain treatments.\(^{106}\) Mental patients are confined to institutions following civil commitment proceedings in which they are found to be insane. Thus both the state and the mental patient have an interest in including the patient in psychiatric treatment programs. Convicts, on the other hand, are confined to prison following criminal proceedings in which they are found to be guilty of a crime. Unless the state demonstrates in an objective proceeding that the convict is insane, the state has only a minimal interest in subjecting the inmate to psychiatric treatment without his consent. Thus it seems that inmates should enjoy greater protection than mental patients of their right to be left alone. The *Rules and Regulations of the Director of Corrections* recognize and incorporate this value; treatment is not to be administered to an inmate against his will unless, in unusual circumstances, the inmate is “incompetent to make a personal judgment regarding his treatment.”\(^{107}\)

A more common problem with consent is the probability of uninformed consent. The circumstances under which consent is obtained often give no indication that the inmate was fully aware of the hazards involved, of the amount of pain he would suffer, of his right to withdraw at any time, or of his right to compensation in case of injury.\(^{108}\) In fact, some consent forms still include illegal exculpatory clauses.\(^{109}\) By signing a consent form containing one of these clauses, the inmate is led to believe that he is bound to remain in the experiment and that he has agreed that the researcher is not liable in case of injury.


\(^{105}\) *McCray v. Maryland*, 456 F.2d 1 (4th Cir. 1972).


\(^{107}\) *Department of Corrections, Rules and Regulations of the Director of Corrections* 65 (Revised 1974).

\(^{108}\) See consent forms reproduced in Note, supra note 53, at 684.

\(^{109}\) Mitford, supra note 39, at 153-54.
A number of factors not present in free society affect the inmate's decision to participate and to continue in a medical or psychiatric experiment. It is then reasonable to question whether an inmate can ever truly volunteer. Should an inmate's consent be given the same weight as the consent of a free person? Can the inmate assume some of the risk of the experiment when he consents to the possibility of injury?

The prisoner's environment makes him less likely than a free person to weigh all the risks and injuries before giving his consent. This fact places an ethical burden on the researcher which, as demonstrated, has not always been borne with integrity.

IV. THE ETHICAL CONTEXT

Recent conferences in the United States on the subject of ethics in human experimentation have concluded that the informed consent of the subject obviates the need for further ethical concern on the part of the researcher. The American medical, pharmaceutical and psychiatric professions are unique in this view. World conferences have expressed a greater concern for the protection of the human subject and have imposed a corresponding responsibility on the researcher.

After the atrocities performed in the name of human experimentation in Germany before and during World War II, the medical and related professions became particularly sensitive to the ethical questions raised by experimentation on human beings. One of several world conferences convened on the question resulted in the Declaration at Helsinki which was adopted by the World Medical Association in 1964. The Declaration at Helsinki is based on the Nuremberg Code, which was a code of ethics in human experimentation laid down at the Nuremberg trials in 1947. Both the Declaration and the Code require that the researcher obtain the free and informed consent of each subject. But beyond consent, both require the researcher to take full responsibility for the close supervision of the experiment and for the protection of the subject. The documents also require an assessment of risk to the subject in comparison with the foreseeable benefits of the experiment.

The Nuremberg Code includes a very clear requirement of consent in human experimentation:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to

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110 See, e.g., Symposium, supra note 6.
give consent; should be so situated as to be able to exercise free
power of choice, without intervention of any element of force,
 fraud, deceit, duress, overreaching or other ulterior form of con-
straint or coercion...113

On the issue of coercion the Declaration at Helsinki provides that
 "the subject of clinical research should be in such a mental, physical
and legal state as to be able to exercise fully his power of choice."114
An additional clause regarding the prisoners who "being captive
groups should not be used as subjects of experiments" was deleted
largely because of opposition by American doctors.115

Some of the experiments described might have been ethically
sound if they were carried out with closer medical or professional
supervision. The Nuremberg Code provides: "The experiment should
be conducted only by scientifically qualified persons. The highest
degree of skill and care should be required through all stages of the
experiment of those who conduct and engage in the experiment."116
The Declaration at Helsinki requires that "clinical research should
only be conducted by scientifically qualified persons under the su-
pervision of a qualified medical man."117 As noted in previous sec-
tions, many of the experimental psychological programs are ad-
ministered by para-professional or lay personnel. In addition, nearly
all of Dr. Stough's medical and commercial experiments were con-
ducted by inmate technicians.118 Use of inmate technicians is a com-
mon practice,119 yet under California law these technicians are not
required to qualify for the usual licensing of medical technicians.120

When confronted with facts of unethical experimentation in pri-
sons, the public has exhibited strong human concern.121 The self-
policing lacking in the professions could be mended by pressure from
the public. Public pressure has not played a significant part in prison
experimentation as yet, because the public has been kept uninformed.
Prisons are by their nature closed institutions.122 Prisons offer a
unique sanctuary for the occasional unscrupulous researcher, for the
untrained staff member, or for the overzealous scientist. Public
scrutiny of the experimental programs could provide an element of

113 Nuremberg Code, supra note 112, § 1.
114 Declaration, supra note 111, § III-3-b.
115 MITFORD, supra note 39, at 139.
116 Nuremberg Code, supra note 112, § 8.
117 Declaration, supra note 111, § I-2.
118 Rugaber, supra note 41, at 20.
119 See, e.g., Drug Tests, supra note 20.
120 CAL. BUS. & PROF. CODE § 1241(d) (West 1970).
121 See, e.g., text accompanying note 78, supra.
122 A California legislator recently expressed his frustration that even legislators
have difficulty getting into the prisons in order to observe whether prison prac-
tices are effectively implementing public policy. Assemblyman Meade at Hearing
on Prison Experimentation, supra note 8.
control that is not available under current policies and regulations.

Some of the examples in Part II raise the question whether some experiments are by their nature unethical. The Nuremberg Code provides that the experiment “should avoid all unnecessary physical and mental suffering and injury.” 123 The experiment must be “such as to yield fruitful results, not procurable by other methods . . . not random or unnecessary.” 124 The Code further provides that “the degree of risk . . . should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.” 125 The Declaration at Helsinki echoes these concerns: “Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.” 126

Can it fairly be said that the pain and injury of the ascorbic acid experiment 127 or the pain tolerance test 128 was necessary and “such as to yield fruitful results?” Are there circumstances under which an inmate can be said to have consented to the possibility of contracting cancer or leukemia? 129 The discussions at several professional conferences on human experimentation have fallen short of responding to these questions. The inquiry in the United States that is allowed to end with a requirement of informed consent is an abdication of the full responsibility of medical and psychiatric professionals to protect the human subject.

V. REMEDIES

Some controls upon experimentation in California and remedies for abuse of prisoner rights exist. These controls and remedies have varying effects and are best explored by organizing them under the following topics: administrative remedies, civil remedies, criminal actions, professional sanctions, non-publication of data, and legislative remedies. In the sections that follow, this topical outline will be used to describe the efficacy of existing controls and remedies as well as possible future controls and remedies.

A. ADMINISTRATIVE REMEDIES

The federal government through the FDA and the HEW has made institutional review committees available as control devices for the review of the rights and welfare of inmate subjects in experimenta-

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123 Nuremberg Code, supra note 112, § 4.
124 Nuremberg Code, supra note 112, § 2.
125 Nuremberg Code, supra note 112, § 6.
126 Declaration, supra note 111, § I-3.
127 Hodges et al., supra note 37
128 MITFORD, supra note 39, at 158. See also text accompanying note 46.
129 Volunteers Behind Bars, supra note 47.
tion. These committees determine that informed consent is secured for investigational new drug (IND) research and for research activities supported by HEW grants or contracts.

Under the FDA regulations regarding IND research, a drug sponsor (usually a pharmaceutical company) must file a Notice of Claimed Investigational Exemption for a New Drug with the FDA. If the FDA does not object within thirty days, the drug sponsor may ship drugs in interstate commerce for testing in humans.

The Notice constitutes a drug company’s recital of the clinical investigator’s compliance with requirements of scientific training and experience, personal supervision, and informed consent. "Adequate information" about pre-clinical investigations (i.e., studies on laboratory animals) "on the basis of which the sponsor has concluded that it is reasonably safe to initiate clinical investigations with the drug" is also included in the Notice. In addition, the procedures of the institutional review committee are outlined in the Notice.

The drug sponsor and not the FDA has the primary responsibility for policing the requirements for clinical investigation. The only

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130 Investigational new drug (IND) research is governed by procedures and standards promulgated by the Food and Drug Administration found at 21 C.F.R. § 130 (1973).
131 Institutional research is often sponsored by the Department of Health, Education and Welfare, in which case the procedures set forth in HEW GRANTS ADMINISTRATION MANUAL, ch. 1-40, are applicable to the protection of human subjects. These procedures are explained and elaborated upon in the INSTITUTIONAL GUIDE DHEW POLICY ON PROTECTION OF HUMAN SUBJECTS, DHEW Publication No. (NIH) 72-102 (U.S. Gov’t Printing Office, 1971). 45 C.F.R. § 46 as proposed by Caspar W. Weinberger, Secretary of HEW at 38 Fed. Reg. 27882 et seq. (1973) further prescribes the policy on protection of human subjects regarding activities supported by HEW grants or contracts. The report of a special study group which reviewed policies and procedures relevant to the proposed changes was published in draft form in order to invite early public comment in 38 Fed. Reg. 31738 et seq. (1973).
133 The investigators must have scientific training and experience appropriate to qualify them as suitable experts to investigate the safety of the drug. 21 C.F.R. § 130.3(a)(2)(8) (1973).
134 The investigators must sign agreements stating that subjects to whom the drug is administered shall be under their personal supervision. 21 C.F.R. § 130.3(a)(2)(10)(c) (1973).
135 Informed consent must be elicited from all subjects. Id.
136 Id.

At present, the regulations place the responsibility for monitoring clinical investigators on the drug sponsors ... There may be some
information received by the FDA is that which the drug sponsor has chosen to abstract from the clinical investigator's statements as submitted to the drug sponsor.\textsuperscript{139} In the normal course of events the FDA never sees the investigator's statements at all.\textsuperscript{140} Therefore, the drug sponsor's Notice contains remarkably little specific information about the clinical investigator or his methods.\textsuperscript{141}

Although the FDA theoretically has the legal power to disqualify an investigator in clinical studies for failure to comply with regulations, the impediments to FDA access to information concerning clinical investigation render this sanction largely a hypothetical one.\textsuperscript{142} From 1962 through mid-1969, only eleven investigators were disqualified by FDA and three of these have been reinstated.\textsuperscript{143}

The impediments to FDA access to information are attributable to the performance of institutional review committees. The IND regulations do not clearly define the powers of institutional review committees nor their means of communication with the FDA. The responsibilities, powers and sanctions of the institutional review committees under the IND regulations are described in \textit{HEW Grants Administration Manual}, ch. 1-40.\textsuperscript{144} Communication between the FDA and institutional review committees could reasonably be expected; however, the regulatory language fails to so specify. In fact, the strongest HEW language points out the HEW "review group's need to benefit from the institutional review committee's opinions."\textsuperscript{145} FDA regulations recommend "that these [HEW] guidelines be followed in establishing institutional review committees and that the committees function according to the procedures prescribed therein."\textsuperscript{146}

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misunderstanding that the FDA approves clinical investigators and clinical research projects conducted by pharmaceutical firms. FDA neither approves clinical investigators nor do we approve the firms' clinical research projects.
\textsuperscript{139} 21 C.F.R. § 130.3(a)(2)(13) (1973).
\textsuperscript{140} There is a provision in the regulations for inspection of such records "upon request of a scientifically trained and properly authorized employee of the Department . . . ," but this is an extraordinary remedy seldom invoked. The Bureau of Drugs has allocated only two persons to on-site record inspections. Herbert L. Ley, Jr., testified in the 1969 \textit{Senate Drug Industry Hearings}, supra note 138, that only 22 on-site inspections of IND clinical investigators were made in 1968 and 1969 at which time 1,815 Notice forms were submitted by sponsors and more than 25,000 investigators were registered with the FDA. Cavers, \textit{The Legal Control of Clinical Investigation of Drugs}, 1969 \textit{DAEDALUS} 427.
\textsuperscript{142} \textit{Id.}
\textsuperscript{143} 1969 \textit{Senate Drug Industry Hearings}, supra note 138, at 5646.
\textsuperscript{144} 21 C.F.R. § 130.3(a)(2)(10)(c) (1973).
\textsuperscript{146} 21 C.F.R. § 130.3(a)(2)(10)(c) (1973).
One commentator has recently examined the FDA institutional review committee scheme from the standpoint of protecting human beings and has found it totally lacking in that respect.\textsuperscript{147} That criticism was confirmed when FDA officials disclaimed responsibility for the 500 cases of viral hepatitis and six deaths caused by the prison IND project in Alabama.\textsuperscript{148} By abdicating responsibility for such tragedies the FDA leaves the burden of protecting institutional subjects with the institutional review committees.

Within the current regulatory scheme, there is no means of assuring the effectiveness of institutional review committees in fostering informed consent and in assessing risks to institutionalized subjects. Under the HEW scheme, "no grant or contract for an activity involving human subjects shall be made unless the application for such support has been reviewed and approved by an appropriate institutional committee."\textsuperscript{149} This appears to put teeth into institutional committees. However, this is misleading in that (1) institutional review committees in California prisons generally consist of Department of Corrections personnel\textsuperscript{150} and (2) HEW grants and contracts are awarded when HEW receives either special assurances signed by committee members\textsuperscript{151} or general assurances signed by institutional officers (including the clinical investigator).\textsuperscript{152} These assurances include a description of the review and implementation procedures involved in the HEW-supported activities. Thus, corrections personnel who have no particular interest in the use of inmates as experimental subjects other than a rehabilitative interest may file assurances to secure HEW grants and contracts. In addition, clinical investigators with an interest in pursuing research may file the assurances to secure such funding.

The filing of assurances by prison personnel and clinical investigators has not been the only means of financing experimentation on prisoners. Drug sponsors who finance their own research have done so after filing Notices with the FDA. The drug sponsors have an interest in conducting IND research in order to market new drugs; their interest will affect the approach they take in filling out Notices. Thus, the FDA and HEW have refused to limit human experimentation upon receipt of Notices and assurances.

For a more adequate review procedure, the FDA and HEW should

\textsuperscript{147} Horstman, \textit{supra} note 141.
\textsuperscript{148} 1969 \textit{Senate Drug Industry Hearings}, \textit{supra} note 138, at 5688.
\textsuperscript{149} HEW \textit{Grants Administration Manual}, ch. 1-40-20-A.
\textsuperscript{152} 21 C.F.R. § 130.3 (1973); HEW \textit{Grants Administration Manual}, ch. 1-40-40-A,B,C,D.
require periodic communication with the institutional review committees rather than Notices and assurances which merely describe the procedures of institutional review committees. Requirements for committee membership should be regulated to discourage disproportionate representation of the institutional personnel on the committees. If the committees had power to veto experimental activity or to secure immediate FDA or HEW action, the risks involved in experimentation on human subjects could be minimized. An increase in the number of FDA and HEW field representatives to communicate with institutional review committees would also result in more effective control.

In short, a more clear-cut delineation of the control such committees can exercise over proposed experiments is clearly warranted. The FDA and HEW need to revise or implement their regulations to give themselves or the institutional committees more effective responsibility and power to police experimentation on prisoners.

B. CIVIL REMEDIES

A California inmate or ex-convict may seek redress for physical or mental injury suffered by participation in negligently performed experiments or psychological therapy. In pursuit of civil remedies, he or his counsel must consider various tort actions, the effect of the doctrine of sovereign immunity, the limitations of a civil disability statute, damages and injunctive relief under 42 U.S.C. section 1983 and state and federal habeas corpus relief.

First, possible tort actions include assault and battery,\(^{153}\) invasion of privacy,\(^{154}\) intentional infliction of mental distress,\(^{155}\) and medical malpractice.\(^{156}\) However, an inmate’s rights to bring such actions in state courts are limited by the doctrines of sovereign immunity and civil disability as embodied in California Government Code section 844.6 and California Penal Code section 2600, respectively.

According to California Government Code section 844.6(a), “[a] public entity is not liable for ... (2) an injury to any prisoner.” However, section 844.6(d), a statutory codification of the doctrine of *respondeat superior*, makes the state liable for the malpractice of a public employee engaged in the practice of the healing arts. That is to say that if medical malpractice damages are sufficiently alleged against an employee of the California Department of Corrections, then the state is liable as employer without specific proof of its negligence.

\(^{154}\) Id. at 802-18.
\(^{155}\) Id. at 49-62.
\(^{156}\) Id. at 16-66.
Although a prisoner may not be able to secure damages from the state for torts other than malpractice, he can still seek to enjoin the state. California Government Code section 814 provides any plaintiff with the right to obtain injunctive relief against a public entity or employee.\textsuperscript{157} The 1970 amendment to section 844.6(a) makes section 814 an express exception to the immunity of public entities.\textsuperscript{158}

However, a California prisoner is further limited in exercising his civil right to sue in a state court by the civil disability statute\textsuperscript{159} and related judicial decisions.\textsuperscript{160} The Adult Authority has the power to restore a prisoner’s right to bring an action in a state court.\textsuperscript{161} If the Adult Authority refuses to restore a prisoner’s right to sue, the prisoner will have to wait until he is discharged or released on parole in order to bring an action for damages or injunctive relief under the provisions of the California Government Code.\textsuperscript{162}

Secondly, to secure redress or an end to injurious activity, an inmate may pursue a suit for damages and injunctive relief under the Federal Civil Rights statute, 42 U.S.C. section 1983. An action under section 1983 will circumvent the prohibitions of California’s civil disability statute.\textsuperscript{163} A section 1983 action may sound in tort and the usual tort damages may be recovered.\textsuperscript{164} In appropriate cases, there may be recovery for pain, anguish and mental suffering.\textsuperscript{165} However, the only elements which need to be present in order to establish a claim for damages under the Civil Rights Act are that the conduct complained of was engaged in under color of state law, and that such

\textsuperscript{157} \textsc{Cal. Gov’t Code} § 814 (West 1966); see Legislative Comment which clearly establishes that the right to injunctive relief is not impaired by the subsequent sections of the Cal. Tort Claims Act, \textsc{Cal. Gov’t Code} §§ 810-996.6 (West 1966 and West Supp. 1974).

\textsuperscript{158} \textsc{Cal. Stats.} 1970, ch. 1099, p. 1957, § 5.

\textsuperscript{159} \textsc{Cal. Pen. Code} § 2600 (West 1970) reads in relevant part as follows:

A sentence of imprisonment in a state prison for any term suspends all civil rights of the person so sentenced . . . But the Adult Authority may restore to said person during his imprisonment such civil rights as the authority may deem proper . . .

\textsuperscript{160} Acting as a plaintiff in a civil suit is a civil right that is suspended during incarceration for a felony. Castera v. Superior Court of Los Angeles, 29 Cal. App. 694, 159 P. 735 (1916), \textit{Ex parte Maro}, 248 P.2d 135 (1952).

\textsuperscript{161} \textsc{Cal. Pen. Code} § 2600 (West 1970).


\textsuperscript{163} In McCollum v. Mayfield, 130 F. Supp. 112, 116 (N.D. Ca. 1955), the federal district court rejected defendant’s assertion that \textsc{Cal. Pen. Code} § 2600 (West 1970) deprived the plaintiff of the capacity to sue and held in reference to the rights of prisoners under 42 U.S.C. § 1983 that the “plaintiff is a person within the jurisdiction of the United States in spite of the fact that he is an imprisoned felon, and consequently is empowered to sue in the federal courts under this section.”


\textsuperscript{165} Jenkins v. Averette, 424 F.2d 1228 (4th Cir. 1970).
conduct subjected the plaintiff to the deprivation of rights, privileges or immunities secured by the Constitution of the United States.\textsuperscript{166}

An example of constitutional questions that might be raised in filing a complaint against prison authorities under section 1983 for medical experimentation is presented in the case of \textit{Mackey v. Procu nier}.\textsuperscript{167} In this case, Circuit Judge Merrill examined the complaint and supporting memoranda of a prisoner at Folsom State Prison, Represa, California. The documents alleged that at the California Medical Facility at Vacaville in 1967 the plaintiff had been injected with a "fright drug" (anectine) without consent. The court held that the complaint sufficiently alleged cruel and unusual punishment or "impermissible tinkering" with the mental processes.

Thirdly, an inmate may file a writ of habeas corpus in either a state\textsuperscript{168} or federal court\textsuperscript{169} in order to bring an end to abusive treatment or experimentation during confinement. The remedies available through habeas corpus include release from confinement in both federal and state courts.\textsuperscript{170} In unusual and exceptional circumstances, federal courts are empowered to fashion appropriate equitable relief in the form of orders and injunctions directed to correctional officers.\textsuperscript{171} Thus, a number of prisoners’ rights decisions have resulted from federal habeas corpus petitions.\textsuperscript{172} In California courts, orders and injunctions have been set to resolve many issues. Among the prison issues litigated in state habeas corpus proceedings have been racial and religious discrimination,\textsuperscript{173} guard brutality,\textsuperscript{174} access to the courts,\textsuperscript{175} possession of literature,\textsuperscript{176} confinement in segregation,\textsuperscript{177} proceeds of manuscripts,\textsuperscript{178} parole revocation,\textsuperscript{179} and confidential communications with attorneys.\textsuperscript{180} In California, damages are available if a correctional officer fails to comply with a court order in a

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\item \textsuperscript{166} \textit{Marshall v. Sawyer}, 301 F.2d 639, 646 (9th Cir. 1962).
\item \textsuperscript{167} \textit{477 F.2d 877} (9th Cir. 1973).
\item \textsuperscript{169} \textit{28 U.S.C.} §§ 2241-2255 (1971).
\item \textsuperscript{170} \textit{CaL Pen. Code} §§ 1485, 1487 (West 1970); Bens v. U.S., 266 F. 152 (2d Cir. 1920); Doss v. Lindsley, 53 F. Supp. 427 (E.D. Ill. 1944), \textit{aff’d} 148 F.2d 22 (7th Cir. 1945).
\item \textsuperscript{172} \textit{Landman v. Peyton}, 370 F.2d 135 (4th Cir. 1966); Howard v. Smyth, 365 F.2d 428 (4th Cir. 1966), \textit{cert. denied}, 385 U.S. 998 (1966); Coonts v. Wainwright, 282 F. Supp. 893 (M.D. Fla. 1968), \textit{aff’d} 409 F.2d 1337 (5th Cir. 1969).
\item \textsuperscript{173} \textit{In re Jones}, 57 Cal. 2d 860, 372 P.2d 310 (1962).
\item \textsuperscript{174} \textit{In re Cathey}, 44 Cal. 2d 679, 361 P.2d 426 (1961).
\item \textsuperscript{175} \textit{In re Ferguson}, 44 Cal. 2d 683, 361 P.2d 417 (1961).
\item \textsuperscript{176} \textit{In re Harrell}, 2 Cal. 3d 675, 470 P.2d 640 (1970).
\item \textsuperscript{177} \textit{In re Hutchinson}, 23 Cal. App. 3d 337, 100 Cal. Rptr. 124 (1972).
\item \textsuperscript{178} \textit{In re vanGeldern}, 5 Cal. 3d 832, 489 P.2d 578 (1971).
\item \textsuperscript{179} \textit{In re Tucker}, 5 Cal. 3d 171, 486 P.2d 657 (1971).
\item \textsuperscript{180} \textit{In re Jordan}, 7 Cal. 3d 930, 500 P.2d 873 (1972).
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habeas corpus proceeding.\footnote{181}{CAL. PEN. CODE § 1505 (West 1970).}

Of the two methods of seeking federal judicial review of internal state prison practices, by habeas corpus and section 1983 suit, ordinarily a section 1983 suit will be preferable for a number of reasons: (1) Exhaustion of state remedies is not required in a section 1983 action\footnote{182}{Houghton v. Shafer, 392 U.S. 639 (1968).} whereas a federal habeas corpus statute requires exhaustion.\footnote{183}{28 U.S.C. § 2254 (1971).} (2) As one commentator has stated, any significant prisoners' rights action will require extensive use of the liberal discovery techniques allowed in the Federal Rules of Civil Procedure.\footnote{184}{Turner, Establishing the Rule of Law in Prisons: A Manual for Prisoners' Rights Litigation, 23 STAN. L. REV. 473, 505 (1971) [hereinafter cited as Turner].} These may be employed as a matter of course in a section 1983 action, but discovery in a habeas corpus proceeding is a more doubtful matter.\footnote{185}{Id.} In \textit{Harris v. Nelson},\footnote{186}{394 U.S. 286, 299 (1969).} a habeas corpus proceeding, the United States Supreme Court held that in certain circumstances limited discovery may be had upon application to the court. Therefore, it is advantageous to avoid the necessity of obtaining a court order for routine discovery by using section 1983.\footnote{187}{In a prisoner class action in Morris v. Travisno, 310 F. Supp. 857 (D.R.I. 1970), the court ordered that notice of new regulations be given to all prison inmates, with inmates permitted to make uncensored responses to the court.} (3) Maintenance of a class action under Federal Rules of Civil Procedure section 23(b)(2) is possible in a section 1983 suit, assuming that the usual class action requirements can be met. Class actions provide a basis for broad injunctive relief going beyond a particular prisoner's situation.\footnote{188}{Turner, supra note 184.} In habeas corpus, however, substantial doubt surrounds the propriety of a class action.\footnote{189}{Turner, supra note 184.}

Therefore, a California inmate is left with the alternatives of a section 1983 action and state and federal habeas corpus actions to counteract the dangers of medical and psychological experimentation during the period of his incarceration. If the civil disability statute could be rescinded, a new forum at the state level would be available to inmates seeking redress for the tortious acts of clinical investigators. Opening state courts to inmate suits against state and prison officials would provide some assurance that prisoners are not abused as experimental subjects.

C. CRIMINAL ACTIONS

Several seldom invoked California Penal Code sections exist as a
possible deterrent to medical and psychological experimentation on prisoners. These code sections make injurious acts against prisoners punishable by fines, by removal from office, and by criminal sanctions. Persons who are guilty of willful inhumanity or oppression toward a state prisoner under their care or study are punishable by a fine not exceeding $2000 and by removal from office. The unauthorized injury of a state prisoner is punishable in the same manner as though he were not convicted or sentenced. The use of cruel or unusual punishment or the infliction of any treatment which would injure or impair the health of a prisoner constitutes a misdemeanor.

There is a lack of prosecutions under these code sections. This lack may be attributed to judicial reluctance to interfere with prison discipline and control. This attitude of the court was demonstrated by Justice Peters of the California Supreme Court in the following admonition regarding habeas corpus petitions in In re Riddle:

The courts are and should be reluctant to interfere with or to hamper the discipline and control that must exist in a prison. Petitions containing such charges must be carefully scrutinized and the facts carefully weighed with the thought in mind that they are frequently filed by prisoners who are keen and ready, on the slightest pretext, or none at all, to harass and to annoy the prison officials and weaken their power and control. These prisoners include many violent and unscrupulous men who are ever alert to set law and order at defiance within and without the prison walls.

With the California Supreme Court expressing such a reluctant attitude, it seems unlikely that California's district attorneys will attempt to prosecute prison officials whose actions result in mental or physical injury to inmates. In order for these code sections to function as an effective deterrent to abusive experimentation on prisoners, such enforcement would clearly be necessary.

190 CAL. PEN. CODE § 2653 (West 1970).
191 CAL. PEN. CODE § 2650 (West 1970).
192 CAL. PEN. CODE § 2652 (West 1970).
193 Interview with Walter Barkdahl, Chief of Correctional Planning and Development, California Department of Corrections, April 4, 1974; Mr. Barkdahl indicated that the personnel officers and attorneys for the CDC, who would know of the criminal prosecution of Department employees or of the Department itself, maintain no statistics on these and cannot recollect more than one currently pending case (in Humboldt County) in recent years.
194 57 Cal. 2d 848, 852, 122 Cal. Rptr. 472, 474, 372 P.2d 304, 306 (1962); Justice Mosk found it useful in In re Allison, 66 Cal. 2d 282, 294, 57 Cal. Rptr. 593, 599-600, 425 P.2d 193, 199-200 (1967) to recite Justice Peters' words. In In re Hutchinson, 23 Cal. App. 3d 337, 340-1, 100 Cal. Rptr. 124, 127 (1972) the court agrees that "courts are and naturally should be reluctant to enter the thicket of prison discipline and control" and that court finds it "unnecessary to second-guess the reasonableness" of the action of the superintendent at Deuel Vocational Institute in segregating an inmate during a period of tension. However, that court questions the reasonableness of the inmate's continued segregated confinement, thereby making an inroad against judicial reluctance.
D. PROFESSIONAL SANCTIONS

An inmate and his counsel may consider invoking professional sanctions. They may initiate disciplinary proceedings in order to suspend or revoke a professional license to practice medicine, to practice as a psychiatric technician or to practice as a psychiatrist. However, the means of suspension and revocation of the licenses of all clinical laboratory licensees of the State Department of Public Health (including directors, technicians and trainees) do not apply to clinical laboratories owned and operated by the California Department of Corrections. No such exemption exists regarding licensees in the practice of medicine, psychiatry and psychology within the California Department of Corrections. However, the application of professional sanctions to an investigator in the field of research on human subjects has been rare in and out of prisons.

An exceptional example of the application of professional sanctions occurred in the New York case of Drs. Chester M. Southam and Emanuel E. Mandel. These physicians injected live cancer cells into twenty-two debilitated patients at the Jewish Chronic Disease Hospital of Brooklyn without the patients’ voluntary and informed consent in a 1963 experiment financed by the U.S. Public Health Service and the American Cancer Society. The Board of Regents of the University of the State of New York found the two doctors guilty of fraud and deceit and unprofessional conduct in the practice of medicine. Their medical licenses were suspended for one year, but the suspensions were stayed and the doctors were put on probation for one year.

The grounds for revocation of a certificate or license to practice in the various healing arts are generally similar. The disciplinary proceedings of all fields are subject to procedures set forth in California Government Code sections 11500 et seq.

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200 Id. at 99-100.
201 The board’s action was taken under N.Y. EDUC. LAW § 6514 (2)(a), (g) (McKinney 1953); see REGENTS COMM. ON DISCIPLINE, UNIV. OF THE STATE OF N.Y., REPORT ON THE MATTER OF SOUTHAM AND MANDEL, Nos. 158, 159 (undated).
202 The grounds for revocation or suspension of the licenses of physicians, psychologists, psychiatric technicians and clinical laboratory licensees are embodied in CAL. BUS. & PROF. CODE §§ 2361.5, 2960, 4521 and 1320 (West Supp. 1974) respectively.
203 According to CAL. BUS. & PROF. CODE §§ 2360, 2965, 4520 (West Supp. 1974) and 1322 (West 1962), respectively, the disciplinary proceeding regarding physicians, psychologists, psychiatric technicians and clinical laboratory licensees are indicated in CAL. GOV’T CODE §§ 11500 et seq. (West 1966 and West Supp. 1974).
The disciplinary proceedings against practitioners in the healing arts, while normally instituted by a public officer in his official capacity or by an employee of the appropriate licensing agency, may be instituted by any party. An inmate wishing to invoke this remedy would begin by filing and serving on the practitioner a verified accusation. The accusation should state in ordinary and concise language the facts showing violations of the particular statute(s) under which the charge is being made and should specify the statute(s) alleged to have been violated.204 Rather than filing the accusation himself, an inmate may request that the appropriate licensing agency file the accusation. The accusation need not be verified if filed by a public officer in his official capacity or by an employee of the appropriate licensing agency, e.g., the Board of Medical Examiners, the Department of Public Health, the Board of Vocational Nurses and Psychiatric Technicians.205 The agency may use its discretion in determining whether such accusation should be filed. Mandamus lies to compel the agency to file an accusation only if there has been an abuse of discretion.206

The discretion of California's licensing agencies may account for the rare incidence of professional sanctions being applied against practitioners of the healing arts. As for California's prison clinical investigators, the prohibitions of California Business and Professions Code section 1241(d) preclude the application of professional sanctions against them. Such blanket exemption from discretionary review by a licensing agency is in direct conflict with the notions which foster the existence of professional sanctions. California Business and Professions Code section 1241(d) should be changed to subject the prison medical experimenters licensed as clinical laboratory technologists and trainees to the professional sanctions applicable to other medical personnel.

E. NON-PUBLICATION OF DATA

The opportunity to publish experimental results is a primary reason for conducting experimentation. Dr. H.K. Beecher has suggested that unethically obtained data should not be allowed to be published.207 His suggestion is based on the rationale that the threat of refusal to publish will deter investigators from using unethical procedures. This approach is analogous to that of the American courts in the exclusion of illegally obtained evidence. Such evidence is rejected in spite of its probative value in order to deter the police

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from using illegal methods.\textsuperscript{208}

It has been argued that the sounder view in the case of unethical experiments is to accept the findings for their actual contribution to medical knowledge, regardless of the methods by which they were obtained.\textsuperscript{209} The publication may be very useful to science and may obviate the need for performance of another possibly dangerous experiment. Moreover, the deterrent effect of non-publication is doubtful; the overly enthusiastic investigator does not work primarily for the publication of data in the manner of a policeman working for the conviction of a suspect.\textsuperscript{210}

\section*{F. LEGISLATIVE REMEDIES}

Federal and California legislators have considered the rights of human subjects in experimentation. Legislators have delegated to legislative committees the authority to hold hearings and to investigate relevant matters,\textsuperscript{211} and they have proposed legislation.\textsuperscript{212}

The federal legislation proposed in the 93d Congress, 1st Session, included a Senate joint resolution, two Senate bills and four House of Representatives bills. Under Congressional committee consideration has been the creation of a fifteen-member National Advisory Commission on Health Science and Society,\textsuperscript{213} a five-member National Human Experimentation Standards Board,\textsuperscript{214} and an eleven-member National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.\textsuperscript{215}

The National Advisory Commission on Health Science and Society would study the ethical, social and legal implications of advances in biomedical research and technology.\textsuperscript{216} Its studies would include analysis of the use of human subjects for experimental purposes.\textsuperscript{217}

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\textsuperscript{210} \textit{Id.}
\textsuperscript{211} \textit{Hearings on Quality of Health Care — Human Experimentation, Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 93d Cong., 1st Sess. (1973); Hearing on Prison Experimentation, supra note 8.}
\end{flushleft}
The National Human Experimentation Standards Board, an executive agency, would establish guidelines for biomedical and behavioral research and for psychosurgery to be followed where federal funds are involved. The Board would have power to institute suits for injunctive relief against violation of the guidelines. The guidelines would include informed consent provisions and a provision requiring compensation of the victim of non-conforming experiments. In addition, as this proposal would provide: (1) a moratorium would be established on psychosurgery in federally funded programs until after the Board has sufficiently studied psychosurgery, (2) aggrieved subjects of experimentation could sue in federal district court for equitable relief and damages for acts in violation of the guidelines, and (3) institutional review committees would be established with means of communication with the Board.\footnote{218}

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research would function within HEW. The Commission would develop guidelines for biomedical and behavioral research and recommend to Congress a mechanism for compensation of the injured subjects of experimentation and their families. The Commission would conduct studies of psychosurgery and of the ethical, social and legal implications of advances in biomedical and behavioral research. In addition, means of communication between institutional review boards and the commission would be set up.\footnote{219}

In California, legislative committees have considered the issues raised by experimentation on prisoners.\footnote{220} Legislative proposals have

\footnote{219} H.R. 7724, 93d Cong., 1st Sess. (1973), H.R. 10403, 93d Cong., 1st Sess. (1973); according to XXXI CONG. Q. WEEKLY REPORT, no. 52, at 3440 (Dec. 29, 1973), the role of the Commission as embodied in H.R. 7724 received Senate approval on September 11, 1973. However, the House version of H.R. 7724, which had been passed on May 31, 1973, contained no provisions regarding the rights of human subjects in research. A conference was then requested by the Senate to work out the differences between the two versions, but the conference committee did not meet before the adjournment of the 1st Sess. of the 93d Cong. Nevertheless, H.R. 10403, which was introduced on September 19, 1973, contained the provisions lacking in the House version of H.R. 7724 and was referred to the Interstate and Foreign Commerce Committee of the House.
\footnote{220} The agenda of Hearing on Prison Experimentation, supra note 8, as outlined in a letter dated August 20, 1973, from Cal. Assembly Committee on Criminal Justice to Dr. Philip Shapiro, Sr. Visiting Psychiatrist, Mt. Zion Hospital, San Francisco, California, indicates the consideration of the following issues:

(1) Current practices in the area of human experimentation within and without prisons;
(2) Whether or not favorable consideration is being given to the inmates who participate in such experiments;
(3) Comparison of compensation given between non-inmate and inmate subjects;
included a nine-member State Board on Penal Psychological and Medical Ethics (with one former prisoner as a member)\(^{221}\) and controls on the administration of organic therapy.\(^{222}\) The State Board of Penal Psychological and Medical Ethics would review all medical research and psychological treatment of individuals in the custody of the California Department of Corrections and Youth Authority. If the research or treatment fails to meet professionally recognized methods of diagnosis and therapeutic treatment normally associated with the medical care of a prisoner, Board approval and written informed consent would be required.\(^{223}\)

Proposed controls on organic therapy would protect prisoners from being administered without informed consent psychosurgery, shock therapy, drug therapy and other forms of organic therapy. California courts would be authorized to enjoin the administration of any organic therapy.\(^{224}\)

Also under consideration by the California Assembly Committee on Criminal Justice is the prohibition of all medical experimentation in prisons,\(^{225}\) and the creation of an indemnification or insurance fund to be financed by the state of California in cooperation with the investigator and the pharmaceutical company involved in experimentation.\(^{226}\) California Government Code section 844.6 which entitles a public entity to immunity from tort damages for the wrongful injury of a prisoner has been criticized; proposals have been made by legal scholars for its repeal and replacement with other statutory

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(4) Informed consent;
(5) The process of approval and review of experiments;
(6) Procedural safeguards; and
(7) Inmate attitudes toward such projects.

\(^{221}\) A.B. 1107, Cal. Legislature (1973), which would have created a nine-member State Board on Penal Psychological and Medical Ethics, has died in the Ways and Means Committee, according to interview with Sara Michaels, Legislative Assistant to Assemblyman Ken Meade, author of A.B. 1107, April 4, 1974.

\(^{222}\) A.B. 2296, Cal. Legislature (1973), which deals with the administration of organic therapy, is under consideration by the Senate Judiciary Committee, but has not been set for hearing as of April 4, 1974, according to interview with Larry Briskin, Legislative Assistant to Assemblyman Alan Sieroty, author of A.B. 2296, April 4, 1974.


\(^{224}\) A.B. 2296, Cal. Legislature (1973); The Friends Committee on Legislation, while contending that all medical experimentation and interference with a prisoner's mind and personality should be banned, has noted that "the protection outlined in A.B. 2296 would eliminate the most flagrant abuses" at XXIII FRIENDS COMM. ON LEGIS. NEWSLETTER No. 2, at 1 (Feb. 1973).

\(^{225}\) ORE. REV. STATS., Ch. 371, which became law on October 5, 1973, makes medical, psychiatric or psychological experimentation on inmates unlawful and gives inmates the right to sue to enjoin or recover damages for violations of this law.

\(^{226}\) Hearings on Prison Experimentation, supra note 8 (Testimony of Michael Shapiro, Professor of Law, U.S.C.).
language.227

Legislative action is also necessary to delete California Penal Code section 2600, the civil disability statute, and California Business and Professions Code section 1241(d), which protects clinical investigators from professional sanctions. The prohibitive effects of these statutes as discussed above severely limit the remedies available to inmates who find themselves subject to abusive experimentation.

VI. CONCLUSION

The question of the ethics of clinical investigation in or out of the prison context deserves the concern of citizens and their legislators. The lack of clear standards for effective review and communication of institutional committee findings indicates a need for definitive action for the protection of the human subject in prison. Effective action may be on its way through legislative channels in California. Until then, abused inmates must pursue the available civil remedies and ponder the less effective professional sanctions and criminal actions at their disposal.

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