PRISONERS AND RESEARCH EXPERIMENTATION: PAST AND PRESENT PRACTICES, A REVIEW AND UPDATE

by

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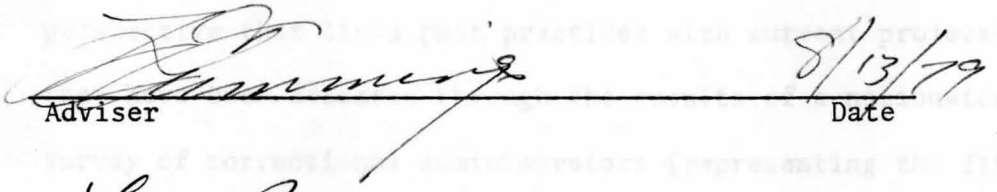

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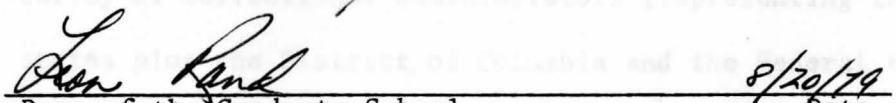

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ABSTRACT

PRISONERS AND RESEARCH EXPERIMENTATION:

PAST AND PRESENT PRACTICES, A REVIEW AND UPDATE

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The purpose of this paper is to examine the use of prisoners as experimental subjects in the research areas of disease studies, pharmaceutical and consumer product testing, and the emerging field of psychological-behavioral research. A study in depth of the issue of research experimentation in prisons must by necessity include an historical perspective that links past practices with current projects that have been assessed through the results of a nationwide survey of correctional administrators (representing the fifty states plus the District of Columbia and the Federal Bureau of Prisons) and research directors of twenty-two major pharmaceutical companies. The results of this survey intend to show the present status of research experimentation in American penal institutions and to demonstrate the changing character of research projects as a reaction to past criticism and the need to develop future programs compatible with public demands and official guidelines.

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CHAPTER I.

Introduction

The issue of human experimentation with prisoners subjects is not limited to modern times, for historical accounts indicate that criminals were used as well in ancient times for medical research. However, it has been in the past decade that the use of prisoners as "guinea pigs" in research projects was exposed to academic and public scrutiny. Prior to exposés by Mitford (1974), Chavkin (1978), Schrag (1978), and others, the issue of human experimentation in penal institutions was basically unknown to the general public. This issue had been discussed to a limited degree in medical literature by Hodges and Bean (1949) who attempted to explain the motivation of prisoners to participate in biomedical research. However, it was with the emergence of dramatic cases of research abuse that the public was made aware of the ethical issues involved in human experimentation.

To examine the subject of research experimentation in the prison in recent times, it is useful to explore the historical perspective of this issue. The use of criminals as research subjects has had an extensive history dating back to ancient times. The underprivileged status of offenders was taken advantage of in earlier times by the ancient Persian kings and Egyptian pharoahs who treated the criminal population as expendable experimental material, much as modern lab

researchers treat rats.[1]

Later in eighteenth century England Princess Caroline of Wales "begged the lives" of six condemned criminals for an experimental smallpox vaccination before the procedure was to be used on her own children. In the early part of the twentieth century Richard P. Strong, later Professor of Tropical Medicine at Harvard, infected some Philippine prisoners with plague and later produced beri-beri in another group of 29 inmates, two of whom died as a result. As a reward for their participation, the convict "volunteers" received cigars and cigarettes. Though Strong did not request the permission of the prisoners to participate in these experiments, he did seek the permission of the governor of the island.[2]

In the United States Goldberger in an experiment in 1915 produced pellagra in twelve white Mississippi convicts to discover a disease cure. With the onset of World War II. both federal and state prisoners were used in malaria projects and experimental trials of new drugs to treat this disease. In one particular case, over four hundred Chicago convicts were infected with malaria as part of the wartime crash program to develop new drugs to treat Allied troops in the Pacific Theatre. As a result of these clinical studies, some inmates became extremely ill from the disease or from the toxic side effects

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[1]Louis Lasagna, "Special Subjects in Human Experimentation," in Experimentation with Human Subjects, ed. Louis Lasagna (New York: George Braziller, 1969), p. 262.

[2]Roy Hemming, "Should Experimentation on Prisoners Be Stopped?" Senior Scholastic (November 3, 1969): 11.

of the experimental cures.[3]

Such experiments aroused little public attention until tales of medical research on concentration camp prisoners in Nazi Germany shocked the world. As a result in 1947, fifteen German doctors were convicted of criminal acts by the Nuremburg Military Tribunal. The "Nuremburg Code", "a set of basic principles embodying moral, ethical, and legal concepts for the conduct of acceptable experiments", was introduced at this time and though later subjected to much criticism, this code served as the foundation for many national and international standards for ethical research.[4] Many of the principles formulated at Nuremburg were incorporated in the Helsinki Declaration in which the issue of "informed consent" was first addressed.

In the United States Governor Green of Illinois in 1948 appointed a commission to draft regulations for research experimentation in his state's penal institutions. The Green Commission developed principles (outlined below) that are employed in many contemporary guidelines that will be discussed in greater detail in Chapter VI., Ethical Concerns of Research Experimentation.

1. It is essential that the subject truly volunteer with no coercion involved.

2. The subject should be informed of all hazards and should freely

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[3]Lasagna, "Special Subjects," p. 263.

[4]Nathan Hershey and Robert D. Miller, Human Experimentation and the Law (Germantown, Maryland: Aspen Systems Corp., 1976): 5.

consent.

3. The experiment should be based on knowledge of the natural history of the disease under study.

4. The experiment "must be so designed that the anticipated results will justify the performance of the experiment."

5. The results must be unprocurable by any other method and must be "necessary for the good of society."

6. The investigator must be scientifically qualified and the experiment must be conducted to avoid any unnecessary suffering on the part of the subject.

7. The research project can be undertaken only after prior animal testing has indicated that serious injury or death is highly unlikely.

8. If a known hazard is present, investigators should also serve as subjects.[5]

Despite these efforts to establish humane guidelines for the use of human subjects in research, the exploitation of inmates in such projects did not cease. Incidences of subject abuse in American correctional institutions came to light in the past decade with exposés such as Jessica Mitford's Kind and Usual Punishment that depicted the shocking conditions that often accompanied research programs in the prisons. In spite of these accounts, the use of inmate subjects in experimentation has not ceased and continues on a limited basis in American penal systems

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[5]Henry K. Beecher, Research and the Individual: Human Studies (Boston: Little, Brown, 1970): 70.

even today, taking on a more subtle form of investigation in the area of behavioral research.

The following chapters will discuss the extent of use of prisoner subjects in the research areas of disease studies, pharmaceutical and consumer product testing, and behavior modification. This study will attempt to link past practices of the past few decades with current projects that have been assessed through the results of a nationwide survey sent to fifty-two correctional administrators (representing the fifty states plus the District of Columbia and the Federal Bureau of Prisons) to probe the degree of research experimentation occurring in American prisons today. Chapter II., Research Methodology, explains the basic nature of the research format as it was applied to this study.

CHAPTER II.

Research Methodology

Prerequisite to an examination of current research practices in American prisons, it is necessary to consider the research design employed in this study. To update information concerning the use of inmates in correctional institutions as subjects for research experimentation --the last study of this nature was done approximately seven years ago by the American Correctional Association--, it was necessary to survey state and federal prison systems regarding these practices. In addition to ascertaining the extent of such research programs in the American prison today and in the recent past, it was also the intent of this study to discover the procedures, guidelines, and payment schedules used in those institutions where such experimentation is or has been performed.

The format of this study was that of a questionnaire mailed to the directors of the fifty state corrections departments plus the Federal Bureau of Prisons and the Washington, D.C. Department of Corrections.[6] Due to the relatively small population involved in this phase of the study, it was possible to survey all respondents. The questionnaire sent to the directors was short and concise, and a cover letter explaining the purpose of the study and requesting cooperation

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[6]A copy of this questionnaire to the correctional administrators is found in Appendix A.

in updating information on prison experimentation accompanied the questionnaire. The survey form was so designed to be completed within a matter of minutes by the administrator or his designate (e.g. medical director) and a business reply envelope was included with each questionnaire to facilitate mailing. Furthermore, the cover letter was addressed personally to each director (e.g. Mr. George Denton, Ohio Department of Rehabilitation and Correction) to lend a more personal quality to the survey. The names of these directors and the addresses of the corrections departments were taken from the most recent directory of the American Correctional Association, a listing of correctional officials at all levels of government.

Also included in the cover letter was a deadline for completion of the questionnaire --approximately three weeks from the date of mailing-- to serve as an inducement to complete the questionnaire as quickly as possible and to reduce chances that the form would be mislaid, lost, et cetera. After the deadline date had passed, a follow-up letter with another copy of the questionnaire was sent to the departments not responding to the first mailing. The follow-up procedure proved beneficial, for the final response rate was approximately 92%.

In the area of pharmaceutical and consumer product testing, efforts to substantiate the information provided by the correctional systems took the form of another brief questionnaire sent to twenty-two major pharmaceutical manufacturers selected at random from the Physicians' Desk Reference (PDR), a listing of approximately seventy manufacturers and their products. This second survey concerned the

use of human subjects in drug and consumer product testing to determine whether inmates in correctional facilities were still a major source of subjects for this type of research.[7] The questionnaire was mailed to the directors of medical research in the companies chosen[8] and as before, a cover letter explaining the purpose of the study and a business reply envelope were included with this questionnaire. As this random sample of drug manufacturers was to serve primarily as a means of verification of results reported by the correctional administrators, no effort was made to improve the response rate via a follow-up letter.

The fruits of this research design will be examined more closely in the individual chapters that deal with particular experimentation areas as in the next chapter, Disease Studies.

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[7]A copy of the questionnaire sent to the medical directors of the pharmaceutical companies is found in Appendix B.

[8]A list of the pharmaceutical companies surveyed in this random sample is found in Appendix C.

CHAPTER III.

Disease Studies

Medical experimentation in the prison takes a variety of forms, but it is used here to refer to disease studies, those studies "on the processes and progress of infectious and other diseases in order that more might be learned about them and cures or antitoxins developed."[9] This type of experimentation is generally understood to be nontherapeutic in nature, i.e. the subject does not receive any direct benefit from the research being done.[10]

Apart from the earlier cases of malaria and plague research, there is evidence to indicate that disease studies have been conducted to a limited degree in American prisons during the past few decades. The most noted case of subject abuse in recent times, however, did not use prison inmates, but rather six hundred black men, mostly poor and uneducated, in the Tuskegee Study, an experiment in which the U.S. Public Health Service monitored the progress of syphilis in these men who were later denied penicillin treatment for the disease.[11] This case did much to alarm the public of abuses of medical research and

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[9]Peter E. Meyer, Drug Experiments on Prisoners (Lexington, Mass.: D.C. Heath, 1976): 17.

[10]Dretha M. Phillips and Mervin F. White, "The Dilemma of Justice in Medical Experimentation on Prisoners," a paper delivered at the Academy of Criminal Justice Sciences Meeting, 14-16 March 1979.

[11]Jack Slater, "Condemned to Die for Science," Ebony (November 1972): 184-185.

within time, attention was focused on the use of inmates in these biomedical studies.

Disease studies, despite the isolated conditions of the prison, are well-documented. This contemporary medical research can be as simple as the allergy experiments conducted on inmates in the Oregon State Penitentiary in which the convicts had various substances injected under their skin to gauge their effect, or as complex and controversial as the 1971 study demonstrating the effects of Vitamin C deficiency on prisoners recruited from the Iowa State penitentiary. This study was in and of itself totally pointless, for the cause and cure of scurvy had been known for generations prior to this particular research. The rewards for the inmates participating in this project included the severe side effects of the disease --joint pains, excessive loss of hair, skin hemorrhages, shortness of breath, mental depression, anemia-- as well as the dehumanizing and uncomfortable conditions of the experiment (e.g. extensive tubal feedings). Monetary rewards were one dollar per day with extra money paid for unpleasant things, such as skin biopsies.[12]

Furthermore, Mitford reports that there is some evidence that prisoners in Ohio and Illinois correctional facilities had been injected with live cancer cells and blood from leukemic patients to study the progress of this disease firsthand.[13]

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[12]Jessica Mitford, Kind and Usual Punishment (New York: Vintage Books, 1974): 163.

[13]Ibid., p. 154.

Results from the nationwide survey of state and federal correctional systems indicate that of the forty-eight departments responding to questions concerning disease studies, all reported that such studies are not currently being conducted in their penal institutions. Moreover, thirty-one of the respondents stated that such medical research had never been conducted in their prisons, or that no information was available to indicate that such experimentation had occurred in recent times. The remaining departments (25% of the total number of respondents) did indicate, however, that disease studies had taken place at one time in their correctional facilities. These medical research projects in the prisons include the following:

1. The Mississippi Department of Corrections affirmed that the Goldberger studies (1914) that led to the isolation of pellagra, a chronic vitamin-deficiency disease linked to the lack of nicotinic acid in the diet, employed paid volunteers in experimental and control groups. Much later in 1970-71, a psychoactive drug, a phenothiazine, (trade name Repoise) was tested to gauge its effect on typhus.
2. The Division of Corrections in the Department of Health and Social Services in Alaska claimed to use inmates at some unidentified date in research studies of such contagious diseases as tuberculosis and venereal disease.
3. Studies on cancer and cold viruses were reported by the Ohio Department of Rehabilitation and Correction to have been conducted during the 1950's, 1960's and terminating in the early

1970's.

4. The District of Columbia Department of Corrections indicated that in the 1960's specific research was conducted under the auspices of the National Institute of Health in the development of cold relief agents.

5. The Wisconsin Department of Corrections stated that the last disease studies were done in 1965 with a mild flu virus project conducted by the Virology Department of the University of Wisconsin Medical School. This particular project involved twenty-five inmates and lasted for one month.

6. The Federal Bureau of Prisons reported that disease studies ceased in their institutions in 1970.

7. Research programs in the Oregon correctional system terminated in 1972 through the enactment of state statute. Prior to 1972, programs involving testicular radiation and the provision of blood to a commercial laboratory were done in this state's prisons.

8. The last major disease study (nature of study not mentioned) conducted within the Pennsylvania Bureau of Correction was prior to 1973.

9. The most recent reported disease research was stopped by the Texas Department of Corrections on January 1, 1978. Before that date studies of upper respiratory infections, primarily influenza, were being conducted by the Department of Microbiology of Baylor College of Medicine. Also cholera research was done by the Department of Microbiology of John Sealy Hospital.

It would seem from the results reported by the correctional departments that disease studies are no longer being performed in American penal institutions. In those systems that indicated that medical research of this nature had occurred in the past, the majority of such studies ceased in the early 1970's, as depicted in the table below.

TABLE 1

DISEASE STUDIES

Correctional Systems in which Disease Studies Occurred in the Recent Past	Years in which Disease Studies in American Prisons Ceased													
	'65	'66	'67	'68	'69	'70	'71	'72	'73	'74	'75	'76	'77	'78
Federal						X								
Alaska							X							
Alabama								X						
Massachussetts									X					
Mississippi							X							
North Carolina												X		
Ohio						X								
Oregon								X						
Pennsylvania									X					
Texas														X
Wisconsin	X													
Washington, D.C.	X													

CHAPTER IV.

Pharmaceutical and Consumer Product Testing

Less spectacular than the disease studies conducted in the American prison as discussed in the preceding chapter is the research area that involves the testing of consumer products, such as over-the-counter medications and toiletry items sold on the retail market, and pharmaceutical drugs prescribed by the physician. Such testing is closely regulated by the Food and Drug Administration, especially in the area of clinical drug studies. These FDA research regulations were promulgated in 1962 as an amendment to the Federal Food, Drug, and Cosmetics Act and specified that the informed consent of all subjects must be obtained before research begins. In 1971 another stipulation was added to require an institutional review committee to examine all applications for new drug studies being conducted in the prisons.[14] This measure, like many others that will be discussed later, is directly linked to adverse publicity regarding research experimentation with human subjects. These FDA guidelines and the issue of informed consent will be examined more closely in Chapter VI., Ethical Concerns of Research Experimentation.

With the continual proliferation of new drugs and consumer products on the market each year, it became important for many manufacturing compa-

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[14] Hershey, Human Experimentation, p. 6.

nies to find sources of human subjects to test such items according to FDA standards before consumer release. The isolated nature of the prison setting provides an excellent research site for such experimentation, i.e. inmates are available for constant observation in a controlled situation. Moreover, inmates seeking extra money to buy commissary goods and hoping to break the monotony of confinement often volunteer to participate in such research projects. The testing of consumer products is fairly easy to administer; there is no cash transfer and prisoners with limited financial resources readily welcome the acquisition of such products.

Consumer product testing in the prison ressembles marketing studies done to test for consumer appeal, taste, packaging and other aspects of such products as deodorants, mouthwashes, cold and cough remedies, and countless others. These commercial tests sponsored by such companies as Bristol-Myers and Johnson & Johnson measure product deficiency and provide marketing indicators of success or failure. However, another aspect of consumer product testing that receives less publicity is the attempt to discover possible negative side effects of these products "for purposes of including disclaimers in packaging and otherwise anticipating possible litigation about negative unintended consequences of use."[15]

It is a well-known, yet largely unreported, fact that prisoners have been used for many years in the testing of cosmetics, food ad-

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[15]Meyer, Drug Experiments, p. 18.

ditives and over-the-counter drugs (those medications sold without a prescription):

> Sweeteners, expanders, smoothers, fresheners, brighteners, preservatives and other chemicals of the food industry must also be checked for safety: prisoners gulp them in massive doses. Miracle ingredients for face creams and wrinkle removers must pass a mundane test to be sure they are harmless (their efficacy being left for consumers to judge), and that occurs in prison.[16]

Mills and Morris reported in 1974 that one private research laboratory, Hill Top Research, used inmate subjects from the Indiana State Prison to test deodorant soaps, checking the men's olfactory reactions to the soaps. Another group of inmates spend more than two weeks testing cosmetics, soaps, and antiperspirants for irritation and sensitivity. Similarly, a surgical scrub soap was tested to ascertain its ability to remove surface skin bacteria. Despite the extensiveness of such projects in the prison, the Hill Top president indicated that more consumer product testing was occurring outside the prison with church and other volunteer groups as a means of fund-raising. For such nondrug tests, these free-world subjects are as valuable as inmates because precise control and monitoring are not as critical as in the clinical drug trials.[17]

The survey of state and federal correctional systems indicated that only one state department, the Connecticut Department of Corrections,

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[16]Michael Mills and Norval Morris, "Prisoners as Laboratory Animals," Society 11(July/August 1974):63.

[17]Ibid.

currently permits such consumer products as antihistamines, tooth desensitizers, and reformulations of current products to eliminate dyes and saccarin to be tested in its correctional facilities. Data provided by Connecticut's Director of Research for correctional institutions indicates that inmate subjects receive payment fees for such non-drug studies that range from $25 to $200 with no other benefits provided. Approximately seven such projects are conducted each year with about 8% (maximum) of the inmate population participating in any single project. Six other states indicated that such testing had occurred in their penal institutions at one time, but like disease studies, many of these marketing studies were halted in the 1970's, as shown in the table below.

TABLE 2

CONSUMER PRODUCT TESTING

Years in which Consumer Product Testing Ceased in American Prisons

States in which Consumer Product Testing Occurred	'65	'66	'67	'68	'69	'70	'71	'72	'73	'74	'75	'76
Indiana												X
Kentucky									X			
Minnesota	X											
New Jersey								X				
Pennsylvania									X			
Virginia										X		

The most prevalent form of experimentation --and also the most profitable for some researchers-- occurring in the American prison in recent years has been the testing of pharmaceuticals (prescription drugs) according to Food and Drug Administration standards to document drug toxicity and efficacy before release for human consumption. Unlike consumer product testing, this government agency does attempt to closely monitor drug manufacturers' compliance with research regulations. Contemporary clinical research with new drugs recognizes three stages that are embodied in FDA regulations. These stages designated Phase I., Phase II., and Phase III. include the first exposure of the new drug to humans after initial animal studies have been completed. Phase I. testing is the most crucial stage before release for public consumption, for during this period of research the pharmaceutical is tested to determine absoption, dosage, bioavailability (the degree to which the drug can be absorbed into the blood system), toxicity and side effects.[18] For the testing of most drugs, the FDA has urged that healthy subjects be employed in Phase I. research, hence anyone can be used as a subject without having the condition the drug is intended to treat. In this stage fewer than one hundred normal, healthy individuals are administered the compound to gauge its reaction on the body's metabolism. Due to the need to find healthy subjects willing to participate in these clinical drug trials, many pharmaceutical manufacturers turned to the prison setting complete with its ideal monitoring conditions

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[18]Ibid., p. 62.

as a vital source of Phase I. subjects. In fact, prisons at one time supplied virtually all (estimated as high as 90%) of Phase I. subjects needed by the pharmaceutical manufacturers.[19] "Prison inmates are, for practical purposes, the only segment of the population that can participate in these experiments without an unacceptable disruption of their normal lives."[20] Indeed, the closed environment of the prison coupled with an abundant supply of research subjects does facilitate experimentation, particularly when close medical monitoring of side effects is needed. Moreover, the circumstances of imprisonment insure proper medical follow-up procedures if they should ever be required, for even after the inmate is released from the institution parole supervision will maintain contacts with the individual in the majority of cases.

Accepting that the investigation of experimental drugs with inmate volunteers has a necessary place in research, such experiments need to be minutely covered by FDA regulations to insure safety of the human subject. Before actual testing is begun, an Investigational New Drug application (IND) must be filed with the Food and Drug Administration which would contain all information known about the drug from animal studies, chemical composition and manufacture, et cetera. The IND is next reviewed by chemists, physicians, and pharmocologists from FDA who carefully consider the available data before the drug

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[19]Mitford, Kind and Usual Punishment, p. 153.

[20]E.R. Pinson, "Prisoner Volunteers in Drug Research," pamphlet published by Pfizer, Inc., New York (no date given): 6.

studies can commence. In addition, the FDA also requires that an institutional review committee operating as prescribed by Department of Health, Education and Welfare protocol for the protection of human subjects also review the research proposal before testing begins in the institution. Unlike the IND review committee, this group within the prison also includes lawyers, social workers and administrative personnel among its membership.[21] In some prisons inmates have been placed on these review committees in response to inmates' demands for more participation in self-government and institutional affairs that affect them directly. An outline of one state's research advisory committee that deals with biomedical research approval at the institutional level is included in Appendix D. of this paper to demonstrate the complexity of research approval.

Phases II. and III. of the clinical drug trials which largely determine the effectiveness of the new drug in treating specified conditions are not as popular in the prison setting as the more dangerous toxicity and bioavailability studies of Phase I. In Phase II. the drug is used on a small number of patients who have the condition to be treated; this condition may be naturally occurring or medically induced. In Phase III. after the drug has been determined to be safe and effective, field trials are begun which may include as many as five thousand patients.[22]

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[21]Ibid., pp. 8-12.

[22]Mills and Morris, "Prisoners as Laboratory Animals," p. 61.

It has proven economical for the pharmaceutical companies to use inmate volunteers in their clinical drug studies, for large manufacturers such as Squibb, Upjohn, Bristol-Myers and others were able to acquire prisoners at one-tenth the price --generally $1 to $2 per day-- paid freeworld volunteers.[23] Moreover, research costs are further reduced by using inmates as lab workers in the drug projects.

Many pharmaceutical companies have invested a great deal of money in the past in cultivating the prison setting as a source of human subjects for clinical drug trials. In a mutually beneficial arrangement drug manufacturers Upjohn and Parke-Davis invested over $1 million in modern research clinics at the Southern Michigan State Prison at Jackson through which pass approximately 2500 inmates each year to participate in drug experiments. Moreover, Upjohn also provides pharmacy services and emergency equipment to the prison's hospital in this exchange. Likewise, the screening of prisoners for participation in research often reveals medical problems that can be referred to a physician for treatment, another benefit of this arrangement.[24]

However, despite precautions on the part of the Food and Drug Administration, the prison review committee, and the research staff itself, there have been cases of subject abuse reported in the press that have alarmed the public and subjected research experimentation

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[23]Mitford, Kind and Usual Punishment, pp. 153-156.

[24]Mills and Morris, "Prisoners as Lab Animals," p. 62.

in the prison to increased scrutiny and standardization. Instances of careless research in the area of pharmaceutical testing were uncovered in the past decade, such as in the controversy linked with the development of a male contraceptive pill. For their participation in this drug program, these Oregon inmates received ten dollars per month for weekly sperm specimens plus twenty-five dollars for periodic biopsies of the scrotal skin. After a year they received an additional bonus of one hundred dollars for mandatory vasectomies, necessary in some cases because their testicles had been possibly exposed to radiation damage.[25]

In another case involving drug experimentation, a federal prisoner sought damages in court (Clay v. Martin, 1975) for having suffered a heart attack allegedly as a result of drug testing in which he participated. The Court of Appeals held that that inmate may have valid claims of negligence against the U.S. Bureau of Prisons under the Federal Tort Claims Act, and also valid claims of malpractice against those physicians who conducted the experiments.[26]

> Not all prison testing of new drugs is done with the scientific rigor and medical sophistication that..Upjohn and Parke-Davis plainly apply to their work in..Michigan. Many drug companies contract for research with individual physicians, university hospitals, clinics and profit-making firms. The nature and extent of this farmed-out work is

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[25]Time Magazine, "Cons as Guinea Pigs," (March 19, 1973): 45.

[26]Hillel Hoffmann, Prisoners' Rights (New York: Matthew Bender, 1976): Section 6-30.

> known only to the FDA, and only dimly to that agency. Dr. Alan Lisook, of the FDA's Office of Scientific Evaluation, told us that records of test sites are not routinely kept and could be obtained only by laboriously searching through each of the approximately 1,000 new drug applications filed each year.[27]

Due to this laxity on the part of the FDA, such researchers as Dr. Austin Stough, an Oklahoma physician, are able to reap great financial benefits from prison research while leaving behind a path of corruption. Mitford in her book Kind and Usual Punishment documents the case of this researcher whose activities in a good year grossed him nearly $1 million from 37 drug companies. The prisoners for their part in the experimentation received minimal pay plus in many cases acquired infectious hepatitis from which a few died a very slow and painful death.[28]

Possibly in light of these emerging cases of research abuse, many correctional systems in the 1970's halted pharmaceutical testing in their institutions. Approximately 18% of the survey respondents indicated that drug testing had occurred at one time in their correctional facilities, but had since been discontinued by administrative directive or by statute. Table 3 on page 24 indicates the years in which pharmaceutical testing was halted in American prisons. Similiar to disease studies and consumer product testing, this type of research largely came to an end in the early 1970's , as may be seen in the next table.

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[27]Mills and Morris, "Prisoners as Lab Animals," p. 62.

[28]Mitford, Kind and Usual Punishment, p. 152.

TABLE 3

PHARMACEUTICAL TESTING

States in which Pharmaceutical Testing Occurred in the Recent Past	Years in which Pharmaceutical Testing Ceased in American Prisons											
	'65	'66	'67	'68	'69	'70	'71	'72	'73	'74	'75	'76
Federal						X						
Alabama								X				
Connecticut									X			
Indiana												X
Kentucky									X			
Massachussetts									X			
Mississippi							X					
Ohio						X						
Nebraska										X		
Pennsylvania									X			
Virginia								X				

Only two correctional systems surveyed, Michigan and Montana, reported that pharmaceutical testing is still occurring in their penal institutions. The Michigan Department of Corrections is permitting Phase I. testing of pharmaceutical products to continue at the State Penitentiary of Southern Michigan at Jackson. These results also verify the fact that Parke-Davis Pharmaceutical Research Division of Warner-Lambert does employ Michigan prisoners in their clinical drug trials.

Approximately 19% of the inmate population at Jackson participates in these studies with a minimum pay provision of 60 cents a day guaranteed to those participating in a study that lasts twenty-eight days or longer. Additional fees are paid to inmate volunteers for relatively simple sampling procedures (e.g. fifty cents for urine specimens) and upwards of $15 for special sampling procedures such as spinal taps and bone marrow aspirations.[29]

The Montana Division of Corrections indicated that Phase I. testing that included single and multiple dose tolerance, pharmacokinetic and bioequivalency studies are being conducted at the Deer Lodge Research Unit of the Montana State Prison. These results were substantiated by Hoffmann LaRoche, Inc., in the survey of pharmaceutical manufacturers. Approximately 30% of the inmate population at Deer Lodge is involved in these drug studies, receiving monetary reimbursement based on dosage and monitoring procedures.

With limited data available --an approximate 32% response rate-- from the survey of twenty-two major pharmaceutical companies, it is difficult to assess with any finality the pharmaceutical testing practices with human subjects in the prison environment. However, it would seem from the response received --57% of the respondents-- that many companies are now using paid volunteers in testing facilities owned by the pharmaceutical companies themselves or private testing organizations, both settings designed to evaluate the bioavailability

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[29]Taken from the Michigan Department of Corrections Pharmaceutical Research Volunteer Fee Schedule.

of such products. Another prevalent source of human subjects for drug testing appears to be non-paid volunteers who are patients in private or public clinics. Only two pharmaceutical manufacturers, Parke-Davis and Hoffmann LaRoche, still reported the use of inmate subjects in Phase I. testing in Michigan and Montana, respectively. Four other companies --A.H. Robins, CIBA-Geigy, Dow Chemical, and Eli Lilly-- responded that prisoners were employed in past drug studies, but in most instances such testing had ceased in 1974. The table below shows the major sources of human subjects for drug testing as reported by the pharmaceutical companies surveyed in this study.

TABLE 4

PHARMACEUTICAL COMPANIES' SOURCES OF HUMAN SUBJECTS IN DRUG EXPERIMENTATION

Current Sources of Human Subjects in Pharmaceutical Testing	Pharmaceutical Companies Responding to Survey							
	CIBA	Dow	×Hoffmann	Lilly	Pfizer	Robins	SK&F	×Warner
Prisoners, State								
Prisoners, Federal								
Residents, Mental Health Facilities	x				x		x	
Paid Volunteers, Facilities Owned by Drug Company	x		x	x				
Paid Volunteers, Private Clinics		x	x		x	x		
Paid Volunteers, Public Clinics			x			x		

This apparent shift from the use of prisoners as human subjects in pharmaceutical testing is linked in many cases to the bad publicity that such research received as a result of publicized cases of careless experimentation discussed earlier. Faced with public and legislative pressure (e.g. National Research Act of 1974) to comply with humane testing guidelines, it would seem that many pharmaceutical manufacturers turned to the use of freeworld subjects to replace inmates and thus escape further criticism. One medical director responding to the questionnaire felt that many drug companies had "already buckled to public pressure" --a fact that this medical director found rather disconcerting in light of his view of the positive effects derived by the inmates from their participation in such research. He commented: "Having had direct contact with prisoners, both in the past and present, I am impressed with the positive effect of clinical studies on the inmates. They are both interested in the outcome and willing to take the discomforts involved when apprised of them.[30]

This medical researcher's view is shared by many who value the quest for further scientific knowledge, as contrasted to those who question the validity of human experimentation and its inherent inequality. This inequality was alluded to by Senator Edward Kennedy in his statement before the 1975 Senate hearings to amend the National Research Act: "All Americans have been touched by and have profitted from the products of biomedical research. And yet, the burden of devel-

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[30]Quote taken from a letter received from the medical director of Pennwalt Pharmaceutical Division of Detroit, Michigan.

oping these products is not equally shared..In our society the risk is taken most often by the poor, the minority groups and the institutionalized." [31] This issue of inequality and ethics involved in human experimentation --in this instance, with prisoner subjects-- will be dealt with extensively in the chapter on the Ethical Concerns of Research Experimentation.

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[31]Meyer, Drug Experiments, p. 5

CHAPTER V.

Behavioral Research

More elusive than the other types of experimentation conducted in the American prison are the behavioral research programs that employ psychoactive drugs, psychosurgery and other forms of therapy which have recently come to the public's attention, largely through the means of the popular press. Many professionals in the corrections field, however, maintain that modern psychotherapy does have a place in the prison and its benefits outweigh the potential for abuse. Yet there appears to be a fine line between therapy and experimentation. Dr. Charles Nemeth of Niagara University notes in his comments about Maryland's Patuxent Institute, a "model" prison with innovative programming that includes behavior modification, that

> What is exceedingly disturbing..is the likelihood of abuse--that aside from the present psychotherapy and other behavior modification techniques currently in use at Patuxent, severe forms of experimentation could be instituted under the guise of therapy.[32]

Many of Nemeth's fears have been echoed by others --journalists such as Trotter, Sage, and Weiner-- who view many therapeutic programs in prisons --particularly aversive therapy-- as reminiscent of Anthony Burgess' science fiction novel A Clockwork Orange. In some recorded cases aversive drug therapy has been extended beyond the research setting

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[32]Charles P. Nemeth, "Experimentation in a Prison Setting: Ethics and Consent," a paper delivered at the Academy of Criminal Justice Sciences Meeting, 14-16 March 1979.

to control or modify the behavior of troublesome inmates, and in "programs across the country, drugs, hypnosis, electroconvulsive shocks, brainwashing and psychosurgery have been added to an arsenal of therapies prison officials are labeling behavior modification."[33] Indeed, behavior modification has come to the prisons at a time when such institutions are struggling to maintain themselves as a viable element of the criminal justice system, moving beyond warehouses of confinement and punishment to facilities for rehabilitation. The use of behavior modification (actually the term "behavior therapy" was used) by Ogden Lindsley, who was one of the first to apply B.F. Skinner's operant conditioning in an institution, demonstrated marked success with chronic mental patients. However, when such techniques as desensitization, assertiveness training, aversion therapy and operant conditioning are applied to the prison setting there exists the potential for abuse because of the nature of imprisonment itself, i.e. loss of liberty, long periods of deprivation, removal from public view.[34]

Brain surgery that began with the lobotomy fad of the 1950's became the more sophisticated psychosurgery or "sedative neurosurgery" of the past two decades. It is estimated by psychiatrist Peter Breggin that 400 to 600 cases of psychosurgery are performed each year in the United States to obstensibly treat such emotional problems as depression,

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[33]Wayne Sage, "Crime and the Clockwork Lemon," Human Behavior (Sept. 1974): 168.

[34]Robert Sommer, The End of Imprisonment (New York: Oxford University Press, 1976): 128.

drug addiction and criminal tendencies.[35] Numerous cases of lobotomies and other forms of psychosurgery have been reported at the Medical-Psychiatric Diagnostic Unit (MPDU) at Vacaville Prison in California in the treatment of "violent-prone" inmates. Yet the horror of this particular treatment came to light in the Michigan case of Kaimowitz v. The Department of Mental Health (1973) in which the court ruled that psychosurgery could not be performed without the informed consent of the subject and "even apparently acquiescing patients could not submit to the procedure because such persons would be unable to give legally adequate informed consent."[36] Furthermore, the three-judge court ruled that psychosurgery was indeed experimental and that

> Experimental psychosurgery, which is irreversible and intrusive, often leads to a blunting of emotions, the deadening of memory, the reduction of affect, and limits the ability to generate new ideas. Its potential for injury to the creativity of the individual is great and can impinge on the right of the individual to be free from interference with his mental processes.
>
> The State's interest in performing psychosurgery and the legal ability of the involuntarily detained..to give consent must bow to the First Amendment, which protects the generation and free flow of ideas from unwarranted interference with one's mental processes.[37]

This celebrated case involved an incarcerated criminal sexual psychopath who, among twenty-eight others, was slated for "experimen-

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[35]Robert J. Trotter, "A Clockwork Orange in a California Prison," Science News (March 11, 1972): 174.

[36]David B. Wexler, "Treatment Issues," The Prison Journal (Spring-Summer, 1978): 12.

[37]Peter Schrag, Mind Control (New York: Pantheon Books, 1978): 178.

tal psychosurgery" and it was only through the concerted efforts of Attorney Kaimowitz that this procedure was halted. Subsequently, it was discovered that in 1968 three prisoners from Vacaville did undergo brain surgery to control violent seizures[38], and to further complicate the issue, it was also discovered that funds from the Law Enforcement Assistance Administration (LEAA) were being used for such experimentation. Only in 1974 after a Senate investigation did LEAA issue a public announcement that the agency would no longer fund medical research in psychosurgery and behavior modification. Despite this announcement LEAA has subsidized 537 research projects involving behavior modification.[39]

Another form of behavior modification that gained much notoriety occurred at the Somers, Connecticut, maximum-security prison in which classical conditioning was employed with convicted child molesters. In this program the offender received a small electrical shock on his inner thigh near the genital area when a slide of a naked child was flashed on a screen before him. No shock was administered when a picture of an adult was shown.[40]

Such behavioral research programs have come to the prisons at a time when institutional administrators are in search of answers that will satisfy the public's demand for credible programs of rehabilitation.

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[38]Trotter, "A Clockwork Orange," p. 174.

[39]Samuel Chavkin, The Mind Stealers (Boston: Houghton Mifflin, 1978): 80.

[40]William E. Cockerman, "Behavior Modification for Child Molesters," Corrections Magazine 1(Jan./Feb. 1975): 77-80.

Treatment programs such as START (Special Treatment and Rehabilitative Training) at the Federal Medical Facility in Springfield, Missouri, have revamped the solitary confinement cells into "adjustment centers" where an inmate is locked up twenty-four hours a day in a 6' x 10' cell containing only a bunk and toilet, often with no light bulb (a form of sensory deprivation). All contact with the outside world, including visitors and mail, is forbidden in order to maintain the almost complete isolation and psychological deprivation of the offender. Fortunately, the abusive nature of this program began to surface as inmates challenged the constitutionality of such treatment in such court cases as Sanchez v. Ciccone in which prisoners told of alleged beatings and tear gassings in these "adjustment centers".[41] Such testimony led to the closing of the START program by the Federal Bureau of Prisons in 1974.

Before its closure the START program was challenged once again in court in 1974 in the case of Clonce v. Richardson. This action was "aimed at the level of deprivation in the lower tiers of the program, where reading materials, exercise opportunities, and visitation rights were sharply limited. Because the Bureau of Prisons decided, while the litigation was still in process, to terminate the Springfield START program,"[42] many issues went unresolved and were declared moot by the court. Despite these problems, the Federal Bureau of Prisons has indicated its support of positive reinforcement principles in future correctional programs.

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[41] Wexler, "Treatment Issues," p. 14.

[42] Ibid., p. 10.

It is questionable whether the Federal Bureau of Prisons has withdrawn from the area of behavioral research, for the initial design of its newest facilities at Butner, North Carolina, was of a research complex for testing new behavioral programs on prisoners. Butner's prime objective as first conceived was to modify antisocial behavior through a variety of procedures, including psychodrama and "attack sessions". These techniques intended to emotionally overhaul the inmate have been questioned by prisoners' rights groups like the American Civil Liberties Union (ACLU).[43] It is suspected that many of the program objectives have not as yet been realized at this facility which is in part attributable to the adverse publicity that the programming received. Moreover, any conclusive evidence about the effectiveness of this complex has not been reported to any great degree in scholarly journals, largely due to the relative newness of this facility.

It has been predicted by James V. Bennett, former director of the U.S. Bureau of Prisons, that by the year 2000 "the prison system will increasingly be valued and used as a laboratory and workshop for social change."[44] Facilities such as Butner seem to point to his prediction and in light of these emerging programs of psychological experimentation, it has become increasingly necessary to redefine standards for the use of prisoners in research or face the consequences of court challenges.

Perhaps one area of behavioral research, the use of psychoactive drugs and aversive drug therapy, has received more challenges in the

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[43]Sage, "Crime and the Clockwork Lemon," p. 168.

[44]Chavkin, The Mind Stealers, p. 88.

judiciary than all other modification procedures. Powerful tranquilizers such as Librium and Thorazine are commonly used in the prison as a means of sedation to treat violent, aggressive inmates. Antipsychotic medications like Prolixin are more than just a means of sedation. It is advertised by the manufacturer E.R. Squibb as a "highly potent behavior modifier" that is capable of inducing a catatonic state in some individuals or producing a "pseudoparkinsonian syndrome" that in some subjects is irreversible.[45] Permanent brain damage has been noted in some individuals who have received this drug over an extended period of time. In a petition written by prisoners from the California Men's Colony the results of this medication are described firsthand:

> The simple fact that a number of prisoners are walking the yard of this institution like somnambulists, robots and vegetables as a result of this drug (Prolixin) should be reason enough to make people apprehensive as to the effect it is having. That no person feels safe because he never knows when he will become a candidate for said drug is another factor in producing tension in this institution.[46]

Another group of prisoners and their attorneys have attempted to halt the transfer of inmates to the Medical-Psychiatric Diagnostic Unit at Vacaville who were pressured to sign consent forms for "voluntary" treatment at this facility.

> Several have filed class-action suits to prevent all inmate transfers to the MPDU. One San Quentin prisoners says he was told by a guard, "You'll stay in here until you die if you don't sign that consent form." Another inmate said that he signed the form while drugged on the tranquilizer Thorazine, and that it was never made clear to him what it was he was "volunteering" to do.

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[45] Sage, "Crime and the Clockwork Lemon," p. 169.

[46] Ibid.

> Prisoners have traditionally been used as "volunteers" ..for a variety of medical experiments -testing vaccines, drugs, therapy techniques, etc.- usually to earn some extra money or to increase their chances for early parole or a reduction in their indeterminate sentence. However, even a former San Quentin associate warden, Douglas Rigg, doubts the voluntary nature of any of these programs. "There is a real question in my mind," he told me, "whether any prisoner can be considered in the true sense of the word, a volunteer for any program. The possibilities for direct or subtle coercion are all too obvious."[47]

In the recent court case of Tucker v. Hutto (1979), the largest damage award ever won by a prisoner ($518,000) was granted to Henry Tucker, a state prisoner who with the help of the National Prison Project of the ACLU sued nineteen Virginia corrections, medical and mental health officials for medical and psychiatric malpractice which resulted in the permanent paralysis of his arms and legs because of the improper use of the drug Prolixin.[48]

Other cases have challenged the use of psychoactive drugs in research programs. One such court action involved the drug Anectine, a derivative of curare, used to simulate death. "Within 30 to 40 seconds of injection, it brings on paralysis..the inmate cannot move, or breath, and yet remains fully conscious as though drowning and dying, while a researcher shouts commands to behave."[49] This procedure has been used on hundreds of troublesome inmates from Vacaville and

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[47]Bernard Weiner, "The Clockwork Cure," The Nation (April 3, 1972): 433.

[48]Taken from the press release of the National Prison Project, January 5, 1979.

[49]Sage, "Crime and the Clockwork Lemon," p. 169.

Atascadero State Mental Hospital for the Criminally Insane in California. This use of "anectine therapy" has raised serious questions about violations of the inmate's Eighth and First Amendment (protection of mental privacy) rights, as addressed in the U.S. Court of Appeals case of Mackey v. Procunier (1973).[50]

The psychoactive drug apomorphine had been used with convicts at the Iowa Medical Facility to produce uncontrollable vomiting for fifteen to sixty minutes as an inducement against lying or swearing. In the court case of Knecht v. Gillman (1973), it was ruled that the administration of apomorphine to a subject without his informed consent violated Eighth Amendment rights against cruel and unusual punishment.[51]

In another case now pending in Federal District Court in New York State (Liles v. Ward), seven female prisoners from the Bedford Hills Correctional Facility Annex are suing the New York State Commissioner of Corrections for alleged damages incurred while they were placed in behavioral programs that involved the coercive administration of such psychotropic medication as Haldol, Thorazine, Prolixin, Elavil and others; a treatment which they maintain violates their Eighth Amendment rights.[52]

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[50] Wexler, "Treatment Issues," p. 8.

[51] Ibid.

[52] Taken from the Amended Complaint filed in the U.S. District Court, Southern District of New York in the case of Liles v. Ward (1979).

In results from the survey of correctional systems done for this study, 77% of the respondents reported that psychoactive drugs are being currently used in penal institutions, largely as prescribed treatment for various symptomology, but not for research. However, three states --Connecticut, Utah and New Jersey-- did indicate on the questionnaire that such drugs had been used in the past in conjunction with behavioral research programs. Though Utah provided no further information, the correctional administrator in Connecticut did indicate that a study conducted about three years ago involved the regular administration of lithium carbonate, a drug widely used to treat manic-depressive psychosis, to measure the degree to which this drug reduced the assaultive behavior in 16-21 year old males. The New Jersey Department of Corrections reported that in 1962 that behavioral research projects were performed that involved the use of lysergic acid diethylamide (LSD), an hallucinogenic drug; no other information regarding the nature of the research was provided by the respondent.

Though not reported in the survey, it is well-known that other studies employing psychoactive drugs have been performed in American prisons. One case in point are the studies conducted by research teams from Ohio State University that involved the drug epinephrine to measure the cardiovascular hyperreactivity of sociopaths at the Ohio Penintentiary and the Marysville Reformatory for Women. These empirical studies demonstrated a "close relationship between undesirable social behavior and deviant sympathetic nervous system activ-

ity." [53]

It would be unfair to leave the subject of behavioral research in the prison without mentioning some of the positive contributions of this therapeutic programming. Certainly, the widespread use of drug therapy in the mental health setting with both the institutionalized individual and the outpatient has been readily accepted by the public for the past few decades. For many patients and their families, psychoactive drugs have had a liberating effect, freeing them from the myths and stigma that have surrounded the care of the mentally ill prior to the introduction of these therapy agents. However, it has only been in the past few years that the public became aware of the fact that these psychoactive drugs were also being used in prisons as a form of treatment, both voluntary and coerced. Little is still known about the true nature of drug therapy in the correctional setting regarding the extent of use, the purposes of such therapy, and the application of drug therapy to individual cases. It is important to remember that many of the applications of drug therapy in the prison have merely been transposed from the mental health setting because of the demonstrated effectiveness of psychotropic medications with the psychotic, the depressed, and the behavior disordered individuals in institutions for the mentally ill. There was hope that this form of therapy could be applied successfully in the penal setting, too. Certainly, all types of psychoactive drugs are now found in the prison: in behavior therapy, in medical treatment, or illicitly in drug abuse.

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[53] Harry Allen, et al., "Hostile and Simple Sociopaths: An Empirical Typology." Criminology (May, 1971): 31.

Applications of operant conditioning and other forms of behavior modification are to be found in the prison and some programs like the Experimental Manpower Laboratory for Corrections (EMLC) at Elmore, Alabama, have proven successful in achieving their objectives. The early work of this EMLC program at the Draper Correctional Center involved the utilization of behavior modification techniques and contingency management procedures in remedial education and vocational training. The focus of this program in the maximum security institution was on providing basic education courses through the use of programmed instruction to inmates who were judged to be low-achievers, both socially and intellectually. The EMLC project was later expanded to include token economies for the inmates and specialized correctional officer training to develop the potential of the line staff as "behavior technicians". This particular program is generally regarded to be effective in achieving academic and vocational success for the inmates as well as developing positive qualities in the correctional officers.[54]

From an examination of the information concerning the use of behavior modification in the correctional setting, one is struck by the preponderance of literature counter to the use of such programs in the prison. Very little information is now available on the successful application of operant conditioning, desensitization, drug therapy and other techniques in the American penal institution, and the information

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[54]Michael A. Milan and John McKee, "Behavior Modification: Principles and Applications" in Handbook of Criminology, ed. Daniel Glaser (Chicago: Rand McNally, 1974): 762-763.

available is often lacking in empirical verification to substantiate any positive claims about behavior modification. Hence, there is an imperative need to critically evaluate the performance of behavioral research in the prison to measure both its strengths and weaknesses. Perhaps these programs represent --as many investigative writers would have us believe-- another form of coercion and containment; but alternatively, they may represent a positive factor in corrections, a field marred by many disappointments masked as reform. More empirical research needs to be done to assess the validity of behavior modification in the prison: Is it coercion or therapy? Such programs discussed earlier in the chapter cannot be regarded as voluntary in nature, hence psychotherapy has acquired a bad reputation based on these past experiences. Yet many people are looking hopefully to such institutions such as Butner to determine where the fine line exists between human experimentation and treatment.

CHAPTER VI.

Ethical Concerns of Research Experimentation

The problems involved in research experimentation with human subjects, particularly with inmate subjects, are complex and often paradoxical. While on the one hand the subject in the research project may benefit both economically and morally, i.e. with a sense of self-righteousness, he must also face the possibility of negative consequences. Moreover, adherents of research experimentation in the prison setting stress the need for verified accurate information that may benefit the public with important new miracle drugs and cures. Alternatively, opponents often find these researchers lacking in compassion who use the scientific ethos to coerce deprived people into participation.

> The difficulty involved in attempts to gain consensus on working principles for correctional experimentation with offender populations stems in part from the fact that both major competing values have almost total support. Few persons are opposed to verified, accurate information; and few persons are opposed to the idea of human decency and justice. The dispute centers about the point at which one value is to be given priority, and it is also involved in judgments regarding the true character of the experimental intervention, the statistical likelihood of different outcomes, and the general importance of the findings, measured in terms of their cost.[55]

The argument for research experimentation with human subjects was generally supported for many years by private and government

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[55]Gilbert Geis, "Ethics of Prisoner Experimentation," in Justice and Corrections ed. Norman Johnston and Leonard D. Savitz (New YorK: John Wiley and Sons, 1978): 615.

funding agencies and the general public. It was not until instances of careless research in the prisons were revealed in the popular press that there began a noticeable shift away from the scientific viewpoint. Human experimentation itself is regarded as both beneficial and necessary, but when the question arises concerning the use of "unfree" populations and the ethical standards of their participation, the paradox becomes an emotion-laden enigma.

The Nuremburg tribunal originally set the tone for this ethical debate that is reflected even today in the guidelines and codes of ethics issued by national and international professional associations and governmental agencies. Perhaps the most important issue that surrounds the use of "unfree" populations is the issue of "informed consent", that elusive phrase found in all research guidelines. Informed consent, as first dealt with in the Nuremburg judgement, specified that

> the voluntary consent of the human subject is absolutely essential. This means the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice..and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding, enlightened decision.[56]

The degree to which participation is voluntary depends upon informed consent, i.e. adequate information to appraise the choice of action. According to the National Institute of Health:

The informed consent of subjects will be obtained by

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[56]Mitford, Kind and Usual, p. 167.

> methods that are adequate and appropriate.
>
> Informed consent is the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity.
>
> The basic elements of informed consent are:
>
> 1. A fair explanation of the procedures to be followed, including an identification of those which are experimental
> 2. A description of the attendant discomforts and risks
> 3. A description of the benefits to be expected
> 4. A disclosure of appropriate alternative procedures that would be advantageous to the subject
> 5. An offer to answer any inquiries concerning the procedures
> 6. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.
>
> In addition, the agreement, written or oral, entered into by the subject should include no exculpatory language through which the subject is made to waive, or appear to waive, any of his legal rights, or to release the institution or its agents from liability for negligence.[57]

Aside from the issue of informed consent, there are other principles of human experimentation -- risk, coercion, voluntariness, competence-- that must be dealt with by the prison researcher. By definition alone, experimentation is a risky enterprise, for the outcome is unknown. According to the code published by the Department of Health, Education and Welfare:

> An individual is considered to be "at risk" if he may be exposed to the possibilities of harm -physical, psychological, sociological, or other- as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs.
>
> Institutional committees should carefully examine applications, protocols or descriptions of work to arrive

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[57] Seth Allan Bloomberg and Leslie T. Wilkins, "Ethics of Research Involving Human Subjects in Criminal Justice" Crime and Delinquency (october 1977): 439-440.

> at an independent determination of possible risks. The committee must be alert to the possibility that investigators, program directors or contractors may, quite unintentionally, introduce unnecessary or unacceptable hazards, or fail to provide safeguards.[58]

Written safeguards like those created by the Department of Health, Education and Welfare are intended to insure the proper balance between the benefits of scientific knowledge versus the harm that may be done in the process of acquiring that knowledge. "Insuring that the proper balance between the two is maintained in the conduct of experimentation is a matter of establishing and following ethical principles."[59]

The risk of acting as an experimental subject is not incurred solely at the time of the actual research, but can be distributed over the lifetime of the subject. "Such risk derives in part from the unknown long-range effects..associated with any medical procedure" or the ingestion of an experimental drug.[60]

However, as empirical data becomes available, the risks taken by a research subject are not as great as one would assume.

> According to..estimates, the risk of physical or psychological harm from Phase I. drug testing is slightly greater than that involved in being an office secretary, one-seventh that of window washers, and one-ninth that of miners... They found that in "non-therapeutic research," the risk of being disabled either temporarily or permanently was sub-

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[58]Ibid., p. 437.

[59]Phillips and White, "The Dilemma of Justice," p. 5.

[60]Meyer, Drug Experiments, p. 25.

> stantially less than that of being similarly harmed in an accident...The risks of being a subject in "therapeutic research" were substantially higher. However, the risk either of disability (temporary or permanent) or fatality was substantially less than the risk of similar unfortunate outcomes in other medical settings involving no research.[61]

In the area of psychological research, the concept of risk is closely linked to the problem of confidentiality; i.e. the need to insure that personal information about the subject is not used inappropriately to harm the individual. To deal with this problem, the American Psychological Association in its code of ethics has drafted the following guidelines:

> Principle 6: Confidentiality. Safeguarding information about an individual that has been obtained by the psychologist (or any researcher)..Such information is not communicated to others unless certain important conditions are met:
>
> a. Information received in confidence is revealed only after the most careful deliberation and when there is clear and imminent danger to an individual or to society...
>
> b. ..every effort should be made to avoid undue invasion of privacy.
>
> c. Clinical and other case materials are used in.. teaching and writing only when the identity of the persons involved is adequately disguised.
>
> d. The confidentiality of professional communications about individuals is maintained...
>
> e. Only after explicit permission has been granted is the identity of research subjects published...
>
> f. The psychologist makes provision for the maintenance of confidentiality in the preservation and ultimate disposition of confidential records.[62]

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[61]Donald M. Gallant and Robert Force, eds. Legal and Ethical Issues in Human Research and Treatment, Psychopharmacologic Considerations (New York: Spectrum Publications, 1978): 92.

[62]Bloomberg and Wilkins, "Ethics of Research,"pp. 442-443.

The concept of risk becomes more complex when prisoners are the subjects of experimentation, for the condition of imprisonment and the use of an "unfree" population leads to other problems, particularly the problem of coercion. Coercion, closely tied to the issue of informed consent, is a major argument offered by those who oppose the use of inmate subjects in research experimentation. They present the following reasons for their opposition:

1. Inmates can never be considered volunteers for research, for they cannot give "informed consent" simply because they are prisoners. "The prisoner is never free to decide, nor is he completely informed and consenting, particularly when facing a doctor proposing to experiment on him."[63] There exists the question of coercion involved in obtaining volunteers; "apparent volunteers may not be volunteers if there are insinuations that failure to cooperate may lead to reprisals, or that cooperation may insure more lenient treatment in the future."[64]
2. Monetary compensation though small may represent a lot to the destitute, particularly in light of the poor wages generally paid in prison industry. Hence, inmates may volunteer for paid experiments in which they might not otherwise be willing to participate.
3. The inmate within the isolated and demoralizing confines of the

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[63]Marc Klein, "Problems Arising from Biological Experimentation in Prisons," Medical Care of Prisoners and Detainees (New York: Associated Scientific Publishers, 1973): 67.

[64]Maurice B. Visscher, Ethical Constraints and Imperatives in Medical Research (Springfield, Ill.: Charles C. Thomas, 1975): 63.

institution may risk hazard to his health to relieve the monotony of prison life.

"To demonstrate that coercion exists in prisons in regard to experimentation, the poor state of prison conditions is often mentioned. If the conditions are sufficiently poor, and the enticements to participate are sufficiently great, there is little question that coercion can exist."[65] Specific situations in prisons where duress and undue influence have played a major factor in prisoner participation in research are related in Informed Consent to Human Experimentation by Annas, Glantz, and Katz (1977). One case involving nontherapeutic experimentation at the Maryland House of Corrections included the exposure of inmates to such diseases as malaria and typhoid to determine the efficacy of certain drug treatments. Due to the deplorable and overcrowded conditions of the prison itself which included overpriced commissary goods and poorly-paid prison labor, participation in the Infectious Disease Area with its air conditioning and spacious, well-lit rooms with televisions plus the excellent pay ($10 per day) was quite appealing. The wide disparity in living conditions provided a coercive force in this situation.

> If the prisoners in this case lived in a prison that provided them with the minimal requisites for a decent standard of living so that the prisoner would not have to participate in experiments to acquire this standard of living,.. the better living conditions would not be coercive. It might

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[65]George J. Annas, Leonard H. Glantz and Barbara F.Katz, Informed Consent to Human Experimentation: The Subject's Dilemma (Cambridge, Mass.: Ballinger Publishing Company, 1977): 113.

> be fairer to say that the prison environment, not the offer by the IDA (Infectious Disease Area), is what was coercive...the prisoners should not have to risk their lives or health to get those things which they deserve.[66]

Like the Maryland House of Corrections, the Texas State Penitentiary at Huntsville permitted undue influence to exist in its institutional research programs. In studies of respiratory diseases and cholera conducted to develop new vaccines, inmate subjects were paid $5 per day while their counterparts in the prison industry received no monetary compensation.[67]

This issue of coercion in experimentation impinges directly on informed consent; i.e. the degree to which the inmate actually volunteers to participate in such research and the degree to which this volunteering is meaningful in light of economic and other persuasions. Voluntariness and information are regarded as essential elements of informed consent. Much attention is paid to the type of information to be made available to the subject, and it is generally thought that information about the proposed research should be provided in terms that the subject can easily understand, rather than the language of the medical professional.

Voluntariness, in contrast to the provision of adequate information, is a more difficult issue to assess. "In determining the voluntary or involuntary nature of a prisoner's consent, his motivation becomes an

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[66]Ibid., p. 115.

[67]Ibid.

important factor. If he is motivated to participate in an experiment for improper reasons, or by forces that are coercive and unduly influence him, his consent may be involuntary and therefore invalid."[68] The motivation of prisoner volunteers for research experimentation has been discussed at length in medical and sociological literature since the 1940's and can be summarized in the following arguments:

1. The overriding factor in volunteering is the monetary incentive that such research work provides, especially for those inmates with limited financial resources. Generally speaking, experimentation programs in the institution pay more than prison industry. However, it is agreed for the most part that the financial gain should not be so great to unduly influence the inmate subject to volunteer and to override his caution about possible risks.

2. Another important reason that prisoners volunteer for research studies is to break the monotony of prison life, to gain some measure of relief from institutional patterns. Research participation can be both refreshing and exciting, for it gives the inmates something to talk about. Volunteers may even be regarded as "heroes" or the "elite" by fellow inmates. Suddenly they are no longer nonentities, they are important.

Certainly the conditions of the research units are more desirable than those of the cellblock or prison workshop. "Participation in ex-

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[68] Ibid., p. 106.

periments provides an immediate temporary escape from the pervasive fear, endemic brutality and total anonymity of the typical American megaprison."[69]

The opportunity to associate with people outside the institution is an additional benefit. The inmate volunteer may also profit from positive contacts with the research staff and if the staff includes women, it is natural to assume that some may volunteer because of a "longing for feminine proximity".[70] A major attraction for research participation, as one New York lawyer notes from his conversations with convicts, is that "for awhile you are treated as a human being, even though you are a guinea pig."[71]

3. Participation in experimentation that may benefit others may provide the inmate with a sense of self-worth, an altruistic means of repaying society. For many subjects participation may enhance self-esteem.

> ..the very idea of participating in studies which may be of benefit to society may serve to elevate the prisoner from the dehumanizing effect of prison status and becomes an ego strengthening device. Volunteers often become subjects of interset throughout the prison in a way that makes them, for a time at least, the elite of their society. In volunteering the prisoner can prove to himself and to his friends that he can do something worthwhile. Volunteers seem to develop a genuine esprit

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[69]Mills and Morris, "Prisoners as Lab Animals," p. 64.

[70]Lasagna, "Special Subjects," p. 266.

[71]Time, "Cons as Guinea Pigs," p. 45.

de corps that has a positive effect on their behavior and conduct toward each other.[72]

4. Surely, the hope of earlier release or preferential treatment in the future, i.e. a favorable report to the parole board, is another influencing factor inducing inmates to volunteer.

> Inmates of state and federal prisons know that the fact of their volunteering for medical experiments is noted on the records seen by the parole board. But they do not deceive themselves that volunteering has more than marginal influence on their chances for parole. Prisoners tend to see parole decisions as so capricious and unprincipled that participation in medical experiments cannot be a reliable key to unlock the prison gates. A temporary escape to a less brutal imprisonment, yes -but a sure path to an early freedom, certainly not.
>
> Nathan Leopold, of the Loeb and Leopold case, an early volunteer for the Stateville Malaria Project, put it well: "There was no assurance whatever that volunteers would be rewarded by having their time cut. Of that fact each group was solemnly and emphatically reminded..But the possibility did exist that there would be time cuts. And that was a chance I could not afford to miss."[73]

These four factors seem convincing particularly in light of the studies performed by McDonald and Hodges and Bean in 1967 for the American Medical Association which indicate that many of the inmates gave similar reasons for participation in research projects. It would seem above all else that the need to relieve the boredom of prison life is the most convincing factor in these studies. Yet it is the monotony and hope for better treatment coupled with small monetary enticements

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[72]Pinson, "Prisoner Volunteers," pp. 15-16.

[73]Mills and Morris, "Prisoners as Lab Animals," p. 64.

that make the inmate susceptible to use and abuse in research programs.[74]

> In their study of prisoners volunteering for research on malaria, Martin, Arnold, Zimmerman, and Richart (1968) found about half to report that payment was the major reason for their participation, while the other half reported altruistic motives as their major reason for participation. Another motive..is the implicit hope that a parole board might take into favorable account the prisoner's participation in research. That such hopes are implicit rather than explicit stems from the.. terms that make clear that volunteering will in no way affect the prisoner's term of time to be served. Nevertheless, parole boards are likely to know that a prisoner participated in research, and they are likely to view this with increasing favor as a function of the degree of jeopardy into which they feel the prisoner has placed himself.[75]

In several studies conducted by Martin to determine why individuals volunteer as research subjects, he discovered in his work that

> clearly prisoners and low-income individuals were more likely to volunteer for risky experiments. However, all groups were more willing to volunteer for the less risky experiments than for those that had higher risks. Thus, the element of risk certainly entered into the decision-making process for all the people involved.
>
> This study also found that there was a greater willingness to volunteer when the volunteer was not obligated to others. Half of the persons living alone would have volunteered.. whereas only a fifth of those who had family responsibilities would have volunteered for the experiment.[76]

From these studies it is evident that prisoners are motivated by a variety of reasons to volunteer for research experimentation. Despite

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[74]Lasagna, "Special Subjects," p. 267.

[75]Robert Rosenthal and Ralph L. Rosnow, The Volunteer Subject (New York: John Wiley and Sons, 1975): 94.

[76]Annas, Glantz, and Katz, Informed Consent, pp. 108-109.

the inmates' willingness to volunteer for such research, the question of their competence to make such a decision must also be examined. This issue of competence has received little attention, for in the majority of cases prisoners are considered to be competent enough to make rational informed choices. Phillips and White in their paper "The Dilemma of Justice in Medical Experimentation on Prisoners," discuss two distinct aspects of competence: first, the issue of mental capacity and second, the issue of intellectual maturity. While the vast majority of inmates possess adequate mental capacity or intelligence to make a rational choice, there are many prisoners who, because of environmental factors, do not have enough intellectual maturity to capably weigh the risks and benefits of experimentation. Education, the relationship with one's peers and authority figures, and the general sociocultural background of the individual are important aspects of intellectual maturity which provide "stable standards of reference from which exposure to risk can be adequately evaluated. To the extent that these factors are disturbed, one's intellectual maturity will likely be deteriorated and one's competency to make informed consent choices will be diminished."[77]

If the majority of inmates have diminished intellectual maturity, as Phillips and White would have us believe, then human experimentation is invalid and unethical and should be stopped. In light of the arguments advanced that experimentation does indeed benefit society, science

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[77]Phillips and White, "The Dilemma of Justice," pp.10-11.

and even the individual inmate who freely chooses to participate in such research projects; there is more likely a need to closely monitor, rather than discontinue, such experimentation to make it more equitable, more ethical. Mills and Morris have suggested the following conditions to improve the state of research experimentation in the American prison:

> 1. Prisoners must be paid what would be required to attract a free volunteer to the same research project. So long as internal prison wages are low, the difference between the low prison wage and a free volunteer's reward must be paid into a fund for the general welfare of prisoners.
> 2. Any prison permitting research must establish, in addition to a scientific review group, a subject advisory group, a majority of whose members are prisoners.
> 3. Prisoners must be compensated for all lasting injury or loss of earnings suffered as a result of participation in a research project.
>
> With these minimum safeguards as a precondition to the ethical participation of this vulnerable group, we believe that medical research in prisons can be beneficial to society, to the prison system and to the prisoner himself.[78]

These safeguards proposed by Mills and Morris reflect many of the principles found in numerous guidelines and codes of ethics issued by government and private organizations. In fact, the enormous proliferation of new medical advances in research is matched by the abundant production of standards at all levels --international, national and state-- that regulate the conditions of research experimentation in the penal setting. The forerunner of contemporary research standards is the Nuremburg Code which represented the first major effort by law to deal with the problems of biomedical experimentation, particularly the issue of informed consent (see page 43 of this text). Since World

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[78]Mills and Morris, "Prisoners as Lab Animals," p. 66.

War II. and the Nuremburg Tribunal, no less than thirty-three different guidelines and codes of ethics have been created, all of which contain these five general principles:

> 1. A research subject must be a person who volunteered on the basis of having all the necessary information for his decision to be an informed one.
> 2. He should be allowed to withdraw from the research at whatever point he wishes.
> 3. All unnecessary risks should be eliminated in the design of the research through prior animal experimentation.
> 4. The benefits of the experiment, either to the subject or to society, should outweigh the risk to the subject.
> 5. An experiment should be conducted only by individuals qualified to do so.[79]

The Declaration of Helsinki formulated by the World Medical Association in 1964 embodied such principles in the recommendations it prepared to guide physicians all over the world in clinical research. This declaration made a distinction in clinical research between therapeutic (research beneficial to the subject) and non-therapeutic (research beneficial to scientific knowledge and generally the nature of prison experimentation). In both forms of research the physician was advised to exercise special caution "in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure."[80]

Regulation of biomedical research at the national level has come primarily from the Department of Health, Education and Welfare pursu-

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[79]Phillips and White, "The Dilemma of Justice,"p.7.

[80]Hershey and Miller, Human Experimentation, p.282.

ant to its powers under the Public Health Services Act and from the Food and Drug Administration which establishes standards for the safety and efficacy of drugs. "The Institutional Guide to DHEW Policy on the Protection of Human Subjects" first published in 1971 established safeguards for the welfare of human subjects in activities supported by grants or contracts from this federal agency and dealt in particular with the duties of the organizational review committee as outlined below.

> 46.404 Additional duties of the organizational review committee where prisoners are involved.
> (a)(1) Determine that there will be no undue inducements to participation by prisoners..,taking into account such factors as whether the earnings, living conditions, medical care, quality of food,and amenities..would be better that those generally available to the prisoners;
> (a)(2) Determine that all aspects of the activity would be appropriate for performance on nonprisoners, or activity involves negligible risk to the subjects...
> (a)(4) Determination that rates of remuneration are consistent with the anticipated duration of the activity, but not in excess of that paid for other employment generally available to inmates..[81]

As discussed earlier in the chapter on pharmaceutical and consumer product testing, Food and Drug Administration guidelines were formulated in 1962 as amendments to the Federal Food, and Cosmetic Act. Pursuant to this federal mandate, the FDA published a policy statement in 1967 regarding research experimentation, and in 1971 added the requirement of institutional review committees before clinical drug trials could begin in the prisons.

Later in 1974 efforts to establish a commission to protect human

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[81]Visscher, Ethical Constraints, p. 62.

subjects in research projects culminated in the creation of the National Research Act which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was given the responsibility of investigation, developing guidelines, and making recommendations in the area of human experimentation which considered the following:

> (i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.
> (ii) The role of assessment of risk-benefit criteria in the determination of the appropriatenss of research involving human subjects.
> (iii) Appropriate guidelines for the selection of human subjects for participation...
> (iv) The nature and definition of informed consent in various research settings.
> (v) Mechanisms for evaluating and monitoring the performance of Institutional Review Boards...[82]

As compared to these federal legal standards, those state laws and regulations that deal with research experimentation tend to focus on more specific matters rather than to create general procedures for institutional review. These state laws are reflected quite often in the research guidelines established by the corrections departments at the state and institutional levels. In 1976 twenty-one states had legislation which permitted biomedical research and twenty-three states permitted behavioral research. Eight states have banned biomedical research either by statute or moratorium while five states have prohibited behavioral research in the prisons. In almost all of the states that allow research experimentation in penal institutions the informed consent of the inmate subject must be obtained. Some states

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[82]Ibid., 110.

like California have detailed requirements regarding informed consent, e.g. a statute that bans the use of aversive behavioral therapy such as psychosurgery without the consent of the inmate.[83]

In these state legislative and regulatory guidelines, the issue of compensation is treated in a variety of ways. "In North Carolina.. the Department of Corrections should make no promise of pecuniary award, sentence commutation, or any other kind of reward, or else coercion is intimated to the inmate."[84] Other states like Connecticut set forth detailed fee schedules in its administrative directives (e.g. $15 for spinal puncture) as well as procedures for financial payment to inmates, i.e. fifty per cent of the money paid to the inmate subject must be paid to the prison welfare fund.[85]

There is no uniformity from state to state in the regulations for experimentation with human subjects. The majority of state laws were formulated to deal with specific matters in this area and generally, federal regulations issued by HEW and FDA provide a common framework for most research projects in the state prisons.

In addition to these state and federal guidelines, professional organizations have developed standards for research experimentation in the prison. Though not legally enforceable, these guidelines are in-

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[83]Annas, Glantz and Katz, Informed Consent, pp. 128-129.

[84]Ibid.

[85]Taken from the Administrative Directives of the Department of Correction of Connecticut.

fluential when combined with public pressure and accreditation measures. Certainly cases of prisoner abuse did much to promote the development of these standards, for during the 1960's and 1970's careless research projects received widespread publicity and extensive official scrutiny. Their disclosure contributed to the support for closer monitoring of research by such groups as the American Medical Association (AMA), the American Correctional Association (ACA) and the American Bar Association (ABA).

In 1966 the AMA endorsed the ethical principles outlined in the Declaration of Helsinki. Earlier in 1953 this professional group adopted a resolution to "express its disapproval of the participation in scientific experiments of persons convicted of murder, rape, arson..or other heinous crimes", not out of any altruistic motivation, but because they believed that persons convicted of such vicious crimes did not deserve commendatory treatment for their participation in research programs (e.g. early release).[86]

In 1972 the American Correctional Association entered the ethics arena with its "Protocol for Medical Experimentation and Pharmaceutical Testing" in which the term "informed consent" was expanded to mean a full verbal and written explanation of the research to the subject. Moreover, each volunteer was to be screened for both physical and emotional preparedness before participation in the research project. Subsequent standards updating by the ACA Commission on Accreditation in 1976 pro-

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[86]Hershey and Miller, Human Experimentation, p. 158.

hibited inmates from participating in medical or pharmaceutical testing. In comparison, the Department of Justice and the American Bar Association drafts of correctional standards also prohibit inmates' participation in medical or pharmaceutical experimentation, except for therapeutic programs designed to benefit inmates and specified in the guidelines.[87]

By and large, however, such guidelines appear to be unnecessary in the majority of state and federal correctional systems, because research experimentation has largely been halted in American prisons due to public pressure, salient court decisions involving prisoners' rights, and the enactment of more stringent legislation in this area. In fact, results from the survey of correctional systems conducted in the preparation of this paper indicate that the vast majority (84%) of the thirty-six departments responding to questions regarding research guidelines had no form of research standards for human experimentation. This fact is largely attributable to the lack of research experimentation, both past and present, in these penal systems. Those correctional departments employing standards in past and present research programs indicated that the Department of Health, Education and Welfare guidelines were used most often with standards from FDA, ACA, ABA and the American Psychological Association (APA) also in use in some departments. Generally speaking, those states which report continued research experimentation in their penal institutions have national standards or in-

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[87]Richard S. Allinson, "The Politics of Prison Standards" Corrections Magazine V(March 1979): 56.

house directives to follow in these matters. Also, with a call by major correctional groups to end such research, it is doubtful that those states which have not been actively involved in research programs will, in the future, begin experimentation in the prison.

CHAPTER VII.

Conclusion

The final results of this study[88] regarding research experimentation in the areas of disease studies, pharmaceutical and consumer product testing, and behavioral research have pointed to certain conclusions. The most important revelation stemming from these efforts to update information on penal research is that in almost all American correctional systems such experimentation has ceased, even though it may still be permitted by state statute or federal regulations. In most instances all research projects occurring in state and federal prisons were discontinued in the 1970's, largely as a reaction to unfavorable publicity and increased official scrutiny of research practices. Actions and reactions in the press, the courts, and the legislatures were generated by cases of faulty research in which inmate subjects were exposed to physical and psychological harm. The popular reaction to these research abuses was similar to that when the general public learned of the use of prisoners of war in human experimentation in the Nazi concentration camps during the second World War. The outrage that led to the Nuremburg Tribunal's formulation of guidelines

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[88] For a summary of the final results received from state and federal corrections departments, see Table 5 on page 66 of this text.

Note: Results from the California Department of Corrections were received after the completion of the final draft of this study. These results indicate that pharmaceutical and consumer product testing --the testing of antibiotics and antihistamines and consumer products such as perfumes and cosmetics-- is still occurring in this state's prisons. Moreover, behavioral research that involved the administration of lithium carbonate was last conducted in 1971.

for biomedical research was reborn in the 1970's at which time more stringent state and federal mandates (e.g. The National Research Act of 1974) as well as standards and codes of ethics from the medical, legal and correctional professions were created to monitor research programs in American penal institutions.

In the majority of correctional systems the response to this increased scrutiny was to halt experimentation in the prisons to avoid further criticism. Even the most prevalent and the most profitable forms of research programs, the clinical drug trials, were discontinued in most states. Only in those states --Michigan and Montana-- where pharmaceutical companies had invested large sums of money to construct special research centers was drug testing allowed to continue. In most instances, pharmaceutical manufacturers were forced to turn to other sources of human subjects for clinical drug trials (e.g. paid volunteers who work at facilities owned by the pharmaceutical companies) when the major source of volunteers, prison inmates, dried up.

Behavioral research in the prison represents a case of extremes: the extreme nature of this research exemplified in psychosurgery combined with the extreme deficiency of empirical information to assess the quality of such projects. Before adequate evaluations of behavioral programs could be performed, many correctional systems influenced by adverse publicity halted this form of research to avoid court challenges and ethical debates. As a result, it has been difficult to examine the true nature of such research in the modern prison and its value as a therapeutic tool, rather than as a vehicle for psychological experimentation.

The question still remains if research experimentation in the prison is indeed ethical. This moral debate centers around the issue of informed consent; i.e. whether the inmate subject can ever truly give informed consent in light of the nature of his confinement. Inducements to participate in research programs that are regarded merely as coercion must be weighed against the benefits of human experimentation reaped by society, by science, and the inmate. Certainly the introduction of guidelines and codes of ethics have done much to relieve the research abuses that occurred at one time in American prisons and have succeeded in halting many research programs, a result which pleased many opponents of human experimentation in the correctional setting. The positive value of reform measures in this area, whether enacted by statute or in professional guidelines, demonstrates the success of official standardization in relieving the abuses of institutional life. Moreover, the importance of the popular press in calling attention to needed reform must be underscored, for it was in this case that the efforts of such writers like Mitford were instrumental in initiating public concern and official reform. Certainly, the combined efforts of an informed public, the legislatures and special interest groups (e.g. AMA) can do much to improve the quality of life in the American prison, as witnessed in the case of research experimentation with inmate subjects. In turn, these efforts can be directed to other needed penal reforms to improve the condition of institutional life for thousands of prisoners incarcerated in the United States today.

TABLE 5

COMPOSITE SUMMARY OF RESULTS RECEIVED IN SURVEY OF CORRECTIONAL DEPARTMENTS

Y= Done in Past N= Never Done C= Currently Done N/A= Not Applicable

	Disease Studies	Consumer Testing	Drug Testing	Behavioral Research		Disease Studies	Consumer Testing	Drug Testing	Behavioral Research
Federal	Y	N	Y	N	Nebraska	N	N	Y	N
Alabama	Y	N	Y	N	Nevada	N	N	N	N
Alaska	Y	N	N	N	New Hamp.	N	N	N	N
Arizona	N	N	N	N	New Jersey	Y	Y	N	Y
Arkansas	N	N	N	N	New Mexico	N	N	N	N
Colorado	N	N	N	N	N. Carolina	Y	N	N	N
Conn.	N	C	Y	Y	N. Dakota	N	N	N	N
Delaware	N	N	N	N	Ohio	Y	N	Y	Y
Florida	N	N	N	N	Oklahoma	N/A	N/A	N/A	N/A
Georgia	N	N	N	N	Oregon	N	N	N	N
Hawaii	N	N/A	N/A	N/A	Penn.	Y	Y	Y	N
Idaho	N	N	N	N	Rhode Is.	N	N	N	N
Illinois	N	N	N	N	S. Carolina	N	N	N	N
Indiana	N	N	Y	N	S. Dakota	N/A	N	N	N
Iowa	Y	N	N	N	Tennessee	N	N	N	N
Kansas	N	N	N	N	Texas	Y	N	N	N
Kentucky	N	N	N	N	Utah	N	N	N	Y
Maryland	N	N	N	N	Vermont	N	N	N	N
Mass.	Y	Y	Y	N	Virginia	Y	Y	Y	N
Michigan	N	N/A	C	N	Washington	N	N	N	N
Minnesota	N	Y	N	N	W. Virginia	N	N	N	N
Miss.	Y	N	N	N	Wisconsin	Y	N	N	N
Missouri	N	N	N	C	Wyoming	N	N	N	N
Montana	N	N	C	N	Wash.,D.C.	Y	N	N	N

APPENDIX A

Survey Form for Correctional Departments

SURVEY FORM FOR CORRECTIONAL DEPARTMENTS

Youngstown State University Criminal Justice Department:
SURVEY OF RESEARCH EXPERIMENTATION PRACTICES IN STATE CORRECTIONAL FACILITIES

Name of Correctional System _____

Director of Corrections _____ Number of penal institutions in system _____

General Instructions: The following questions are designed to evaluate the extent of research experimentation occurring in the American prison today. Please answer the questions as completely as possible; in most cases you need check only a "yes" or "no" answer. When the question is answered affirmatively, please provide further information about the type of program, the degree of prisoner participation, the name of the institution(s), and the name of the research firm (e.g. pharmaceutical company) that is conducting the research. If printed materials or outlines of the program are available, please include with this form.

I. Disease studies - (e.g. vitamin deficiency studies, anemia research, cancer research) In these studies a disease and possible cures are being examined.

1. Are disease studies now being conducted in your state's prisons?
( ) yes ( ) no

If YES, briefly describe the type of disease study being conducted.

If NO, when was the last time such studies were conducted, if ever, in your state's correctional facilities? Briefly describe such studies.

II. Drug testing

1. Are any drugs currently being tested in your state's correctional institutions by pharmaceutical companies before release for public comsumption?
( ) Yes ( ) No

If YES, are these drugs being tested as part of Phase I. testing required by the Food and Drug Administration?
( ) Yes ( ) No
Briefly describe such testing in the prisons, listing drug manufacturers if possible.

If NO, when was the last time such testing occurred, if ever, in your state's prison system?

2. Are consumer products such as over-the-counter medications and toiletry items (e.g. deodorants) currently being tested in your state's correctional facilities?
( ) Yes ( ) No

If YES, are these tests in accordance with Phase I. testing of the Food and Drug Administration guidelines for product marketing?
( ) Yes ( ) No

Briefly describe the products being tested.

If NO, when, if ever, were such consumer products tested in your state's prisons?

APPENDIX B

Survey Form for Pharmaceutical Manufacturers

SURVEY FORM FOR PHARMACEUTICAL MANUFACTURERS

ungstown State University Criminal Justice Department:
RVEY OF PHARMACEUTICAL TESTING PRACTICES WITH HUMAN SUBJECTS

ne of Pharmaceutical Company _____

rector of Research _____

neral Instructions: The following questions are designed to evaluate the use of prisoner
bjects in pharmaceutical testing. Please answer the questions as completely as possible
most cases you need check only a "yes" or "no" answer. When possible, please provide
ief explanations of the programs, the types of drugs being tested, and the type of human
bject being used. If printed materials or outlines are available, please include with
is form.

Are prisoners in state and federal institutions currently being used in the testing of pharmaceutical products in compliance with testing regulations of the FDA?
( ) yes ( ) no

If YES, please explain briefly the extent of testing and give the names of the institut in which these drugs are being tested.

If NO, when were prisoners last used by your company for pharmaceutical testing?

Are inmates of other facilities --both correctional and mental health-- currently being used in pharmaceutical testing?
( ) yes ( ) no
If YES, what is the major site for this pharmaceutical testing?

( ) City jails
( ) County or regional jails
( ) Community-based corrections (e.g. halfway houses)
( ) Mental health facilities (e.g. hospital for the mentally ill)
( ) Other _____ (please specify)

What now is your major source of human subjects for drug testing?

( ) Prisoners in state and federal institutions
( ) Inmates in local or regional correctional facilities (e.g. jails)
( ) Residents of mental health facilities
( ) Paid volunteers in facilities owned by the pharmaceutical company
( ) Paid volunteers in public clinics
( ) Paid volunteers in private clinics
( ) Other _____(please specify)

Completed by _____

Title _____

Phone _____

APPENDIX C

Sample List of Pharmaceutical Manufacturers

SAMPLE LIST OF PHARMACEUTICAL MANUFACTURERS

Pharmaceutical Companies Surveyed Concerning Testing Practices With Human Subjects

Abbott Laboratories
North Chicago, Illinois 60064

Bristol Laboratories
Division of Bristol-Myers Co.
Syracuse, New York 13201

Bristol-Myers Products
New York, New York 10022

Cutter Laboratories
Berkeley, California 94710

The Dow Chemical Company
Indianapolis, Indiana 46268

Eli Lilly and Company
Indianapolis, Indiana 46206

GEIGY Pharmaceuticals
Division of CIBA-GEIGY Corporation
Ardsley, New York 10502

Lederle Laboratories
Pearl River, New York 10965

McKesson Laboratories
Division Foremost-McKesson Inc.
Fairfield, Connecticut 06430

Merck Sharp and Dohme
Division of Merck and Company, Inc.
West Point, Pennsylvania 19486

Parke, Davis and Company
Detroit, Michigan 48232

Pennwalt Pharmaceutical Division
Rochester, New York 14603

Pfizer, Inc.
New York, New York 10017

A.H. Robins Company
Richmond, Virginia 23220

Roche Laboratories
Division of Hoffmann-LaRoche Inc.
Nutley, New Jersey 07110

McNeil Laboratories, Inc.
Fort Washington, Pennsylvania 19034

Schering Corporation
Kenilworth, New Jersey 07033

Smith Kline and French Laboratories
Division of Smith Kline Corporation
Philadelphia, Pennsylvania 19101

Squibb Professional Services Dept.
Princeton, New Jersey 08540

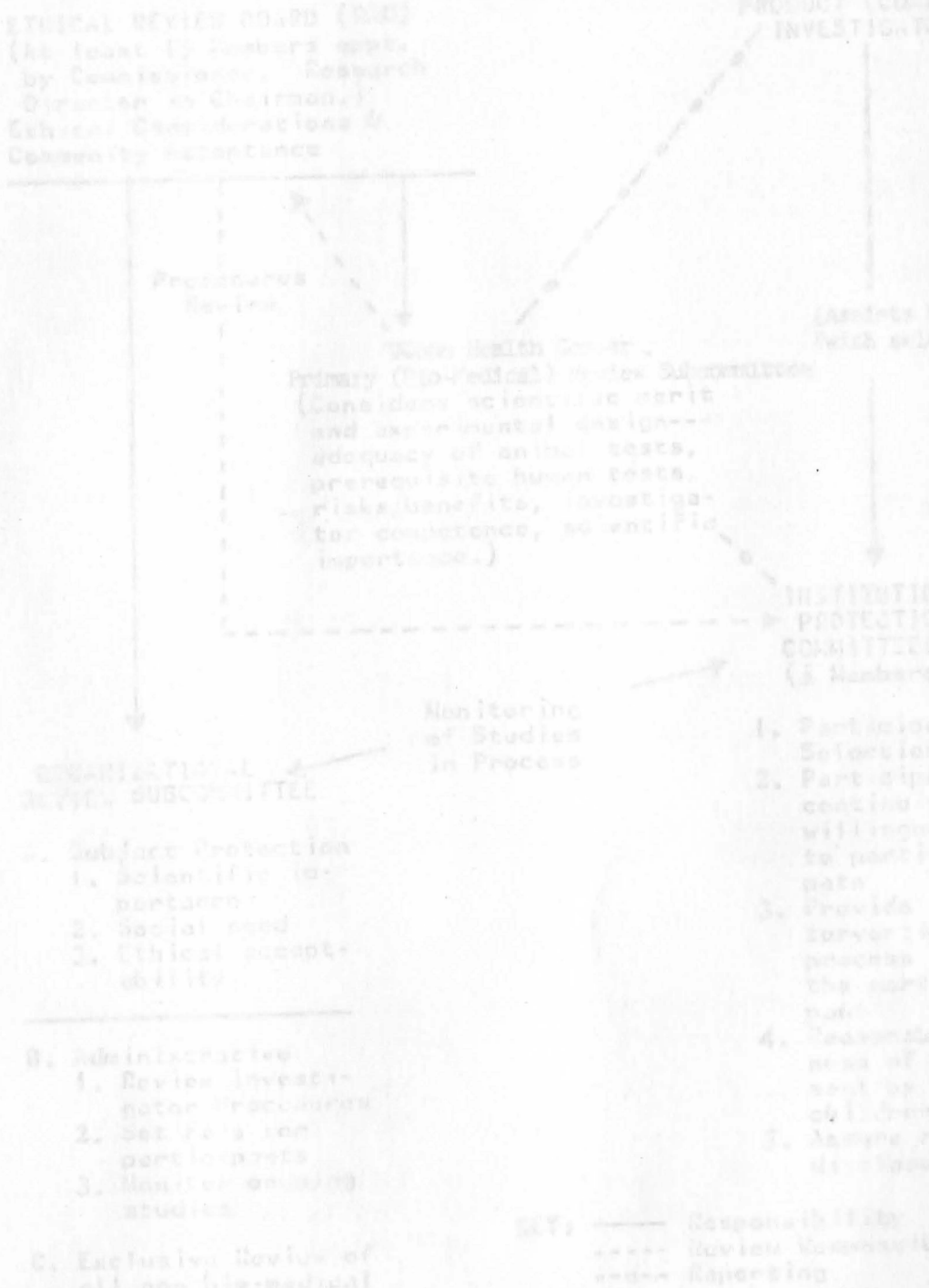
The Upjohn Company
Kalamazoo, Michigan 49001

Winthrop Laboratories
New York, New York 10016

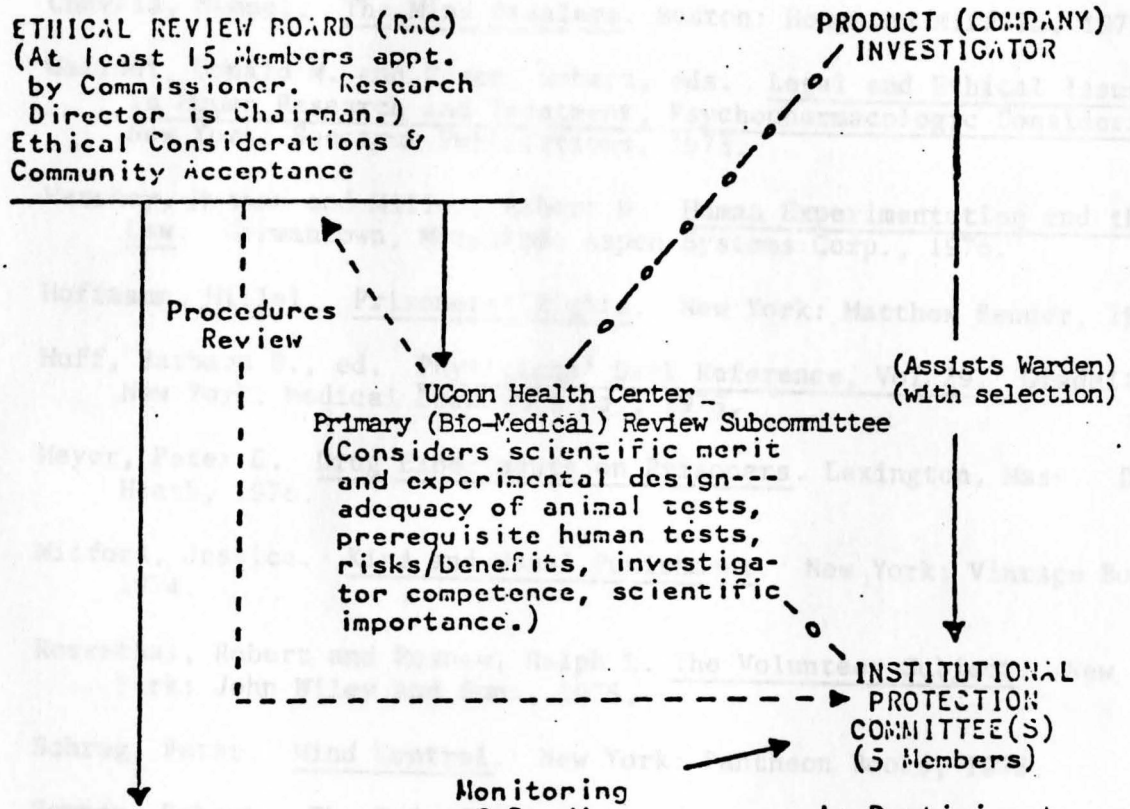
Wyeth Laboratories
Philadelphia, Pennsylvania 19101

APPENDIX D

Sample Institutional Review Committee Outline



ADMINISTRATIVE DIRECTIVES STATE OF CONNECTICUT DEPARTMENT OF CORRECTION	DATE 5/20/74	PAGE NUMBER OF 2 18	CHAPTER NO. 6.8
	SUBJECT RESEARCH ADVISORY COMMITTEE (General)		G-2



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