

BENEFICIAL AND UNUSUAL PUNISHMENT: AN ARGUMENT IN SUPPORT OF PRISONER PARTICIPATION IN CLINICAL TRIALS

SHARONA HOFFMAN*

INTRODUCTION

Until the last few decades of the Twentieth Century, prisoners were widely used in biomedical experimentation in the United States.¹ Prisoners served as test subjects for substances ranging from perfume, soap, and cosmetics, to dioxin, psychological warfare agents, and radioactive isotopes.² By 1969, eighty-five percent of new drugs were tested on incarcerated persons in forty-two prisons,³ and prisoners in the United States were even utilized to test drugs for researchers in other countries.⁴ In the following decade investigations revealed that prisoners who were the subjects of clinical research often suffered serious adverse consequences and severe abuses.

Allen Hornblum, who, in his book *Acres of Skin*, wrote a moving expose of medical research that was conducted in one prison, stated in an early chapter:

For two decades—from the early 1950s to the early 1970s—Philadelphia's Holmesburg Prison played host to one of the largest and most varied medical experimentation centers in the country. Only the inmates, and the doctors who experimented on them, know just exactly what took place, but whereas the latter choose not to discuss their earlier medical exploits, the prisoners are not asked. In that respect, Holmesburg is little different from the dozens of other institutions that contained vulnerable populations and [sic] were exploited in the name of scientific advancement. This sad but wide-spread twentieth-century phenomenon has much to teach us about our ethical standards and our capacity for human compassion.⁵

In light of the discovery of severe research abuses, several entities, including the Federal Bureau of Prisons, the American Correctional Association, and the

* Assistant Professor of Law, Case Western Reserve University School of Law. B.A., 1985, Wellesley College; J.D., 1988, Harvard Law School; LL.M. in Health Law, 1999, University of Houston. This Article was made possible in part by a grant from the AAUW Educational Foundation. The author wishes to thank Mary Anne Bobinski and T. Howard Stone for their helpful comments on earlier drafts of this Article.

1. See 4 ENCYCLOPEDIA OF BIOETHICS 2056 (Warren T. Reich ed., rev. ed. 1995).

2. See NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING PRISONERS, 42 Fed. Reg. 3076, 3076-3091 (1976) [hereinafter REPORT].

3. See Kathleen Schroeder, *A Recommendation to the FDA Concerning Drug Research on Prisoners*, 56 S. CAL. L. REV. 969, 971 (1983).

4. See ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, at 2057.

5. ALLEN M. HORNBLUM, *ACRES OF SKIN: HUMAN EXPERIMENTS AT HOLMESBURG PRISON* 71 (1998).

U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, called for a moratorium on prisoner experimentation.⁶ These institutions further advocated the development of standards to regulate medical experimentation in the prison setting and to safeguard the welfare of prisoners who were included in clinical trials.⁷

Subsequently, regulations regarding the use of biomedical experimentation on prisoners were issued by the federal government. Department of Health and Human Services ("DHHS") regulations⁸ limit inmate participation in clinical investigations to the following: (1) studies of the possible causes, effects, and processes of imprisonment and criminal behavior so long as the research involves only minimal risk and inconvenience to the subject; (2) studies of prisons as institutional entities or of inmates as incarcerated individuals, so long as the research involves only minimal risk and inconvenience to the subject; (3) research on particular conditions affecting prisoners as a class so long as the research is approved by the Secretary of Health and Human Services or an authorized DHHS employee ("Secretary"); and (4) research involving a treatment likely to benefit the prisoner himself or herself.⁹ In addition, the institutional review board assessing the clinical trial must include at least one prisoner or prisoner representative¹⁰ and must certify that a variety of conditions have been met and that a number of precautions have been taken.¹¹ As a result of these and other stringent requirements, only about fifteen percent of institutions engaging in clinical research in the United States include prisoners in their research protocols.¹²

Abuse of prisoner subjects in biomedical research or failure to obtain meaningful informed consent from inmates can lead to violations of their constitutional rights. The constitutional provisions that may be implicated in controversies regarding biomedical experimentation on prisoners include the Fourth Amendment, Eighth Amendment, and Fourteenth Amendment. Nevertheless, prohibiting seriously ill prisoners from participating voluntarily in clinical research may constitute an equivalent contravention of their constitutional rights under the Eighth Amendment and the Due Process and Equal

6. See ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, at 2056.

7. See *id.*; REPORT, *supra* note 2.

8. Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, 45 C.F.R. § 46.301 (1998).

9. See 45 C.F.R. § 46.306(a)(2). If a prisoner might be assigned to a placebo control arm, the study can proceed only with approval by the Secretary. See *id.* § 46.306(a)(2)(iv).

10. See *id.* § 46.304(b).

11. See *id.* § 46.305(c).

12. Interview with Paula Knudson, Executive Coordinator of the University of Texas Health Science Center Committee for the Protection of Human Subjects (Sept. 18, 1998). See also Reid J. Schar, *Downward Sentencing Departures for HIV-Infected Defendants: An Analysis of Current Law and a Framework for the Future*, 91 NW. U. L. REV. 1147, 1185 n.235 (1997) ("Only 18% of state and federal prisons offer experimental drugs and only 12% allow inmates access to clinical trials of drugs.").

Protection clauses. Because many clinical trials involve potential cures for diseases that frequently affect prison populations, such as hepatitis,¹³ HIV infection, and tuberculosis,¹⁴ regulations that are excessively stringent may deprive prisoners of life-saving therapy.¹⁵ Currently, 1.8 million people are in jail in the United States at any given time.¹⁶ Therefore, policies that bar prisoner participation in biomedical research adversely affect a very large number of Americans.

This Article will analyze the constitutional issues implicated in biomedical research involving prisoners. It will argue that, in light of contemporary regulatory safeguards, the constitutional rights of prisoners enrolled in clinical studies will not be jeopardized. Moreover, the Article will encourage the inclusion of prisoner subjects in biomedical research involving potentially beneficial experimental treatment for life-threatening diseases and will assert that regulations banning the inclusion of prisoners in clinical studies are constitutionally suspect. This Article begins with an overview of clinical trials and informed consent. Next, a brief history of the abuses suffered by prisoners in clinical trials will be presented. The Article will then discuss the Nuremberg Code and the federal regulations applicable to research involving inmates. The constitutional issues relating to prisoners' participation in or exclusion from clinical trials will be analyzed at length. Finally, the author will address the practical and ethical difficulties of conducting biomedical experimentation in which prisoners participate and will provide specific recommendations regarding these impediments.

I. CLINICAL TRIALS AND INFORMED CONSENT

Clinical trials for drugs and devices are regulated by the Food and Drug Administration (FDA).¹⁷ Clinical trials for procedures such as surgeries or bone marrow transplants are not regulated by the FDA but often must comply with DHHS regulations.¹⁸ Drugs studied in clinical trials are called Investigational New Drugs ("INDs").¹⁹ Sponsors wishing to conduct a clinical trial to test a new

13. See 45 C.F.R. § 46.306(a)(2)(iii).

14. See Schar, *supra* note 12, at 1156.

15. See *id.* at 1184-85.

16. See Walter Shapiro, *1.8M Reasons for Criminal-Justice Reform*, USA TODAY, Mar. 17, 1999, at 2A.

17. See 21 C.F.R. § 7.3(f) (1999) ("Product means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use . . .").

18. See 45 C.F.R. § 46.101 (applicable to any research that is conducted, funded, or regulated by any federal department or agency); Richard S. Saver, Note, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1110-11, 1122 (1992).

19. See 21 C.F.R. § 312.23(a).

drug must submit an IND application to the FDA.²⁰ In some circumstances, a drug still under investigation may be used to treat patients not participating in a clinical trial.²¹ Specifically, an IND may be used in treatment of patients if the drug is intended to treat a serious or immediately life-threatening disease,²² and there is no comparable or satisfactory alternative drug or therapy.²³ The drug can be utilized in treatment if it is currently under investigation in a clinical trial, or if clinical trials have been completed and the sponsor is actively pursuing marketing approval with due diligence.²⁴

Medical research for drugs and other treatments is conducted in three or four phases of clinical trials.²⁵ In Phase I, the new drug is given to patients or healthy individuals to determine its toxicity, most effective method of administration, and safe dosage range.²⁶ Participants in the trial receive increasing dosages of the substance in order to determine its metabolism, absorption, and side effects and to gain early evidence of its effectiveness, if possible.²⁷ Phase I clinical trials generally involve only twenty to eighty subjects, last about a year, and have a very high failure rate.²⁸ Seventy percent of drugs submitted for Phase I clinical trials fail to progress to Phase II.²⁹

Phase II trials are designed to determine the effectiveness of the therapy.³⁰ The treatment is administered to patients afflicted with the disease for which the therapy is intended, and the trial often involves 100 to 300 people and lasts about two years.³¹ Approximately thirty-three percent of drugs submitted for clinical trials fail in Phase II testing.³²

Phase III clinical trials are conducted only after the treatment has proven effective through Phase I and II trials.³³ The third phase attempts to assess the medical results of the experimental therapy in comparison with standard therapy or no therapy at all.³⁴ Phase III studies usually involve 1000 to 3000 patients and last about three years.³⁵

20. *See id.*

21. *See id.* § 312.34(a).

22. *See id.* § 312.34(b)(I).

23. *See id.* § 31.234(b)(ii).

24. *See id.* § 312.34(b)(iv).

25. *See id.* § 312.21(a)-(c); *see also* Veronica Henry, *Problems with Pharmaceutical Regulation in the United States*, 14 J. LEGAL MED. 617, 621 (1993).

26. *See* 21 C.F.R. § 312.21(a) (1999); *see also* Henry, *supra* note 25, at 621.

27. *See* 21 C.F.R. § 312.21(a); Henry, *supra* note 25, at 621.

28. *See* 21 C.F.R. § 312.21(a); Henry, *supra* note 25, at 621.

29. *See* Henry, *supra* note 25, at 621.

30. *See* 21 C.F.R. § 312.21(b).

31. *See* Henry, *supra* note 25, at 621.

32. *See id.*

33. *See id.*; *see also* 21 C.F.R. § 312.21.

34. *See* Henry, *supra* note 25, at 621; 21 C.F.R. § 312.21 (1999).

35. *See* Henry, *supra* note 25, at 621.

The FDA may also require postmarketing or Phase IV clinical trials.³⁶ These studies are designed to determine the existence of less common adverse reactions, the effect of the drug on morbidity or mortality, and the effect of the drug on a particular patient population, such as children.³⁷

Research that is conducted, supported, or regulated by any federal department or agency must be reviewed by an Institutional Review Board ("IRB").³⁸ An IRB is a committee designated by an institution to review, approve, and periodically monitor biomedical research studies.³⁹ The IRB receives a document known as the "protocol" regarding each clinical trial, which describes eligibility requirements for participants, the number of subjects to be tested, and the objective of the research.⁴⁰ Each participant must sign an "informed consent" document through which he or she is fully informed of the details of the clinical trial.⁴¹

Both IRBs and the contents of informed consent forms are extensively regulated by the Department of Health and Human Services. Each IRB must have at least five members with varying backgrounds and diversity in terms of race, gender, and culture.⁴² Each IRB must include at least one member whose principal concerns are in the scientific realm and one individual whose primary concerns are nonscientific (e.g. a lawyer or minister).⁴³ Furthermore, each IRB must include at least one member who is not otherwise affiliated with the entity and who has no immediate family member affiliated with the institution.⁴⁴

Unless an expedited review is necessary, research protocols must be reviewed at meetings at which a majority of the members of the IRB are present, including at least one member whose professional expertise is nonscientific.⁴⁵ A majority of the members present must vote for the approval of the research before the medical investigator is permitted to proceed.⁴⁶

An IRB has authority to approve or disapprove the research activities it reviews or to require that they be modified.⁴⁷ The IRB must provide written notification of its decisions to those who proposed the research and must conduct continuing reviews of research it approved at least yearly, or more often if the risks entailed necessitate a more frequent assessment.⁴⁸

In order to approve proposed research, an IRB must ensure that specific

36. See 21 C.F.R. § 312.85.

37. See *id.*; see also Henry, *supra* note 25, at 622.

38. See 45 C.F.R. §§ 46.101(a); 46.103 (1998).

39. See 21 C.F.R. § 56.102(g); 45 C.F.R. § 46.102(g) (1998).

40. See 21 C.F.R. § 56.115; 45 C.F.R. § 46.115.

41. See 21 C.F.R. § 50.20; 45 C.F.R. § 46.116.

42. See 21 C.F.R. § 56.107(a); 45 C.F.R. § 46.107(a).

43. See 21 C.F.R. § 56.107(c); 45 C.F.R. § 46.107(c).

44. See 21 C.F.R. § 56.107(d); 45 C.F.R. §§ 46.107(d).

45. See 21 C.F.R. § 56.108(c); 45 C.F.R. § 46.108(b).

46. See 21 C.F.R. § 56.108(c); 45 C.F.R. § 46.108(b).

47. See 21 C.F.R. § 56.109(a); 45 C.F.R. § 46.109(a).

48. See 21 C.F.R. § 56.109(e), (f); 45 C.F.R. § 46.109(d), (e).

criteria are met. These include: (1) risks to participants are minimized; (2) risks to subjects are reasonable in light of anticipated benefits; and (3) selection of participants is equitable, and the protocol is sensitive to the particularized problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled individuals, or economically or educationally deprived persons.⁴⁹

The information provided to participants on the informed consent document must be written in language that is comprehensible to the subject.⁵⁰ Informed consent may not include language that waives or appears to waive any of the subject's rights or releases the institution or personnel involved in the research from liability for negligence.⁵¹ The regulations further require that informed consent be obtained in writing from each participant, though certain exceptions are allowed.⁵²

The regulations detail the data that must be featured on the informed consent documentation. This information includes a description of the research, an explanation of its risks, benefits, and alternatives, a discussion of confidentiality, a list of contact people, and a statement that participation is voluntary and may be discontinued at any time.⁵³

49. See 21 C.F.R. § 56.111(a); 45 C.F.R. § 46.111(a).

50. See 21 C.F.R. § 50.20; 45 C.F.R. § 46.116.

51. See 21 C.F.R. § 50.20; 45 C.F.R. § 46.116.

52. See 21 C.F.R. § 50.27; 45 C.F.R. § 46.117.

53. See 21 C.F.R. § 50.25(a), (b); 45 C.F.R. § 46.116(a), (b). The provision reads in part as follows:

(a) Basic elements of informed consent. . . in seeking informed consent the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether

While extensive federal regulations protect contemporary research subjects in the United States, regulatory safeguards are a relatively recent phenomenon.⁵⁴ Absent governmentally-mandated constraints, medical researchers often abused and even tortured those involved in clinical trials, particularly when the participants were prisoners. The history of medical experimentation on prisoners both in this country and abroad is grim and sobering.

any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - (3) Any additional costs to the subject that may result from participation in the research;
 - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
 - (6) The approximate number of subjects involved in the study.

45 C.F.R. § 46.116(a)-(b) (1998).

54. The relevant federal regulations were promulgated only in the 1970s, as discussed in Part III below.

II. THE ABUSE OF PRISONERS IN CLINICAL TRIALS

Throughout history many different cultures used prisoners for biomedical experimentation. In ancient Persia physicians were permitted to utilize incarcerated individuals as research subjects.⁵⁵ The Roman empire subjected prisoners to the testing of poisons.⁵⁶ Eighteenth century European physicians exposed prisoners to venereal disease, cancers, typhoid, and scarlet fever in order to conduct medical research.⁵⁷

In the United States the earliest known experimentation involving prisoners dates back to 1914, when white male convicts in Mississippi were used in pellagra studies.⁵⁸ Pellagra is a disease that causes dermatitis, diarrhea, dementia, and, at times, death.⁵⁹ The purpose of the experiment was to induce pellagra in twelve volunteers and to study the effects of diet on the disease.⁶⁰ All twelve received pardons and survived, but they were not permitted to leave the clinical trial, even after suffering severe symptoms and begging to be released from it.⁶¹

In California, between 1919 and 1922, hundreds of prisoners took part in a testicular transplant experiment, designed to test whether lost male potency could be reinvigorated.⁶² During World War II great enthusiasm developed for prisoner experimentation, and prisoners signed up for research trials in large numbers in order to show their patriotism.⁶³ In New York scores of inmates volunteered for daily doses of various drugs to assist the Army in determining whether soldiers could carry full workloads under the drugs' influence.⁶⁴ New Jersey supplied the Army with willing participants for research regarding sleeping sickness, sand-fly fever, and dengue fever.⁶⁵ In the Stateville Penitentiary in Illinois, more than 400 prisoners were included in a two-year-long study aimed at finding a cure for malaria, and at the U.S. Penitentiary in Atlanta 600 inmates participated in other malaria research.⁶⁶ As these experiments were developed, researchers began utilizing informed consent forms to provide test subjects with information regarding the trials so that investigators could claim that participants understood the studies in which they enrolled and so that authorities could be absolved from legal repercussions.⁶⁷ A considerable portion of participants in the malaria

55. See ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, at 2056.

56. See *id.*

57. See *id.*

58. See *id.*

59. See HORNBLUM, *supra* note 5, at 77.

60. See *id.* at 78.

61. See *id.* at 78-79.

62. See *id.* at 79.

63. See ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, at 2056.

64. See HORNBLUM, *supra* note 5, at 81.

65. See *id.*

66. See *id.* at 81, 83.

67. See *id.* at 82.

studies received pardons as a reward for their bravery.⁶⁸

The most notorious large-scale medical experimentation in human history was conducted by the Nazis during World War II. The elite of the German medical community subjected innocent victims in concentration camps to "a broad range of 'ghastly' and 'hideous'" experimentation.⁶⁹ In Buchenwald and Natzweiler, numerous healthy inmates were involuntarily infected with yellow fever, smallpox, typhus, cholera, and diphtheria germs that caused hundreds of them to die.⁷⁰ In other camps Nazi doctors conducted experiments relating to high altitude, malaria, freezing, mustard gas, bone transplantation, sea water, sterilization, and incendiary bombs.⁷¹

The full extent and inhumanity of the medical experimentation conducted by Nazi doctors in concentration camps became public knowledge during the Nuremberg Trials after World War II.⁷² The Nuremberg Trials were opened on November 20, 1945 at the Palace of Justice in Nuremberg, Germany.⁷³ Twenty three Nazi physicians were found guilty of "war crimes and crimes against humanity," and seven of them were sentenced to death.⁷⁴ At the trials the defense argued that the Nazis' research was no worse than "the wartime experiments in the United States such as those carried out at the Joilet, Illinois, prison in which treatments for malaria were sought by physicians who had to first infect the *volunteer* prisoners with the disease."⁷⁵ These arguments failed, however, because the prosecution focused on the fact that in the concentration camps inmates had no choice regarding the torments to which they were subjected, and in the United States prisoners volunteered to participate in clinical trials.⁷⁶

Japanese researchers also conducted barbarous experiments on prisoners in Manchuria during World War II.⁷⁷ The Japanese investigators, however, were never tried, and their crimes remained hidden from public scrutiny for over thirty-five years.⁷⁸ In exchange for silence, the Japanese agreed to share with the American government the data they had gathered regarding biological warfare through experimentation with Chinese captives.⁷⁹

As a result of the Nuremberg Trials, the Nuremberg Code was

68. *See id.*

69. *Id.* at 75.

70. *See id.*

71. *See id.* at 75, 77.

72. *See* Colleen M. McCarthy, Note, *Experimentation on Prisoners: The Inadequacy of Voluntary Consent*, 15 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 55, 57 (1989).

73. *See* Bernard D. Meltzer, "War Crimes:" *The Nuremberg Trial and the Tribunal for the Former Yugoslavia*, 30 VAL. L. REV. 895, 896 (1996).

74. *See* McCarthy, *supra* note 72, at 57 n.10.

75. *Id.* (citing A.M. Capron, *Human Experimentation*, in 1 BIOLAW § 10, at 229 (1986)).

76. *See id.*

77. *See id.*

78. *See id.*

79. *See id.*

promulgated.⁸⁰ The Code is included in the Nuremberg Military Tribunal's decision in the case of *United States v. Karl Brandt*.⁸¹ The Code features ten points that delineate the circumstances under which medical experimentation on human subjects is permissible.⁸² During the latter part

80. *See id.* at 57.

81. *See* 5 ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, app. at 2763.

82. Nuremberg Code (1947). The full text of the Nuremberg Code is as follows:

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

of the Twentieth Century, prisoners have rarely, if ever, been involved in clinical trials outside of the United States.⁸³

In the United States, however, medical research involving prisoners continued for several decades after World War II. In 1953 testing on federal prisoners included research regarding hepatitis, heart disease, intestinal protozoan parasites, athlete's foot, and the common cold.⁸⁴ In the early 1950s nearly 100% of participants in Phase I clinical trials across the United States were prisoners, according to the former chief of clinical investigations for the FDA, Dr. Alan B. Lisook.⁸⁵

The Ohio prison system was involved in some of the most dangerous and controversial experiments of the mid-1950s.⁸⁶ The research was conducted in conjunction with the Sloan Kettering Institute for Cancer Research and Ohio State University's medical research department.⁸⁷ Inmates volunteered to be injected with live cancer cells in both forearms.⁸⁸ Two weeks after the injection, the affected area of one forearm would be surgically removed for study, while the malignant cells remained in the other forearm for an indefinite period of time.⁸⁹

Medical experimentation in the 1950s was not limited to physical ailments. At the Ionia State Hospital in Michigan, at least 142 inmates participated in secret mind-control experiments for the CIA.⁹⁰ The CIA gave numerous "sexual

-
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Id. at 2763-64.

83. See Schroeder, *supra* note 3, at 970; REPORT, *supra* note 2, at 3077.

84. See HORNBLUM, *supra* note 5, at 89-90.

85. See *id.* at 43.

86. See *id.* at 93.

87. See *id.*

88. See *id.*

89. See *id.*

90. See *id.* at 95.

psychopaths" LSD and marijuana in order to "test the effectiveness of certain medication in causing individuals to release guarded information under interrogation."⁹¹

Biomedical experimentation on prisoners could be extremely lucrative for doctors. Dr. Austin R. Stough, an Oklahoma physician, is estimated to have earned approximately \$1 million a year by selling blood plasma extracted from volunteer prisoners in Oklahoma, Arkansas, and Alabama and by using the prisoners for drug testing.⁹² His customers included Bristol-Myers, Merck, Sharp & Dohme, Upjohn, Lederle, and American Home Products.⁹³

Throughout the 1960s, in fact, drug companies competed for access to prison populations.⁹⁴ In 1964, Upjohn and Parke-Davis contributed over a half million dollars to build a state of the art laboratory inside the State Prison of Southern Michigan at Jackson, which was the largest walled penitentiary in the world and housed 4100 inmates.⁹⁵ Inmates were trained to run the tests in prison labs themselves and were paid between \$.35 and \$1.25 per day, a small fraction of what employees doing such work would earn in a non-prison environment.⁹⁶

Medical experimentation in prisons continued throughout the 1960s and early 1970s.⁹⁷ In 1969 eighty-five percent of all new drugs were tested on prisoners in forty-two prisons.⁹⁸ As late as 1975 at least 3600 prisoners in the United States were used by drug companies as the first humans on whom the safety of new medication was tested.⁹⁹ The federal government, through the Atomic Energy Commission, funded a decade-long radiation study on inmates in Oregon and Washington State prisons.¹⁰⁰ The experiments were designed to determine how much radiation U.S. astronauts could tolerate during space flights.¹⁰¹ Prisoners volunteered for the testing and received small monetary payments, but were required to undergo radiation exposure to their testicles at rates equivalent to approximately twenty diagnostic x-rays.¹⁰² Test subjects suffered painful, lasting effects, and, according to some estimates, almost half of them have since died.¹⁰³ From 1970 to 1975 five agencies of the federal government utilized prison inmates in 125 biomedical experiments and nineteen behavioral research studies.¹⁰⁴

91. *Id.*

92. *See id.* at 97.

93. *See id.*

94. *See id.* at 103.

95. *See id.*

96. *See id.*

97. *See id.* at 108.

98. *See* Schroeder, *supra* note 3, at 971.

99. *See* ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, at 2056-57.

100. *See* HORNBLUM, *supra* note 5, at 107.

101. *See id.*

102. *See id.*

103. *See id.* at 108.

104. *See* ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, at 2056.

In Petersburg, Virginia, Dr. John L. Sever of the National Institutes of Health conducted a rubella project, exposing prisoners to the disease for sixteen weeks at a time.¹⁰⁵ Inmates earned twenty dollars for their participation.¹⁰⁶ In California and Arizona prisoners were involved in weightlessness experiments for the National Aeronautic and Space Administration.¹⁰⁷ Prisoners were required to remain in bed at all times, some for over six months.¹⁰⁸ In addition, some were placed in compression suits and were forced to endure repeated blood and calcium tests and radioactive isotope injections.¹⁰⁹ Subjects were paid fifty dollars per month and an additional fifty dollars for completing the study.¹¹⁰ They also signed informed consent forms, and these, unlike their predecessors, provided inmates with some degree of protection by stating that the consent forms "shall not be construed as a release of NASA from any future liability."¹¹¹

In *Acres of Skin*, Allen M. Hornblum wrote an expose of the twenty-year testing program at Philadelphia's Holmesburg Prison. The program was run by Dr. Albert M. Kligman, a University of Pennsylvania dermatology professor.¹¹²

Hornblum is particularly critical of three biomedical experiments conducted by Kligman at the prison. First, in conjunction with the Army, he tested a mind-altering substance known as EA 3167 on prisoners in an effort to determine whether it should be added to the Army's chemical warfare stock.¹¹³ Inmates suffered confusion and hallucinations for up to three weeks.¹¹⁴ In addition, Kligman tested radioactive isotopes at the prison despite having little education or experience in radioactive medicine.¹¹⁵ Hornblum alleges that Kligman made various misrepresentations to the U.S. Atomic Energy Commission in order to obtain a required license from the federal government.¹¹⁶ The third experiment denounced by Hornblum is one conducted for Dow Chemical Corporation, involving dioxin, a component of Agent Orange.¹¹⁷ According to the book, Kligman subjected several prisoners to 7500 micrograms of the toxic substance, 468 times the dosage he was instructed to administer by Dow Chemicals.¹¹⁸

Hornblum observes in his book that "[t]he Holmesburg experiments took place before the rise of investigative journalism, and the media, the government,

105. See HORNBLUM, *supra* note 5, at 108.

106. See *id.*

107. See *id.*

108. See *id.* at 109.

109. See *id.*

110. See *id.* at 108.

111. *Id.* at 109.

112. See *id.* at xix-xx, 35. Kligman is the inventor of Retin-A, the acne cream and wrinkle remover, which he tested on Holmesburg prisoners. See *id.* at 214.

113. See *id.* at 127-30, 137, 141-43.

114. See *id.* at 129.

115. See *id.* at 149-61.

116. See *id.*

117. See *id.* at 163-83.

118. See *id.* at 169.

and the public in general, neither knew nor cared about the events occurring daily within the walls of the old city jail."¹¹⁹ That indifference would vanish in the 1970s.

III. THE OUTCRY AGAINST EXPERIMENTATION ON PRISONERS AND ITS CONSEQUENCES

Concern regarding the mistreatment of medical research subjects in the United States developed in the early 1970s, largely as a result of publicity concerning the Tuskegee syphilis study.¹²⁰ The Tuskegee study was conducted from the 1950s until the beginning of the 1970s and was designed to study the effects of untreated syphilis in a group of African American men.¹²¹ The researchers professed to treat the patients, but never divulged to them that they were not being provided with the easily available and fully effective cure¹²² of penicillin.¹²³ The subjects thus continued to suffer from the debilitating illness while believing that they were receiving adequate care.¹²⁴

The Senate held subcommittee hearings in 1973 and subsequently established the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research through the National Research Act of 1974.¹²⁵ The National Commission operated between 1974 and 1978.¹²⁶ In 1976 the Commission recommended to the Secretary of the Department of Health, Education and Welfare ("HEW") (now "DHHS") that the government declare a moratorium on funding and approving prisoner studies until any prison that allowed inmate experimentation met at least minimum criteria to protect inmate subjects.¹²⁷ HEW published regulations for prisoner protection in clinical trials in 1978.¹²⁸ Although DHHS modified the regulations addressing biomedical research when it succeeded HEW, it retained the sections relating to prisoners.¹²⁹ In general, DHHS regulations apply to any research involving human subjects that is conducted, supported, or regulated by any federal department or agency.¹³⁰

DHHS regulations are designed to limit the circumstances in which researchers may include prisoners in their studies and to provide adequate

119. *Id.* at 242.

120. *See* McCarthy, *supra* note 72, at 58.

121. *See* WILLIAM J. CURRAN ET AL., HEALTH CARE LAW AND ETHICS 276 (5th ed. 1998).

122. *See id.*

123. *See* THE BANTAM MEDICAL DICTIONARY 424 (rev. ed. 1990).

124. *See* CURRAN ET AL., *supra* note 121, at 276.

125. *See* Pub. L. 93-348, 88 Stat. 342, § 201; McCarthy, *supra* note 72, at 58-59.

126. *See* BARUCH A. BRODY, ETHICAL ISSUES IN DRUG TESTING, APPROVAL AND PRICING 103 (1995).

127. *See* ENCYCLOPEDIA OF BIOETHICS, *supra* note 1, at 2056; REPORT, *supra* note 2, at 3079-81.

128. *See generally* 45 C.F.R. § 46.301 (1998).

129. *See* McCarthy, *supra* note 72, at 59.

130. *See* 45 C.F.R. § 46.101(a).

protection to inmate subjects. The regulations recognize that prisoners living in a harsh prison setting may be coerced into accepting risks that free citizens would not and that investigators may be tempted to utilize a "captive" group to undergo biomedical studies that would not be tolerated by civilians who are not incarcerated.¹³¹

The regulations impose special requirements and duties upon IRBs assessing clinical trials that involve prisoners. An IRB reviewing such research must include at least one prisoner or prisoner advocate, and a majority of its members may not be otherwise associated with the prison at issue.¹³²

The IRB must ensure that the advantages that the prisoners enjoy through participation in the trial with respect to living conditions, healthcare, food, amenities, and potential earnings are not so great as to render the inmate unable to weigh the risks of the study against its benefits in the prison environment.¹³³

131. See Eileen Kelly, *Expanding Prisoners' Access to AIDS-Related Clinical Trials: An Ethical and Clinical Imperative*, 75 THE PRISON JOURNAL 48, 57 (1995).

132. See 45 C.F.R. § 46.304. The provision reads in relevant part as follows:

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

- (a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- (b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

Id.

133. See *id.* § 46.305(a)(2). The regulation found at 45 C.F.R. § 46.305(a) reads as follows:

- (a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:
 - (1) The research under review represents one of the categories of research permissible under § 46.306(a)(2) [*see infra* note 139];
 - (2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
 - (3) The risks involved in the research are commensurate with risks that would

In addition, the risks involved in the trial must be equivalent to those that would be acceptable to non-inmate volunteers,¹³⁴ and the procedures implemented for the selection of participants should be fair and not subject to arbitrary intervention by prison officials or prisoners.¹³⁵ Information provided to prisoners for purposes of informed consent must be articulated in language that is comprehensible to the inmate population.¹³⁶ In addition, Parole boards may not consider prisoner participation in clinical trials when making parole decisions, and prisoners must be informed of this fact.¹³⁷ Finally, adequate follow-up care must be provided, when appropriate, to participants.¹³⁸

The regulations limit inmate participation in clinical investigations to the following: (1) studies of the possible causes, effects, and processes of imprisonment and criminal behavior so long as the research involves only minimal risk and inconvenience to the subject; (2) studies of prisons as institutional entities or of inmates as incarcerated individuals so long as the research involves only minimal risk and inconvenience to the subject; (3) research on particular conditions affecting prisoners as a class so long as the study is approved by the Secretary; and (4) research involving a treatment likely

be accepted by nonprisoner volunteers;

- (4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- (5) The information is presented in language which is understandable to the subject population;
- (6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- (7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Id.

134. *See id.* § 46.305(a)(3).

135. *See id.* § 46.305(a)(4).

136. *See id.* § 46.305(a)(5).

137. *See id.* § 46.305(a)(6).

138. *See id.* § 46.305(a)(7).

to benefit the prisoners themselves.¹³⁹ If a prisoner might be assigned to a placebo control arm, the study can proceed only with the Secretary's approval.¹⁴⁰

The FDA, an agency of DHHS,¹⁴¹ published its own proposed regulations in 1980.¹⁴² The regulations were substantially the same as those issued by

139. *See id.* § 46.306(a)(2). The regulation reads in relevant part:

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary [Health and Human Services] the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

Id.

140. *See id.* § 46.306(a)(2)(iv).

141. *See Kelly, supra* note 131, at 57.

142. *See Schroeder, supra* note 3, at 984-85.

DHHS.¹⁴³ Nevertheless, on July 29, 1980 inmates in the Michigan State Penitentiary at Jackson filed a lawsuit challenging the proposed FDA regulations.¹⁴⁴ On November 12, 1980, the Upjohn Company, the primary sponsor of drug research at Jackson, intervened as a plaintiff in the case.¹⁴⁵ The plaintiffs alleged that the FDA's proposed ban on prisoner participation in nontherapeutic drug experimentation violated the Equal Protection and Due Process clauses of the Fifth Amendment.¹⁴⁶ With the lawsuit pending, the FDA stayed the effective date of its regulations.¹⁴⁷ The FDA has never removed its stay or repropounded its regulations.¹⁴⁸

Existing federal regulations provide significant protection for prisoners participating in clinical trials.¹⁴⁹ Prisoner participation must be informed and voluntary and cannot pose more than minimal risk to the research subject. Despite the many safeguards implemented by DHHS, few inmates have access to clinical trials.¹⁵⁰ According to a survey conducted by the American Correctional Health Services Association, biomedical research involving inmates is prohibited in twenty-two states.¹⁵¹ Relatively few research institutions have accepted prisoners in clinical trials in recent years. These include facilities in Colorado, Connecticut, Maryland, New York, Texas, and Virginia.¹⁵²

In light of history, a concern may exist that individuals cannot, under any circumstances, be adequately protected in a prison setting and that any biomedical experimentation will lead to a violation of the prisoners' legal and moral rights. While it is wise for researchers to be mindful of the sensitive

143. See Kelly, *supra* note 131, at 59.

144. See *Fante v. Department of Health and Human Services*, Civil Action No. 80-72778, (E.D. Mich. filed July 29, 1980), *cited in* 46 Fed. Reg. 35085 (1981).

145. See *id.*; Schroeder, *supra* note 3, at 986.

146. See *Fante*, 46 Fed. Reg. at 35085; Schroeder, *supra* note 3, at 986.

147. See Kelly, *supra* note 131, at 56.

148. See *id.*

149. A recent statement issued by the Office of the Inspector General of the U.S. Department of Health and Human Services is highly critical of the institutional review board system. According to the report, the regulations are inadequately implemented and human subjects are insufficiently protected by IRBs. However, the report did not focus specifically on review of protocols involving prisoners, a process that is subject to higher standards. See OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVICES, INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM (1998); see also discussion *infra* Part V.B. Nevertheless, while the regulations themselves provide ample protection for prisoners, some IRBs may be inconsistent in applying the guidelines. The IRB system may therefore need to undergo scrutiny and improvement in order to ascertain that, in practice, prisoners consistently enjoy the benefits of the regulatory safeguards.

150. See Schar, *supra* note 12, at 1185 n.235.

151. See Kelly, *supra* note 131, at 58 (citing Kathryn Duke, *Achieving Balance: Biomedical Research and Inmates*, CORHEALTH, Fall 1993, at 1, 2).

152. See *id.* at 59. GARY L. STEIN & LINDA D. HEADLEY, NORTH JERSEY COMMUNITY RESEARCH INITIATIVE, PRISONERS WITH HIV: GUIDELINES FOR IMPLEMENTING CLINICAL TRIALS IN CORRECTIONAL SETTINGS 7 (July 1995).

circumstances of prisoners, it is also unwise to exclude inmates from all clinical trials. Denying seriously ill prisoners access to experimental treatments may constitute an equivalent violation of prisoner rights and is similarly problematic in moral and legal terms. The next section will focus on the potential constitutional issues implicated in biomedical experimentation involving prisoners.

IV. ANALYSIS OF THE CONSTITUTIONAL RIGHTS OF PRISONERS AS THEY RELATE TO BIOMEDICAL EXPERIMENTATION

A. While Irresponsible Clinical Research May Violate Prisoners' Eighth Amendment Rights, Denial of Potentially Life-Saving Experimental Treatment to Prisoners Also Constitutes Unconstitutional Cruel and Unusual Punishment

1. *Eighth Amendment Overview.*—The Eighth Amendment to the Constitution of the United States prohibits the infliction of “cruel and unusual punishment.”¹⁵³ The Supreme Court originally construed the Eighth Amendment as only precluding punishments of torture and unnecessary cruelty¹⁵⁴ or sentences that are grossly disproportionate to the crime committed.¹⁵⁵ The Supreme Court subsequently broadened its interpretation of the Eighth Amendment and determined that it applies to the treatment inmates receive while incarcerated,¹⁵⁶ including improper medical treatment.¹⁵⁷ The Amendment is understood to embody “broad and idealistic concepts of dignity, civilized standards, humanity, and decency”¹⁵⁸

Nevertheless, it is not easy for prisoners to prevail in Eighth Amendment cases. An inmate alleging an Eighth Amendment violation must establish a grave deprivation of rights to which prison officials have reacted with deliberate indifference.¹⁵⁹ In determining whether a punishment violates the Eighth

153. U.S. CONST. amend. VIII. The text provides that “[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishment inflicted.” *Id.*

154. See *Wilkerson v. Utah*, 99 U.S. 130 (1878) (holding that death by firing squad is not cruel and unusual punishment).

155. See *Weems v. United States*, 217 U.S. 349, 382 (1910). In *Weems* the Court held that the Eighth Amendment’s cruel and unusual punishment clause was “progressive, and is not fastened to the obsolete, but may acquire meaning as public opinion becomes enlightened by a humane justice.” *Id.* at 378. See also Samantha A. Moppett, Case Comment, *Constitutional Law—Extending Eighth Amendment Protections to Prisoners Involuntarily Exposed to Unreasonable Levels of Environmental Tobacco Smoke—Helling v. McKinney*, 28 SUFFOLK U. L. REV. 200, 202 (1994).

156. See *Helling v. McKinney*, 509 U.S. 25, 31 (1993); Moppett, *supra* note 155, at 202.

157. See *Estelle v. Gamble*, 429 U.S. 97, 106 (1976).

158. *Jackson v. Bishop*, 404 F.2d 571, 579 (8th Cir. 1968) (summarizing the Supreme Court’s cases and concluding that the limits of the Eighth Amendment are “not easily or exactly defined”).

159. See *Gamble*, 429 U.S. at 106 (“In order to state a cognizable claim, a prisoner must

Amendment, the Supreme Court has assessed the challenged punitive measure in light of the “evolving standards of decency that mark the progress of a maturing society.”¹⁶⁰ Furthermore, the Court has found that deliberate indifference “entails something more than mere negligence . . . [but] something less than acts or omissions for the very purpose of causing harm or with knowledge that harm will result.”¹⁶¹ In order to establish a deliberate indifference claim based on improper medical treatment, an inmate must show that prison officials (1) were aware of the individual’s serious medical need; and (2) disregarded, ignored, or refused to provide the inmate with treatment for that need.¹⁶²

If an Eighth Amendment violation arises not from the acts of particular prison officials but from a prison policy, a different test, first articulated by the Supreme Court in 1987 in *Turner v. Safley*,¹⁶³ will be applied. In *Safley*, the Court held that “when a prison regulation impinges on inmates’ constitutional rights, the regulation is valid if it is reasonably related to legitimate penological interests.”¹⁶⁴ In assessing the reasonableness of a regulation, the court must consider the following four factors:

- (1) ‘there must be a “valid, rational connection” between the prison regulation and the legitimate governmental interest put forward to justify it;’
- (2) the court should determine whether there are alternative means of exercising the constitutional right that remain open to the inmates;
- (3) the court is to consider the impact that accommodation of the asserted constitutional right will have on guards, other inmates, and on the allocation of prison resources; and
- (4) the court should assess whether there are ready alternatives to the prison regulation—the absence of such ready alternatives suggests that the regulation is reasonable while their existence may be evidence of the opposite.¹⁶⁵

2. *Bailey v. Lally*.—The case of *Bailey v. Lally*¹⁶⁶ provides a uniquely thorough analysis of an Eighth Amendment challenge to the inclusion of prison inmates in clinical trials. In *Bailey*, state prisoners brought a class action under 42 U.S.C. § 1983 alleging that prisoners who participated in clinical investigations at the Maryland House of Correction’s medical research unit had

allege acts or omissions sufficiently harmful to evidence deliberate indifference to serious medical needs.”).

160. *Trop v. Dulles*, 356 U.S. 86, 101 (1958).

161. *Farmer v. Brennan*, 511 U.S. 825, 835 (1994).

162. *See id.* at 837.

163. 482 U.S. 78 (1987). In *Safley* inmates challenged two regulations promulgated by the Missouri Division of Corrections. The Court upheld the regulation concerning inmate-to-inmate correspondence but found the inmate marriage regulation to be invalid.

164. *Id.* at 89. *See also* *Lewis v. Casey*, 518 U.S. 343, 361 (1996).

165. *Walker v. Sumner*, 917 F.2d 382, 385 (9th Cir. 1990) (quoting *Safley*, 482 U.S. at 90-91).

166. 481 F. Supp. 203 (D. Md. 1979).

suffered violations of their constitutional rights to due process, privacy, and protection against cruel and unusual punishment.¹⁶⁷ After careful consideration and lengthy discussion, the court ruled against the plaintiffs.

A recitation of the facts is important to understanding the court's analysis and thus, will be provided in some detail. The Maryland House of Correction ("MHC") was opened in 1879 and was designed to house approximately 1100 inmates.¹⁶⁸ During the early 1970s the inmate population ranged from 1498 to 1617, and many cells designed for only one person housed two occupants at a time.¹⁶⁹ Until 1976, hot water was unavailable to prisoners.¹⁷⁰ During the winter, inmates suffered from the cold because the prison's heating system was sorely inadequate, and in the summer months, the facility was very hot.¹⁷¹ A large percentage of prisoners had no work, educational, or vocational activities and spent between sixteen and seventeen hours per day in their cells.¹⁷² Those with jobs earned between \$.63 and \$1.46 per day, with the vast majority earning under \$1.10 a day.¹⁷³

A medical research unit was established at the MHC by doctors from the University of Maryland School of Medicine, and research involving prisoners commenced in 1958.¹⁷⁴ Prisoners participating in clinical trials were paid two dollars per day, including Saturdays and Sundays, and additional payments were made if the prisoner underwent particular medical procedures.¹⁷⁵ Approximately one third of the participants lived full-time in a designated section of the medical research unit that, unlike the rest of the prison, had hot water, color television, and three separate bathroom facilities.¹⁷⁶ The patients could retain their jobs and enjoy the income earned from the medical research as a supplement to other earnings.¹⁷⁷ Participation in clinical trials, however, had no impact on parole decisions.¹⁷⁸ This fact was disclosed to some, but not all of the inmates.¹⁷⁹

Prisoners learned of the medical research unit via word of mouth or from an application that some were given when they entered MHC and that was also published in the prison newspaper.¹⁸⁰ Inmates wishing to be included in the medical experimentation were required to complete the application, which

167. *See id.*

168. *See id.* at 205.

169. *See id.*

170. *See id.*

171. *See id.*

172. *See id.*

173. *See id.* at 205-06. Prisoners working in the laundry earned \$2.22 per day. *See id.*

174. *See id.* at 206.

175. *See id.*

176. *See id.*

177. *See id.*

178. *See id.*

179. *See id.* at 209-10.

180. *See id.* at 207.

included detailed information regarding the research.¹⁸¹ When a study was to be commenced, all applicants would be gathered as a group and addressed by a nurse or a doctor, who explained the reason for and nature of the experimentation as well as its possible risks. Inmates who again expressed interest in participation underwent a physical examination and were given repetitive oral explanations in layman's terms, with opportunities for questions and answers.¹⁸²

Those who were ultimately accepted as participants in the studies were given additional verbal data about the research and were told that they could withdraw at any time.¹⁸³ Many in fact did withdraw both before and during various stages of experimentation.¹⁸⁴ Prisoners were also asked to sign a written consent form.¹⁸⁵

The medical research unit at MHC conducted nontherapeutic studies of various infectious diseases including malaria, cholera, shigella, viral diarrhea, influenza, typhoid, e. coli, and rhinovirus.¹⁸⁶ Nontherapeutic studies are those that do not provide any direct medical benefit to the patient but seek to produce general knowledge about a particular disorder or condition.¹⁸⁷ All of the diseases investigated, with the exceptions of the common cold and the flu, had known cures.¹⁸⁸ Approximately fourteen percent of the prisoners incarcerated at MHC from 1971 to 1975 participated in the medical studies.¹⁸⁹

The plaintiffs alleged in their lawsuit that the poor prison conditions, their idleness, and the salary, which far exceeded earnings from other prison jobs, rendered their participation in the clinical trials coerced and consequently resulted in violations of their Eighth Amendment and other constitutional rights.¹⁹⁰ The Eighth Amendment claim revolved around the question of whether individuals incarcerated in a prison setting can give truly meaningful consent and rationally choose to volunteer for the trial with a full understanding of both its benefits and its risks.¹⁹¹

The *Bailey* court found that the prisoners were adequately informed in light of the numerous verbal explanations and the written consent forms they received.¹⁹² The plaintiffs' strongest allegations were thus rooted in the issue of voluntariness. The plaintiffs argued that the overcrowded and extremely uncomfortable conditions of regular institutional life at MHC caused them to over-value the potential earnings and hours away from their cells and deprived

181. *See id.*

182. *See id.* at 208.

183. *See id.* at 210.

184. *See id.*

185. *See id.*

186. *See id.* at 212 n.15.

187. *See* 45 C.F.R. § 46.406 (1998).

188. *See Bailey*, 481 F. Supp. at 212.

189. *See id.* at 220.

190. *See id.*

191. *See id.* at 219-20.

192. *See id.*

them of the ability to make a meaningful decision.¹⁹³

The court rejected the plaintiffs' claims. It noted that in fact a very small minority of prisoners (only fourteen percent) found the medical research programs appealing and that there was a constant shortage of volunteers.¹⁹⁴ In addition, the court noted the following:

Prisoners at the MHC were not subject to physical abuse, or confined in segregated cells, or restricted to meagre [sic] diets, until they consented to participate in MRU studies. Prisoners were not pressured to participate. To the contrary, prisoners had a viable choice and, even after choosing to participate, had the option to withdraw from the medical studies.¹⁹⁵

The court decision also emphasized that the experiments did not create a danger to the subjects' lives or future health and that the risks of temporary discomfort were fully disclosed to the inmates.¹⁹⁶ Finally, the court focused upon the fact that participation in the clinical studies did not facilitate the inmates' release from MHC, and thus, early parole was not an incentive for enrollment.¹⁹⁷ The court found that the plaintiffs' Eighth Amendment claim failed because the defendant's conduct was not "incompatible with evolving standards of decency"¹⁹⁸ and did not subject them to undue coercion.¹⁹⁹

The medical research in the *Bailey* case was conducted before the DHHS issued its regulations for prisoner research in 1978.²⁰⁰ Today prisoners involved in clinical trials would enjoy far greater protection than that available to the plaintiffs in the *Bailey* case.²⁰¹ Moreover, the experimentation conducted in *Bailey*, which was found not to violate any constitutional rights, would be prohibited by DHHS regulations because it was nontherapeutic, did not benefit the subjects, and did not fall into any of the categories of permissible research.²⁰² In light of contemporary regulatory safeguards and the restrictions placed on investigators conducting research involving prisoners, it is extremely unlikely that prisoner participants would suffer a violation of Eighth Amendment rights in the context of a clinical trial that complies with federal guidelines.

3. *Seriously Ill Prisoners May Greatly Benefit from Experimental Therapies.*—In many instances, experimental treatments provided through clinical trials constitute last chance therapies for desperately ill patients who

193. See *id.* at 220.

194. See *id.*

195. *Id.*

196. See *id.* at 221.

197. See *id.*

198. *Id.* at 219.

199. See *id.* at 221.

200. See McCarthy, *supra* note 72, at 59.

201. See discussion *supra* Part III.

202. See 45 C.F.R. § 46.306(a)(2) (1998).

cannot be cured by conventional medicine.²⁰³ In the prison setting, where a significant percentage of inmates are HIV positive, experimental treatments could benefit many individuals and save many lives.²⁰⁴ Experimental treatments may also be sought by inmates suffering from cancer,²⁰⁵ hepatitis,²⁰⁶ tuberculosis,²⁰⁷ and other diseases.

HIV is one of the predominant health problems in U.S. prisons.²⁰⁸ While HIV had an incidence rate of eighteen cases per 100,000 in the general population in 1992, the rate among prisoners was estimated to be 362 per 100,000 that same year.²⁰⁹ Accounting for up to two-thirds of all inmate deaths in some states, AIDS is the leading killer in correctional facilities.²¹⁰ A 1992-93 survey conducted by the National Institutes of Justice ("NIJ") and the federal Centers for Disease Control and Prevention ("CDC") revealed a total of more than 11,500 AIDS cases and almost 3500 AIDS-related deaths among prisoners in state, federal, county, and large city correctional facilities.²¹¹ The New Jersey Department of Health estimates that almost nine percent of adult male inmates and more than fourteen percent of adult female inmates are infected with HIV.²¹² The Department further estimates that among prisoners with a history of illegal drug use, forty percent of the men and 42.6% of the women are HIV positive.²¹³

Inmates who are HIV positive are highly susceptible to tuberculosis.²¹⁴ From 1976 to 1978, tuberculosis had an incidence rate of 15.4 per 100,000 among New York state prisoners.²¹⁵ By 1992 there was a 1300% increase to a rate of 189 per 100,000.²¹⁶

Despite significant advances in the treatment of AIDS, contemporary treatment modalities offer only limited relief to patients.²¹⁷ Participation in clinical trials can provide inmates with access to promising experimental drugs.²¹⁸ At times, experimental protocols may constitute the only meaningful

203. See Angela R. Holder, *Funding Innovative Medical Treatment*, 57 ALB. L. REV. 795, 795 (1994).

204. See Kelly, *supra* note 131, at 48.

205. See Holder, *supra* note 203, at 795-96.

206. See 45 C.F.R. § 46.306(a)(2)(iii).

207. See Schar, *supra* note 12, at 1156.

208. See James W. Marquart et al., *Health Condition and Prisoners: A Review of Research and Emerging Areas of Inquiry*, 77 THE PRISON JOURNAL 185 (1997).

209. See *id.*

210. See Kelly, *supra* note 131, at 49.

211. See STEIN & HEADLEY, *supra* note 152, at 4.

212. See *id.*

213. See *id.*

214. See Curtis Prout, *Clinical Challenges in the Climate of Prison*, 107 TRANSACTIONS OF THE AM. CLIMATOLOGICAL AND CLINICAL ASS'N 287, 290 (1995).

215. See *id.*

216. See *id.*

217. See STEIN & HEADLEY, *supra* note 152, at 4.

218. See *id.* at 9. Since prisoners are precluded from participating in placebo-controlled

opportunity for a prisoner to receive treatment.²¹⁹ Biomedical research may also provide inmates with the moral satisfaction of contributing to the advancement of AIDS research²²⁰ and with the opportunity “to give something back to society, to redeem, atone, and reconcile.”²²¹ Several commentators have urged the inclusion of prisoners in clinical trials relating to HIV and AIDS²²² and in other studies that might benefit prisoners.²²³

Regulations prohibiting seriously ill prisoners from participation in clinical trials in all cases, including those in which their exclusion results in the denial of potentially life-saving therapy, are vulnerable to constitutional attack. Although no court has rendered a decision regarding this issue, a viable constitutional argument can be made that prisoners with life-threatening illnesses that cannot be otherwise treated have a right to participate in biomedical research that complies with federal regulations.²²⁴

4. *The Eighth Amendment Right to Medical Treatment.*—The Supreme Court has determined that the government is obligated to provide medical care for prisoners because incarcerated individuals cannot independently obtain healthcare.²²⁵ The Court has further stated that “deliberate indifference to serious medical needs of prisoners constitutes the ‘unnecessary and wanton infliction of pain,’ proscribed by the Eighth Amendment.”²²⁶ A prisoner may bring a cause of action for an Eighth Amendment violation under 42 U.S.C. § 1983 if

studies unless the research is approved by the Secretary, prisoners will rarely be deprived of active therapy as research subjects. Generally, those assigned to the control arm of the study will be given standard therapy from which they are likely to benefit.

219. See Dale L. Moore, *An IRB Member's Perspective on Access to Innovative Therapy*, 57 ALB. L. REV. 559, 571-72 (1994) (“[A] significant component of the treatment available to AIDS patients is provided through clinical research trials of new drugs or drug combinations.”).

220. See STEIN & HEADLEY, *supra* note 152, at 9.

221. Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455, 481 (1996).

222. See, e.g., STEIN & HEADLEY, *supra* note 152, at 9; Kelly, *supra* note 131, at 55; Moore, *supra* note 219, at 571-72.

223. See, e.g., Prout, *supra* note 214, at 291. Prout argues that “[t]here is a crying need for genetic studies” because significant evidence indicates that many prisoners have fathers and grandfathers who were also incarcerated. *Id.* Prout admits, however, that this proposal is controversial because of “fears of breaches of confidentiality, manipulation of the data, and possible political implications having to do with race and ethnicity.” *Id.* at 291-92.

224. Several commentators have argued that the Eighth Amendment requires that sexual offenders who request castration as therapy for their paraphiliac disabilities be provided with the surgical treatment once proper medical evaluation and informed consent have been obtained. Their thesis features several parallels to the arguments made in this Article. See William Winslade et al., *Castrating Pedophiles Convicted of Sex Offenses Against Children: New Treatment or Old Punishment?*, 51 SMU L. REV. 349 (1998).

225. See *Estelle v. Gamble*, 429 U.S. 97, 103 (1976).

226. *Id.* at 104 (quoting *Gregg v. Georgia*, 428 U.S. 153, 171 (1976)).

authorities show deliberate indifference to his or her serious illness or injury.²²⁷

In *Helling v. McKinney*²²⁸ a prisoner alleged that prison authorities had subjected him to cruel and unusual punishment by assigning him to a cell with an inmate who smoked five packs of cigarettes a day, and thus the officials had jeopardized his health.²²⁹ The complaint further asserted that cigarettes were sold to inmates in the prison and that nonsmoking inmates were not informed of the health hazards associated with breathing smoke produced by their cellmates.²³⁰

The Supreme Court held that the Eighth Amendment's protection against deliberate indifference to a prisoner's health problems extends not only to current serious health problems, but also to conditions that threaten to cause health problems in the future.²³¹ Consequently, the prisoner stated a cause of action under the Eighth Amendment when he alleged that prison officials had, with deliberate indifference, exposed him to levels of environmental tobacco smoke that created an unreasonable risk of serious damage to his health in the future.²³² In order to obtain injunctive relief, however, the plaintiff would be required on remand to prove both an objective and a subjective element.²³³ First, he would have to prove that society considers the risk of which he complains "to be so grave that it violates contemporary standards of decency to expose *anyone* unwillingly to such a risk."²³⁴ Second, the inmate would be required to establish the subjective factor that prison officials had shown deliberate indifference to the hazards posed to his health.²³⁵ To do so, the plaintiff would need to focus upon the officials' current attitudes and conduct.²³⁶

If exposure to environmental tobacco smoke can constitute an Eighth Amendment violation, it stands to reason that the denial of experimental therapy to an incarcerated person who is seriously ill could also rise to the level of a constitutional violation. If a clinical trial is available for a prisoner who suffers from AIDS or another serious illness and prison officials deny the inmate access to the trial, the inmate might be able to establish a valid cause of action. The prisoner would have to show that failure to allow him access to the available clinical study is so grave that it violates contemporary standards of decency.²³⁷ If the illness at issue is a terminal one, such as cancer or AIDS, for which conventional treatments have failed, this element may not be difficult to establish. In addition, the prisoner will have to prove that the prison officials had shown deliberate indifference to his medical condition by preventing him from

227. *See id.* at 105.

228. 509 U.S. 25 (1993).

229. *See id.* at 28.

230. *See id.*

231. *See id.* at 33.

232. *See id.* at 35.

233. *See id.* at 36.

234. *Id.*

235. *See id.*

236. *See id.*

237. *See id.*

participating in the biomedical research.²³⁸ Success in establishing this element will depend upon the prison officials' reasoning and motivations.²³⁹ However, under *Helling*, the prisoner will not be required to prove that exclusion from the clinical trial posed an immediate risk of physical deterioration, but rather, only that his or her future health may be jeopardized.²⁴⁰ This principle is important for prisoners who are HIV positive since HIV patients may be asymptomatic or minimally symptomatic for many years. However, their future prognosis will depend upon the therapy that they receive throughout the course of the disease, and therapy for HIV patients often includes experimental drug combinations.²⁴¹

If a state implements a regulation that prohibits prisoner participation in clinical trials, as many states have done, the *Safley* test would be used to evaluate any constitutional claim asserted by a prisoner.²⁴² If the prisoner could establish that the regulation denying access to research studies impinges upon inmates' Eighth Amendment rights as discussed above, the prisoner would have to address the following issues: (1) whether a valid, rational connection exists between the prison regulation and the legitimate governmental interest that purportedly justifies it; (2) whether alternative means of exercising the constitutional right remain open to the prisoners; (3) the impact that accommodating the constitutional right will have on guards, other inmates, and prison resources; and (4) whether there are ready alternatives to the prison regulation.²⁴³

Prisoners denied access to potentially life-saving experimental treatments because of a prison regulation should be able to establish all four elements. Under the *Safley* test, it is not enough for state officials merely to articulate a reason for their decision. Rather, the officials' reasoning is subjected to judicial scrutiny.²⁴⁴ The *Safley* test has served as a basis for invalidating prison policies in several cases. The case of *Muhammad v. Pitcher*,²⁴⁵ for example, involved a prison policy of treating inmate mail from the State Attorney General's Office as ordinary mail rather than legal mail and opening it while the addressee was not present.²⁴⁶ The court found that opening the mail in the absence of the prisoners burdened the inmates' First Amendment rights and was not reasonably related to legitimate penological interests.²⁴⁷ Contrary to the defendant's contentions, the court found that a requirement that mail from the Attorney General's Office be opened only in the presence of the addressee would not waste prison resources.²⁴⁸ Moreover, treatment of mail from the Attorney General as ordinary mail left no

238. *See id.*

239. *See id.*

240. *See id.* at 33.

241. *See Moore, supra* note 219, at 571-72.

242. *See Turner v. Safley*, 482 U.S. 78, 89 (1987).

243. *See id.* at 89-90.

244. *See id.*

245. 35 F.3d 1081 (6th Cir. 1994).

246. *See id.*

247. *See id.* at 1085.

248. *See id.*

alternative for prisoners who wished to communicate confidentially with the Attorney General in order to redress grievances.²⁴⁹ Similarly, in *Castillo v. Gardner*,²⁵⁰ the court found that a prison policy of conducting digital rectal probes without cause failed the *Turner v. Safley* test because it was not reasonably related to a legitimate penological goal.²⁵¹

In the case of a policy barring access to clinical research, the governmental entity promulgating the regulation would presumably assert that the reason for its regulation is the protection of prisoners against the abuses of biomedical experimentation. As discussed above, however, DHHS regulations implement multiple safeguards to protect prison populations.²⁵² In light of these regulatory requirements and precautions, it will be difficult for prison authorities to justify complete denial of access to clinical trials as a reasonable antidote to prisoner abuse.²⁵³

If promising treatment for a particular disease is available to the inmate only through an experimental study, as is often the case for AIDS patients,²⁵⁴ prisoners will have no alternative and no way to exercise their constitutional right to medical treatment outside of the clinical trial. In some cases, last-chance experimental therapies provided through clinical trials constitute the only meaningful healthcare available to a terminally ill patient. Prisoners seeking participation in such biomedical research will therefore be able to prevail with respect to the second element of the *Safley* test.

The third element of the *Safley* test might provide the greatest hurdle for inmates challenging a prison regulation that prohibits access to clinical trials, but it should not be insurmountable. Prison officials might argue that accommodation of the prisoner's desire to participate in a study may have an adverse impact on guards, other inmates, and prison resources. The prison may contend that special treatment of some prisoners for medical research purposes might cause jealousy among inmates, require additional security measures for prisoners transported to and from the medical site, and result in added costs for the correctional facility.

The inconvenience for correctional institutions allowing prisoner participation in clinical trials, however, should be minimal. Under FDA regulations, sponsors of drug studies are generally required to pay for the investigational drugs provided in trials.²⁵⁵ Consequently, the drug companies

249. *See id.*

250. 854 F. Supp. 725 (E.D. Wa. 1994).

251. *See id.* at 726.

252. *See discussion supra* Part III.

253. The state might also argue that the regulation is necessary for security and cost reasons. Allowing an inmate to leave the prison in order to receive the experimental treatment could potentially raise expenses and security concerns for prison authorities. These arguments are addressed with respect to the third element of the *Safley* test below.

254. *See Kelly, supra* note 131.

255. *See* 21 C.F.R. § 312.7(d)(1)(1999). "Charging for an investigational drug in a clinical trial under an IND is not permitted without the prior written approval of FDA. In requesting such

themselves pay for the treatment of prisoners who receive experimental therapy in clinical research.²⁵⁶ Moreover, during the 1960s, prior to the constraints imposed by federal regulations, drug companies competed for access to prisoner populations.²⁵⁷ Upjohn and Parke-Davis built a state of the art laboratory inside the State Prison of Southern Michigan at Jackson.²⁵⁸ If researchers were encouraged to utilize prisoners in clinical trials that would benefit both the sponsors and the prisoners, as required by the regulations, drug companies and research institutions may once again be eager to provide medical facilities within the prisons at which the studies would be conducted. In the past decade, researchers in Maryland and Colorado have in fact conducted AIDS-related clinical trials at correctional facilities.²⁵⁹ At other locations, clinical studies have taken place at hospitals that provide routine medical services to prisoners and to which prisoners are transported for healthcare on a regular basis.²⁶⁰

In addition, experience has shown that prisoners do not vie with one another for the opportunity to be research subjects and that there is often a dearth of inmates willing to participate in clinical research.²⁶¹ Therefore, it is unlikely that the availability of experimental protocols for seriously ill inmates will be perceived as favoritism and cause morale problems within the prison. On the contrary, all prisoners might be reassured by the enhanced quality of the medical care and the new treatment opportunities available at the correctional facility. The cost and inconvenience for prison authorities would thus be slight.

With respect to the fourth element of the *Safley* test, it should not be difficult to show that prison authorities wishing to protect prisoners from coerced or uninformed participation in clinical research or from abusive medical practices have ready alternatives to an absolute ban on access to clinical studies. Prison authorities could ensure that an appropriately constituted IRB has approved the proposed clinical study and that all other regulatory requirements are being followed by those conducting the research. In this manner, prison officials will be able to protect the prison population without denying seriously ill patients potentially life-saving therapy.

approval, the sponsor shall provide a full written explanation of why charging is necessary in order for the sponsor to undertake or continue the clinical trial, e.g., why distribution of the drug to test subjects should not be considered part of the normal cost of doing business." *Id.*

256. *See id.* If the inmate receives standard therapy in a control arm, the drug sponsor does not have to cover the expense. However, this does not add costs for the state since the patient would have to be treated with standard therapy at the state's expense if no experimental therapy were available.

257. *See* HORNBLUM, *supra* note 5, at 103.

258. *See id.*

259. *See* Kelly, *supra* note 131, at 61.

260. *See id.* at 60.

261. *See* Bailey v. Lally, 481 F. Supp. 203, 220 (D. Md. 1979); STEIN & HEADLEY, *supra* note 152, at 21 ("The [prison] population is not very anxious to participate.").

*B. The Fourteenth Amendment Does Not Bar Prisoner Access to
Experimental Treatment and May, in Fact, Mandate
Inmates' Inclusion in Clinical Trials*

1. *Due Process and Equal Protection.*—The Fourteenth Amendment provides that no state may “deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.”²⁶² The Supreme Court has stated that “[d]ue process of law is a summarized constitutional guarantee of respect for those personal immunities which . . . are ‘so rooted in the traditions and conscience of our people as to be ranked as fundamental’²⁶³ . . . or are ‘implicit in the concept of ordered liberty.’”²⁶⁴ Traditionally, the Supreme Court has held that a state violates substantive due process when its acts “shock the conscience” of humanity.²⁶⁵

Governmental action is subjected to strict scrutiny if it impermissibly interferes with the exercise of a fundamental right or disadvantages a suspect class.²⁶⁶ If no fundamental right or particular suspect class is adversely affected, the challenged governmental action will be assessed under “rational basis scrutiny” to determine whether it bears a rational relationship to a legitimate governmental interest.²⁶⁷ The Supreme Court has determined that the fundamental rights protected by the Due Process Clause include the rights to marry, to marital privacy and contraception, to abortion, to have children, to control the education and upbringing of one’s children, to bodily integrity, and to refuse unwanted lifesaving medical treatment.²⁶⁸ The suspect classifications that warrant strict scrutiny under the Equal Protection Clause are race, alienage, and national origin.²⁶⁹

The *Bailey*²⁷⁰ court held that the defendants’ conduct did not rise to the level of a constitutional due process violation.²⁷¹ The court acknowledged that some of the living conditions that were prevalent at MHC at the time were unacceptable and, that the research studies offered prisoners a partial escape from

262. U.S. CONST. amend. XIV.

263. *Rochin v. California*, 342 U.S. 165, 169 (1951) (citing *Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934)).

264. *Id.* (citing *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).

265. *See Bailey*, 481 F. Supp. at 219 (citing *Rochin*, 342 U.S. at 172).

266. *See Massachusetts Bd. of Retirement v. Murgia*, 427 U.S. 307, 312 (1976).

267. *See Harris v. McRae*, 448 U.S. 297, 326 (1980).

268. *See Washington v. Glucksberg*, 521 U.S. 702, 719-20 (1997).

269. *See Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440 (1985). An intermediate level of scrutiny has been applied in cases involving classification based on sex or illegitimacy. *See Clark v. Jeter*, 486 U.S. 456, 461 (1988). To be upheld, a classification analyzed under the intermediate level of scrutiny must be substantially related to an important governmental objective. *See id.*

270. 481 F. Supp. at 203.

271. *See id.* at 225.

those conditions and an opportunity for higher earnings.²⁷² These circumstances suggest that the prisoners might have enrolled in the clinical trials not because they wished to participate in the biomedical research and understood its purpose and implications, but solely because they hoped to escape some of the intolerable prison conditions. Prisoners who underwent experimentation for which they did not provide meaningful consent arguably suffered a violation of their right to bodily integrity or liberty. Nevertheless, considering all the evidence in the case and the informed consent provided by participants, the court found that the inclusion of inmates in the medical experiments at issue did not "shock the conscience" or defy constitutional standards.²⁷³

On the other hand, prisoners who desire access to experimental treatment and are denied permission to participate in a clinical trial may be able to establish that their exclusion from therapeutic medical research violates the Fourteenth Amendment. Although federal law permits the inclusion of prisoners in clinical trials in limited circumstances, state laws and correctional policies continue to prohibit prisoners' access to biomedical studies in many jurisdictions.²⁷⁴ Prisoners may challenge state laws or regulations barring access to clinical trials by asserting that the state action violates the due process and equal protection clauses of the Fourteenth Amendment. They may contend that the state is depriving them of the liberty to enjoy the benefits of clinical research or is endangering their lives if it is precluding access to potentially life-saving treatment. Likewise, they may argue that they are subjected to unequal treatment based on their status as prisoners.

In *Fante v. Department of Health and Human Services*,²⁷⁵ prisoners from the State Prison of Southern Michigan at Jackson challenged proposed FDA regulations limiting prisoner access to clinical trials on due process and equal protection grounds.²⁷⁶ Cecil Cone, an inmate who had volunteered to participate in trials involving radioactive tracers, tuberculosis tests, medicated skin lotions, and antacids, stated that he wished to continue participating in nontherapeutic studies because they relieved the sheer boredom of prison life and allowed him to supplement his meager prison income.²⁷⁷ The drug testing, according to Cone, provided "a change of pace. It's like a little vacation."²⁷⁸ In addition, the money provided a powerful incentive.²⁷⁹ The FDA apparently found the prisoners' arguments to be compelling because it withdrew its proposed regulations and

272. See *id.* at 219.

273. See *id.*

274. See Kelly, *supra* note 131, at 58.

275. Civil Action No. 80-727788 (E.D. Mich. filed July 29, 1980), cited in 46 Fed. Reg. 35085 (1981).

276. See Schroeder, *supra* note 3, at 986.

277. See Marjorie Sun, *Inmates Sue to Keep Research in Prisons*, 212 SCIENCE 650, 650 (May 8, 1981).

278. *Id.*

279. See *id.*

never reissued a different proposal.²⁸⁰ However, no court decision was issued regarding the question of the prisoners' constitutional rights.

The prisoners in the *Fante* case argued that the proposed FDA regulations would deprive them of the liberty to enjoy the benefits of clinical research without due process of law and that they were denied the equal protection of the law because of their status as prisoners.²⁸¹ Seriously ill prisoners seeking participation in clinical trials for medical reasons rather than for income or a break from routine would have a far more persuasive argument than did the *Fante* plaintiffs and may well be able to prevail in a court action.

It must be noted, however, that it will be difficult to establish the existence of a fundamental right of access to clinical trials for incarcerated individuals. Although prisoners have a constitutional right to receive medical care in prison,²⁸² no court has deemed this fundamental right to extend to nonconventional, experimental treatments. In addition, prisoners are not among the identified suspect classes and thus are not entitled to heightened scrutiny under the Equal Protection Clause.²⁸³ State laws or correctional policies prohibiting the participation of prisoners in biomedical studies would therefore be analyzed under the rational basis test.

In defending a Fourteenth Amendment claim, the state would presumably argue that its reason for precluding prisoners from involvement in biomedical research is to protect them from coerced or uninformed participation or from the abuses of irresponsible research. As discussed above, however, existing federal regulations provide numerous safeguards against research abuses so long as they are conscientiously implemented by IRBs.²⁸⁴ The regulations mandate that prisoners can participate only in studies that will directly benefit the subject or the inmate population in general and prohibit prisoner involvement in nontherapeutic clinical trials.²⁸⁵ Moreover, the regulations implement safeguards relating to IRB review, selection of subjects, informed consent, and the performance of the experimentation.²⁸⁶ In light of these extensive federal regulations, it will be difficult for the state to establish that a complete ban on prisoner studies, including those with life-saving potential, bears a rational relationship to the goal of providing prisoners with meaningful protection.²⁸⁷ A state law or policy barring prisoner access to potentially life-saving experimental therapy may consequently be revoked even under Due Process or Equal Protection "rational basis" scrutiny.

280. See Kelly, *supra* note 131, at 56.

281. See Sun, *supra* note 277, at 650.

282. See *Estelle v. Gamble*, 429 U.S. 97, 103 (1976).

283. See *Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440 (1985).

284. See discussion *supra* Part III.

285. See 45 C.F.R. § 46.306 (1998).

286. See *id.* §§ 46.304, 46.305.

287. If the state argues that its ban is motivated by concerns about cost and security, these arguments too will prove weak and could be defeated under the rational basis test. See discussion *supra* Part IV.

It is tempting to assert an Equal Protection argument based on the reality that minorities are disproportionately affected by bans on studies involving prisoners. This argument, however, is destined to fail.

Scholars have noted that African Americans and Hispanics constitute a disproportionately large percentage of the prison population, compared to their general population rates.²⁸⁸ African Americans make up approximately half of the United States' 1.8 prison population, and Hispanics account for fifteen percent, while only twelve percent of the U.S. population is Black, and eleven percent is Hispanic.²⁸⁹ AIDS and other diseases also affect African Americans and Hispanics disproportionately.²⁹⁰ As of June 1994, fifty percent of all AIDS patients were Black or Hispanic.²⁹¹ By 1998 Blacks accounted for forty-nine percent of AIDS deaths, and eighteen percent of AIDS deaths were among Hispanics.²⁹² Black men have a higher risk of cancer and cirrhosis of the liver than non-African American men, and Hispanics report higher rates of heart disease, cancer, and chronic liver disease than do non-Hispanics.²⁹³

No constitutional claim can be based on these statistics. The Constitution prohibits only purposeful discrimination, and facially neutral governmental actions cannot be constitutionally challenged using a disparate impact theory.²⁹⁴ Nevertheless, the fact that minorities are disproportionately affected by both imprisonment and particular diseases, provides a compelling reason for the inclusion of inmates in clinical studies, as will be discussed in Part V.A below.

2. *The Right to Privacy.*—The constitutional right to privacy is somewhat amorphous and may be rooted in a variety of provisions.²⁹⁵ The right to privacy has been described most often as stemming from the Fourteenth Amendment's concept of personal liberty.²⁹⁶ It may also be found in the Ninth Amendment's reservation of rights to the people.²⁹⁷ In *Griswold v. Connecticut*,²⁹⁸ the Supreme Court determined that "the First Amendment has a penumbra where privacy is protected from governmental intrusion."²⁹⁹ The right to privacy also includes the right to be free from governmental surveillance and intrusion in one's private affairs, which stems from the Fourth Amendment.³⁰⁰

288. See Kelly, *supra* note 131, at 51.

289. See Michael A. Fletcher, *The Crime Conundrum; Policing Is Tougher, Jails Fuller, and Crime Is at a 30-Year Low*, WASH. POST, Jan. 16, 2000, at F1; Shapiro, *supra* note 16, at 2A.

290. See Fletcher, *supra* note 289, at F1; Shapiro, *supra* note 16, at 2A.

291. See Fletcher, *supra* note 289, at F1; Shapiro, *supra* note 16, at 2A.

292. See Karen Gullo, *Clinton to Seek AIDS Funds*, AP ONLINE, Jan. 18, 2000 (citing CDC figures).

293. See Marquart et al., *supra* note 208, at 188.

294. See *Washington v. Davis*, 426 U.S. 229 (1976).

295. See *Whalen v. Roe*, 429 U.S. 589, 598-99 nn.23-25 (1977).

296. See *id.* n.23 (citing *Roe v. Wade*, 410 U.S. 110, 153 (1973)).

297. See *id.*

298. 381 U.S. 479 (1965).

299. *Id.* at 483.

300. See *Whalen*, 429 U.S. at 599 n.25.

The right to privacy generally encompasses the right to maintain confidentiality regarding medical information, and some courts have held that even prisoners enjoy this right, particularly with respect to HIV status.³⁰¹ Other courts have found, however, that inmates do not retain a constitutional right to the confidentiality of their medical records.³⁰² Prisoners do, nonetheless, have a restricted constitutional right to bodily privacy.³⁰³

The *Bailey*³⁰⁴ court only briefly addressed the privacy issue. It found the plaintiffs' privacy claims to be unfounded because the prisoners volunteered for the experimental procedures at issue and were not subjected to involuntary treatment as was the case in the precedents they cited.³⁰⁵ Likewise, under contemporary regulatory guidelines, prisoner enrollment cannot be coerced. Thus, it is highly unlikely that biomedical research will give rise to violation of constitutional privacy rights.

A related but different claim may arise from the Fourth Amendment, which establishes "[t]he right of the people to be secure . . . against unreasonable searches and seizures."³⁰⁶ Invasive medical procedures, such as blood tests, can constitute searches and seizures that impinge upon the constitutional rights of the patient, even in the prison context.³⁰⁷ The *Bailey* court did not address any potential search and seizure claims. Nevertheless, if bodily fluids are extracted from prisoners who have not provided informed consent, Fourth Amendment violations may arise. Clinical studies that comply with DHHS regulations requiring voluntariness and informed consent, however, should not infringe upon any participant's right to be free of unreasonable searches and seizures.

If prisoners provide genuine informed consent to biomedical experimentation, if the study is thoroughly reviewed by an IRB, and if the research conforms to the guidelines of federal regulations, then sufficient safeguards will be implemented to assure that the subjects' rights to bodily integrity and privacy will not be sacrificed. Nevertheless, a significant concern exists that adequate confidentiality regarding medical records may not be maintained in the prison setting. The DHHS regulations governing research involving inmates do not address the issue of confidentiality.³⁰⁸ As discussed below, precautions must be taken to assure confidentiality for inmate participants.

301. See, e.g., *Harris v. Thigpen*, 941 F.2d 1495, 1513 (11th Cir. 1991); *Clarkson v. Coughlin*, 898 F. Supp. 1019, 1041 (S.D.N.Y. 1995); *Nolley v. County of Erie*, 776 F. Supp. 715, 729-31 (W.D.N.Y. 1991).

302. See *Tokar v. Armontrout*, 97 F.3d 1078, 1084 (8th Cir. 1996); *Anderson v. Romero*, 72 F.3d 518, 524 (7th Cir. 1995).

303. See *Covino v. Patrissi*, 967 F.2d 73, 78 (2d Cir. 1992).

304. *Bailey v. Lally*, 481 F. Supp. 203 (D. Md. 1979).

305. See *id.* at 221.

306. U.S. CONST. amend. IV.

307. See *Stanley v. Swinson*, No. 93-16078, 1995 WL 46181, at *4 (9th Cir. Feb. 6, 1995); *Thompson v. City of Los Angeles*, 885 F.2d 1439, 1447 (9th Cir. 1989).

308. See discussion *supra* Part III.

Constitutional concerns do not justify the exclusion of prisoners from medical research. It is arguable that the Eighth and Fourteenth Amendments mandate the provision of life saving therapy to seriously ill prisoners even if the treatment is available only through a clinical trial. While inmate participation in clinical trials may be hampered by certain practical hurdles, these obstacles are not insurmountable, as demonstrated by several programs that successfully integrate prisoners into research protocols.³⁰⁹ The following section will discuss the experience of medical institutions that include prisoners in therapeutic clinical studies and will outline recommendations to facilitate the implementation of such programs.

V. POLICY ISSUES AND RECOMMENDATIONS

A. *Several Jurisdictions Recognize the Importance of Including Prisoners in Clinical Trials*

In July 1995 the New Jersey Community Research Initiative issued a report entitled *Prisoners with HIV: Guidelines for Implementing Clinical Trials in Correctional Settings*.³¹⁰ The report found that “[m]any leaders in medical ethics have concluded that the coercive nature of correctional settings should not prevent prisoners from participating in medically appropriate clinical studies.”³¹¹ It cited the findings of a 1989 consensus panel of leaders in corrections, prison health care, and public health that likewise found that “although a prison setting precludes the voluntary and uncoerced choice classically envisioned by the federal regulations, prisoners should be permitted to choose to participate in therapeutic trials . . . that hold out the possibility of benefit.”³¹² The report further noted that “public health officials, including the World Health Organization and the former National Commission on AIDS, have advocated prisoner access to clinical research.”³¹³

Including prisoners in biomedical studies is important for reasons that go beyond benefits to the subjects themselves. Traditionally, African Americans, Hispanics, intravenous drug users, and women have been underrepresented in clinical trials.³¹⁴ Two important studies in which AZT was tested were conducted with a population that was more than ninety-two percent White and male.³¹⁵ A 1991 report produced by the AIDS Clinical Trial Group concluded that African Americans made up only ten percent of participants in this national consortium of clinical trials, Hispanics twelve percent, and IV drug users and

309. See Kelly, *supra* note 131, at 60.

310. STEIN & HEADLEY, *supra* note 152.

311. *Id.* at 3.

312. *Id.*

313. *Id.*

314. See Kelly, *supra* note 131, at 51.

315. See *id.*

women accounted for eleven percent and six percent, respectively.³¹⁶

Researchers have found that members of different races at times respond to treatments in different ways.³¹⁷ Whites and Blacks, for example, respond differently to hypertensive therapy.³¹⁸ Women may respond differently from men because of variations in size, body fat, and hormonal levels.³¹⁹ Similarly, the efficacy of drugs may be significantly affected by other drugs, including illegal substances taken by the patient.³²⁰ Exclusion of minority subjects from drug studies is thus "bad science" and will adversely impact both the researcher and future patients.³²¹ The prison environment provides a diverse population, with a high concentration of minorities. Allowing prisoners to participate in therapeutic clinical studies will benefit not only the inmate patients, but also the medical community and society at large.

Research institutions in several states have succeeded in integrating prisoners into clinical trials. In Texas, Virginia, and New York research entities provided standard medical care to prisoners before establishing programs that included inmates in clinical studies.³²² In Texas, the University of Texas Medical Branch at Galveston ("UTMB") has served as the primary prison hospital for the Texas Department of Criminal Justice ("TDCJ") since 1983.³²³ It is staffed by security personnel who report to TDCJ and health care professionals who answer to the University.³²⁴ For many years, Texas inmates have been enrolled in clinical trials involving protocols that may be of direct benefit to them.³²⁵ Historically, the majority of the studies at UTMB in which prisoners have been included have been cancer-related, but an increasing number in recent years have focused on AIDS treatment.³²⁶

In New York City, the Spellman Center for HIV-Related Disease at St. Clare's Hospital has provided care to many HIV-infected New York inmates and involved prisoners in clinical trials for several years beginning in 1986.³²⁷ In Albany, New York, Albany Medical College provides hospital care for prisoners in twenty-five correctional facilities.³²⁸ The facility began enrolling prisoners in AIDS-related trials in 1988 and included inmates in oncologic clinical trials in

316. *See id.* at 52.

317. *See id.*

318. *See id.*

319. *See id.*

320. *See id.*

321. *See id.*

322. *See id.* at 60.

323. *See id.*

324. *See id.*

325. *See id.*

326. *See id.* As of 1992, over 500 TDCJ inmates had participated in clinical trials at UTMB.

See id.

327. *See id.*

328. *See id.*

prior years.³²⁹ The Division of Infectious Diseases at the Medical College of Virginia has served the Virginia state prison population since 1985 and has enrolled prisoners in clinical trials since 1990.³³⁰

Not all research institutions that include inmates in medical studies provide healthcare services to prisoners outside of clinical trials.³³¹ Johns Hopkins University in Maryland has established several AIDS-related clinical trials in Maryland prisons since 1991, although it is not otherwise a provider of treatment for Maryland prisoners.³³² In Colorado, the Department of Health has also allowed prisoner participation in AIDS-related trials.³³³ Likewise, Yale University Medical School has worked with prisoners in medical research studies.³³⁴

B. The Challenges of Prisoner Involvement in Clinical Trials

The commentators who advocate the inclusion of prisoners in clinical studies recognize the existence of certain obstacles inherent to the prison setting.³³⁵ Nevertheless, the obstacles are not insurmountable, as evidenced by the fact that research is successfully conducted by some institutions, as discussed above.

1. *Confidentiality*.—Prisoners participating in AIDS-related clinical trials risk disclosure of their HIV status either because it is obvious that they are receiving frequent and specialized medical care or because of the prison's record-keeping policies.³³⁶ Disclosure of HIV status may be particularly dangerous for inmates because of the risk that other prisoners or correctional officers will subject the patient to persecution and violence.³³⁷

The Forum on Prisoner Access to Clinical Trials in New Jersey acknowledged that maintaining fully effective confidentiality in the prison setting is nearly impossible.³³⁸ However, it suggested several alternatives to safeguard the privacy of research participants. Although it is not clear that prisoners retain a right to confidentiality regarding HIV status,³³⁹ every effort should be made to prevent disclosure of inmates' receipt of HIV-related experimental therapy. Such precautions will safeguard the prisoners' constitutional rights to the extent they exist, will encourage inmates to participate in clinical trials, and will reduce prisoner grievances and litigation regarding confidentiality matters. Where the research institution provides routine medical care to inmates and frequently sends

329. *See id.* at 60-61.

330. *See id.* at 61.

331. *See id.*

332. *See id.*

333. *See id.*

334. *See* STEIN & HEADLEY, *supra* note 152, at 7.

335. *See* Kelly, *supra* note 131, at 61-64; STEIN & HEADLEY, *supra* note 152, at 23-26.

336. *See* Kelly, *supra* note 131, at 63-64.

337. *See id.* at 64.

338. *See* STEIN & HEADLEY, *supra* note 152, at 23.

339. *See* discussion *supra* Part IV.B.2.

staff to the correctional facility, it is easiest to maintain confidentiality for clinical trial enrollees. Inmates should be allowed to communicate directly with investigators about clinical trials without having to request permission from prison officials.³⁴⁰ Investigators could publicize the research through newsletters or postings that are seen by all inmates. Enrollment could then occur during a routine medical visit by the institution's staff rather than on a day specifically designated for discussion of the AIDS-related study.³⁴¹

Moreover, the Forum on Prisoner Access to Clinical Trials recommends that medical records that contain information about HIV status be maintained in secured areas that can be accessed only by medical personnel directly responsible for the inmate's treatment.³⁴² Correctional officers and other inmates should not have access to sensitive medical records even if they are assigned to work in the prison's medical department.³⁴³

Finally, the Forum suggests that prisoners also have confidential access to investigators in the event that they suffer adverse side effects from investigational drugs.³⁴⁴ Prisoners involved in clinical trials should be allowed to place collect calls to designated medical personnel or to an answering service twenty-four hours a day.³⁴⁵ In Maryland, investigators are available by beeper around the clock.³⁴⁶ Where telephone usage by prisoners is restricted, however, inmates may be limited to reaching research staff through prison medical personnel and thus may be forced to disclose confidential information to correctional officials.³⁴⁷

2. *Logistics and Communication.*—Transportation issues may constitute another hurdle to prisoner participation in biomedical research.³⁴⁸ Where studies are conducted in correctional facilities, researchers must travel to prison clinics, bringing with them all necessary medical equipment and carrying out of the prison bodily fluid samples for testing.³⁴⁹ They must also undergo time-consuming security checks each time they arrive at the prison.³⁵⁰ Where clinical trials are conducted on hospital grounds, prisoners must be transported under guard to and from the hospital. Significant delays are often caused by prison lockdowns, inmate counts, and other security precautions.³⁵¹

Restrictions on items that can be possessed by prisoners may also be problematic for clinical research purposes. Since bottles and pills are contraband

340. See STEIN & HEADLEY, *supra* note 152, at 24.

341. See *id.*

342. See *id.* at 25.

343. See *id.*

344. See *id.* at 26.

345. See *id.*

346. See *id.*

347. See *id.*

348. See Kelly, *supra* note 131, at 62.

349. See *id.*

350. See *id.*

351. See *id.*

in most prisons, procedures must be implemented to allow prisoners to keep experimental drugs with them or to have them administered in a manner that maintains confidentiality.³⁵² In some New Jersey jails prisoners have a self-dosing system for their prescription medications that features locked boxes.³⁵³ A similar mechanism could be implemented in other prisons, though correctional officers would have to be educated to maintain confidentiality regarding the nature of prisoners' medications and any modifications of general prison policies that apply to clinical trial participants.³⁵⁴

Another problem may arise in instances where prisoners are transferred from one facility to another.³⁵⁵ Inmates should be able to continue receiving the experimental treatment at the new facility.³⁵⁶ A "medical hold" could be placed on trial participants designated for relocation so that the central administration, in consultation with medical investigators, may evaluate whether the transfer will cause any adverse consequences to the patient or the research study.³⁵⁷ Thus, prison administrators will avoid potential violation of the inmates' Eighth Amendment right to adequate medical care and will not jeopardize the prisoners' health by sudden and unmonitored discontinuation of experimental treatment.

Similarly, continuity of care should be assured for prisoners who are paroled or released.³⁵⁸ In Maryland, a research nurse meets with the prisoner prior to release and encourages the individual to continue trial participation once released.³⁵⁹ Researchers should offer former prisoners assistance with transportation to and from the research site and work with parole officers to assure appropriate sustained treatment.³⁶⁰

A recent statement issued by the Office of the Inspector General of the U.S. Department of Health and Human Services is highly critical of the institutional review board system.³⁶¹ It noted that a "1995 Advisory Commission on Human Radiation Experiments found in their interviews with actual research subjects that few realized they were participants in research and many had little understanding of the informed consent forms they signed."³⁶² The statement further denounced the limited continuing review conducted by most IRBs that, burdened by ever-increasing workloads, do no more than review paperwork submitted by research investigators and fail to solicit feedback from research

352. See STEIN & HEADLEY, *supra* note 152, at 26.

353. See *id.*

354. See *id.*

355. See *id.* at 35.

356. See *id.*

357. See *id.*

358. See *id.* at 36; Kelly, *supra* note 131, at 63.

359. See STEIN & HEADLEY, *supra* note 152, at 36.

360. See Kelly, *supra* note 131, at 63.

361. See JUNE GIBBS BROWN, OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM (1998).

362. *Id.* at 6.

subjects.³⁶³ The Office of the Inspector General also urged research institutions to provide adequate education for IRB members concerning ethical issues and scientific questions and noted that currently IRB training is minimal to nonexistent.³⁶⁴

As discussed throughout this Article, IRBs approving clinical trials involving prisoners must meet stringent requirements that are inapplicable to reviews of other studies. The IRB must include a prisoner advocate, review the proposed study in light of guidelines specific to the prison setting, and provide prisoners with data presented in language that they can understand.³⁶⁵ IRBs are therefore likely to review protocols involving prisoners more meticulously than they might review other research proposals. Nevertheless, the comments of the Office of Inspector General are prudent admonitions for anyone reviewing research protocols designed to include prisoner participants. IRBs should be well versed in the ethical dilemmas that are potentially involved in prisoner research, must ensure that meaningful informed consent is obtained, and should conduct thorough and conscientious continuing reviews of the clinical trials in question.

CONCLUSION

Although federal regulations permit the inclusion of prisoners in therapeutic clinical trials from which they may gain direct treatment benefits, prisoners are able to enroll in clinical trials in only a few locations.³⁶⁶ Although perhaps well-intentioned, policies that ban the inclusion of inmates in biomedical studies are detrimental to prisoners, to science, and to society at large because they preclude research utilizing a particularly diverse and disadvantaged segment of society. In the words of Justice Brandeis:

Experience should teach us to be most on our guard to protect liberty when the Government's purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding.³⁶⁷

Clinical trials that comply with federal regulations will not violate any of the participants' constitutional rights. In *Bailey v. Lally*,³⁶⁸ the court found no constitutional violations despite extremely harsh prison conditions that often motivated prisoner participation in research studies that were nontherapeutic and had not been scrutinized by a reviewing entity such as an IRB.³⁶⁹ In light of

363. *See id.* The authors found an average increase in initial reviews of 42% over five years at the sites they visited. Some IRBs currently review more than 2000 protocols a year. *See id.*

364. *See id.* at 11-12.

365. *See* 45 C.F.R. §§ 46.304-46.306 (1998).

366. *See* Kelly, *supra* note 131, at 58.

367. *Olmstead v. United States*, 277 U.S. 438, 479 (1928) (Brandeis, J., dissenting).

368. 481 F. Supp. 203 (D. Md. 1979).

369. *See id.*

contemporary regulations, it is difficult to imagine that any subsequent court would deem voluntary participation in therapeutic studies to impinge upon the constitutional rights of an enrollee.

The exclusion of seriously ill prisoners from clinical trials through which they may receive potentially life-saving treatment is constitutionally dubious and morally troubling. It is arguable that prisoners have a right to participation under the Eighth Amendment, the Due Process clause, and the promise of Equal Protection. In addition, moral considerations impel the allowance of prisoner enrollment in therapeutic biomedical research. Two commentators have summarized the arguments well:

Inmates as a group . . . need to be provided with access to clinical trials of new and innovative therapies that present the possibility of direct benefit. . . . They must be presented with the opportunity for informed choice when appropriate, despite recognition that the systematic deprivations and inherent coerciveness of the institutions and the desperate character of HIV infection compromise the consent process. As in other areas of public policy and public health, HIV infection demands a fresh examination of equity and justice. Whether access is provided to promising investigational therapies will measure the mettle, courage, inventiveness, and flexibility of the medical research community. It will also test the humanity of correctional administrators, who must provide the setting and support services to permit the conduct and monitoring of clinical trials.³⁷⁰

Policy makers, legislators, and prison authorities must meet the challenge of providing appropriate treatment for seriously ill prisoners, including that which is available through experimental protocols. To fail to do so would defy the "broad and idealistic concepts of dignity, civilized standards, humanity, and decency"³⁷¹ embodied in the Constitution and in American jurisprudence.

370. STEIN & HEADLEY, *supra* note 152, at 38 (quoting Nancy Neveloff Dubler & Victor W. Sidel, *On Research on HIV Infection*, JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES 174, 204 (1994)).

371. Jackson v. Bishop, 404 F.2d 571, 579 (8th Cir. 1968).

