

Experimentation on Prisoners: Persistent Dilemmas in Rights and Regulations

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INTRODUCTION

Between 1965 and 1966, Dr. Albert M. Kligman exposed approximately seventy-five prisoners at Holmesburg prison in Pennsylvania to high doses of dioxin, the main poisonous ingredient in Agent Orange.¹ Dow Chemical paid Dr. Kligman \$10,000 to conduct the experiments on the toxicity effects of this Vietnam War-era chemical warfare agent. Dr. Kligman exposed prisoners to a dosage 468 times greater than that in the Dow Chemical protocol for the experiments.² Records from the experiments have been destroyed, and the Environmental Protection Agency's 1981 investigation into the matter failed to identify the exact participants, rendering the long-term effects of the exposure untraceable.³ Nonetheless, prisoners who participated in dermatological experiments under Dr. Kligman's hand in 1965 and 1966 report that they still experience scars, blisters, cysts, and ongoing rashes.⁴ Indeed, at least two prisoners filed lawsuits against Dow Chemical in the 1980s for the exposure they suffered in the 1960s; both settled their claims for undisclosed sums.⁵ Dr. Kligman is perhaps better known for developing the skin treatment Retin-A, at

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1. See ALLEN M. HORNBLUM, *ACRES OF SKIN*, 163-83 (1998) (chronicling the story of Dr. Kligman's dioxin experiments at Holmesburg prison).

2. *Id.* at 169.

3. William Robbins, *Dioxin Tests Conducted in 60's on 70 Philadelphia Inmates, Now Unknown*, N.Y. TIMES, July 17, 1983, at A16.

4. HORNBLUM, *supra* note 1, at 181.

5. *Id.*

least partially on the basis of experiments he conducted on prisoners at Holmesburg prison.⁶ The story of Dr. Kligman's experiments was fully explored in 1998 in a book entitled *Acres of Skin*; the title is based on a quotation from Dr. Kligman himself, who recalled visiting Holmesburg prison for the first time and seeing "acres of skin" on which he could experiment.⁷

In response to experiments conducted in prisons across the United States, under the supervision of doctors such as Dr. Kligman and sponsored by drug companies such as Dow Chemical, the United States Department of Health, Education, and Welfare released a report in 1976 condemning the use of prisoners in human subjects research.⁸ This report (1976 DHEW Report) inspired the federal government to pass strict regulations limiting prisoner experimentation to narrow categories of non-intrusive, low-risk, individually beneficial research.⁹ Congress passed these regulations, codified at Title 45 of the Code of Federal Regulations, in 1978, a scant two years after the release of the DHEW Report.¹⁰ Following the 1976 DHEW Report's release and the codification of its recommendations into Title 45, Upjohn and Parke Davis, two of the largest drug companies in the United States, closed their Phase I drug-testing facilities in Michigan state prisons.¹¹ Simultaneously, state prison systems forced doctors like Dr. Kligman to stop their research programs in the prisons.¹²

But medical experimentation on prisoners was far from over. Forty years after Dr. Kligman conducted his dioxin experiments, and thirty years after the implementation of strict federal regulations virtually banning the use of prisoners in medical experiments, prisoner subjects continue to be used in medical experiments. For instance, between 2006 and 2008, a drug company called Hythian contracted with jurisdictions in at least five different states including Indiana, Washington, Texas, Louisiana, and Georgia to enroll criminal defendants in an experimental drug addiction treatment program.¹³ As part of this program, state judges "divert" drug court participants, who have been found in possession of drugs, into an experimental treatment program

6. *Id.* at 211-31 (documenting how "Retin-A's Birthplace was at Holmesburg Prison").

7. *Id.* at 37.

8. Protection of Human Subjects, 42 Fed. Reg. 3076-91 (DHEW Jan. 14, 1977) (to be codified at 45 C.F.R. pt. 46), *available at* <http://www.hhs.gov/ohrp/documents/19770114.pdf> [hereinafter 1976 DHEW Report].

9. 45 C.F.R. § 46.306(a)(2)(i)-(iv) (2007) (describing the four categories of research in which prisoners might permissibly be included: (1) research about the effects of incarceration, (2) research about prisons as institutions, (3) research about conditions particularly affecting prisoners, and (4) research about practices expected to improve the health of individual subjects).

10. *See* 45 C.F.R. §§ 46.301-.306 (2007).

11. *See infra* notes 61-76 and surrounding text.

12. HORNBLUM, *supra* note 1, at 187.

13. *See* Gregory Dober, *Junk Bonds to Junk Science? Drug Treatment Program Questioned*, PRISON LEGAL NEWS, March 2008, *available at* <http://breakallchains.blogspot.com/2008/04/junk-bonds-to-junk-science-drug.html>.

called Prometa. Hythian runs the Prometa program at a cost of \$15,000 per participant. The program involves thirty days of treatment with three different drugs, none of which has been approved for use in addiction treatment by the Food and Drug Administration (FDA).¹⁴ At least one Collin County, Texas, participant in the Prometa program died; the court recorded the death as a suicide.¹⁵ Unlike Dr. Kligman's experiments, the Prometa program has not yet inspired an investigative journalism project. No participants have been publicly interviewed, and no federal agency has investigated the effects of the program.

Taken together, the stories of Dr. Kligman's dioxin experiments and Hythian's drug-addiction treatment trials, occurring over the span of forty years, reveal a number of critical facts about the use of prisoners for medical experimentation in the United States. First, a wide variety of research has been—and continues to be—conducted on prisoner subjects in the United States; universities, the federal government, and private drug companies alike have sponsored such research.¹⁶ Second, this research takes place behind prison walls, inside non-traditional confinement facilities like drug addiction treatment centers, governed by private contracts, and often beyond the reach of public regulation. And, finally, this research evades restrictions.

Each of these facts—the continued participation of prisoners in experimental protocols despite federal regulations forbidding such participation, the lack of transparency in this research and the associated difficulty of oversight, and the particular resistance of private drug company researchers to regulation—motivated the recommendations in a recent federal report entitled *Ethical Considerations for Research Involving Prisoners* (2006 IOM Report). In 2006, the Department of Health and Human Services (DHHS), which is responsible for enforcing the federal human subjects research regulations implemented in the 1970s, commissioned the Institute of Medicine (IOM) to reevaluate the federal standards governing medical experimentation on prisoners.¹⁷

The 2006 IOM Report calls for significant changes in the ethical standards

14. See LAWRENCE M. WEINSTEIN ET AL., SCIENTIFIC BASIS OF THE PROMETA TREATMENT PROGRAM 1 (2007), available at <http://www.prometainfo.com/site/special/A8x1513x8x1.pdf>.

15. Dober, *supra* note 13.

16. As the Prometa drug-treatment studies described above suggest, private drug companies continue signing contracts to use criminal defendants and prisoners as subjects in experimental addiction treatment drug trials. As recently as 2007, determination letters from the Department of Health and Human Services cited violations of the federal regulations prohibiting experimentation in prisons. These letters suggest that medical experiments in prisons have taken place at least since 2000 and may have been ongoing for the past thirty years. See *infra* note 151 and surrounding text.

17. The Institute of Medicine, "chartered in 1970 as a component of the National Academy of Sciences," is a nonprofit organization that works to "ensure scientifically informed analysis and independent guidance" and "to serve as adviser to the nation to improve health." Inst. of Med. of the Nat'l Acads., About, <http://www.iom.edu/CMS/AboutIOM.aspx> (last visited Oct. 14, 2008).

governing medical experiments on prisoners.¹⁸ Of the many recommendations in the 265-page report, two are critical. First, the Report recommends streamlining and expanding oversight of prisoner experimentation.¹⁹ Second, the Report recommends replacing the current categorical limitations on prisoner experimentation codified at Title 45 with case-by-case risk-benefit analyses of individual experiments.²⁰ This Comment argues that the first category of recommendations—increasing oversight of experimentation on prisoner subjects—is absolutely necessary. However, the second category of recommendations—implementing cost-benefit analyses—should not be implemented.

According to a staff member at the Office for Human Research Protections (the division of the DHHS that regulates federally-funded human subjects research), Congress might consider and adopt the new standards suggested by the IOM at any time.²¹ However, the process requires legislative initiative and a public comment period, so any change will likely be slow. In the interim, the DHHS can and should take steps to implement some aspects of the 2006 Report, while encouraging further research on the more controversial recommendations. For instance, Report recommendations calling for more rigorous oversight, expanding definitions of who is a prisoner, and encouraging enhanced transparency around human subjects research on prisoners should be implemented immediately.²² Specifically, the DHHS should alter its recommendations to incorporate as broad a definition of prisoner as possible and should initiate “a publicly available, national registry of research involving prisoners.”²³ Additionally, Congress should legislate expanded regulatory authority for the DHHS and other federal agencies.

On the other hand, those regulations that suggest replacing the categorical limitations on prisoner experimentation with case-by-case risk-benefit analyses of individual experimental protocols should *not* be implemented. Before Congress considers any such regulatory change, additional research in two areas should be conducted. First, further research is needed to determine the prevalence and scope of current prisoner subjects experimentation. (Of course, implementing the 2006 IOM Report recommendations for increased oversight

18. INST. OF MED. OF THE NAT'L ACADS., *ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS* (2007) [hereinafter 2006 IOM Report].

19. *Id.* at 6-7.

20. *Id.* at 8-10.

21. An Office for Human Research Protections staff member said that changes to the regulations will “literally require[] a Congressional Act.” In the interim, the office has “written some new guidance documents to help clarify the office’s position,” and “will continue to work through to get new regulations written.” Telephone Interview with Lynda Lahl, Education/Quality Improvement staff, Office for Human Research Protections, in Rockville, Md. (April 24, 2008).

22. For instance, recommendations 2.1, 3.1, and 6.7, noted in the Summary of the Report, in a section describing those recommendations that “Ensure Universal, Consistent Ethical Protections,” should be implemented immediately. 2006 IOM Report, *supra* note 18, at 6-7.

23. *Id.* at 7.

mechanisms would be a first step toward achieving this preliminary research goal.) Second, further research is needed to explore the relationship between current U.S. prison conditions and prisoners' abilities to provide informed consent, participate in experimentation, and challenge inhumane practices. Detrimental prison conditions, from overcrowding to constitutionally inadequate healthcare, to provide just two examples, may both compromise prisoners' abilities to protect themselves from medical experiments gone-wrong and also compromise the enforcement of current and potential regulations.²⁴ A supplemental IOM report, a Congressional mandate, or further DHHS initiatives could facilitate pursuit of this twofold research agenda.

The public response to the 2006 IOM Report has been limited. A few national newspapers ran short editorials responding to the Report's recommendations immediately after its release.²⁵ Only three scholarly articles have addressed the recommendations in the Report: one of these articles provides a simple summary of the regulations authored by the Chair of the 2006 Report Committee; another article focuses on the ethics of consent; a third uses hypothetical case studies to argue in support of the Report's recommendations.²⁶ In sum, scholarly analysis of the Report's recommendations, to date, as well as public debate over the pros and cons of the recommendations, has been limited. This Comment represents the first critical analysis of the recent recommendations on prisoner experimentation, situated in the particular context of the history of continuous medical experimentation in U.S. prisons in the twentieth and twenty-first centuries, including new investigative research on current practices. Furthermore, this Comment draws on analyses of international law and domestic court cases to suggest that both current U.S. regulations and the changes proposed in the 2006

24. The detrimental prison conditions in U.S. prisons currently are described in Part I.B.2 on "Human Sardines," below.

25. A small flurry of articles challenging the Report recommendations and threatening a return to the horrors inflicted by Nazi doctors in concentration camps and by United States Public Health Service doctors during the Tuskegee syphilis experiments greeted the release of the 2006 IOM Report. See, e.g., Allen M. Hornblum & Osagie K. Obasogie, "Medical Exploitation: Inmates Must Not Become Guinea Pigs Again," *PHILA. INQUIRER*, Sept. 13, 2007; Ian Urbina, "Panel Suggests Using Inmates In Drug Trials," *N.Y. TIMES*, Aug. 13, 2006, at 1; see also Osagie K. Obasogie, "Prisoners and Clinical Trials: Cruel and Unusual Ethics?" *GENETIC CROSSROADS*, June 29, 2007, available at <http://geneticsandsociety.org/article.php?id=3203>.

26. See Lawrence O. Gostin (Chair of the Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research), *Biomedical Research Involving Prisoners: Ethical Values and Legal Regulation*, 297 *JAMA* 737 (2007) (summarizing the recommendations in the 2006 IOM Report); Andrea Lynn Osganian, Note, *Limitations on Biomedical and Behavioral Research Involving Prisoners: An Argument Supporting the Institute of Medicine's Recommendations to Revise Regulations*, 34 *NEW ENG. J. ON CRIM. & CIV. CONFINEMENT* 429 (2008) (addressing the hypothetical effects on prisoners and society of implementing the regulations); Rachel Wener, Comment, *Not Situated to Exercise Free Power of Choice: Human Subject Research in Prison Settings*, 26 *TEMP. J. SCI. TECH. & ENVTL. L.* 365 (2007) (analyzing how the 2006 IOM Report recommendations interact with common law understandings of consent).

IOM Report provide inadequate legal protections for prisoner subjects of experimentation.

Part I reviews the history of medical experimentation in U.S. prisons to date, both before and after the first set of federal regulations on prisoner experimentation took effect in 1976. This history reveals both the risks of allowing medical experimentation without implementation of rigid safeguards and the limitations of existing safeguards. Indeed, investigative research reveals that medical experimentation currently occurs in prisons across the United States in spite of federal regulations attempting to curtail such practices. Part II compares the 1976 DHEW Report to the 2006 IOM Report, exploring each Report's different recommendations and analyzing the potential effects of these differences. Part III catalogues the applicable standards—international and domestic, legal and medical—that currently govern medical experimentation on prisoners. This analysis reveals current protections for U.S. prisoners of experimentation to be inadequate, both in comparison to international standards and in the face of strict federal limitations on the rights of prisoners to challenge conditions of confinement and healthcare inadequacies. Part IV suggests how the federal government should regulate research in prisons in the future.

In the Conclusion, this Comment returns to its central analysis of the 2006 IOM Report. Congress and the DHHS should implement regulatory changes that streamline and expand oversight of experiments that involve prisoner subjects. However, neither Congress nor the DHHS should implement a risk-benefit analysis to evaluate research proposals on prisoners. Implementing a risk-benefit analysis standard of review requires two preconditions. First, minimum human rights standards must exist in U.S. prisons and be incorporated into standards of review. Otherwise, a risk-benefit approach cannot feasibly and accurately determine the risks or the benefits of any individual prisoner's participation in medical experimentation. Second, any risk-benefit analysis must focus solely on the risks and benefits to the individual prisoner participant, and not on any potential benefit to general scientific knowledge or society-at-large. Until these two conditions are met, regulatory agencies should seek to curtail severely, rather than to expand, human subjects research on prisoners. In sum, while many of the suggestions in the 2006 IOM Report make sense in isolation, as a whole they add up to an idealistic and infeasible vision of the controls that regulators might exert over future research conducted on prisoners.

I

CONTEXT: WHY CHANGE REGULATIONS GOVERNING PRISONER EXPERIMENTATION?

While "human subjects research" is a modern term, human beings have been used in experiments throughout the world since at least the ancient

times.²⁷ In the United States, biomedical research “unrelated to the health or well-being” of prisoners took place at least as early as 1934, when a program at Leavenworth Prison in Kansas evaluated the effects of narcotic analgesics on prisoners.²⁸ In fact, the popularity of human subjects experimentation, especially on prisoners, has waned only in the last thirty years.

A series of public revelations about the human rights abuses perpetuated in the name of science on prisoners and other vulnerable populations precipitated the decline in popularity of human subjects experimentation. First, the Nuremberg Trials in the late 1940s revealed the brutality of Nazi concentration camp medical experiments. Closer to home, the U.S. government’s experiments on prisoners and similarly vulnerable populations came under scrutiny. For instance, revelations about the Heller Experiments, which the U.S. government funded between 1963 and 1973, to examine the effects of radiation on the testes of Oregon prisoners, shocked the nation.²⁹ Similarly, revelations that, from 1932 through 1972, U.S. government officials supervised the Tuskegee syphilis experiments, which evaluated the long-term effects of untreated syphilis in African American men, drew public ire.³⁰

The history of experimentation in prisons and on other vulnerable populations reveals the extreme risks of using these kinds of vulnerable subjects in either state-sanctioned or private medical experiments, especially without clear and enforceable regulations. In 1978, Congress acted on the public outrage over such abuses, passing an act for the “Protection of Human Subjects.”³¹ This act, codified at Title 45, regulates all categories of human

27. Ancient Persian and Roman authorities used prisoners as research subjects. Similarly, eighteenth-century European physicians used prisoners in infectious disease studies, deliberately infecting them with everything from cancer to typhoid. Sharon Hoffman, *Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials*, 33 *IND. L. REV.* 475, 482 (2000) (citing 4 *ENCYCLOPEDIA OF BIOETHICS* 2056 (Warren T. Reich ed., rev. ed. 1995)). In the nineteenth-century United States, doctors, with the permission of slave owners, subjected enslaved people in Alabama and Georgia to medical experimentation. See Barbara L. Bernier, *Class, Race, and Poverty: Medical Technologies and Socio-Political Choices*, 11 *HARV. BLACKLETTER L.J.* 115, 118-20 (1994). For instance, one doctor experimented on slave women suffering from vesico-vaginal fistulas by conducting multiple surgeries without anesthetics to find the most effective “treatment.” Similarly, a Georgia doctor experimented with the effects and remedies of sunstroke by placing a slave into an “open-pit” oven. *Id.* at 118-20 (citing Diana E. Axelsen, *Women as Victims of Medical Experimentation: J Marion Sims’ Surgery on Slave Women, 1845-59*, 2 *SAGE* 10 (1985); TODD L. SAVITT, *MEDICINE AND SLAVERY: THE DISEASES AND HEALTH CARE OF BLACKS IN ANTEBELLUM VIRGINIA* 280 (1978)).

28. 1976 DHEW Report, *supra* note 8, at 3081.

29. See *Bibeau v. Pac. Nw. Research Found.*, 980 F. Supp. 349, 351-52 (D. Or. 1997).

30. See JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* (2d ed. 1993). Note that although the Tuskegee subjects were *not* prisoners, they did constitute a vulnerable population: poor, illiterate, African-American sharecroppers in the South prior to the civil rights movement. The Tuskegee study, like many medical experiments involving prisoner subjects, suffered from a lack of transparency, an absence of a therapeutic aim, and a significant knowledge and power imbalance between the subjects and the experimenters, all of which created serious questions regarding consent.

31. See 45 C.F.R. §§ 46.101-.409 (2007).

subjects research, including research on three specific categories of vulnerable populations: children, pregnant women, and prisoners.³²

The contrast between the widespread use of prisoners in medical experiments prior to 1978 and the terms of the regulations strictly limiting the use of prisoners in medical experiments after 1978 suggests an ethical dilemma: should prisoners be permitted to participate in medical experimentation, and under what conditions? In the 1950s, society and the prisoners themselves expressed gratitude for the benefits of prisoner participation in medical experimentation. Indeed, in the 1940s and 1950s, doctors and prison officials considered such participation in experiments a “privilege” for prisoners; the American Medical Association actually discouraged participation of less worthy prisoners, defined as prisoners convicted of “particularly serious crimes.”³³

During the Nuremberg Trials in the late 1940s, however, Nazi doctors defended themselves against charges of atrocities committed in the name of medical science with evidence of the medical experimentation taking place in American prisons.³⁴ At that point, not surprisingly, prisoner experimentation came under fire worldwide.³⁵ But proponents still justified medical experimentation on prisoners as a socially beneficial practice through the early 1970s.³⁶ Meanwhile, though, critics spoke out against this “social benefit” idea, suggesting that such justifications were actually an unethical manipulation of the prisoner’s desire to contribute to the social good, particularly where the experiments provided no conceivable benefit to the prisoner participant.³⁷

32. See *id.* §§ 46.401-409 (“Additional Protections for Children Involved as Subjects in Research”); *id.* §§ 46.201-207 (“Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research”); *id.* §§ 46.301-306 (“Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects”).

33. 1976 DHEW Report, *supra* note 8, at 3081; see also HORNBLUM, *supra* note 1, at 78-79 (documenting wartime prison medical experiments).

34. An article in the *Austin American-Statesman* noted that the Nazi doctors were referring specifically to two American medical experiments conducted in the first decades of the twentieth century: the infection of prisoners in the Philippines with a “defective cholera vaccine” that resulted in thirteen deaths in 1906, and testicular transplants—implanting the testicular glands of “boars, rams and goats”—inflicted on at least 500 prisoners at California’s San Quentin State Prison between 1919 and 1922. Mike Ward & Bill Bishop, *Becoming Guinea Pigs to Avoid Poor Prison Care: Ill Inmates Urge Each Other to Join Experiments*, AUSTIN AM.-STATSMAN, Dec. 17, 2001, at A1.

35. HORNBLUM, *supra* note 1, at 75.

36. See *infra* notes 82-83 and surrounding text.

37. In particular, Jessica Mitford fueled this perspective by writing about behavioral modification and medical experiments gone wrong in her 1973 book, *Kind and Usual Punishment*. See 1976 DHEW Report, *supra* note 8, at 3077-78 (referencing the influence of JESSICA MITFORD, *KIND AND USUAL PUNISHMENT* (Vintage Books 1974) (1973) [hereinafter MITFORD, *KIND AND USUAL PUNISHMENT*]). Jessica Mitford was a well-known investigative journalist who published a number of exposés about American institutions. The first, about the American funeral industry, was called *The American Way of Death* and was first published in 1963. See JESSICA MITFORD, *THE AMERICAN WAY OF DEATH* (1963).

The 2006 IOM Report recommendations suggest that current opinion once again favors at least some experimentation on prisoners as potentially beneficial. The remainder of Part I reviews the history of the pendulum swing in opinion between all-benefit and all-detriment perspectives on prisoner experimentation. Part A below reviews the pre-1976 history of experimentation on prisoners. Rampant pre-1976 abuses of vulnerable population participants in medical research convinced courts, researchers, some prisoners, and federal policy makers alike that medical experimentation on prisoners, particularly unregulated experimentation, was almost universally detrimental. Hence, Congress sought to eliminate the vast majority of this experimentation through the passage of the strict human subjects regulations codified at Title 45. Part B below reviews the limited information available about experimentation on prisoners between 1976 and 2008, describes what little is known about the benefits and detriments of this experimentation, and evaluates the post-1976 implementation and effectiveness of the Title 45 regulations governing experimentation on prisoners. Part B also provides an overview of relevant prison conditions in 2008.

A. Human Subjects Research in Prisons Prior to 1976

The 1970s transition in social norms from embracing to condemning experimentation on prisoners helps to frame the 1976 DHEW Report and its recommendations. Moreover, the abusive conditions that prisoner subjects of medical experimentation experienced up until the late 1970s serve as a forceful reminder of the risks of inadequate limitations on such experimentation.

A number of factors coalesced to inspire the 1976 DHEW Report and its subsequent congressional ratification and codification into a federal statute, which severely curtailed biomedical experimentation in prison.³⁸ First, prison medical experimentation expanded in sheer quantity across the United States. Second, media outcry and public awareness of the kinds of medical tests performed, as well as of the associated dangers, grew. Third, as prisoners brought lawsuits challenging the terms of experimentation and seeking damages for experiments gone wrong, courts and prison administrators also became acutely aware of the dangers and the liabilities of medical testing. Prior to the 1976 DHEW Report and the codification of regulations in Title 45,³⁹ public regulation of human experimentation in any form had been minimal, or based on non-binding recommendations like the Nuremberg Code.⁴⁰

38. 2006 IOM Report, *supra* note 18, at 95 (noting that biomedical research in prison is “rare,” particularly non-therapeutic biomedical research, which only two state Departments of Corrections permitted as of 2006).

39. This statute is codified at 45 C.F.R. § 46.306.

40. See *infra* note 257 and surrounding text.

1. *Human Guinea Pigs*

Three broad categories of experiments took place in prisons in the 1970s: behavior modification research conducted by prison officials; biomedical research, often supported or directed by federal agencies; and pharmaceutical research, largely funded and controlled by private drug companies.⁴¹ Ultimately, the 1978 federal statute regulating experimentation on prisoners prohibited all non-therapeutic biomedical and drug research on prisoners but permitted biomedical and behavioral research specifically seeking to improve the health of the research subject.⁴² However, even the regulations permitting behavioral research suggest that any research must involve “no more than minimal risk and no more than inconvenience to the subjects.”⁴³ These limitations allude to the experiments that led to the worst abuses—research with no directed, therapeutic purpose and research which, even if ostensibly therapeutic, involved excessive risks and inconvenience.

Although behavioral modification research is, by definition, designed to be therapeutic, many pre-1976 behavioral research experiments were not only risky and inconvenient, but also abusive.⁴⁴ Because behavioral modification is theoretically therapeutic and integral to the rehabilitative punishment model dominant in the 1970s, behavioral modification “experiments” can be difficult to distinguish from punishment and from everyday prison policies.⁴⁵ The difficulty of detecting and defining behavioral modification experiments makes this category of experiments ripe for abuse.

A few examples of behavioral modification experiments, from the 1950s through the 1970s, will illustrate the need for regulation of this kind of experimentation. For example, in 1972, Missouri prison officials initiated the Special Treatment and Rehabilitation Training (START) program, which functioned for approximately eighteen months. In START, prison officials placed prisoners in solitary confinement with no programming and with only a

41. The 1976 DHEW Report documents the variety and prevalence of human subjects research taking place in prisons in the United States in the early 1970s. *See* 1976 DHEW Report, *supra* note 8, at 3081-83. Jessica Mitford also addresses this topic. *See* MITFORD, *KIND AND USUAL PUNISHMENT*, *supra* note 37, at 151-84. The court cases challenging some of these experiments provide further documentation of the kinds and numbers of experiments taking place in prisons across the United States in the 1970s. *See infra* notes 87-89 and surrounding text.

42. 45 C.F.R. § 46.306(a)(2)(i)-(iv).

43. *Id.* § 46.306(a)(2)(i), (ii). The regulations specifically define *minimal risk* as “the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.” *Id.* § 46.303(d).

44. *See, e.g.*, GARRY MARTIN & JOSEPH PEAR, *BEHAVIOR MODIFICATION: WHAT IT IS AND HOW TO DO IT* (8th ed. 2005) (discussing and defining the benefits of behavior modification as a therapeutic technique); *see also* discussion of the START program in Missouri and electric shock programs in California in this section for examples of abusive behavioral modification “therapies.”

45. 1976 DHEW Report, *supra* note 8, at 3081, 3087.

Bible as reading material; as the prisoners met certain behavioral benchmarks, they received additional reading material or access to programming. The program abruptly shut down after the American Civil Liberties Union successfully challenged its overly punitive conditions.⁴⁶ Even more egregiously, in a program at San Quentin in the 1950s, a psychiatrist employed “electric shock, insulin shock, fever treatment, hydrotherapy, Amytal and Pentothal interviews, spinals, and cisternals,” all as “therapeutic practices.”⁴⁷

The very existence of such practices suggests that prison officials and physicians did not need evidence of therapeutic success to run extreme behavioral modification programs. Other extreme “treatments,” inflicted as late as the 1970s, included “castration for sexual offenders and psychosurgery for uncontrollable violence.”⁴⁸ This history reminds us that even the most innocuous category of medical experimentation on prisoners, behavioral research—which current federal regulations still permit—had a sinister quality in at least some pre-1976 experiments.⁴⁹

46. See *Clonce v. Richardson*, 379 F. Supp. 338, 345 (W.D. Mo. 1974).

47. MITFORD, KIND AND USUAL PUNISHMENT, *supra* note 37, at 111. Note that cisternals are punctures of the upper spine, in the neck area, conducted in order to retrieve spinal fluid; they are an alternative to a spinal, or a spinal tap, in which a doctor punctures the lower spine to obtain fluid. Luiz Antonio Pezzi Portela et al., *Laceration of the Posterior Inferior Cerebellar Artery by Suboccipital Puncture of the Cisterna Magna*, 62 ARQ NEUROPSIQUIATR 882-84 (2004). Cisternals are rarely if ever conducted today, because the “dura matter” in the area of a brain where a cisternal needle punctures can buckle inward, drawing the needle into the central nervous system, where needles have been known to puncture an artery, a vein, or the medulla, causing permanent damage and even sudden death. *Id.* at 883-84. A 1964 paper described a number of deaths resulting from cisternals, and the procedure has been little used since then. *Id.* at 883, 884 n.3.

48. 1976 DHEW Report, *supra* note 8, at 3081. The 1976 DHEW Report also documents some less abusive behavioral modification experiments taking place in the Federal Bureau of Prisons and under the supervision of the National Institute of Mental Health (NIMH). NIMH, for instance, conducted studies of behavioral issues particularly affecting prisoners, such as the effects of institutionalization and the psychological and social sources of individual violence. *Id.* at 3082.

49. Because “behavioral modification” is such a flexible term, often indistinguishable from everyday prison policies for punishment, calculating just how many abusive behavioral modification experiments have taken place, in the manner of the START program or the San Quentin program of electric shock and other invasive “therapies,” is nearly impossible. Such a determination would depend on the definition of a program as a “behavior modification” program, a definition often at the discretion of prison officials themselves. Indeed, many prison practices today recall the “behavioral modification” experiments that Mitford and others condemned in the 1970s. For instance, state prison systems across the United States maintain “supermaximum” security facilities, where prisoners are locked in solitary confinement, without reading material, for indefinite periods. See, e.g., Craig Haney, *Mental Health Issues in Long-term Solitary and “Supermax” Confinement*, 49 CRIME & DELINQUENCY, 124, 124–156 (2003) (describing supermaximum security facilities and chronicling what is known about the as-yet undetermined long-term health effects of such practices); see also TERRY A. KUPERS, PRISON MADNESS: THE MENTAL HEALTH CRISIS BEHIND BARS AND WHAT WE MUST DO ABOUT IT, at ix-xiv (1999) (same). Such programs are eerily reminiscent of the START program. Likewise, some states even today allow castration for sexual offenders. See, e.g., Candace Rondeaux, *Can Castration Be a Solution for Sex Offenders? Man Who Mutilated Himself in Jail Thinks So, but Debate on Its Effectiveness Continues in Va., Elsewhere*, WASH. POST, July 5, 2006, at B1 (noting that eight states allow chemical castration of sex offenders; Texas allows surgical castration). These

The more gruesome pre-1976 experiments did not involve behavior-modification programs but were conducted instead for purely non-therapeutic purposes. These non-therapeutic experiments included a range of biomedical interventions, from inducing scurvy in prisoners to infecting prisoners with measles or malaria to irradiating prisoners. For instance, at Iowa State Penitentiary, starting in the late 1940s, one doctor induced scurvy in five prisoners by feeding them ascorbic-acid-free liquid solutions through a stomach tube for months at a time. The doctor, affiliated with the University of Iowa, published a scholarly article about his research findings in 1971; the article included research documenting the effects of scurvy in these prisoner-patients: shortness of breath, dental cavities, hair loss, skin hemorrhaging, and permanent nerve damage.⁵⁰ In another project at Petersburg Prison in Virginia, in the late 1960s and 1970s, National Institutes of Health affiliates systematically exposed prisoner subjects to measles and documented the effects.⁵¹ And, in a federally-sanctioned project run from 1969 to 1975, the Public Health Service, on behalf of the National Aeronautics and Space Administration (NASA), forced prisoners in San Francisco to spend six months or more in bed, wearing compression suits, while being injected with radioactive isotopes.⁵² Similarly, as mentioned in the introduction, the researchers running the decade-long Heller Experiments tested the effects of radiation on the testes of Oregon prisoners.⁵³ And the University of Maryland conducted experiments at the Maryland House of Corrections between 1971 and 1975, infecting prisoners with either malaria or a species of bacteria causing severe diarrhea.⁵⁴

Sanctioned by universities and federal agencies alike, these non-therapeutic biomedical experiments took place across the United States until the late 1970s. These experiments do not represent isolated instances of human subjects experimentation gone wrong but rather widespread abusive practices with abusive results in the years leading up to the 1976 DHEW Report. Indeed, the DHEW Report Commission found, as the examples above suggest, that many government agencies were involved in a wide variety of biomedical

programs are not regulated as “behavioral modification” experiments, but instead remain in place as “administrative procedures” implemented within the discretion of prison officials and policymakers.

50. MITFORD, KIND AND USUAL PUNISHMENT, *supra* note 37, at 159-63 (describing a study reported by Robert Hodges: Robert Hodges et al., *Clinical Manifestations of Ascorbic Acid Deficiency in Man*, 24 AM. J. CLINICAL NUTRITION 432 (1971), available at <http://www.ajcn.org/cgi/reprint/24/4/432>).

51. HORNBLUM, *supra* note 1, at 108-09.

52. *Id.*

53. *Bibeau v. Pac. Nw. Research Found.*, 980 F. Supp. 349, 351-52 (D. Or. 1997) (describing the Heller Experiments in the context of participants’ challenge to the validity of the informed consent they provided).

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

experiments in prisons in the 1970s.⁵⁵ Between 1970 and 1976, five of six Public Health Service agencies “conducted or supported” biomedical research in prisons, including drug detection methods analysis, studies of the properties and effects of addictive drugs such as morphine and methadone, and studies of alcoholism and violence.⁵⁶ In this same period, the Centers for Disease Control ran three prisoner studies testing vaccines and studying skin sensitization to parasitic skin diseases, and the FDA conducted eight studies on prisoners, including “oral administration of a standard dose of a commercially available antibiotic” and skin sensitivity tests.⁵⁷ Similarly, the Health Services Administration conducted thirteen studies on prisoners concerning “metabolic responses to prolonged bed rest.”⁵⁸ The Research Division of the Federal Bureau of Prisons likewise conducted thirty-three studies on prisoners.⁵⁹ In sum, as of 1976, twenty-one states specifically permitted biomedical research, and seven states had ongoing biomedical experiments on prisoners.⁶⁰

In addition to these non-therapeutic biomedical experiments, prisoners also participated in a wide variety of Phase I drug tests in the 1970s. Like many of the biomedical experiments described above, Phase I drug tests are inherently non-therapeutic; they require healthy volunteers, who, by design, are not expected to benefit from the treatment in question.⁶¹ In 1976, the largest drug companies depended on prisoners for anywhere from 2 percent to 100 percent of their Phase I drug testing research.⁶² Although only one company surveyed used prisoners for 100 percent of its Phase I drug testing, the median company used prisoners for 50 percent of its Phase I drug testing.⁶³

For instance, Upjohn and Parke Davis, two of the largest drug companies in the United States in the 1970s, had “exclusive rights” to access prisoners at Jackson State Prison in Michigan for Phase I drug tests.⁶⁴ Specifically, Upjohn and Parke Davis paid to build the facilities in which prisoners were housed and tested; the drug companies then transferred the title to the facilities to the State of Michigan in exchange for corporate tax breaks.⁶⁵ The facilities not only used prisoners as the subjects of drug trials but were also largely run by prison

55. 1976 DHEW Report, *supra* note 8, at 3082-83.

56. *Id.* at 3082.

57. *Id.*

58. *Id.*

59. *Id.* The Report notes that some of these experiments were not biomedical, but behavioral.

60. *Id.*

61. “Phase I trials try to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects. Usually, a small number of healthy volunteers (between 20 and 80) are used in Phase I trials.” Carol Rados, *Inside Clinical Trials: Testing Medical Products in People*, FDA CONSUMER MAG., Sept.-Oct. 2003, available at http://www.fda.gov/FDAC/features/2003/503_trial.html.

62. 1976 DHEW Report, *supra* note 8, at 3082-83.

63. *Id.*

64. MITFORD, KIND AND USUAL PUNISHMENT, *supra* note 37, at 171.

65. *Id.*

laborers, who served as technicians and nurses.⁶⁶ The drug companies paid these laborers between thirty cents and \$1.25 per day for their services.⁶⁷ Prisoners who participated as subjects of drug trials usually received around \$1 per day, or \$30 per month, for participation.⁶⁸ In other words, a prisoner could make considerably more than the lowest-paid prison laborer simply by participating in a drug trial.⁶⁹ Likewise, using prisoners as the subjects of Phase I drug tests constituted tremendous savings for drug companies like Upjohn and Parke Davis.⁷⁰

Even those running the experiments on behalf of the drug companies benefited financially. For instance, as noted in the introduction, Dr. Kligman received \$10,000 in direct payments from Dow Chemical for his work testing dioxin on prisoners in Pennsylvania in 1965 and 1966.⁷¹ Similarly, two doctors who ran a number of experiments on Oklahoma prisoners in the mid-to-late 1960s on behalf of various pharmaceutical companies, including Upjohn and Merck, received \$300,000 annually for their work.⁷²

In total, of fifty-one drug companies responding to a Pharmaceutical Manufacturers Association (PMA) survey in 1976, fourteen companies used more than thirty-five hundred prisoners to conduct Phase I drug tests of seventy-one different substances. Although only fourteen companies used prisoners for Phase I drug tests, the money spent by these companies on the drug tests comprised “three-fourths of the [PMA] members’ annual

66. *Id.*

67. *Id.* Interestingly, the average wage for prison labor in 2008, nearly forty years later, is approximately the same as the wages Upjohn and Parke Davis were paying their prisoner subjects and laborers. See Bob Egelko, *Lawyer Slams Prison Wages: Tony Serra Files Suit on Behalf of Federal Inmates for Low Rate of Pay for Labor by the Incarcerated*, S.F. CHRON., Mar. 22, 2007, at B1, available at <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/03/22/BAGIOPM0K1.DTL> (noting that J. Tony Serra, a prominent California defense attorney who served time in federal prison for boycotting federal taxes, had brought suit against the federal prison industries program to challenge their low wages—which range from five cents to \$1.65 an hour).

68. MITFORD, KIND AND USUAL PUNISHMENT, *supra* note 37, at 157.

69. In some human subjects experiments, prisoners received even greater amounts of compensation. For instance, in the Heller Experiments, discussed above at note 53 and surrounding text, the prisoner subjects received \$5 per month for participation, \$10 for every biopsy, and \$100 at the conclusion of the study. Gregory Dober, *Cheaper than Chimpanzees: Expanding the Use of Prisoners in Medical Experiments*, PRISON LEGAL NEWS, Mar. 2008, at 5, available at http://www.prisonlegalnews.org/19630_displayArticle.aspx. Relative to prison wages that were as low as \$9 per month, such payments certainly constituted a windfall for a prisoner, if he could withstand the effects of the experimentation.

70. Free-world subjects receive a huge variety of payments for participation in drug trials; a 2008 *New Yorker* article suggested that payments for participation vary depending on how invasive a study is. Carl Elliott, *Guinea-Pigging*, NEW YORKER, Jan. 7, 2008, at 36. For instance, within two studies the *New Yorker* profiled, one participant received \$7,500 for an invasive five-week study of gastro-intestinal tracts, and another received \$3,300 dollars for a less-invasive, shorter “drug delivery study.” *Id.* at 36, 40.

71. HORNBLUM, *supra* note 1, at 169.

72. Dober, *supra* note 69, at 5; HORNBLUM, *supra* note 1, at 97-98.

expenditures for research and development.”⁷³ In 1976, the total population of federal and state prisoners in the United States was just over 200,000.⁷⁴ In other words, around 2 percent of the total prison population participated in Phase I drug testing.

According to both the 1976 DHEW Report and Jessica Mitford, changes to the FDA regulations that govern drug testing drove the expanding use of prisoners in commercial drug tests.⁷⁵ In 1962, the FDA amended its regulations to require that drugs be tested on human subjects prior to approval for marketing.⁷⁶ Given the difficulty of finding such subjects, the new regulations had the presumably unintended effect of creating incentives for drug companies to turn to prisoners—a conveniently captive and cheap subject base—for use in drug trials. As noted above, drug companies received tax breaks for building testing facilities, if the facilities housed or employed prisoners. Drug companies then filled these facilities with prisoner subjects who were readily available in large numbers, would not fail to return for follow-up tests as they were literally captive, and could be compensated very cheaply. And, finally, drug companies staffed these facilities with prison laborers who were even cheaper to compensate than the prisoner subjects.

The federal regulations inspired by the 1976 DHEW Report and implemented in Title 45 explicitly forbid such non-therapeutic prisoner experimentation.⁷⁷ Despite the federal regulations limiting prisoner participation in drug trials, the FDA still requires drug companies to find human subject participants for all phases of drug trials, and drug companies continue to have great difficulty attracting and retaining experimental subjects.⁷⁸ Indeed, a recent *New Yorker* article noted the difficulties drug companies face, and the perverse incentives companies have to target vulnerable populations in need of money as subjects of potentially dangerous drug trials.⁷⁹ While little information on continued Phase I drug testing in prisons exists, lucrative incentives to find and retain human subjects for all phases of drug trials persist in 2008.⁸⁰

73. 1976 DHEW Report, *supra* note 8, at 3082-83.

74. See Figure 3.1 and surrounding text in FRANKLIN E. ZIMRING, *THE GREAT AMERICAN CRIME DECLINE* 46 (2007).

75. 1976 DHEW Report, *supra* note 8, at 3081 (citing the 1962 Kefauver-Harris Amendments to the Food and Drug Act, which expanded the requirements for testing drugs prior to marketing); MITFORD, *KIND AND USUAL PUNISHMENT*, *supra* note 37, at 153 (noting that the FDA requires that new drugs be tested on humans prior to marketing).

76. 1976 DHEW Report, *supra* note 8, at 3081.

77. 45 C.F.R. § 46.306(a)(2)(i)-(iv).

78. See, e.g., Elliott, *Guinea-Pigging*, *supra* note 70, at 36-41.

79. *Id.*

80. The impacts of these incentives are explored further in Part B, below.

2. Oversight: Media, Courts, and Regulations

As medical experimentation in prisons exploded between the 1950s and the 1970s, media investigations and condemnations of such experiments also increased. In 1971, influential investigative journalist Jessica Mitford published *Kind and Usual Punishment*, cited by the authors of the 1976 DHEW Report.⁸¹ The book includes a chapter entitled “Cheaper than Chimpanzees,” which chronicles the investments made by drug companies in prisoner experimentation, as well as the range of biomedical experimentation on prisoners resulting in medical journal publications in the 1950s and 1960s.⁸² In fact, medical journals continued to publish the results of biomedical experiments conducted on prisoners through the early 1970s.⁸³ The continued publication of such research results in peer-reviewed journals indicates that the medical community at least tacitly condoned the use of prisoners for biomedical experimentation well into the 1970s.

Nonetheless, local and national media increasingly criticized the practice. For instance, in a series of exposés, the Montgomery, Alabama, *Advertiser* documented the extensive drug experiments conducted by one physician on behalf of thirty-seven major drug companies in Alabama, Arkansas, and Oklahoma.⁸⁴ The *New York Times* reported on the same physician’s projects in 1969.⁸⁵ Furthermore, editorials calling for new federal regulations and documenting the findings of the 1976 DHEW Report appeared in national newspapers, including the *Washington Post* and the *New York Times*.⁸⁶

81. See, e.g., John Bruce Moore, Book Note, 65 J. CRIM. L. & CRIMINOLOGY 423 (1974) (reviewing JESSICA MITFORD, *KIND AND USUAL PUNISHMENT* (1973)); 1976 DHEW Report, *supra* note 8, at 3078.

82. MITFORD, *KIND AND USUAL PUNISHMENT*, *supra* note 37, at 151-84.

83. *Id.* at 161 (noting that the results of a study in which doctors induced scurvy in prisoners at Iowa State Penitentiary were published in a 1971 issue of the *American Journal of Clinical Nutrition*); see also *Bailey v. Lally*, 481 F. Supp. 203, 217 (D. Md. 1979) (noting that studies conducted on prisoners in the Maryland House of Corrections by the University of Maryland were still being published in elite medical journals such as the *New England Journal of Medicine* and *The Journal of Infectious Diseases*, even as federal restrictions on such prisoner experiments expanded).

84. MITFORD, *KIND AND USUAL PUNISHMENT*, *supra* note 37, at 155.

85. HORNBLUM, *supra* note 1, at 97-98 (citing Walter Rugaber, *Prison Drug and Plasma Projects Leave Fatal Trail*, N.Y. TIMES, July 29, 1969, at 1). According to Hornblum, before the late 1960s and early 1970s, there had been favorable reports in national newspapers regarding experiments on prisoner subjects that led to breakthroughs in hepatitis and malaria treatments. *Id.* at 101 (citing, e.g., Walter Sullivan, *Scientist Reports Isolation 2 Strains of Hepatitis*, N.Y. TIMES, June 29, 1961; Marjorie Hunter, *Drug is Reported to Avert Malaria*, N.Y. TIMES, Nov. 2, 1962, at 33).

86. In particular, both the *New York Times* and the *Washington Post* printed many stories and editorials detailing the recommendations in the 1976 DHEW Report and supporting changes to the law. See, e.g., *Ill Dept of Correction Orders End to All Malaria Experiments*, N.Y. TIMES, April 28, 1974, at 50; *Medical Research in Prisons*, WASH. POST, Mar. 12, 1978, at C6 (supporting bill to end experimentation, referencing Maryland experiments); Harold M. Schmeck, *1st Natl Minority Conf on Human Experimentation Drafts Recommendations*, N.Y. TIMES, Jan. 9, 1976, at 29; Jonathan Steele, *U.S. to Keep Testing Drugs on Prisoners*, WASH. POST, Aug. 27,

The courts, too, reflected the ongoing controversy over the experiments taking place in U.S. prisons.⁸⁷ In *Clay v. Martin*, the Second Circuit stated that the plaintiff complained of “callous disregard for the safety of human subjects in medical experimentation,” and noted that human subjects experimentation was “a problem which has drawn increasing public and governmental attention.”⁸⁸ Similarly, in *Bailey v. Lally*, the Maryland District Court chronicled the regulatory and legal attention that biomedical testing in prisons had received in the 1970s, including increasingly rigid restrictions on experimentation.⁸⁹ As awareness of the existence and effects of medical experiments on prisoners grew among courts, government officials, and the general public, standards of humane testing and scientific rigor changed.

Although medical research on prisoner subjects continued into the 1970s, restrictions on medical research in prisons steadily increased throughout the decade. Congress initiated some of these restrictions. In 1974, responding to public outcry over the Tuskegee syphilis study, a U.S. Senate subcommittee led by Senator Edward Kennedy from Massachusetts held hearings on prisoner experimentation.⁹⁰ Later in 1974, Congressman Parren Mitchell from Maryland introduced a bill seeking to end medical experimentation on prisoners in the federal prison system.⁹¹ Also in 1974, Congress passed the National Research Act, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.⁹² Congress charged this Commission with reviewing the ethical principles for medical research on human subjects and developing appropriate research guidelines.⁹³ This Commission eventually produced the 1976 DHEW Report.

Federal agencies also played a role in limiting medical experimentation practices. Although the 1974 Congressional bill to end medical experimentation in the federal prison system failed, Norman A. Carlson, the director of the federal prison system, initiated plans in 1976 to discontinue biomedical research in federal prisons.⁹⁴ According to the 1976 DHEW Report, only one state had passed legislation banning biomedical research in prisons, but six more had departmental policies prohibiting such research.⁹⁵ Between 1971 and 1978, the Department of Health, Education, and Welfare issued five different

1977, at A6.

87. See, e.g., *Clay v. Martin*, 509 F.2d 109 (2d. Cir. 1975); *Bailey*, 481 F. Supp. 203.

88. 509 F.2d at 112. The *Clay* court further noted that prisoner cases challenging the terms of medical experimentation raised a particularly complex legal issue about whether or not the plaintiff had given informed consent. *Id.* at 114.

89. 481 F. Supp. at 214-15.

90. HORNBLUM, *supra* note 1, at 110.

91. *Id.*

92. *Clay*, 509 F.2d at 112-13 (citing National Research Act, Pub. L. No. 93-348, § 202(a)(1)(A), 88 Stat. 342, (1974)).

93. *Id.* at 112.

94. 1976 DHEW Report, *supra* note 8, at 3082 n.2; HORNBLUM, *supra* note 1, at 113.

95. 1976 DHEW Report, *supra* note 8, at 3082. The Report does not identify the states.

notices about proposed limitations on federally funded human subjects research.⁹⁶ These regulatory changes reflected what one historian has characterized as “overwhelming” opposition to prison medical testing by the mid-1970s.⁹⁷

The convening of the commission that wrote the 1976 DHEW Report (DHEW Commission), as well as the Report’s resulting recommendations, represented the culmination of public, political, legal, and regulatory foment over prison medical testing. The DHEW Commission included eleven people: three medical doctors, four medical professors, two law professors, one attorney, and the President of the National Council of Negro Women. These eleven members were drawn from research institutions across the country. In making its recommendations, the Commission sought input from prisoners, prison officials, and government agency representatives.

The 1976 DHEW Report ultimately recommended strict regulation of medical testing in U.S. prisons.⁹⁸ The recommendations were quickly codified into law as part of the Code of Federal Regulations on Protection of Human Subjects, at Title 45, Part 46, Subpart C, which was adopted by Congress in November of 1978.⁹⁹ Title 45 closely parallels the recommendations made in the 1976 DHEW Report.¹⁰⁰ Such quick Congressional action reflected the public awareness of—and outcry against—experimentation on prisoners.

The following year, the National Committee for the Protection of Human Subjects Research released *The Belmont Report*.¹⁰¹ The stated goal of the report was “to summarize the basic ethical principles identified by the Commission in the course of its deliberations.”¹⁰² Although short, at ten pages in length, *The Belmont Report* has become the benchmark for human subjects research, detailing the ethical principles that must guide such research with requirements for informed consent, risk-benefit assessments, and subject selection.¹⁰³ *The Belmont Report* represents a continuation of the trend toward rigid restrictions on human experimentation, particularly when that experimentation takes place in prisons. In subsequent years, the FDA and the American Correctional

96. *Bailey v. Lally*, 481 F. Supp. 203, 214-15 (D. Md. 1979) (noting that after the first restrictions in 1971: “Further HEW notices of proposed rulemaking were published in 1974, [39 Fed. Reg. 18,914 (May 30, 1974)], [39 Fed. Reg. 30,648 (Aug. 23, 1974)], and in 1978, [43 Fed. Reg. 1049 (Jan. 5, 1978)], followed by published rules on November 16, 1978, [43 Fed. Reg. 53,652], restricting research on prisoners (45 C.F.R. §§ 46.301-46.306”).

97. HORNBLUM, *supra* note 1, at 113-14.

98. *See* Part II *infra* (discussing the specifics of the regulations).

99. *See* 45 C.F.R §§ 46.301-306.

100. *See* 1976 DHEW Report, *supra* note 8, at 3080-81; 45 C.F.R §§ 46.301-306.

101. NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS RESEARCH* (1979), *available at* <http://medschool.umaryland.edu/geei/BelmontReport.pdf>.

102. *Id.* (quote in summary).

103. *Id.*

Association, an independent prison-accrediting body, have followed recommendations in the DHEW Report and *The Belmont Report* and have adopted regulations similar to those codified at Title 45.¹⁰⁴

Specifically, in 1978, the FDA itself moved to forbid the use of prisoners for drug tests. However, the FDA regulations on prisoner experimentation are in a state of semi-permanent confusion and have been since the FDA first adopted them.¹⁰⁵ In theory, FDA regulations forbidding prisoner participation in drug trials would cover a broader range of human subjects than the Title 45 regulations. For instance, Title 45 regulations cover only those facilities receiving federal funding. Therefore, a private contractor running a state prison could conceivably contract with a private university, or with a private drug company, to run drug trials. Such a contract would be beyond the regulatory authority of the Department of Health and Human Services under Title 45. The FDA regulations in Title 21, on the other hand, govern all companies seeking federal approval to market their drugs publicly, so the regulations cover private actors through the mechanism of federal regulation.¹⁰⁶ Therefore, FDA standards forbidding the use of prisoners in any drug trials could compensate for the regulatory gap left by Title 45. Unfortunately, the FDA, like most federal agencies, has not “chosen to follow the more rigid regulations for protection of prisoners in medical studies” recommended in the 1976 DHEW Report and codified at Title 45.¹⁰⁷

So, although Title 45 implemented rigid restrictions on the use of prisoner subjects in biomedical research, the reach of Title 45 is limited to research receiving federal funding. Therefore, Title 45 leaves open a number of regulatory gaps, which individual agencies must each close through voluntary regulatory changes. Although the FDA attempted to close one such regulatory gap by implementing regulations on the use of prisoner subjects in drug trials conducted for purposes of federal regulatory approval, these regulations have never been formally adopted. Nonetheless, the parts of Title 21 dealing with prisoner subjects remain “reserved” today, resulting in a *de facto* ban on the use of prisoners for drug testing at any phase.¹⁰⁸

104. See generally 21 C.F.R. pts. 50, 56 (describing standards specifically applicable to drug testing that parallel the human subjects research standards described in Title 45).

105. As soon as the FDA adopted the regulations forbidding prisoner participation in drug trials, a group of prisoners sued the agency for attempting to curtail their rights to participate in human subjects research. The FDA then suspended those specific regulations restricting the use of prisoners in drug trials. 2006 IOM Report, *supra* note 18, at 88.

106. See 21 C.F.R. § 50.1 (describing the scope of the FDA’s regulatory authority vis-à-vis human subjects regulations).

107. Dober, *supra* note 69, at 3 (noting that the National Institutes of Health, the Central Intelligence Agency, and the Social Security Administration are the only federal agencies that have officially adopted the rigorous standards for experimentation on prisoners in Title 45).

108. 2006 IOM Report, *supra* note 18, at 88.

B. Human Subjects Research in Prison Between 1976 and 2008

By 1978, the Title 45 provisions for strict regulation of all medical experimentation in prison constituted binding law. Under Title 45, only four narrow categories of federally-funded research may include prisoner subjects: (1) research about the effects of incarceration; (2) research about prisons as institutions; (3) research about conditions particularly affecting prisoners; and (4) research about practices expected to improve the health of individual subjects.¹⁰⁹ Title 45 requires that independent review bodies both conduct strict evaluations of all human subjects research and ensure fulfillment of minimum conditions of consent and comfort.¹¹⁰

In sum, the provisions forbid non-therapeutic biomedical and drug testing on prisoners. By many accounts, medical experimentation in prisons decreased dramatically as a result of the 1976 regulations. In addition to these federal regulations limiting experimentation on prisoners to narrow categories of research, independent governmental agencies like the FDA, as well as state correctional authorities, took steps to enact regulations in the late 1970s to limit biomedical experimentation and drug research in prisons.¹¹¹

In lawsuits challenging experimentation on prisoners, courts assumed that the experiments had ceased in the second half of the 1970s.¹¹² Indeed, a LexisNexis search for prisoner or former prisoner plaintiffs' suits challenging experimentation practices, procedures, or after-effects, found only eleven cases that either mentioned experimentation on prisoners, or characterized treatments or practices as experimental.¹¹³ Of course, this list of eleven cases is by no

109. 45 C.F.R. §46.306(a)(2)(i)-(iv).

110. *See id.*

111. *See supra* notes 104-107 (discussing FDA and other agency regulations).

112. *See, e.g.,* Clay v. Martin, 509 F.2d 109, 111 (2d Cir. 1975) (noting that experiments were conducted in the early 1970s); Bailey v. Lally, 481 F. Supp. 203, 205 (D. Md. 1979) (noting that experiments were conducted from 1958 to 1976); Bibeau v. Pac. Nw. Research Found., 980 F. Supp. 349, 351-52 (D. Or. 1997) (noting that the experiments were conducted from 1963 to 1973).

113. The search terms used were "prisoner," "experiment," "research," and "ethics"; no date restriction was applied. While hundreds of cases were reviewed, only eleven actually dealt with allegations of experimentation on prisoners. *See* Stanley v. Swinson, No. 93-16078, 1995 U.S. App. LEXIS 2262, at *10 (9th Cir. Dec. 15, 1994) (describing allegations that the use of regular blood tests for HIV constituted an unregulated medical "experiment" in a federal prison in California in the 1990s); Clay, 509 F.2d at 112 (describing drug addiction treatment at the Addiction Research Center, located in a federal prison in Lexington, Kentucky, in 1970; prisoner alleged that the experimental treatment caused a heart attack); Knecht v. Gillman, 488 F.2d 1136, 1137, 1140 (8th Cir. 1973) (describing the use of an injected drug, which caused prisoners to vomit for between fifteen minutes to one hour, as punishment for breaking prison rules in an Iowa state prison in the early 1970s; although the court did not describe the injection practice as experimental per se, the court did describe the drug administered as "unproven . . . for this [behavior modification] purpose," indicating its use was essentially experimental); Mackey v. Proconier, 477 F.2d 877, 877 (9th Cir. 1973) (describing experimental administration of a drug that stopped plaintiff's breathing during shock treatments at a California state prison in 1967); Brown v. Martinez, 2007 U.S. Dist. LEXIS 55350, at *2 (M.D. Pa. July 31, 2007) (describing allegations that food-deprivation and sleep-deprivation constituted behavioral modification

means exhaustive. First, many suits filed by prisoners alleging experimental practices are settled out of court.¹¹⁴ Second, determining exactly what constitutes an experimental practice is difficult. For instance, in *Knecht v. Gillman*, the court did not describe the vomit-inducing drug at issue in the case as experimental, though the court did note that the drug was “unproven” for the kind of behavioral modification use being challenged.¹¹⁵ *Knecht* is included in the list of eleven cases referenced above, as an example of an experimental medical practice described by a court, though the practice is arguably just a bad correctional policy. Indeed, courts often disagree with prisoner plaintiffs about whether an alleged experimental practice is therapeutic, consensual, or simply a legitimate correctional policy.¹¹⁶

Of the eleven cases described above that did explicitly mention experimentation on prisoners, nine of the challenged experiments took place before the codification of the DHEW Report recommendations in Title 45 in 1978.¹¹⁷ The two suits that did challenge post-1978 “experiments” were unpublished and involved claims related to prison practices that arguably were not medical experiments at all.¹¹⁸ For instance, in *Stanley v. Swinson*, prisoners challenged mandatory HIV blood-tests as unconstitutional medical

“experiments” conducted at a Pennsylvania state prison in the 2000s); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 800-02 (S.D. Ohio 1995) (describing the experimental administration of “massive doses” of radiation to prisoners with terminal cancer in Ohio between 1960 and 1972); *Bibeau*, 980 F. Supp. at 352 (describing the experimental radiation of testes that took place in an Oregon state prison between 1965 and 1969); *Cain v. United States*, 643 F. Supp. 175 (S.D.N.Y. 1986) (describing allegations that doctors deliberately infected prisoners with syphilis during experiments conducted in a New York state prison in the 1950s); *Bailey*, 481 F. Supp. at 205 (describing a variety of infectious disease tests run by the University of Maryland medical school within the Maryland House of Correction between 1958 and 1976); *Roach v. Kligman*, 412 F. Supp. 521, 523 (E.D. Pa. 1976) (describing permanent liver damage resulting from participation in dermatological experiments in a Pennsylvania state prison in 1973); *Clonce v. Richardson*, 379 F. Supp. 338, 349 (W.D. Mo. 1974) (describing an experimental behavioral modification program implemented in a federal prison in Missouri between 1972 and 1974).

114. See, e.g., *HORNBLUM*, *supra* note 1, at 181 (describing undisclosed settlement amounts between Dow Chemical Company, the city of Philadelphia, and the University of Pennsylvania and prisoners who suffered Dr. Kligman’s dermatological experiments, during which Kligman exposed the prisoners to dioxin in the 1960s and 1970s).

115. 488 F.2d at 1140.

116. See, e.g., *Tripp v. Carter*, No. 99 C 3304, 1999 U.S. Dist. LEXIS 16487, at *2 (N.D. Ill. Oct. 12, 1999) (describing prisoners allegations that the prison’s use of saccharin constituted a medical experiment and dismissing the claim); *McNeil v. United States*, No. 92 C 0339, 1992 U.S. Dist. LEXIS 7665, at *3 (N.D. Ill. May 29, 1992) (describing infectious disease research that allegedly caused a hepatitis C infection in an Illinois prison in the early 1990s and dismissing the claim). The tally of the eleven cases describing challenges to experiments on prisoners does not include unsubstantiated claims like those in *Tripp* and *McNeil*.

117. See *Clay*, 509 F.2d at 112; *Knecht*, 488 F.2d at 1137, 1140; *Mackey*, 477 F.2d at 877; *In re Cincinnati Radiation Litig.*, 874 F. Supp. at 800-02; *Bibeau*, 980 F. Supp. at 352; *Cain*, 643 F. Supp. 175; *Bailey*, 481 F. Supp. at 205; *Roach*, 412 F. Supp. at 523; *Clonce*, 379 F. Supp. at 349.

118. See *Stanley*, 1995 U.S. App. LEXIS 2262, at *10; *Brown*, 2007 U.S. Dist. LEXIS 55350, at *2.

experimentation.¹¹⁹ And in *Brown v. Martinez*, prisoners challenged deprivation conditions in secure housing units as unconstitutional behavioral modification experiments.¹²⁰ One historian of prison medical testing has said that prisoner experimentation was “effectively over” as of 1980.¹²¹ Indeed, the absence of any published prisoner challenges alleging unconstitutional treatment or injury from medical experimentation might seem to confirm this assumption.¹²² Of course, as suggested above, there are many reasons why prisoner suits challenging medical experimentation in prison might not appear in a simple search of case law.

Indeed, despite the absence of published case law on point, medical experimentation on prisoners is far from over. Investigative research reveals that public universities, as well as drug companies, continue to use prisoners and other individuals under correctional supervision as subjects in a variety of medical experiments.¹²³ For instance, the Hythian drug company’s Prometa addiction-treatment program, discussed in the introduction, constitutes an experimental drug trial on criminal defendants.¹²⁴ Recall that the program involves thirty days of treatment with three different drugs, none of which has been approved for use in addiction treatment by the FDA.¹²⁵ In other words, people found in possession of illegal drugs in Texas, or in Washington, or in Georgia, might be assigned to an experimental drug-treatment program closely resembling the drug testing that took place in Michigan and Oklahoma prisons before the DHEW Report.

1. Enforcing Regulations

The Hythian contract relates to one implicit motivation behind the 2006 IOM Report: fear that private companies are conducting experimentation in nontraditional correctional settings, beyond the scope of the regulatory powers of federal agencies. Currently, the Office for Human Research Protections (OHRP), a division of the DHHS, is responsible for monitoring compliance with and enforcing the regulations governing human subjects research as

119. 1995 U.S. App. LEXIS 2262, at *10.

120. 2007 U.S. Dist. LEXIS 55350, at *2.

121. HORNBLUM, *supra* note 1, at 114.

122. A national coalition of prisoners’ rights lawyers knew of no other recent or pending challenges to medical experiments in prison settings. Posting of Keramet Reiter, keramet@post.harvard.edu, to prisonersrights@mail.lawhelp.org (Oct. 4, 2008) (on file with author); e-mail from Alex Friedman, Associate Editor, Prison Legal News, to author (Oct. 4, 2008, 08:10 PST) (on file with author); e-mail from Paul Wright, Editor, Prison Legal News, to author (Oct. 12, 2008, 22:10 PST) (on file with author).

123. See, e.g., Silja J.A. Talvi, *The Prison As Laboratory: Experimental Medical Research on Inmates is on the Rise*, IN THESE TIMES, Jan. 23, 2002, available at <http://www.inthesetimes.com/issue/26/03/feature4.shtml>; Dober, *supra* note 13; Dober, *supra* note 69.

124. Dober, *supra* note 13.

125. See WEINSTEIN ET AL., *supra* note 14, at 1.

codified at Title 45.¹²⁶ However, for reasons discussed below, experimentation conducted by private companies can easily fall outside of the scope of the OHRP's authority.

Any research that is federally conducted or federally supported is within the regulatory authority of the OHRP.¹²⁷ In addition, an institution, such as a state prison system, can voluntarily choose to adopt the DHHS policies codified at Title 45; in such cases, research conducted by those institutions is within the regulatory authority of the OHRP.¹²⁸ Therefore, federal agencies, universities that receive federal funding or that have adopted DHHS regulations, and state prison systems that have adopted DHHS regulations all fall within the regulatory authority of the OHRP. However, in states that have passed human subjects protection statutes that are stricter than the federal regulations, the stricter state statute determines the scope of human subjects research, even for purposes of OHRP regulation.¹²⁹

Despite the various ways the OHRP might be able to regulate human subjects research in non-federal institutions, the OHRP's oversight powers are limited. Specifically, the OHRP regulations dealing with prisoners (those codified at Title 45, Part 46, Subpart C) do not cover participants in drug-addiction treatment programs, or participants in any program run by a private contractor.¹³⁰ The 2006 IOM Report specifically notes that the definition of "prisoner" within the federal regulations is narrow.¹³¹ Of course the fact that the OHRP can only regulate federally-funded research means that private drug companies receiving no federal funding are also beyond the regulatory authority of the OHRP.¹³²

However, medical experimentation on prisoners is not only taking place outside of the regulatory authority of the OHRP, as was the case for the Hythian drug trial. Indeed, public and private universities, as well as state prison systems, have incorporated prisoners into medical experiments in the

126. See 2006 IOM Report, *supra* note 18, at 4-6 (suggesting that the definition of prisoner be expanded to include anyone under the supervision of the criminal justice system).

127. See 45 C.F.R. § 46.301(a).

128. OFFICE FOR HUMAN RESEARCH PROTS. (OHRP), DEP'T OF HEALTH & HUMAN SERVS., OHRP'S COMPLIANCE OVERSIGHT PROCEDURES FOR EVALUATING INSTITUTIONS 2 (2005), available at <http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf>.

129. See, e.g., Tracy Weber, *1997 Drug Test on Teenage Inmates Probed*, L.A. TIMES, Aug. 16, 1999, at A1 (noting that California has its own statute governing human subjects experimentation, and this statute is more strict, i.e. allows less research, than the federal statute); see also 45 C.F.R. § 46.301(b) (noting that the federal regulations do not supersede more restrictive state laws governing prisoner participation in medical research).

130. See 45 C.F.R. § 46.301(a).

131. 2006 IOM Report, *supra* note 18, at 4. According to Title 45, "prisoners" include anyone who is "involuntarily confined or detained," which would include individuals in prisons and jails, but might not include those in nontraditional correctional settings such as drug-treatment facilities or work-release programs. 45 C.F.R. § 46.303(c).

132. 45 C.F.R. §§ 46.101(a), 46.301(a)-(c).

past decade.¹³³ For instance, in 1997, Dr. Steiner, a psychiatrist at Stanford University, conducted an experimental drug trial on sixty-one juvenile prisoners within the California Youth Authority (CYA).¹³⁴ Dr. Steiner administered Depakote, a drug approved by the FDA as a treatment for epileptic seizures, to the youth subjects, in order to test the drug's effectiveness as a treatment for a completely different problem: aggressive and violent behavioral tendencies.¹³⁵ An Institutional Review Board at Stanford approved the study, even though it involved a questionable consent practice—allowing the CYA to consent on behalf of youths whose parents did not respond to mailed consent forms within thirty days.¹³⁶ Also, the CYA apparently neglected to grant official approval for the study; an unidentified lower-level administrator gave Dr. Steiner permission to conduct the study.¹³⁷

Both Stanford and the CYA, as institutions that accept federal funding, are subject to the federal regulations governing research on prisoners. The *Los Angeles Times* interviewed Dr. Thomas Pugliese, then-director of the OHRP, about the research protocol for the Depakote study, and Dr. Pugliese expressed concerns about the research protocol. Specifically, he objected to the use of placebos in the study. Because placebos have experimental but not therapeutic value, their use violates the federal requirement that medical experiments on prisoners directly benefit the individual prisoner subject.¹³⁸ The Inspector General for the State of California also investigated the study for violations of human subjects protection restrictions.¹³⁹

Across the country, in Florida, at the same time Dr. Steiner was conducting the Depakote study, private pharmaceutical companies funded University of Miami researchers to conduct drug trials on HIV-infected prisoners.¹⁴⁰ The *St. Petersburg Times* published a feature story on the drug trials in 2000 and noted a number of potential ethical problems. First, some prisoners did not understand parts of the study; for instance, a reporter noted that one prisoner was taking at least some placebos, without even understanding the meaning of “placebo.”¹⁴¹ Of course, this is doubly problematic, because federal regulations generally discourage the use of placebos in prisoner populations, as former OHRP Director Pugliese suggested in response to the Depakote study in California, and because any subject must

133. See Dober, *supra* note 69, at 6-7, 10.

134. Weber, *supra* note 129.

135. *Id.*

136. Dober, *supra* note 69, at 6.

137. Weber, *supra* note 129.

138. *Id.* As noted above, the applicable California state restrictions on prisoner experimentation supercede the less restrictive federal regulations.

139. *Id.*

140. Sydney P. Freedberg, *Questions Raised over AIDS Research on Inmates*, ST. PETERSBURG TIMES, Mar. 19, 2000, at 1A.

141. *Id.*

at least understand what kind of treatment he is receiving or not receiving in order to provide informed consent to participate in an experiment. Second, while the HIV-positive prisoners received no monetary compensation for participation in the study, they did receive better housing (with air conditioning), new clothing (including more comfortable tennis shoes), and better treatment from university researchers and professional healthcare providers than they had received in the traditional prison setting.¹⁴² In other words, prisoner participants in the University of Miami program faced the choice not just of participating in an experimental drug trial, but of escaping sub-standard housing conditions, without adequate healthcare or air conditioning—a potentially health-compromising condition in Florida. Where unhealthy or inhumane prison conditions influence a prisoner's choice to participate in an experimental protocol, consent is compromised. Finally, drug companies potentially influenced both researchers and correctional officials through compensation packages. Specifically, the researchers at the University of Miami running the study received funding from private drug companies like Glaxo and Merck.¹⁴³ In addition, the director of health services in Florida prisons received honoraria from the drug companies funding the studies.¹⁴⁴

In order to conduct these studies, the state had to lift its ban on human subjects research in prisons. The state also sought and received approval from the ethics arm of the National Institutes of Health, a government agency that was also involved in funding the Florida HIV drug trials. Nonetheless, the OHRP intervened and cited the University of Miami HIV-treatment drug trial for violating the human subjects protections in Title 45 that govern research on prisoners.¹⁴⁵ As the University of Miami HIV-treatment experiment suggests, experimentation on prisoners occurs not only outside of the regulatory power of the OHRP, but also within the OHRP's regulatory power.

The OHRP evaluates compliance with the DHHS regulations codified in Title 45, including the regulations limiting experimentation on prisoners to narrow categories of targeted, therapeutic research. The OHRP conducts both for-cause compliance oversight based on “substantive written allegations” from research subjects, researchers, or research publications, as well as not-for-cause compliance oversight based on a variety of factors, including the volume of research at the targeted institution or agency and previous concerns with compliance.¹⁴⁶

142. *Id.*

143. *Id.*

144. *Id.*

145. Letter from Sanford Leikin, Compliance Oversight Coordinator, to Norman Altman, Vice Provost for Research, Univ. of Miami, Ira Clark, President, Pub. Health Trust, and Gus Godoy, Research Adm'r, V.A. Med. Ctr. (July 31, 2000), available at http://www.hhs.gov/ohrp/detrm_lettrs/jul00l.pdf (criticizing research protocols for experiments involving prisoners conducted by the University of Miami).

146. OHRP, *supra* note 128, at 2, 4. Judging by OHRP noncompliance letters, non-

After learning of a violation, or an alleged violation, the OHRP conducts a review and “issues findings of noncompliance” in determination letters sent to the violating institution or agency.¹⁴⁷ An OHRP finding of non-compliance can result in a range of outcomes—from recommendations for improvements to withdrawal of DHHS funding, removal of investigators or agency heads, and halting of research projects.¹⁴⁸ Determination letters from 2000 through 2008 are publicly available on the OHRP website, with reference to some unresolved issues redacted.¹⁴⁹

A careful review of the publicly-available OHRP non-compliance determination letters spanning the years 2000 through 2008 suggests that experimentation on prisoners regularly occurs. Apparently, drug trials like the Hythian addiction drug trials, the Stanford Depakote trial, and the University of Miami HIV-treatment drug trial occur despite strict federal regulations, which have now been in place for forty years, and which were intended to limit severely such experimentation, if not to eliminate it entirely.¹⁵⁰ The number of OHRP determination letters per year ranges from thirty-seven to over one hundred; in total, there are 778 letters available online. Every year, anywhere from three to more than one dozen of the non-compliance determination letters mention protocols or studies involving research on prisoners or prisoner participants.

The OHRP determination letters indicate that prisoner experimentation has taken place in the past decade, sanctioned by universities across the United States, including the University of California, the University of Texas, the

compliance issues come to the attention of the OHRP through two common means: complaint letters written by researchers or research participants, or notices of suspension or termination of research from individual institutional review boards. *See, e.g.*, Letter from Carol J. Weil, Div. of Compliance Oversight, Dep’t of Health & Human Servs., to Susan Kelly, President, Charles R. Drew Univ. of Med. & Sci. (Feb. 11, 2008), *available at* http://www.hhs.gov/ohrp/detrm_lettrs/YR08/feb08c.pdf (noting researcher initiated the complaint); Letter from Lisa A. Rooney, Compliance Oversight Coordinator, Dep’t of Health & Human Servs., to Robert M. Mahley, President, The J. David Gladstone Insts., Sue Carlisle, Assoc. Dean, Univ. of Cal., S.F., Eugene Washington, Executive Vice Chancellor, Univ. of Cal., S.F. (Dec. 17, 2007), *available at* http://www.hhs.gov/ohrp/detrm_lettrs/YR07/dec07a.pdf (noting research subject initiated the complaint); Letter from Lisa A. Rooney, Compliance Oversight Coordinator, Dep’t of Health & Human Servs., to Kyle De Fur, President, Saint John’s Health Sys. (Nov. 28, 2007), *available at* http://www.hhs.gov/ohrp/detrm_lettrs/YR07/nov07d.pdf (noting OHRP knew research had been suspended).

147. Office for Human Research Prots., Compliance Oversight, <http://www.hhs.gov/ohrp/compliance/> (last visited Oct. 29, 2008).

148. OHRP, *supra* note 128, at 5-7.

149. Office for Human Research Prots., OHRP Fact Sheet, <http://www.hhs.gov/ohrp/about/ohrpfactsheet.htm> (last visited Oct. 29, 2008); *see also* Office for Human Research Prots., 2008 Determination Letters, <http://www.hhs.gov/ohrp/compliance/letters/index.html> (last visited Oct. 29, 2008) [hereinafter Office for Human Research Prots., 2008 Determination Letters]. Un-redacted letters, letters sent prior to the year 2000, and full reports on noncompliance findings are available only in response to Freedom of Information Act requests. *Id.*

150. *See* 45 C.F.R. § 46.301-06.

University of Miami, and the University of Florida.¹⁵¹ The titles of the experimental protocols reviewed in certain OHRP letters—such as “Evaluation of HIV/AIDS Case Reporting of Prisoners in Florida” or “Role of Attachment in Early Onset of Conduct Problems”—indicate that some experiments using prisoner subjects have involved sensitive and private medical information, while others have involved behavioral research.¹⁵² In other words, the experiments might involve more than minimal risks to prisoner subjects, in violation of Title 45 regulations. Often, however, the OHRP omits details of the experiments that might confirm or disprove this suspicion. Indeed, many of the OHRP determination letters that reference research protocols involving prisoners are heavily redacted, and they tend to refer to statutes that have been violated, rather than providing factual details about specific violations.

Even those letters that simply describe procedural violations reveal that institutional review board (IRB) procedures are frequently flawed and fail to provide adequate protections to prisoner subjects of experimentation. For instance, IRBs have approved the use of exculpatory language on consent forms, failed to provide heightened evaluations and specific justifications for the use of prisoner subjects in experiments, and denied prisoner representatives roles on decision-making panels. To name a specific example, in 2000, the OHRP criticized the University of Texas for using the following exculpatory language on its consent forms: “Neither UTMB nor [the investigator] can assume financial responsibility or liability for the expenses of such treatment.”¹⁵³ Not only do the federal regulations strictly forbid such exculpatory language on consent forms, but regulations specifically require that prisoner volunteers not be subjected to any risks beyond those non-prisoner volunteers would face.¹⁵⁴ In addition, IRBs have failed on multiple occasions to conduct appropriate risk-benefit analyses to ensure that all prisoners

151. See generally Office for Human Research Prots., 2008 Determination Letters, *supra* note 149; see also Letter from Michael A. Carome, Chief, Compliance Oversight Branch, Div. of Human Subject Prots., to Dorothea Wilson, Vice President for Research, Univ. of Tex. Med. Branch at Galveston (Sept. 14, 2000), available at http://www.hhs.gov/ohrp/detrm_lettrs/sep00b.pdf; Letter from Sanford Leikin to Norman Altman, Ira Clark, and Gus Godoy, *supra* note 145.

152. Letter from Karena Cooper, Compliance Oversight Coordinator, Div. of Compliance Oversight, OHRP, to John Agwunobi, Sec’y of Health, Fla. Dep’t of Health (Oct. 13, 2004), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR04/oct04a.pdf; Letter from Karena Cooper, Compliance Oversight Coordinator, Div. of Compliance Oversight, OHRP, to John Agwunobi, Sec’y of Health, Fla. Dep’t of Health (Aug. 13, 2004), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR04/aug04n.pdf; Letter from Karena Cooper, Compliance Oversight Coordinator, Div. of Compliance Oversight, OHRP, to Mark A. Emmert, President, Univ. of Wash. (Sept. 9, 2005), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR05/Sep05.pdf.

153. Letter from Michael A. Carome to Dorothea Wilson, *supra* note 151, at 6.

154. 45 C.F.R. § 46.116 (describing general requirements for informed consent and explaining that exculpatory language is forbidden), § 46.305(a)(3) (describing limitations on risks to which prisoner volunteers can be subjected).

participating in experimentation are doing so solely for their own benefit.¹⁵⁵ For instance, a number of the determination letters criticize research protocols and IRB reviews that fail to evaluate whether, when a previously un-incarcerated subject of experimentation enters prison, “it is in the best interests of the subject to remain in the research study while incarcerated.”¹⁵⁶

The University of Miami IRB, which approved HIV-treatment drug trials for prisoner populations, also failed to provide a number of requisite protections to prisoner subjects in the drug trials. First the University failed to include a prisoner representative as a full voting member on the IRB that approved the drug trial. Second, the University failed to document findings that justified prisoner participation in research protocols. Finally, the University failed to prove that the pilot study actually had “a reasonable probability of improving the health or well-being of the subjects.”¹⁵⁷ The OHRP’s concerns were significant enough that it ordered the immediate suspension of all the DHHS-supported research projects at the University of Miami for which violations had been noted.¹⁵⁸

In general, the OHRP seems to scrutinize any mention of prisoners in research protocols, often criticizing IRBs that fail to articulate, on the record, whether a particular experiment falls within one of the four permissible categories of prisoner experimentation.¹⁵⁹ Title 45 prohibits research on

155. See OFFICE OF THE INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM, at ii-iii (1998), available at <http://www.oig.hhs.gov/oei/reports/oei-01-97-00193.pdf> (noting that institutional review boards are overworked, face conflicts of interest, and are insufficiently regulated); DIV. OF COMPLIANCE OVERSIGHT, OFFICE FOR HUMAN RESEARCH PROTS., OHRP COMPLIANCE OVERSIGHT ACTIVITIES: SIGNIFICANT FINDINGS AND CONCERNS OF NONCOMPLIANCE 3-6 (2005), available at <http://www.hhs.gov/ohrp/compliance/findings.pdf> (describing the range of concerns the OHRP frequently identifies in evaluating IRB compliance, or non-compliance, with Title 45).

156. See, e.g., Letter from Kristina C. Borrer, Dir., Div. of Compliance Oversight, to Chiyome L. Fukino, Dir. of Health, Haw. State Dep’t of Health, and James R. Gaines, Vice President for Research, Univ. of Haw. 5 (June 25, 2007), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR07/jun07b.pdf (regarding a study titled “Effects of Upcountry Maui Water Additives on Health”).

157. Letter from Sanford Leikin to Norman Altman, Ira Clark, and Gus Godoy, *supra* note 145, at 2, 5.

158. *Id.*

159. See, e.g., Letter from Kristina C. Borrer, Dir., Div. of Compliance Oversight, OHRP, to Richard Sheridan, J.D., Gen. Counsel, Scripps Health (Apr. 10, 2006), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR06/apr06a.pdf; Letter from Patrick J. McNeilly, Compliance Oversight Coordinator, Div. of Compliance Oversight, OHRP, to Charles F. Zukoski, Vice Chancellor for Research, Univ. of Ill. at Urbana-Champaign 5 (Oct. 12, 2006), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR06/oct06b.pdf; Letter from Robert J. Meyer, Compliance Oversight Coordinator, Div. of Compliance Oversight, OHRP, to C. Bradley Moore, Vice President for Research, Nw. Univ. (Aug. 30, 2005), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR05/aug05f.pdf; Letter from Robert J. Meyer, Compliance Oversight Coordinator, Div. of Compliance Oversight, OHRP, to Lewis J. Smith, Acting Vice President for Research, Nw. Univ. (June 29, 2005), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR05/jun05a.pdf.

prisoners unless the research falls into one of four narrow categories.¹⁶⁰ Therefore, researchers who fail to articulate what exception justifies their research have apparently ignored the general rule against using prisoners as subjects of medical experiments. Indeed, the OHRP itself has expressed concern with researchers' lack of compliance with the Title 45 regulations governing research on prisoners; the OHRP maintains a web page specifically dedicated to explaining the protocols governing research involving prisoners.¹⁶¹ Such failures undermine the assumption in the 2006 IOM Report that IRBs can feasibly be expected to conduct case-by-case risk-benefit analyses for every research protocol involving prisoner subjects.

Although the specific details of experiments involving prisoners cannot be gleaned from many of the OHRP letters, some letters clearly refer to experimental protocols that have been reported in public media outlets or otherwise investigated.¹⁶² These public investigations reveal further details about how prisoners were used in the medical experiments the OHRP has cited for violations of the regulations protecting prisoner research subjects. For instance, the OHRP cited the University of Miami HIV-treatment drug trial for a number of violations; as noted earlier in this section, news reports on this trial from the *St. Petersburg Times* and other local news sources provide more details about the drug trial than do the OHRP letters. The OHRP expressed similar concerns about drug trials conducted in Texas state prisons by the University of Texas Medical Branch (UTMB). Like the drug trials conducted in Florida prisons by the University of Miami, local and national news sources investigated the Texas drug trials and reported on their findings.¹⁶³ According to an investigative series on healthcare in the Texas state prison system, published in the *Austin American-Statesman* in 2001, UTMB ran multiple drug trials that incorporated prisoner participants. In 2001, there were "at least nine

160. See 45 C.F.R. § 46.306.

161. The webpage is called "OHRP Prisoner Frequently Asked Questions"—a clear acknowledgement that medical experimentation takes place in prisons and that the OHRP attempts to monitor this research. See OHRP, U.S. Dep't of Health & Human Servs., OHRP Prisoner Frequently Asked Questions, <http://www.hhs.gov/ohrp/prisonerfaq.html> (last visited Nov. 2, 2008).

162. See Ward & Bishop, *supra* note 34 (describing University of Texas Medical Branch (UTMB) experiments on prisoners; the OHRP cited UTMB for violations of the Title 45 regulations governing research on prisoners in a September 2000 letter: Letter from Michael A. Carome, Chief, Compliance Oversight Branch, Div. of Human Subject Prots., to Dorothea Wilson, Vice President for Research, Univ. of Tex. Med. Branch at Galveston (Sept. 14, 2000), available at http://www.hhs.gov/ohrp/detrm_lettrs/sep00b.pdf); Dober, *supra* note 69, at 11 (noting that the OHRP sent a determination letter to the University of Texas Medical Branch in 2000); see also Freedberg, *supra* note 140 (describing University of Miami experiments on prisoners; the OHRP cited the University of Miami for violations of Title 45 regulations governing research on prisoners in a July 2000 letter: Letter from Sanford Leikin to Norman Altman, Ira Clark, and Gus Godoy, *supra* note 145).

163. See, e.g., Ward & Bishop, *supra* note 34; Julia Lutsky, *Texas and Florida Prisoners Used in Medical Experiments*, PRISON LEGAL NEWS, Apr. 2001, at 6.

drug trials” with approved prisoner participants, and there were at least ninety-nine prisoners participating in these drug trials.¹⁶⁴ The *Austin American-Statesman* article noted that UTMB “doesn’t keep a count” of exactly how many prisoners participate in drug trials.¹⁶⁵ More disturbingly, based on their interviews with multiple prisoners, the reporters summarized the prisoners’ motivations for participating in the drug trials: “[t]he only way to receive what prisoners consider decent medical care was to join a biomedical research trial in Galveston.”¹⁶⁶ Most of the prisoner participants were HIV-positive, and many of the trials focused on HIV treatment, which the *Austin-American Statesman* implies the prisoners had no alternative means of accessing without participating in experimental drug trials.

Because the federal government helped fund these drug trials, the OHRP had authority to investigate whether the researchers were complying with federal human subjects regulations.¹⁶⁷ As noted earlier in this section, the OHRP found numerous violations of the federal regulations in their investigation, from UTMB’s use of exculpatory language on its consent forms to its failure to document its justifications for using prisoners as the subjects of medical experiments.¹⁶⁸ As with the University of Miami, the OHRP ordered the immediate suspension of prisoner participation in all UTMB research projects receiving federal funding.¹⁶⁹

One thing is clear from the fact that 778 OHRP non-compliance determination letters are available online: lack of compliance with the basic protocols governing human subjects research, in and out of prison, has been both frequent and widespread since at least 2000. In fact, a number of the violations cited in the determination letters, though not related to research on prisoners, have disturbing implications for the feasibility of implementing adequate protections in the prison context. For instance, some frequently cited compliance violations include: failure to establish adequate privacy standards for research subjects,¹⁷⁰ failure to ensure standards for informed consent that guarantee disclosure of “risks and discomforts associated with” experimentation,¹⁷¹ overly permissive use of exculpatory statements in

164. Ward & Bishop, *supra* note 34.

165. *Id.*

166. *Id.*

167. *Id.*

168. Letter from Michael A. Carome to Dorothea Wilson, *supra* note 151, at 10-11.

169. *Id.*

170. *See, e.g.*, Letter from Carol J. Weil, Compliance Oversight Coordinator, OHRP, to Winfred M. Phillips, Vice President, Univ. of Fla., and Thomas Sutton, Acting Director, Malcom Randall VA Med. Ctr. (May 2, 2007), *available at* http://www.hhs.gov/ohrp/detrm_lettrs/YR07/may07a.pdf.

171. *See, e.g.*, Letter from Kristina C. Borrer, Dir. Div. of Compliance Oversight, to David McLaughlin, Provost, N.Y.U. 1 (Mar. 5, 2008), *available at* http://www.hhs.gov/ohrp/detrm_lettrs/YR08/mar08b.pdf.

informed consent documents,¹⁷² and IRB memberships that are incomplete (such as when no prisoner representative serves on the board) or compromised (as when a board member has invested in a drug company whose research protocols the board is reviewing).¹⁷³ If violations of the current regulations, which have been in place for thirty years, occur this frequently, then relaxing the guidelines for research on particularly vulnerable populations, like prisoners—with their diminished abilities to assert their rights, to consent, or to seek alternative medical care—appears dangerous indeed.

While the OHRP determination letters provide a window into the experimentation taking place in prisons, these letters certainly do not capture the full extent or frequency of prisoner participation in medical experimentation. As noted above, the OHRP does not have the authority to regulate private research taking place in non-traditional correctional settings. If the term “prisoner” were interpreted to include individuals in such settings, including closely-monitored probation programs, or work-release programs, or drug-treatment facilities, even more experimentation would likely be found to be occurring.¹⁷⁴ Nonetheless, the four case studies cited above of recent drug trials—the Hythian drug-addiction trial in Texas, the Stanford psychiatric and anger-management drug trial in California, the University of Miami HIV-treatment drug trial in Florida, and the University of Texas HIV-treatment trials in Texas—reveal the variety of medical experiments in which prisoners have participated in the past decade, the difficulties of regulating these experiments, and the ethical problems that arise even within regulated experiments. Ironically, these cases, along with the OHRP determination letters from the 2000s, suggest that the changes made to the federal regulations in the 1970s did not end experimentation in prisons, but did succeed in removing this experimentation from the public eye.

2. *Human Sardines and Other Problems with Prison Conditions Today*

Investigative journalism and a review of OHRP determination letters from the past eight years indicate that prisoners continue to be used in drug trials and as the subjects of biomedical research, despite the federal regulations

172. See, e.g., Letter from Patrick J. McNeilly, Compliance Oversight Coordinator, Div. of Compliance Oversight, OHRP, to Stein Sture, Interim Vice Chancellor for Research & Interim Dean of the Graduate School, Univ. of Colo. at Boulder 2 (July 6, 2006), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR06/jul06a.pdf.

173. See, e.g., Letter from Lisa A. Rooney, Compliance Oversight Coordinator, OHRP, to Albert L. Walker, President, Bluefield State Coll. (Feb. 21, 2008), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR08/feb08d.pdf.

174. Indeed, one OHRP determination letter specifically noted that a program “for previously incarcerated homeless women with substance abuse disorders” was exempt from the special prisoner-related human subjects protections. Letter from Carol J. Weil, Div. of Compliance Oversight, OHRP, to Gary R. Butchen, Executive Dir., Bridge Back Recovery Homes, Inc. 1, 4 (Oct. 15, 2007), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR07/oct07a.pdf.

implemented in 1978. While the use of prisoners in drug trials and as the subjects of biomedical research might not have decreased as much as 1970s reformers would have hoped or expected, other conditions of the prison system have changed more than those reformers could have ever imagined.

First, the prison population has increased more than ten-fold since 1978.¹⁷⁵ This increase in population has led to overcrowding throughout federal and state prisons in the United States.¹⁷⁶ This overcrowding, in turn, causes a variety of problems, from instability and violence within the prison population, to extended delays in receiving medical care.¹⁷⁷ The increased population has been attributed to changes in sentencing policy, both in the duration of sentences meted out and in the sheer numbers of people sentenced to prison for decreasingly violent crimes.¹⁷⁸

The related characteristics of overcrowding and increasingly long sentences are major contributors to a second and growing problem in U.S. prisons: inadequate healthcare. In fact, “inadequate” is an understatement: the

175. See Figure 3.1 and surrounding text in ZIMRING, *supra* note 74, at 46 (graphing the steep increase in incarceration numbers since 1960); Bureau of Justice Statistics, U.S. Dep’t of Justice, Prison Statistics, <http://www.ojp.usdoj.gov/bjs/prisons.htm#publications> (last visited Oct. 14, 2008) (counting 2,299,116 people in prison and jail in the United States at mid-year 2007—the most recent statistics available); see also Bureau of Justice Statistics, U.S. Dep’t of Justice, Correctional Populations: 1980-2006, <http://www.ojp.usdoj.gov/bjs/glance/tables/corr2tab.htm> (identifying 1980 prison population at 319,598, and 2006 prison population at 1,492,973).

176. See, e.g., *Plata v. Schwarzenegger*, No. C01-1351 TEH, 2007 U.S. Dist. LEXIS 56031, at *6 (N.D. Cal. July 23, 2007) (describing overcrowding in California prisons and associated healthcare inadequacies); *Balla v. Idaho Bd. of Corr.*, No. CV81-1165-S-EJL, 2005 U.S. Dist. LEXIS 38804, at *4 (D. Idaho Dec. 9, 2005) (describing “current and ongoing constitutional violations” based on overcrowding, and refusing to terminate a 1987 injunction instituting a population cap to limit overcrowding); *Gomez v. Singletary*, 733 So. 2d 499, 501-04, 507 (Fla. 1998) (describing the history of increasing prison overcrowding in Florida: between 1983 and 1993, overcrowding “exceeded all of the prior thresholds” for maximum capacities; in 1995, the Florida legislature set the “lawful capacity” of the prison system” at 150 percent of design capacity); *County of Gloucester v. State*, 623 A.2d 763, 764 (N.J. 1993) (referencing “the severe and continuing problem of prison overcrowding” and evaluating whether an ongoing emergency existed based on this overcrowding); see also William J. Sabol et al., *Prisoners in 2006*, BUREAU JUST. STATS. BULL., Dec. 2007, at 5, available at <http://www.ojp.usdoj.gov/bjs/pub/pdf/p06.pdf> (noting that “Federal prison system was operating at 37% above its rated capacity at the end of 2006”); Andy Furillo, *Jails Fill up, Inmates Pour out in Capital Region*, SACRAMENTO BEE, Sept. 7, 2008, at A1 (noting that California jails released “86,064 convicted inmates from jail before they had completed their sentences” in 2007); J. Clark Kelso, *State Must Invest in Prison Health-Care Facilities*, S.F. CHRON., Aug. 28, 2008, at B9 (describing overcrowding in the California state prisons “with 172,000 inmates in 33 facilities, the state’s correctional system is operating at double capacity”).

177. See, e.g., *Plata*, 2007 U.S. Dist. LEXIS 56031, at *6 (describing the possible connection between unconstitutional healthcare and prison overcrowding); Ward & Bishop, *supra* note 34 (describing the findings of a National Commission on Correctional Health Care investigation that documented “pill lines as long as 1,000 inmates,” which often kept Texas prisoners from getting to the window in time to get their time-sensitive medications, such as HIV anti-retrovirals).

178. See William J. Sabol et al., *supra* note 176, at 3-4 (describing prison population increase as based at least partially on more admissions than releases).

healthcare in many U.S. prisons borders on inhumane.¹⁷⁹ Relatedly, U.S. prisoners are markedly less healthy than the average U.S. citizen. They are more likely to be HIV positive.¹⁸⁰ Likewise, they are more likely to have other infectious and often fatal diseases like tuberculosis and hepatitis C.¹⁸¹ Moreover, the strains of disease that prisoners have are likely to be drug resistant, in part at least because prisoners tend to have inconsistent access to medication in and out of prison.¹⁸² U.S. prisoners are not only less physically healthy than the general population; they are also less mentally healthy.¹⁸³ Additionally, they suffer from other inflictions of poverty, including very low education levels.¹⁸⁴ Prisoners also tend to have limited access to resources, and what jobs are available in the prisons tend to pay negligible sums.¹⁸⁵

In addition to structural changes in prisons, such as overcrowding, and detrimental demographic factors, such as high disease exposure and low literacy rates, legal impediments have increasingly limited individual prisoners' abilities to bring lawsuits against prison officials and other institutional actors. Specifically, in 1996, the Prison Litigation Reform Act (PLRA) was passed with the intention of severely limiting prisoner lawsuits, particularly around conditions of confinement.¹⁸⁶ The Act has largely accomplished its goals.¹⁸⁷

Each of these problems with prisons in the United States in 2008 has

179. See, e.g., *Plata v. Schwarzenegger*, No. C01-1351 THE, 2007 U.S. Dist. LEXIS 43673 at *4 (N.D. Cal. June 4, 2007) (ongoing lawsuit on behalf of prisoners in the state of California who have suffered from unconstitutionally bad healthcare; the court noted that "one inmate needlessly dies every six to seven days due to constitutional deficiencies"); Mike Ward & Bill Bishop, *'Deadly Inadequacies' Plague Inmate Wards: Gaps in Evaluating Care Let Some Mistakes Go Unnoticed*, AUSTIN AM.-STATESMAN, Dec. 16, 2001, at A1 (describing gruesome and abusive healthcare practices in Texas state prison system such as allowing prisoners to die in their own feces or forcing terminally ill prisoners to crawl onto and out of a transport bus).

180. Theodore M. Hammett, Mary Patricia Harmon & William Rhodes, *The Burden of Infectious Disease Among Inmates of and Releasees from U.S. Correctional Facilities, 1997*, 92 AM. J. PUB. HEALTH 1789 (2002) (noting that U.S. prisoners are HIV positive at five times the infection rate of the general population).

181. Ward & Bishop, *supra* note 34.

182. *Id.*

183. See SASHA ABRAMSKY & JAMIE FELLNER, ILL-EQUIPPED: U.S. PRISONS AND OFFENDERS WITH MENTAL ILLNESS 25 (2003), available at <http://www.hrw.org/reports/2003/usa1003/> (suggesting that up to 40 percent of the U.S. prison population either suffers from significant psychiatric dysfunction or will require some kind of psychiatric intervention during their incarceration).

184. According to the Prison Policy Initiative, 19 percent of the U.S. prison population is completely illiterate, and 40 percent are "functionally illiterate," which means someone would be "unable to write a letter explaining a billing error." PETER WAGNER, THE PRISON INDEX: TAKING THE PULSE OF THE CRIME CONTROL INDUSTRY (2003), available at <http://www.prisonpolicy.org/prisonindex/rootsofcrime.html>.

185. See *supra* note 67 (discussing current pay rates for prison laborers).

186. See *infra* note 202.

187. See SAVE Coalition, Prison Litigation Reform Act (PLRA): Myths and Facts, <http://www.savecoalition.org/myths.html> (last visited Oct. 14, 2008) (noting that between 1981 and 1995, the rate of prisoner filings of civil rights cases decreased from twenty-nine per thousand prisoners to twenty-five per thousand prisoners (while the prison population itself doubled)).

affected and will continue to affect any individual prisoner's ability to participate freely and voluntarily in experimental medical research. First, prisoners are both more likely to be in need of medical care and less likely to have adequate care than the general population. Hence, prisoners might choose to participate in medical experiments because such participation is the only access they have to any form of medical care. Second, because of their high illiteracy rates and low education levels, prisoners are likely to have difficulty understanding complicated consent forms and might even be confused about basic experimental protocols. Third, prisoners who do participate in medical experimentation might have a compromised ability to enforce their rights in a court of law, either because they have no access to legal resources outside of the limited, outdated, hardcopy law books available inside prison libraries, or because they are barred from filing any claim at all under the PLRA.

3. New Oversight Mechanisms: the 2006 IOM Report

Whereas the 1976 DHEW Report Commission convened as regulations around human subjects research were first being formulated, the 2006 IOM Report Committee was the product of more than thirty years of such regulation and included representatives from a variety of regulatory agencies. The 2006 IOM Report Committee included many more people than the 1976 DHEW Commission: in addition to thirteen core committee members, the 2006 IOM Report Committee included one "expert adviser," three consultants, six IOM staff members, and seventeen independent report reviewers.¹⁸⁸ The core committee members were drawn from the humanities, law, and medical programs of elite universities, as well as from nonprofit agencies, policy organizations, and law firms.¹⁸⁹

Overall, these members represent a range of legal and academic perspectives and areas of expertise, from ethics to prison conditions to medical care. Some were pre-existing members of the Institute of Medicine, such as Lawrence O. Gostin, the Chair of the 2006 IOM Report Committee. Many of the members, such as Jeffrey L. Metzner, who has evaluated correctional mental health problems across the United States, and Michael S. Hamden, the former director of the nonprofit Prisoner Legal Services in North Carolina, brought first-hand experience of the prison system to the Committee and appear to be free of substantial conflicts of interest.

188. 2006 IOM Report, *supra* note 18, at v-viii.

189. *Id.* at v. The specific backgrounds and qualifications of the Committee members appear in Appendix E to the 2006 IOM Report. *Id.* at 239-52. While a few critics have accused both the Committee and the Institute of Medicine of having financial interests in the pharmaceutical and biotech industry, *see, e.g.*, Alliance for Human Research Prot., IOM Panel Recommends Using Prison Inmates as Guinea Pigs in Drug Trials_NYT, Aug. 13, 2006, *available at* http://www.ahrp.org/cms/index2.php?option=com_content&do_pdf=1&id=308, these accusations seem to be unfounded, based on the qualifications of the Committee members.

Although this Comment criticizes the recommendations in the 2006 IOM Report, the motivations of the federal agency that commissioned the Report, and the motivations of the Report's authors, were unquestionably ethical. Indeed, the Report's authors appear to have been motivated by an honest desire to review and update regulations that had not been reconsidered since their implementation thirty years prior. Moreover, the Report's authors explicitly stated their awareness that the current regulations are being enforced in a vastly different research environment, in terms of scale, financing, and vulnerable population demographics. For example, the recommendations in the Report that focus on expanding the definition of prisoner and maintaining better databases of ongoing research reaffirm the good intentions of the Report's authors, who should be commended for recognizing the limits of federal oversight.¹⁹⁰

Indeed, the 2006 IOM Report authors identify the changing conditions and demographics of U.S. prisons noted in Part I.B.2. above as one impetus for the report. Specifically, the Report mentions the growing prison population, increasingly composed of minorities and women, many of whom suffer from mental illness, infectious diseases, and inadequate healthcare.¹⁹¹ In the preface to the Report, the authors acknowledge a second impetus for the report: the "considerable amount of confusion and disagreement in the research community regarding the interpretation and application of Subpart C of 45 C.F.R. Part 46," which addresses experimentation on prisoners in a prison setting.¹⁹²

While changing demographics and confusion over current regulations provide the explicit impetus for the Report, there are implicit motivations as well. First, the ongoing use of prisoner subjects in a variety of biomedical experiments, especially in drug trials, may have influenced the decision to commission an investigation into revising the current regulations. Second, not only confusion about federal regulations, but also the clear violations of federal regulations, which the OHRP has cited in the limited category of research projects subject to OHRP authority, may also have played a role in inspiring the Report. Indeed, it was the OHRP itself that commissioned the 2006 IOM Report.¹⁹³ Interestingly, however, the Report makes no mention of either specific examples of the ongoing use of prisoners in medical experiments, or of the OHRP non-compliance letters sent out over the past eight years.

Whereas the 1976 DHEW Report thoroughly catalogued the kinds of experimentation taking place in prisons in the 1970s and pointed to specific human rights violations, the 2006 IOM Report speaks only in generalities about

190. 2006 IOM Report, *supra* note 18, at 7.

191. *Id.* at 24-25; *see also, supra*, Part I.B.2 entitled "Human Sardines and Other Problems with Prison Conditions Today."

192. 2006 IOM Report, *supra* note 18, at 24.

193. *Id.*

the kind of research that might be occurring in prisons today.¹⁹⁴ The IOM Committee's failure to acknowledge the history of prisoner experimentation, either before 1976 or in more recent years, led it to make one central, significantly misguided proposal for reforming research involving prisoner subjects: instituting a risk-benefit framework.¹⁹⁵

The Report fails to discuss how such a standard might be enforced, or whether it might exacerbate violations already taking place under the existing, more straightforward categorical standards that are, nonetheless, frequently breached. Indeed, the Report fails to evaluate whether the existing regulations have succeeded in limiting experimentation on prisoners. Understanding how the 1976 recommendations shaped prisoner experimentation in the subsequent thirty years should be an integral part of making recommendations to further oversee and control experimentation on prisoners.

In sum, while the Report acknowledges changed conditions in U.S. Prisons, it does not adequately account for the current conditions of U.S. prisons, incentives for researchers to incorporate prisoner subjects, or the limitations of even an expanded regulatory authority. Without taking these factors into account, recommendations like the one for a risk-benefit framework are not only unrealistic, but are potentially dangerous to individual prisoner subjects.

II

CHANGE: WHAT ARE THE RECOMMENDED REGULATORY REFORMS?

Both the 1976 DHEW Report and the 2006 IOM Report reflect the historical context in which each was generated. The revelations in the media and the courts regarding the frequency and abusiveness of prison medical experiments in the 1970s were recent and shocking at the time the DHEW Report was written. The DHEW Report broke new ground, setting up the first federal regulatory framework for human subjects research and protections of vulnerable populations. Thirty years later, the 2006 IOM Report seeks to refine that framework, and to reexamine regulations against prisoner experimentation in the context of a larger, more unwieldy criminal justice system. While this new project is admirable and necessary, the resulting recommendations are imperfect. The 2006 IOM Report suffers for its lack of engagement with the kind of details the 1976 DHEW Report contained—about current prison conditions, about current medical experiments in prisons, and about the feasibility of enforcing human subjects protections.

This Part briefly analyzes and compares the kinds of data each report

194. As noted above, the 2006 IOM Report does not even refer to any of the human subjects violations catalogued in the OHRP non-compliance determination letters discussed above. *See infra* Part I.B.1.

195. 2006 IOM Report, *supra* note 18, at 8.

considers and incorporates. Then, in Part A, the 1976 DHEW Report recommendations are reviewed. In Part B, the 2006 IOM Report recommendations are reviewed. Specifically, the 2006 recommendations include two categories: those that seek to expand some human subjects research protections for prisoners, and those that seek to shift the framework for analyzing human subjects research on prisoners from categorical limitations to individual risk-benefit analyses.

The 1976 DHEW Report considers the pros and cons of biomedical testing in particular prisons as well as the institutional and medical systems within which its recommendations will need to function. The Report acknowledges that two principles—“respect for persons” and “justice”—might justify either of two opposite positions: forbidding prisoner participation in experiments in order to protect them from exploitation and abuse, or, alternatively, allowing prisoner participation in experiments in order to protect their right to choose to volunteer and their equal access to the benefits of research.¹⁹⁶ However, the DHEW Commission concludes that within the institutional and medical settings of U.S. prisons, “persons seem regularly to engage in activities which, were they stronger or in better circumstances, they would avoid,” and so “respect dictates that they be protected against those forces that appear to compel their choices.”¹⁹⁷

The 1976 DHEW Report provides rich details about the activities most free citizens would likely try to avoid, but which forces in U.S. prisons seem to compel prisoner subjects to participate in. For instance, in its description of the California Medical Facility at Vacaville (still in operation today), the DHEW Commission describes not only the kinds of biomedical testing being conducted at the prison, but also the more general conditions of prison life at the facility. The Report documents the availability of job opportunities, educational opportunities, legal advice, and prisoners’ level of contact with the outside world through partially-censored mail and pay phones.¹⁹⁸ The Report also emphasizes the relationship between prison conditions and informed consent. In doing so, it notes that sub-par conditions—including limited access to job opportunities and the outside world, parole practices and demands, and the degree to which every aspect of prisoners’ lives is controlled—compromise prisoners’ ability to provide informed consent. In addition, the 1976 DHEW Report reviews a survey commissioned for the Report about international practices of drug testing and notes that the United States is unique in its use of prisoners for drug testing, but also unique in its requirement that Phase I research be conducted on healthy volunteers (as opposed to on sick patients who might benefit from the drug trial).¹⁹⁹

196. 1976 DHEW Report, *supra* note 8, at 3078.

197. *Id.*

198. *Id.* at 3084.

199. *Id.* at 3090.

The DHEW Commission could hardly have imagined the changes that would take place in the U.S. prison system in the years following the release of its report. The prison population in the United States more than quintupled, and the combined prison and jail populations increased ten-fold.²⁰⁰ Twenty years after the 1976 DHEW Report, the repeal of Pell Grant funding virtually eliminated prisoners' access to education in prisons.²⁰¹ At around the same time Pell Grants were repealed, passage of the Prison Litigation Reform Act severely limited the ability of prisoners to challenge any condition of confinement.²⁰² Meanwhile, prisons expanded into rural areas of the United States where civilian populations have severely limited access to healthcare, and prisoners have even less access.²⁰³ In addition, both the levels of crowding and disease in U.S. prisons increased dramatically, along with problems in providing healthcare to the increasing and increasingly sick population.²⁰⁴ Finally, both indeterminate sentences and parole came to a near or total end in many states across the nation, obviating at least one concern of the 1976 DHEW Report's authors: indeterminate sentencing.²⁰⁵ Inasmuch as prison officials had control over any individual's sentence, those officials could exercise coercive influence, trading promises of a shorter sentence for consent to experimental participation.

From its very title, and throughout its 265 pages, the 2006 IOM Report shifts the framework of analysis from particular prison and research communities to broader regulatory frameworks. Rather than being a straightforward report about the status of *Research Involving Prisoners*, the 2006 IOM Report is about *Ethical Considerations* in research involving prisoners. The 2006 IOM Report focuses not on the nature of past or current research in prisons, but on the ethical frameworks within which such research should take place. The 2006 IOM Report does devote thirty pages to "changing demographics" and "health issues" in prisons.²⁰⁶ However, unlike the careful documentation of prison conditions in specific institutions visited by the

200. See *supra* note 175 (citing a number of graphs and statistics documenting the increase in prison and jail populations in the United States in the last thirty years).

201. Pell Grant funding, which allowed prisoners to enroll in college courses, ended in 1994 with the passage of the Violent Crime Control Act. See, e.g., Richard Tewksbury, David John Erickson & Jon Marc Taylor, *Opportunities Lost: The Consequences of Eliminating Pell Grant Eligibility for Correctional Education Students*, 31 J. OFFENDER REHABILITATION 43 (2000); Joshua Page, *Eliminating the Enemy: The Import of Denying Prisoners Access to Higher Education in Clinton's America*, 6 PUNISHMENT & SOC'Y 357 (2004).

202. See generally JOHN BOSTON, THE PRISON LITIGATION REFORM ACT (2004), available at <http://www.wnyc.net/pb/docs/plra2cir04.pdf>.

203. See, e.g., RUTH WILSON GILMORE, GOLDEN GULAG: PRISONS, SURPLUS, CRISIS, AND OPPOSITION IN GLOBALIZING CALIFORNIA (2007) (addressing the economic choices involved in locating prisons in rural areas and the impacts of these choices).

204. See *supra* Part I.B.2 on "Human Sardines."

205. See generally JOAN PETERSILIA, WHEN PRISONERS COME HOME: PAROLE AND PRISONER REENTRY (2003).

206. 2006 IOM Report, *supra* note 18, at 29-59.

Commission that wrote the 1976 DHEW Report, the 2006 IOM Report focuses on aggregate data about the number of people in prison and their general demographic characteristics, like gender, age, and education.²⁰⁷ Similarly, the 2006 IOM Report provides aggregate statistics about mental and physical health of the prison population.²⁰⁸

In the same chapter of the 2006 IOM Report, the Committee reviews the kinds of research permitted and taking place in state prisons across the United States. Again, these are aggregated data, based on in-depth surveys in six states and more cursory surveys in the remaining forty-four states.²⁰⁹ The Committee admitted “it faced a dearth of information as to the recent and current landscape of research involving prisoners as participants.”²¹⁰ Nonetheless, the aggregated form of the data in the 2006 IOM Report is notably different from the combination of aggregate and specific data provided in the 1976 DHEW Report. In particular, the 2006 IOM Report provides less specific information about conditions in prisons and experiments taking place in prisons. Moreover, while the 2006 IOM Report authors acknowledge concern about the dangers of unregulated experiments, they express more hope for regulatory possibilities than the 1976 DHEW Report authors, even though they provide little empirical evidence to justify their hopeful perspectives.

The remainder of the 2006 IOM Report focuses on describing the ethical foundations of the current regulations regarding research on prisoners,²¹¹ the ethical foundations of the 1976 DHEW Report,²¹² and the key definitions that should change based on a comparison between these two ethical perspectives.²¹³ The final chapter specifies the categories of safeguards that should exist and applies these categories to specific examples of potential research projects.²¹⁴ Nowhere does the 2006 IOM Report discuss international drug testing and biomedical experimentation practices, so there is no comparative benchmark with the practices of other countries.²¹⁵

In sum, while the 2006 IOM Report is almost four times as long as the 1976 DHEW Report, the 2006 Report, in terms of content and rigor, is skeletal by comparison. The 2006 IOM Report contains much less discussion of either the history or status of human subjects experimentation in prison, and the 2006 Committee also seems less concerned with determining and analyzing current prison conditions. Further, the Report is generally less engaged with the

207. See, e.g., *id.* at 31-41, Tables 2.1-2.8, mostly reproducing data publicly available through the Bureau of Justice Statistics.

208. See *id.* at 42-58.

209. *Id.* at 59.

210. *Id.*

211. *Id.* at 73-100.

212. *Id.* at 113-36.

213. *Id.* at 101-12.

214. *Id.* at 137-74.

215. See *infra* Section III.A. (discussing comparative international standards).

Committee's own process in reaching recommendations and more concerned with general changes in ethical standards and how these might affect the law around human subjects experimentation.

A. 1976 Recommendations

The recommendations section of the 1976 DHEW Report comprises only seven pages and includes five simple and straightforward recommendations. The first two recommendations concern two kinds of studies on prisoners and in prisons that the Commission approved. First, the Commission approved studies involving only questions about prisons and prisoners themselves. For instance, the Commission approved of research questions about prisons as institutions, incarceration as a process, and prisoner as a status—as long as the studies both “present[ed] minimal or no risk and no more than mere inconvenience” to the prisoner participant and also met the proposed general experimentation requirements in subsequent recommendations.²¹⁶ Second, the Commission approved studies of practices intended to and likely to benefit prisoners themselves—again, as long as the practices met the proposed general experimentation requirements in subsequent recommendations.²¹⁷

The third, fourth, and fifth recommendations set limits on biomedical experimentation in prisons; these limits are so strict as to amount to a presumption against any such experimentation taking place at all.²¹⁸ The third recommendation suggests that experimentation on prisoners take place only after a “national ethical review body” certifies that the research provides a “compelling” justification for using prisoners, “satisfies conditions of equity,” and meets voluntariness standards, including stringent minimum conditions of confinement.²¹⁹ In the comments following this third recommendation, the Commission enumerated seventeen specific confinement conditions that should be met for a prison to satisfy conditions of equity and voluntariness standards.²²⁰ These seventeen conditions included: an absence of overcrowding, the availability of single-occupancy cells, operable toilets, access to functioning showers, “good quality medical facilities . . . adequately staffed and equipped,” sufficient mental health care, educational programming, and assurances of personal safety.²²¹ (Note how many of these conditions were highlighted as ongoing problems in the Part I.B.2 above on “Human Sardines.”) Without these preconditions, the Commission argued, prisoners cannot provide actual informed consent to participate in biomedical research. The enumeration of the seventeen quite specific minimum conditions of confinement suggests that the

216. 1976 DHEW Report, *supra* note 8, at 3080.

217. *Id.*

218. *Id.* at 3080-81.

219. *Id.* at 3080.

220. *Id.* at 3080-81.

221. *Id.* at 3080.

Commission either found such standards absent in their evaluation of prison conditions or was concerned that the standards would be absent in the future. Furthermore, the specificity of the minimum conditions requirements suggests that such standards might be difficult to achieve. Indeed, in the Report's introduction, the Commission states that it "did not find in prisons the conditions requisite for a sufficiently high degree of voluntariness and openness."²²²

The final two recommendations, the fourth and fifth, describe procedures for reviewing and approving prisoner participation in experimentation. The fourth recommendation requires that both institutional agency directors and independent institutional review boards, which should be required to include prisoner or prisoner advocate members, approve any research in prisons.²²³ The final recommendation limits the duration of any then-existing, non-complying, non-certified medical research projects to one year from the date of publication of the recommendations.²²⁴

Congress codified these five succinct recommendations into a federal law designed to eliminate nearly all human experimentation in U.S. prisons: Subpart C of the "Protection of Human Subjects" regulations in the Code of Federal Regulations.²²⁵ Although Congress did not codify the DHEW Report recommendations verbatim, it did incorporate the Report's presumption against biomedical research. Specifically, the federal law allows for only four categories of research on prisoners: studies about incarceration and criminal behavior, studies about prisons and prisoners, "research on conditions particularly affecting prisoners," and "research on practices . . . which have the intent and reasonable probability of improving the health or well-being of the subject."²²⁶ The first two categories of behavioral studies must present "no more than minimal risk and no more than mere inconvenience to the subjects."²²⁷ In sum, the law restricts behavioral and biomedical research "conducted or supported" by the DHHS.²²⁸ Non-therapeutic biomedical research, such as that conducted by drug companies, is absolutely excluded from the permissible categories of research on prisoners. In addition, Title 45, Part 46 provides the standards for institutional review boards governing research on prisoners.²²⁹

222. *Id.* at 3079.

223. *Id.* at 3081.

224. *Id.*

225. 45 C.F.R. §§ 46.301-.306.

226. 45 C.F.R. § 46.306(a)(2)(i)-(iv).

227. *Id.*

228. *Id.*

229. 45 C.F.R. §§ 46.107-.115, 46.304.

B. 2006 Recommendations

The 2006 IOM Report's recommendations appear in small, dense print in its twenty-page summary section, in much more detail than the succinct recommendations that appear in seven double-spaced pages in the 1976 DHEW Report.²³⁰ The 2006 Report recommendations suggest transforming the existing code of federal regulations governing experiments on prisoners, from a system of categorical approval and disapproval of research into a more flexible system of case-by-case analysis of permissible research.

Like the 1976 DHEW Report, the 2006 IOM Report identifies five key categories of reform. However, rather than making straightforward recommendations about exactly what kind of research is and is not acceptable, as the 1976 DHEW Report does, the 2006 IOM Report makes a series of recommendations that are organized around five "objectives":

The committee's recommendations are directed to five distinct objectives: (1) expand the definition of "prisoner," (2) ensure universal, consistent ethical protection, (3) shift from a category-based to a risk-benefit approach to research review, (4) update the ethical framework to include collaborative responsibility, and (5) enhance systematic oversight of research with prisoners.²³¹

At first glance, these objectives seem to call for expanded protections for prisoners involved in research. In fact, in the four-page online summary of the 2006 IOM Report, the Committee notes the "four-fold" increase in the U.S. population under correctional supervision over the past thirty years.²³² The Committee also acknowledges that access to adequate healthcare can be a problem in a correctional population of this size and suggests that "these factors point to a population that is more vulnerable and requires stronger protections than those inspired by the national commission in the 1970s."²³³

Implicit in this focus on expanding protections, however, is an acknowledgement of the continued existence of some forms of experimentation in prison. Thus, the recommendations seek to regulate experimentation rather than simply curtailing or limiting it. On the one hand, reviewing the categorical limitations implemented in the 1970s and refining the regulatory standards

230. The 2006 IOM Report is available for purchase from the National Academies Press at a cost of \$41.40, or for free online at: http://www.nap.edu/catalog.php?record_id=11692#toc.

231. INST. OF MED. OF THE NAT'L ACADS., REPORT BRIEF: ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS 2 (2006) [hereinafter 2006 IOM Report Brief].

232. See Figure 3.1 and surrounding text in ZIMRING, *supra* note 74, at 46 (graphing what looks to be an eight-fold increase in incarceration numbers since 1960); see also Bureau of Justice Statistics, U.S. Dep't of Justice, Correctional Populations: 1980-2006, <http://www.ojp.usdoj.gov/bjs/glance/tables/corr2tab.htm> (identifying 1980 prison population at 319,598, and 2006 prison population at 1,492,973, suggesting a 4.7-fold increase in only twenty years).

233. 2006 IOM Report Brief, *supra* note 231, at 1. The 2006 IOM Report includes not just the prison population in this number, but the total population of people in prisons and jails and on probation and parole.

makes sense. On the other hand, making any refinements without evaluating whether those 1970s regulations have accomplished their goals, or whether adequate safeguards protect prisoners participating in experiments today, is difficult to justify.

A more careful analysis of the recommendations the Committee makes within each of the five objectives identified will illuminate the Report's potential impact on federal regulations of human subjects research in prison. The five objectives fit into two categories: expanding protections for prisoner research subjects and shifting from a categorical to a risk-benefit evaluation of potential research studies.

1. Expanding Protections

To implement the objectives seeking to expand protections, the Committee recommends expanding the vulnerable subjects regulations to protect any person in a setting in which his or her "liberty is restricted."²³⁴ Current Title 45 regulations apply only to people in prisons and in jails, but the Committee's recommendations would incorporate the millions of people in the United States who are on probation, on parole, or in nontraditional correctional settings such as drug treatment facilities.²³⁵ The Commission also recommends expanding the scope of oversight authority of the OHRP and similar offices.²³⁶

In addition, the Report suggests the maintenance of a public database of research involving prisoners, as well as new requirements for both transparency and accountability in this research.²³⁷ These recommendations respond to Committee findings both that procedures for overseeing and regulating research in prison were inconsistent from state to state, and also that reporting of this research was inconsistent and difficult to find.²³⁸ Finally, the Report also insists upon more consistent and rigorous review of proposed studies, with involvement from prisoners and correctional staff.²³⁹ In sum, the refinements the 2006 IOM Report Committee suggest are expansive: create a national database, drastically expand the number of "prisoner" subjects covered by the regulations through altered definitions, and broaden the scope of agency regulation to include non-government-funded projects.

Given the current, ongoing problems with human subjects research—problems the existing, narrowly-defined oversight system identifies annually, as detailed in the Part I discussion of the OHRP's non-compliance determination letters—expanding this system and enforcing new regulations on

234. 2006 IOM Report, *supra* note 18, at 4–5.

235. 45 C.F.R. § 46.303(c) (defining "prisoner").

236. 2006 IOM Report, *supra* note 18, at 6–7; *see also* 45 C.F.R. § 46.306(b) (delineating the limited applicability of the regulations).

237. 2006 IOM Report, *supra* note 18, at 7.

238. *Id.* at 59.

239. *Id.* at 10.

an even grander scale presents at best a considerable challenge and at worst an impossible task. Nonetheless, expanding the oversight system is a laudable goal, and one that Congress, the OHRP, and other oversight agencies should work together to accomplish. Once expanded oversight systems are in place, the systems should be carefully evaluated to determine their effectiveness. Only once expanded oversight has been designed, implemented, and evaluated for its success in achieving its goals, should broader prisoner participation in research even be considered. In other words, a simple proposal to expand oversight of human subjects research on prisoners should not serve as a justification for simultaneously expanding prisoner participation in such research. Any expansion of participation should be contingent on documented successes in expansion of oversight.

2. *Shifting Frameworks*

The second category of objectives the 2006 IOM Report recommends involves shifting the framework for analyzing potential research trials that propose to involve prisoner subjects. Specifically, this Committee objective calls for overhauling the categorical prohibitions against non-beneficial biomedical research (as codified in the federal regulations) and replacing them with a “risk-benefit approach,” which would force researchers to “identify the particular ethical issues that each protocol raises in the specific context of the correctional setting.”²⁴⁰ The 2006 Committee was careful to note that a risk-benefit framework might still maintain blanket prohibitions against cosmetic products testing and Phase I and II FDA-sanctioned drug testing trials, because such biomedical experiments would not directly benefit prisoners, and they pose more than minimal risks.²⁴¹ However, the 2006 IOM Report suggests that Phase III drug testing likely would meet the ethical standards of the risk-benefit framework.

According to the Report, the key determinants of a favorable risk-benefit ratio are not whether the proposed experiment has therapeutic goals, but whether any test being run has already produced “some evidence of safety and efficacy” and whether “the ratio of prisoner to nonprisoner subjects does not exceed 50 percent.”²⁴² In some situations, if a research trial particularly targets a condition specific to a prison population, these two conditions might even be waived.²⁴³ In sum, with the addition of a few significant refinements to safeguards for vulnerable populations, the Committee believes that experimentation on prisoners, even including non-therapeutic research, could be safe and humane.

Although the 2006 IOM Report sets a tone of protective reform, the actual

240. *Id.* at 8.

241. *Id.*

242. *Id.* at 9.

243. *Id.*

recommendations suggest at numerous points that research on prisoners should be expanded. The 2006 Committee freely acknowledges that it does not wish to ban all human subjects research in prison. In the preface to the Report, the Committee notes that recommending “a virtual ban on human subject research involving prisoners” would be a simple, but lazy, solution.²⁴⁴ After all, the Committee notes, research has benefits, including improving “correctional settings” and addressing health problems faced particularly by correctional populations, such as infectious diseases, addiction, and mental health problems.²⁴⁵ Recommendations such as compiling databases seem targeted at regulating and reviewing, rather than necessarily limiting, biomedical research. Moreover, the Report explicitly suggests the possibility of using prisoners in Phase III drug trials and in other biomedical research targeting conditions likely to be found in incarcerated populations.

In fact, the Committee suggests a hope that its recommendations will facilitate prisoner participation in cutting-edge drug trials and treatments for diseases particularly affecting prisoner populations. There are two problems with this hope. First, the current federal regulations already permit just these kinds of therapeutic research projects in correctional settings. Title 45 explicitly suggests that experimental hepatitis treatments should be permitted in prisons, because prisoners are particularly likely to have hepatitis.²⁴⁶ The 2006 IOM Report recommends establishing oversight and creating databases to determine whether any such therapeutic research projects take place in prisons and encourages such projects to take place more often. According to the authors of the 2006 IOM Report, the limited oversight of prisoner experimentation currently in place made it impossible for the Committee to determine whether prisoners are actually participating in experimental treatment trials for diseases they face with particular frequency.²⁴⁷

There is a second problem with the hope for more beneficial research. Although some therapeutic studies targeting prisoners with HIV have recently taken place in Texas and Florida, overcrowded, inhumane, and unhealthy prison conditions compromise the voluntary nature of prisoner participation in these studies. The 2006 IOM Report Committee argues that certain conditions particularly or “almost exclusively” affect incarcerated populations, and, by extension, these conditions might justify allowing increased prisoner participation in medical experiments.²⁴⁸ The Report provides the examples of the high incidence of experiences of repetitive sexual assaults in prisoner populations, suggesting that such a health problem characteristic of the prisoner population might justify prisoner participation in a biomedical research study of

244. *Id.* at x.

245. *Id.*

246. 45 C.F.R. § 46.306(a)(2)(iii).

247. 2006 IOM Report, *supra* note 18, at 59.

248. *Id.* at 9-10.

unknown benefit.²⁴⁹ Indeed, the UTMB and University of Miami studies conducted on HIV-positive Texas and Florida prisoners, respectively, as discussed in Part I.B., might constitute just the kind of prisoner-targeted study that the 2006 IOM Report Committee had in mind. After all, prisoner populations have significantly higher prevalence rates of HIV infection than the general population.²⁵⁰ And without the possibility of participating in HIV drug trials, prisoners in Texas or Florida might not have access to adequate HIV treatments in overcrowded prisons with limited healthcare facilities.

Suddenly those insufficiently regulated studies in Texas and Florida, which the OHRP cited for violations of the federal human subjects regulations, seem like studies where the benefits to an underserved population might far outweigh the risks. Indeed, such studies might be presumptively justifiable under a risk-benefit analysis, rather than presumptively excluded, without further, careful justifications, as they are under the current categorical analysis codified in the federal regulations. This risk-benefit scale tips even further toward the benefit side if the HIV drugs used in the study have already been proven to have at least some potential efficacy. But this is exactly the problem with the risk-benefit framework: under this framework, the very conditions in the U.S. prison system, such as overcrowding and limited healthcare, which make prisoners a particularly vulnerable population, weigh in favor of allowing prisoners to participate in drug trials. In fact, prisoners themselves argue that they should be allowed to participate in such trials.²⁵¹ But this Faustian bargain of “choosing” between sub-standard prison conditions and becoming a guinea pig is hardly a choice at all. Moreover, falsely positing the situation as a choice simply allows universities and private drug companies to invest in and control state prisons that should themselves take responsibility for providing adequate living conditions and healthcare to all prisoners, not simply those infected with HIV who happen to be “lucky” enough to join an external drug trial.

The 2006 IOM Committee failed to explain how a risk-benefit approach would take into account the basic conditions of confinement problems facing U.S. prisons. How would a risk-benefit framework protect prisoners from being forced into therapeutic research as the only means of attaining healthcare? Or, more disturbingly, how could a risk-benefit framework protect prisoners from being forced into non-therapeutic research, where they believe they are receiving treatment but they actually are only receiving a non-therapeutic placebo, often without even understanding the meaning of the term “placebo”? A vitally important point here is that while a risk-benefit ratio “strongly favorable” to prisoners is indisputably a *necessary* condition for any biomedical experimentation in prison, it should not be a *sufficient* condition.

249. *Id.*

250. *See supra* note 180.

251. *See, e.g.,* Ward & Bishop, *supra* note 34 (describing prisoners urging each other to join drug trials).

As the 1976 DHEW Report noted, regulatory authorities must document basic conditions of confinement within the prison system before permitting any experimentation—even targeted, therapeutic research—in prisons. Moreover, adequate regulatory safeguards over such analyses must also be in place. However, the breadth of the regulatory safeguard changes suggested in the 2006 IOM Report, along with the numerous violations of current regulations cited in the public media and the OHRP determination letters, as described in Part I.B., indicate that such safeguards are not in place.

In sum, the recommendations in the 2006 IOM Report for greater oversight of prisoner experimentation are critical to protecting prisoner subjects of any experiment or trial, even therapeutic behavioral research. However, these recommendations are not adequate to justify any expansion of the use of prisoners in experimental research, particularly for non-therapeutic purposes.

As recommended by the 1976 DHEW Report, any new federal legislation should ensure that basic conditions of humane confinement and adequate oversight are satisfied *before* any expansion of prisoner participation in biomedical research should be considered. Moreover, any individualized risk-benefit analysis must focus solely on the risks and benefits to the individual prisoner participant, and research should not be deemed beneficial simply because a prisoner has no alternative means of receiving adequate treatment or healthcare. Until adequate oversight is well-established, and prison conditions ensure all prisoners receive basic healthcare, even without agreeing to participate in drug trials, the 2006 IOM Report recommendation to implement a risk-benefit framework for evaluating proposed biomedical research on prisoners will remain both premature and idealistic.

III

REGULATION: WHAT ETHICAL STANDARDS GOVERN HUMAN MEDICAL EXPERIMENTATION?

One goal unites the many ethical standards—both legal and medical—that govern experimentation on human subjects: an aim to correct the power imbalance between doctor and patient, researcher and subject. The physician or researcher must have sufficient leeway to use his knowledge and resources to treat patients to the best of his professional ability; the patient or subject must have both the right to weigh the risks and benefits of various treatments and the ability to make a reasoned, consensual decision about the kind of care to which he submits. The law, be it international or domestic, tends to assume that the patient or subject holds less power than the doctor or researcher, and that safeguards must be institutionalized in order to protect the patient-subject. This assumption seems both reasonable and necessary in light of the history of medical experimentation reviewed in Part I.

Safeguards protecting patient-subjects from power imbalances include consent requirements, ethical review requirements, and requirements that the

experiment be beneficial, usually both to the patient and to medical practice more generally. The institutional frame of the prison setting not only magnifies the doctor-patient, researcher-subject power imbalance, but also highlights all three concerns about consent, ethics, and benefits—concerns that have shaped the existing safeguards for human subjects experimentation. A careful review of the domestic and international standards, which apply to human subjects research in general and to prisoner experimentation specifically, will help to contextualize any proposed changes to federal standards as recommended by the 2006 IOM Report.

A. *International Standards*

The 1976 DHEW Report contains a chapter entitled “Alternatives and Foreign Practices” in which the DHEW Commission reviews medical experimentation practices in the United States outside of prisons, as well as foreign medical experimentation standards generally.²⁵² The 1976 DHEW Report cites a survey of foreign practice, which documented that most foreign countries permitted pharmacology experiments to be conducted on human subjects such as student, civil servant, or paramedical volunteers, but not on prisoners.²⁵³ The DHEW Report notes that while there is no evidence of foreign countries using prisoners for Phase I drug tests, many countries documented the use of prisoners for “nontherapeutic research.”²⁵⁴ However, the example of foreign, non-therapeutic research noted in the Report is relatively non-invasive: a survey of the prevalence of the XYY chromosome.²⁵⁵

Unlike the 1976 DHEW Report, the 2006 IOM Report contains little analysis of international norms regarding medical experimentation on humans in general or prisoners in particular. Nor does the 2006 IOM Report discuss empirical trends in medical testing on humans outside of the United States. Both reports do mention the Nuremberg Code, the first set of international standards for human subjects research, developed during the Nazi war crimes trials.²⁵⁶ However, the 2006 IOM report provides few details about the development in the twentieth century of international norms around medical experimentation on humans generally and prisoners specifically.

The Nuremberg Code, while a proxy for presumptive international standards of human medical experimentation, is non-binding and actually appears only in the U.S. Nuremberg Military Tribunal decision convicting the Nazi doctors who conducted grotesque medical experiments on concentration

252. 1976 DHEW Report, *supra* note 8, at 3088-90.

253. *Id.* at 3089. Merck Sharp & Dohme Research Laboratories, a private pharmaceutical company, provided the survey.

254. *Id.* at 3090.

255. *Id.*

256. *Id.* at 3076; 2006 IOM Report, *supra* note 18, at 114, 194.

camp prisoners.²⁵⁷ In fact, international standards are now more clearly developed than their first articulation in the Nuremberg Code.²⁵⁸ An examination of these international standards provides an important context for thinking about how to frame American human experimentation standards, especially as those standards pertain to prisoners. First, some of these international standards are binding on the United States as a treaty signatory. Second, assessing how other countries have handled human medical experimentation is critical to analyzing “evolving standards of decency,” a concept drawn from Eighth Amendment jurisprudence evaluating what constitutes cruel and unusual punishment.²⁵⁹ Courts have applied this Eighth Amendment “evolving standards of decency” analysis to evaluate prisoner claims challenging the sufficiency of medical treatment received; the standard is therefore relevant to analyzing both basic conditions of confinement and human subjects research protocols.²⁶⁰

In *United States v. Brandt*, the Nuremberg Medical Trial in which Nazi doctors were tried for war crimes committed in the name of medical science, the Nazi doctors presented a defense based on a claim that the standards governing human subjects research were ambiguous, and so there could be no charge of a violation of an unknowable standard. In response to this claim, the Nuremberg judges wrote the Nuremberg Code into their final judgment.²⁶¹ The Nuremberg Code contains ten points. The Code prioritized the requirement of voluntary consent by making it the first of ten points. The remaining nine

257. Jonathan D. Moreno, *Reassessing the Influence of the Nuremberg Code on American Medical Ethics*, 13 J. CONTEMP. HEALTH L. & POL'Y 347, 348 (1997). Although the Code is nonbinding, it has been mentioned in U.S. case law with great deference. See, e.g., *United States v. Stanley*, 483 U.S. 669, 710 (1987) (O'Connor, J., concurring in part and dissenting in part); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 821 (S.D. Ohio 1995). The Nuremberg Code was also mentioned by the Department of Defense and the National Institutes of Health in the adoption of strict consent standards for human experimentation in the United States in the 1950s. *In re Cincinnati Radiation Litig.*, 874 F. Supp. at 821.

258. See, e.g., World Med. Ass'n, Declaration of Helsinki, available at <http://www.wma.net/e/policy/b3.htm> [hereinafter Declaration of Helsinki]; WORLD HEALTH ORGANIZATION & THE COUNCIL OF INT'L ORGANIZATION OF MED. SCIS., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (rev. 2002), http://www.cioms.ch/frame_guidelines_nov_2002.htm [hereinafter CIOMS Guidelines]; International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (Dec. 16, 1966), 999 U.N.T.S. 171 (entered into force Mar. 23, 1976, in accordance with Article 49), available at http://www.unhcr.ch/html/menu3/b/a_ccpr.htm [hereinafter ICCPR].

259. See *Roper v. Simmons*, 543 U.S. 551, 551, 575 (2005) (referencing international norms around execution of juveniles “as instructive for . . . interpretation of the Eighth Amendment’s prohibition of ‘cruel and unusual punishments’”) (citing *Trop v. Dulles*, 356 U.S. 86, 102-03 (1958)).

260. See, e.g., *Roach v. Kligman*, 412 F. Supp. 521, 525 (E.D. Pa. 1976) (“When a claim against prison officials is based on improper medical treatment, it must depict conduct that is so cruel and unusual as to present a colorable Eighth Amendment claim.”) (citing *Gittlemacker v. Prasse*, 428 F.2d 1 (3d Cir. 1970)).

261. Moreno, *supra* note 257, at 348.

points revolve around protecting human subjects of experimentation from suffering pain, permanent injury, or death, and require constant attention to the “humanitarian importance” of the experiments.²⁶²

A number of commentators have argued that the non-binding code had no immediate influence on Western doctors, who viewed the regulations as directed toward Nazi soldiers, rather than toward themselves.²⁶³ Nonetheless, international law scholars argue that the Code established the preeminence of consent as the core principle that must guide any human subjects experimentation. For instance, one scholar notes that the Nuremberg Code “first was seen as obviously applying to imprisoned and oppressed persons, then to all healthy subjects, then to those who were sick but would not benefit from an experiment, and then finally to those who were sick but stood a chance of benefiting from research participation.”²⁶⁴ In other words, although not binding on any individual nation, the Code has had far-reaching effects on the development of the ethics of medical experimentation, in the United States and throughout the world.²⁶⁵

Indeed, the Nuremberg Code’s ten points have been adopted in numerous international guidelines and laws. Most notably, in 1964, the World Medical Association drafted and ratified the Declaration of Helsinki, which incorporated many of the principles from the Nuremberg Code. Since then, the Declaration has been revised five times, in 1975, 1983, 1989, 1996, and 2000.²⁶⁶ The revisions have included the addition of independent review committees as a requirement of ethical research and changed regulations governing the use of placebos in drug trials. Although the Declaration is not binding, it is intended to function as “a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects” around the world.²⁶⁷

This Declaration has a “more flexible view of subject consent” than the Nuremberg Code.²⁶⁸ The importance of informed consent, in writing, is

262. The Nuremberg Code, <http://www.hhs.gov/ohrp/references/nurcode.htm> (last visited Nov. 2, 2008). For further information and documentation about the Nuremberg Trials, see Harvard Law School Library, Nuremberg Trials Project: A Digital Document Collection, available at http://nuremberg.law.harvard.edu/php/docs_swi.php?DI=1&text=overview.

263. See DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING 62-63 (2d ed. 2003); Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, in THE NAZI DOCTORS AND THE NUREMBERG CODE 227, 231 (George J. Annas & Michael A. Grodin eds., 1992).

264. Moreno, *supra* note 257, at 359.

265. See *id.*; see also Henry Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966); Claire Alida Milner, Comment, *Gulf War Guinea Pigs: Is Informed Consent Optional During War?*, 13 J. CONTEMP. HEALTH L. & POL’Y 199, 211-18 (1996) (cited in Moreno, *supra* note 257, at 350 nn.17 & 21, 357 n.62).

266. Declaration of Helsinki, *supra* note 258. Citations in the text are to the most recent (2000) version of the Declaration.

267. *Id.* ¶ 1.

268. Moreno, *supra* note 257, at 357.

relegated to paragraphs 20 and 22 in the Helsinki Declaration, rather than being the first and most prominent command, as it is in the Nuremberg Code.²⁶⁹ Furthermore, the Helsinki Declaration provides for exceptions to the informed consent rule, where a researcher deems it “impossible or impractical to obtain [consent],” or where consent “would pose a threat to the validity of the research,” as long as an ethics committee approves of the waiver of consent.²⁷⁰ Although the Declaration recommends that no subject should consent under duress, and special precautions should be taken for legally incompetent research subjects,²⁷¹ neither prisons nor prisoners are explicitly mentioned anywhere in the document. Thus, the Helsinki Declaration’s stance on the importance of consent falls short of the Nuremberg Code’s stance on consent.

By contrast, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (hereinafter CIOMS Guidelines), published in 1982 by the World Health Organization and the Council of International Organization of Medical Societies (CIOMS), explicitly mentions prisoners in the commentary to Guidelines 9, 12, and 13.²⁷² Guideline 9 states that where research involves “individuals incapable of giving informed consent,” the research must either be of “direct benefit” to the subject, or have a risk that is “no more likely and not greater than the risk attached to routine medical or psychological examination,” unless approved by an ethical review committee, based on a specifically articulated medical rationale.²⁷³ The commentary to the guideline notes that prisoners are among the category of individuals who have a “limited capacity to give informed consent.”²⁷⁴

Guideline 12 concerns the “equitable distribution of burdens and benefits in the selection of groups of subjects in research,” and includes commentary noting that some groups, such as prisoners, have been overused in some kinds of tests, like Phase I drug testing.²⁷⁵ The commentary to this Guideline further states that while “the burdens of research should not fall disproportionately on socio-economically disadvantaged groups,” or institutionalized groups, “neither should such groups be categorically excluded from research protocols.”²⁷⁶ Finally, Guideline 13 recommends special protections for “vulnerable populations” and notes that prisoners might be considered a vulnerable population.²⁷⁷

These CIOMS Guidelines are critical for understanding international standards around informed consent. First, the Guidelines categorize prisoners

269. World Med. Ass’n, *supra* note 258.

270. *Id.* ¶ 25.

271. *Id.* ¶¶ 23, 24.

272. CIOMS Guidelines, *supra* note 258.

273. *Id.* (Guideline 9).

274. *Id.* (Commentary on Guideline 9).

275. *Id.* (Guideline 12 and Commentary).

276. *Id.* (Guideline 12 Commentary).

277. *Id.* (Guideline 13 and Commentary).

as having a compromised ability to participate in informed consent procedures. Second, the Guidelines insist that any human subjects research, particularly on prisoners, must be beneficial to the subjects, and neither overly inclusive nor overly exclusive of disadvantaged populations. Third, the Guidelines advocate for subject protections, implicitly demanding some sort of ethical review procedure for research.

In addition to the standards promoted by the World Medical Association and the World Health Organization, the International Covenant on Civil and Political Rights (ICCPR), which the United Nations adopted in 1966, and to which the United States is a signatory, addresses medical experimentation and consent.²⁷⁸ Article 7 states: “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”²⁷⁹ As CIOMS says in its Ethical Guidelines: “It is through this statement that society expresses the fundamental human value that is held to govern all research involving human subjects—the protection of the rights and welfare of all human subjects of scientific experimentation.”²⁸⁰ The ICCPR is a binding Covenant.

Similarly, a number of European countries have recently adopted binding regulations to control biomedical experimentation on human subjects. In 1997, the Council of Europe ratified the Convention on Human Rights and Biomedicine (CHRB)—“the first legally binding international treaty to govern human experimentation.”²⁸¹ As of 2005, seventeen European countries had ratified the Convention.²⁸² The Convention mentions consent as a requirement for participation in experimentation, but prisoners are not explicitly mentioned.²⁸³

In sum, the international legal and medical communities have articulated specific guidelines for human medical experimentation. These guidelines include a requirement for consent procedures, definitions of the conditions that compromise a person’s ability to consent, and requirements for ethical review

278. ICCPR, *supra* note 258. The United States ratified the ICCPR on September 8, 1992. Office of the High Commissioner for Human Rights, Status of Ratifications of the Principal International Human Rights Treaties, June 9, 2004, *available at* <http://www.unhchr.ch/pdf/report.pdf>.

279. ICCPR, *supra* note 258, Article 7.

280. CIOMS Guidelines, *supra* note 258, “International Instruments and Guidelines.”

281. Benjamin Mason Meier, *International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent*, 20 BERKELEY J. INT’L L. 513, 528 (2002).

282. Markus Schott, *Medical Research on Humans: Regulation in Switzerland, the European Union, and the United States*, 60 FOOD & DRUG L.J. 45, 49 (2005).

283. Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 7, 1997, *available at* <http://conventions.coe.int/treaty/en/treaties/html/164.htm>.

of experimental protocols and review of the allocation of benefits and burdens in experimentation. Arguably, the range and detail of these international legal standards is both broader and more thorough than the proposals in the 2006 IOM Report.

B. Domestic Legal Standards

The federal standards controlling medical research on human subjects in general are codified in a number of sections of the Code of Federal Regulations. “Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects,” the section codifying the recommendations in the 1976 DHEW Report, has already been discussed in great detail above.²⁸⁴ Other sections of the Code of Federal Regulations, particularly within Title 45, regulate the standards for consent, for institutional review board approval, and for analyzing the benefits of human subjects research.²⁸⁵ Additionally, Title 21 of the Code of Federal Regulations, which governs the FDA, also describes standards specifically applicable to drug testing on humans that are similar to the human subjects research standards described in Title 45.²⁸⁶ In addition to these federal regulations, federal and state courts also apply constitutional standards to evaluations of human medical experimentation and healthcare in prison. These constitutional standards include the Fifth, Eighth, and Fourteenth Amendments.²⁸⁷

The “Protection of Human Subjects” sections of Title 45 of the Code of Federal Regulations apply only to federally funded research.²⁸⁸ Similarly, the “Protection of Human Subjects” sections of Title 21 apply to “clinical investigations regulated by the Food and Drug Administration.”²⁸⁹ Federally funded research includes research not only within government agencies, such as the military or prisons, but also research conducted by public educational

284. 45 C.F.R. § 46.301-.306.

285. See 45 C.F.R. pt. 46.

286. See generally 21 C.F.R. pts. 50, 56 (2008), available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>. Specifically, 21 C.F.R. § 50.20 addresses informed consent; 21 C.F.R. pt. 56 addresses institutional review boards.

287. See, e.g., Samuel Jan Brakel, *Considering Behavioral and Biomedical Research on Detainees in the Mental Health Unit of an Urban Mega-Jail*, 22 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 1 (1996). The Eighth Amendment prohibits cruel and unusual punishment and so could be invoked against abusive experimentation in prison. See, e.g., *Roach*, 412 F. Supp. at 528. Likewise, the Fifth and Fourteenth Amendment “due process” and “equal protection” requirements could protect prisoners from being forced into participating in experimentation, or could justify prisoner participation at rates comparable to the rates of free citizen participation in experimentation. Brakel, at 25, n.86.

288. 45 C.F.R. § 46.101(a) (indicating that the protection policy “applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research”).

289. 21 C.F.R. § 50.1(a) (2007).

institutions.²⁹⁰ A brief survey of the letters sent by the Department of Health and Human Services to non-compliant institutions sheds light on the broad array of human subjects research—from HIV treatment trials run by universities to epidemiological studies conducted by state departments of public health—that receives some federal funding and is therefore subject to the regulations.²⁹¹ There are some other exceptions to the application of the Title 45 regulations: the regulations do not apply to educational testing, consumer products testing, or completely non-intrusive testing such as “collection or study of existing data, documents, [or] records.”²⁹² In other words, Title 45 is broad in both content and application. It covers biomedical as well as behavioral research, as recommended in both the Belmont Report, which established basic ethical principles for human subjects research in general, and the 1976 DHEW Report, which particularly targeted research involving prisoners.

Two sections of Title 45 specifically address informed consent.²⁹³ Any human subjects research under federal regulation requires informed consent, and the elements of informed consent are explicitly defined: a subject must have the “opportunity to consider” participation; as much freedom as possible from “coercion or undue influence”; and an explanation of the proposed research, including risks, benefits, and alternatives, in language he or she understands.²⁹⁴ Additionally, informed consent may not include any waiver of legal rights on the part of the subject or waiver of liability on the part of the researcher.²⁹⁵ These rules set firm boundaries requiring researchers to be frank with the subjects of their experiments. While a rule against coercion, a requirement that explanations be clear, and a prohibition on waiving legal rights and obligations might each seem simple, they can all be difficult both to implement and to regulate.

The dozens of determination letters that the OHRP sends annually to researchers regarding their adherence to Title 45 regulations, as discussed in Part I, above, is just one indication of the frequency with which Title 45 regulations are breached or ignored.²⁹⁶ Rules that are difficult to implement and regulate in the free world often face more implementation obstacles—and, conversely, less oversight—in a prison setting. The federal regulations

290. See also *supra* notes 128-129 and surrounding text (discussing additional categories of regulatory authority to which Title 45 applies).

291. See *supra* Part I.

292. 45 C.F.R. § 46.101(b)(4), (1)-(6).

293. 45 C.F.R. §§ 46.116-.117.

294. *Id.* § 46.116.

295. *Id.*

296. A survey of the compliance letters archived on the OHRP website, from 2000 to 2008 suggests that more than a dozen determination letters are sent monthly to document research in violation of some section of the Title 45 human subjects research regulations. See U.S. Dep’t of Health & Human Servs., Office for Human Research Prots., 2000 Determination Letters, <http://www.hhs.gov/ohrp/compliance/letters/2000.html> (last visited Oct. 17, 2008).

explicitly acknowledge this difficulty, noting that prisoners are among the subjects “likely to be vulnerable to coercion or undue influence.”²⁹⁷ Similarly, the prohibition against waivers of legal rights and obligations is inherently difficult to enforce in a prison setting, where the subjects have already lost many of their legal rights, from freedom of movement to civic participation. Additionally, a prisoner’s ability to enforce those rights he or she does have is severely curtailed, both by a lack of access to resources and by laws which actively seek to limit the prisoner’s access to the courts.²⁹⁸

The informed consent rules depend on the existence of active and engaged institutional review boards (IRBs) to mediate ethical gray areas and police legal boundaries. IRBs are independent advisory bodies that oversee human subjects research; any institution sponsoring such research is usually required to have an established IRB. Title 45 directly addresses IRBs in nine separate subsections.²⁹⁹ First, the federal regulations in Title 45 define IRB membership, requiring at least five members, including members with scientific and non-scientific backgrounds, and members affiliated and not affiliated with the institution in which the IRB functions.³⁰⁰ In both Title 45 and Title 21, which governs the FDA, the sections defining IRB membership suggest that IRBs reviewing research involving “a vulnerable category of subjects, such as . . . prisoners” should at least consider “inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.”³⁰¹

The human subjects regulations of Title 45 go on to delineate appropriate IRB procedures and to specify the IRB’s role in enforcing other regulations within Title 45. Specific criteria for IRB reviews include three key requirements: minimization of risks to subjects, evaluating risks in relation to benefits to subjects and to scientific knowledge in general, and equitable selection of subjects.³⁰² Under the section addressing the equitable selection of subjects, prisoners are particularly identified as a category of subjects creating “special problems of research,” which deserve an increased level of scrutiny.³⁰³ The FDA regulations for IRBs, codified at Title 21, identify parallel requirements for drug testing, again including prisoners within the category of “vulnerable populations” requiring heightened review.³⁰⁴

Both the informed consent rules and the IRB rules in Title 45 mention the importance of articulating, analyzing, and justifying the risks and benefits of any research project that uses humans as subjects. In other words, weighing the risks and benefits of any human subjects experiment has been a critical step in

297. 45 C.F.R. § 46.111(b).

298. See BOSTON, *supra* note 202.

299. 45 C.F.R. §§ 46.107-.116.

300. 45 C.F.R. § 46.107.

301. *Id.* § 46.107(a); 21 C.F.R. § 56.107.

302. 45 C.F.R. § 46.111(a)(1)-(3).

303. 45 C.F.R. § 46.111(a)(3).

304. 21 C.F.R. § 56.111(a)(3).

validating or approving human subjects research on prisoners since the 1970s. The emphasis on this risk-benefit approach in the 2006 IOM Report, then, is not novel. However, using this risk-benefit approach to the exclusion of other methods of evaluation or in place of categorical regulations might eliminate critical safeguards against experimental abuses.

The federal regulations codified at Titles 21 and 45 are prospective, designed to prevent the kinds of problems with human experimentation documented in the 1976 DHEW Report and in exposés like Jessica Mitford's *Kind and Usual Punishment*.³⁰⁵ On the other hand, the case law governing human subjects experimentation is retrospective, articulating standards that should have been in place, or identifying sufficient standards that were already in place.³⁰⁶ The case law, then, is more focused on questions of consent and standards of treatment, and less focused on IRB regulations and balancing tests, than the federal regulations. Indeed, in some instances courts seem to be more in tune with international regulations and the focus in international ethical standards, stemming from the Nuremberg Codes, on consent.

In reviewing human medical experimentation challenges, courts have held that informed and voluntary consent is absolutely critical to any research protocol, particularly those involving prisoners. Without informed and voluntary consent, experimentation on prisoners (and other vulnerable populations) will not withstand constitutional scrutiny. Rather, such experimentation will be subject to equal protection, due process, and cruel and unusual punishment challenges. In articulating the importance of informed and voluntary consent, the Supreme Court has directly referenced the Nuremberg Code. Dissenting in a 1987 Supreme Court case regarding biomedical experiments conducted by the U.S. military in the 1950s to test the effects of LSD, Justice Sandra Day O'Connor referenced the Code as a morally binding standard of consent for medical experimentation, enforceable through constitutional guarantees of due process.³⁰⁷ In a district court case in 1995, in which plaintiffs challenged the Human Radiation Experiments conducted by the Department of Defense from 1960 to 1972, the court stated that the Nuremberg Code represents a moral imperative, "part of the law of

305. See MITFORD, *KIND AND USUAL PUNISHMENT*, *supra* note 37.

306. See, e.g., *Mackey v. Procunier*, 477 F.2d 877, 878 (9th Cir. 1973) (holding that if a prisoner did not consent to experimental treatment, an Eighth Amendment question of cruel and unusual punishment would be at issue). *But cf.* *Bailey v. Lally*, 481 F. Supp. 203, 225 (D. Md. 1979) (holding that consent forms and IRB procedures were adequate to protect subjects of biomedical experimentation).

307. *United States v. Stanley*, 483 U.S. 669, 710 (1987) (O'Connor, J., concurring in part and dissenting in part) ("The standards that the Nuremberg Military Tribunals developed to judge the behavior of the defendants stated that the 'voluntary consent of the human subject is absolutely essential . . . to satisfy moral, ethical and legal concepts.' If this principle is violated the very least that society can do is to see that the victims are compensated, as best they can be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much." (citations omitted)).

humanity.”³⁰⁸ These two references in case law to the Nuremberg Code, which emphasizes the fundamental importance of consent in experimentation in its first principle, suggest that American courts consider informed and voluntary consent in evaluating the constitutionality of human subjects experimentation.³⁰⁹

However, courts are divided on whether the circumstance of being in prison compromises a prisoner’s ability to consent. As one author observes, the application of constitutional standards seems to support medical experimentation on prisoners at some points, and at other points seems to discourage such experimentation:

[Constitutional principles] can be used as readily to argue that the potential harm of research may not be visited on a disadvantaged and “situationally coerced” population such as prisoners, as to support the position that precluding prisoners from participating violates their right to be treated with the same respect and deference to their autonomy accorded other citizens.³¹⁰

For instance, in *Mackey v. Proconier*, the appellate court reversed the trial court’s dismissal and remanded for consideration of the merits of the claim that although the prisoner consented to shock treatments, he did not consent to the administration of an experimental drug, which caused him difficulty in breathing.³¹¹ On the other hand, in *Bailey v. Lally*, a challenge to an experiment in which prisoners were exposed to and infected with a variety of illnesses, from diarrhea-inducing bacteria to malaria-carrying mosquitoes, the court found no undue coercion, found good faith on the part of prison officials and experimenters, and found no proof of any violation of the plaintiff’s constitutional rights.³¹² Similarly, in *Roach v. Kligman*, a prisoner sought damages in compensation for permanent liver damage he suffered from biomedical experiments in which he participated in exchange for a small payment.³¹³ When Roach first fell ill in prison, prison doctors gave him penicillin, without inquiring whether he was participating in a medical experiment; Roach claimed the penicillin aggravated his illness and that

308. *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 821 (S.D. Ohio 1995) (“The Nuremberg Code is part of the law of humanity. It may be applied in both civil and criminal cases by the federal courts in the United States” (citing *Stanley*, 483 U.S. 699)).

309. Of course, in recent years, the authority of international laws and treaties has become a point of contention in federal jurisprudence, and the Supreme Court has split over whether international law should even be a point of reference in American legal decisions. *See Roper v. Simmons*, 543 U.S. 551, 605 (O’Connor, J., dissenting) (describing the marginality of international law as a factor in the decision about the juvenile death penalty); *id.* at 622 (Scalia, J., dissenting) (rejecting international law entirely as irrelevant to Eighth Amendment jurisprudence).

310. Brakel, *supra* note 287, at 24.

311. *Mackey*, 477 F.2d at 877.

312. *Bailey v. Lally*, 481 F. Supp. 203, 225, 206 n.7, 207 n.9 (D. Md. 1979).

313. *Roach v. Kligman*, 412 F. Supp. 521, 524 (E.D. Pa. 1976).

conditions in his cell were “inadequate and unconstitutional.”³¹⁴ The court held that the prisoner was not coerced to enter the experiment, the medical care was at most negligent, and the conditions in which Roach was held did not constitute cruel and unusual punishment.³¹⁵ Thus, while some courts have recognized that the Nuremberg Code is a moral imperative, and that consent is critical to human experimentation, there is little consensus as to what constitutes valid consent.

In fact, *Bailey* and *Roach* epitomize the difficulties prisoners have in bringing suits that challenge the conditions of confinement in general, and the detrimental effects of medical experimentation in particular. Even in the 1970s, when concern regarding the problems with biomedical experimentation on prisoners was at its peak, few courts even heard prisoners’ claims against experimenters and prison officials, let alone found in favor of prisoners. Today, prisoners continue to face a number of procedural hurdles in even getting their challenges to medical care and experimental participation heard before a tribunal, as discussed below. And if they are successful at establishing a prima facie case, prisoners face an even higher bar to making an ultimately successful claim, in terms of the standard of proof the law requires a prisoner to meet in order to win a challenge against the government or a prison official.³¹⁶

Initially, prisoners face many procedural hurdles in bringing any challenge to medical care or experimental participation. First, there is a federal requirement (applicable to state prisoners as well) that prisoners exhaust their administrative remedies—through filing a grievance within the institution where they are confined, and, if they are unsuccessful, appealing this grievance to the highest level possible in the institutional chain of command—before a lawsuit can be filed.³¹⁷ For instance, in *McNeil v. United States*, McNeil’s claim against the U.S. Public Health Service for infecting him with hepatitis C through biomedical experimentation was dismissed, because McNeil had failed to exhaust his administrative remedies under the Federal Tort Claims Act.³¹⁸

Prisoners face additional hurdles; for instance, statutes of limitations may expire before the prisoners can realize the full extent of the damages they have suffered from medical experimentation. This is, of course, a particular problem for a population that is confined in an institutional setting. The low literacy and

314. *Id.*

315. *Id.* at 523, 529.

316. Usually a prison official or government actor is a named defendant in these kinds of prisoner challenges, because the institution had some role in approving, facilitating, or following up on the experimentation in which the prisoner participated, even if the actual experimenter was from a private company or an educational institution. *See, e.g., Bailey v. Lally*, 481 F. Supp. 203 (D. Md. 1979) (Lally was the Secretary of Public Safety and Correctional Services in Maryland at the time the case was brought); *Mackey v. Procunier*, 477 F.2d 877 (9th Cir. 1973) (Procunier was the Director of the California Department of Corrections at the time the case was brought).

317. *See BOSTON, supra* note 202, at 10.

318. *McNeil v. United States*, 508 U.S. 106 (1993).

education level of most prisoners exacerbates the problem of meeting timeliness deadlines and articulating a colorable claim.³¹⁹

If a prisoner or former prisoner is successful in bringing a challenge to participation in medical experimentation, he will still face unique hurdles because of his prisoner status. First, any claim a prisoner makes about his unmet needs will always be balanced against claims prison staff make about limitations on institutional resources and requirements of institutional regulations, especially safety.³²⁰ In other words, whereas a non-incarcerated participant in medical experimentation might claim that the researchers failed to warn him adequately of potential side effects of the experiment, or failed to provide adequate follow-up care to alleviate such effects, a prisoner with a similar claim will likely be required to counter institutional claims that providing such information or care might have placed an undue burden on institutional resources or been in conflict with institutional safety regulations.

In addition to having to overcome this balancing test of institutional versus individual needs, prisoners seeking to challenge experimental participation face potential claims of qualified immunity from public employees. For instance, in *Clay v. Martin*, in which a prisoner challenged the treatment he received while enrolled in drug experimentation at the Addiction Research Center in Lexington, Kentucky, the court noted that although Clay had presented a cognizable claim, he would still need to prove “whether 42 U.S.C. § 233(a) protects these Public Health doctors against tort actions for injuries inflicted before its effective date, and whether, if so, the doctors were acting within the scope of their employment.”³²¹

If a prisoner does successfully present a cognizable claim, and the claim survives counter-arguments about qualified immunity and the needs of institutional regulation, courts still must assess whether informed consent existed. Often, if a court finds that informed consent did exist, then this finding is used as a proxy for assuming that the experiment was valid, thereby preventing the prisoner from either challenging the treatment he received or seeking damages. As one author noted:

It has been held that constitutional remedies will not be granted if the subjects are granted the ability to withdraw from the experiment at any time during such experiment. This is a major problem when the informed consent provisions of 45 C.F.R. § 46.116(a) require that every consent form contain a statement informing subjects that they may discontinue participation at any time without penalty or loss of benefits.³²²

319. See *supra* note 184 (referencing low literacy levels of prisoners).

320. See, e.g., *Washington v. Harper*, 494 U.S. 210, 224-25 (1990).

321. *Clay v. Martin*, 509 F.2d 109, 114 (2d Cir. 1975) (citation omitted).

322. Brian Paul Wyman, *Biomedical and Behavioral Research on Juvenile Inmates: Uninformed Choices and Coerced Participation*, 15 J.L. & HEALTH 77, 99-100 (2000-01).

In addition to these clear constitutional standards, one other aspect of case law indirectly governs experimentation on human subjects in general and on prisoners in particular: the legal standard for medical neglect. For prisoners, the bar for establishing medical neglect is so high as to be almost impossible to satisfy. Whereas an average citizen pursuing a claim for improper medical treatment could bring a civil case subject to a standard tort evaluation of duty, breach, and causation, a prisoner must also establish that experimental procedures were “cruel and unusual” within the confines of the Eighth Amendment: “It is only where an inmate’s complaint of improper or inadequate medical treatment depicts conduct so cruel or unusual as to approach a violation of the Eighth Amendment’s prohibition of such punishment that a colorable constitutional claim is presented.”³²³

The standards go on, in extensive case law, to place further limitations on prisoner challenges to medical care. “The act or omission by the official must either be intentionally injurious, reckless, callous, grossly negligent, shocking to the conscience, unconscionable, intolerable to fundamental fairness, or barbarous.”³²⁴ True, a prisoner might face relaxed standards in attempting to sue a drug company rather than a prison official. However, prison officials will likely ultimately be responsible for identifying and providing any follow-up or side-effect-related care a prisoner participating in an experiment might need, unless the researcher removes the prisoner to a non-government facility run completely by private researchers—an unlikely circumstance. As such, a prisoner seeking to challenge the medical care he has received relating to a research experiment will face innumerable roadblocks in attempting to prove that he received care so inhumane and insufficient as to be “cruel and unusual” under the Eighth Amendment.

One court’s analysis of a prisoner’s claim regarding post-experimentation medical treatment in prison in Pennsylvania is representative:

There is no evidence in the record of malice on the part of these defendants. Quite to the contrary, the record shows that the primary purpose of allowing the medical experiments is to provide a source of income for the inmates. This particular test was reviewed by an outside doctor, before approval. Finally, the nature of the claim itself is medical, and yet none of the Prison defendants is a doctor. Nothing in the record suggests that the Prison defendants knew or had reason to know that the prison doctor, the guards, or Ivy Research would even be negligent toward the plaintiff, let alone subject him to cruel and unusual punishment. The most that can be said of the Prison defendants on this record is that they were negligent in their supervision. It is not enough for the plaintiff to characterize this

323. *Gittlemacker v. Prasse*, 428 F.2d 1, 6 (3d Cir. 1970).

324. *Roach v. Klingman*, 412 F. Supp. 521, 525 (E.D. Pa. 1976) (citing *Rochin v. California*, 342 U.S. 165, 172 (1952); *Ford v. Bd. of Managers*, 407 F.2d 937, 940 (3d Cir. 1969); *Gittlemacker*, 428 F.2d 1; *Martinez v. Mancusi*, 443 F.2d 921 (2d Cir. 1970)).

negligence in a conclusory fashion as “gross” or “reckless” or “malicious”, and then claim this gives rise to a constitutional deprivation. Section 1983 is not designed to be a “font of federal tort law” and the fact that a tort may have been committed by state officials does not mean a federal right has been invaded.³²⁵

Indeed, it is hard to imagine any medical complications pursuant to a biomedical experiment, particularly one that had passed the risk-benefit analysis laid out in the 2006 IOM Report, that would be susceptible to a prisoner lawsuit regarding inadequate medical attention or care—no matter how abusive an experiment had become.

In sum, the standard for evaluating claims of medical mistreatment sets a high bar that few prisoners can surmount. Recall the requirement in the federal regulations governing human subjects research that valid informed consent prohibits research subjects from waiving legal rights and also prevents researchers from waiving legal responsibility. These informed consent procedures are a prerequisite to almost any kind of human subjects experimentation. Given the high bar any prisoner must meet in establishing a *prima facie* claim of medical mistreatment, simply because he or she is a prisoner, the prisoner’s status as prisoner constitutes a *de facto* waiver of the right to sue. All of this analysis points to a vital problem with allowing research on prisoners, given their current rights: prisoners’ effective waiver of the right to sue for mistreatment is nearly indistinguishable from an explicit waiver on an informed consent form. If the latter waiver might be dangerous enough to have inspired a statute to prevent it, then the presence of an entire population already circumstantially subject to such a waiver invites abusive research practices. Indeed, the history of human subjects research suggests that such abuse has been widespread, particularly in the absence of effective human subjects protections—including, but not limited to, protections ensuring a degree of self-advocacy prohibited of prisoners.

This analysis of the modern standards regulating experimentation on prisoners, from across the world and within U.S. courts, suggests that the protections for U.S. prisoner subjects of experimentation proposed in the 2006 IOM Report are inadequate. First, the proposed regulations are inadequate by comparison to international medical and legal standards governing human subjects research on vulnerable populations. Second, the proposed regulations are inadequate within the context of current federal limitations on the rights of prisoners to challenge conditions of confinement, healthcare, and unsatisfactory treatment they might experience as the subjects of medical experimentation.

325. *Roach*, 412 F. Supp. at 528 (citations omitted).

IV

RECOMMENDATIONS: HOW SHOULD HUMAN SUBJECTS RESEARCH ON PRISONERS BE REGULATED?

The 2006 IOM Report does not evaluate either the enforceability of current human subjects regulations or the feasibility of enforcing even broader, more individualized, regulatory authority.³²⁶ Because regulatory standards for human experimentation are difficult to enforce, particularly in prison settings, implementing more complex regulatory standards might simply lead to confusion and haphazard enforcement.³²⁷ Before either legislators or the DHHS attempt to implement complex and individualized risk-benefit standards, three preliminary steps must be taken.

First, as the 2006 IOM Report recommends, current regulatory authority should be expanded to cover all human subjects experimentation on prisoners as well as people under correctional supervision. The Report is right to suggest that information on prisoner experimentation should be better compiled and better reviewed. However, the Report could have been more explicit in acknowledging that medical research, both biomedical and behavioral, is taking place in prisons across the United States today. The idea that the 1976 DHEW Report virtually eliminated medical testing in prisons is simply a myth, as demonstrated by the steady flow of researcher reprimands by the OHRP. Given that medical experimentation is taking place behind closed doors, regulation is unquestionably needed.

Second, once Congress has expanded regulatory oversight, and federal agencies have attempted to implement this expansion and engage in more rigorous and widespread oversight, a second step is required. Some independent body, such as the Institute of Medicine, should evaluate the success of this regulatory oversight. If the regulatory oversight continues to reveal significant compliance problems, such as those the OHRP determination letters discussed in Part I suggest exist today, then further revisions should be made to the regulatory oversight mechanisms. No expansion of research on vulnerable populations should take place until some independent body determines that the regulatory authority of monitoring agencies has successfully achieved widespread compliance with human subjects protections.

326. The report does discuss the legislative feasibility of expanding the legal authority of the DHHS, just not the feasibility of implementing regulatory changes. 2006 IOM Report, *supra* note 18, at 95-99.

327. See Part I *infra* (discussing the sheer number of determination letters sent annually to agencies conducting federally-funded research projects on human subjects in violation of federal regulations); see also OFFICE OF THE INSPECTOR GENERAL, *Institutional Review Boards: A Time For Reform*, *supra* note 155, at ii-iii (noting that institutional review boards are overworked, face conflicts of interest, and are insufficiently regulated).

Third, in addition to evaluating the enforceability of current and potential regulations, any body making or implementing recommendations regarding prisoner research should consider U.S. prison conditions. Imperfect conditions inside U.S. prisons can compromise prisoners' ability both to provide informed consent to participate in experimentation and to challenge inhumane practices. Any regulation must both articulate the baseline human rights standards that should exist in prisons and correctional facilities before consent can freely be given, and also account for the many motivations, whether altruistic, capitalistic, or some combination, that underlie a desire to use prisoners as the subjects of medical experiments.

The 2006 IOM Report fails to clarify these baseline principles. Without satisfaction of these pre-conditions, an individualized risk-benefit analysis of research protocols seeking to incorporate prisoners is bound to lead to abuse rather than protection of human subjects. The specter of pre-1976-era practices in which prisoners participated in federally-approved experiments that had no therapeutic purpose and caused long-term, permanent health damage, should always ground the debate over how to regulate experimentation in prison. Congress and the DHHS should only consider risk-benefit standards (and not necessarily implement them) once these first three regulatory steps—expanding oversight, evaluating oversight, and improving prison conditions—are accomplished.

The key arguments in favor of allowing prisoner participation in human subjects research are: (1) respect for individual autonomy, including prisoners' rights to choose whether or not they want to participate in experiments, and to weigh the risks and benefits of participation for themselves; (2) the potential for improving prisoner healthcare, which in many places is already abysmal, through targeted studies, or through an infusion of resources from those agencies or individuals conducting the experiments; and (3) the transparency achieved when agencies and individuals conducting tests gain access to and become invested in prisons. Adequate human subjects regulations applied to prisoners should further each of these three goals without compromising prisoners' basic human rights or physical health.

The 2006 IOM Report recommendations, which suggest a broader application of federal regulations to all people under any form of correctional supervision and the development of a national research database, will further the goal of transparency and might also improve access to healthcare information for prisoners and non-prisoners alike. However, the Report's other central recommendation, a risk-benefit framework, is not necessary to further the goals of respecting individual autonomy, improving healthcare for prisoners, or achieving transparency. In fact, the federal laws currently regulating prisoner participation in experimental protocols already further each of these goals, or at least have the potential to do so.

The best way to balance the basic rights of the prisoner population, almost

universally acknowledged to be “vulnerable” by both U.S. and international laws, is to prioritize and protect the basic rights of individuals within that population over any other interests—whether scientific, social, or corporate. First, prisoners should have access to experimental practices designed to benefit their health and well-being. For instance, prisoners facing terminal illnesses, whether cancer, tuberculosis, or HIV/AIDS, should be permitted to enroll in experimental treatment programs. In fact, they should have access equivalent to similarly afflicted persons outside of prison. However, prisoners should have sufficiently adequate healthcare in prison to allow them to make an actual and informed choice between enrolling in a drug trial and receiving comfortable and humane care available through the prison.

Second, studies that are non-intrusive and present absolutely no health risks, particularly behavioral research involving only voluntary, confidential interviews, should be permitted. Indeed, both therapeutic and behavioral studies would seem to be permissible under either the current Title 45 regulations, based on the 1976 DHEW Report, or under the suggested Title 45 revisions, based on the 2006 IOM Report. Neither the 1976 DHEW Report nor the current federal regulations prevents prisoners from participating in experiments, which address “conditions particularly affecting prisoners as a class,” or “which have the intent and reasonable probability of improving the health or well-being of the subject.”³²⁸ To the extent that prisoners do not participate in beneficial experimental protocols, this non-participation has little to do with the regulations currently limiting experimentation on prisoners. In fact, experimentation in prison, even in its public heyday between 1950 and 1970, never incorporated very many targeted therapeutic studies, but rather used prisoners to further the interests of others: drug companies, National Institutes of Health researchers, or individual physician-researchers.

Barring radical changes to federal regulation of private drug companies and DHHS regulatory authority, to prison conditions in general, and to prisoners’ ability to exercise their basic legal rights, no other experimental studies should be permitted in prisons. In particular, non-therapeutic studies should be prohibited. One might imagine a world in which prisons faced minimal overcrowding; prisoners had access to adequate healthcare and the ability to exercise legal rights to hold researchers accountable; and independent educational or governmental authorities thoroughly reviewed research protocols. In such a world, medical experimentation on prisoners, based on a risk-benefit analysis, might be a reasonable proposal. Until such conditions are met, however, medical experimentation on prisoners should be subject to extremely tight control—tighter than that which currently passes for adequate oversight, and far tighter than that which the 2006 IOM Report recommends.

328. 45 C.F.R. § 46.306(a)(2)(iii), (iv).

CONCLUSION

Each argument in favor of allowing prisoner participation in medical experiments presupposes a base level of acceptable conditions in prison and ethical motivations among researchers. A review of the kinds of prison conditions currently documented in the United States, the history of medical experimentation in and out of these prisons, and current standards for medical testing in general suggests that the kinds of prison conditions and ethical standards presupposed in the 2006 IOM Report simply do not exist in our prisons or in biomedical research generally. A further comparison of the 1976 DHEW Report, which led to the standards currently in place, and the 2006 IOM Report, which suggests changes in these standards, starkly reveals the shortcomings in the ethical arguments in favor of more flexible standards. International human rights standards, the common law of consent, and domestic legal standards for challenging prison conditions in the United States further confirm the legal problems inherent in moving to a case-by-case, risk-benefit analysis of proposed medical experiments in prisons. All guidelines call for clear procedures for subject complaint, self-exemption, and compensation for damages, but many U.S. prisoners are legally deprived of exercising such rights. Therefore, there is no way for research on prisoners to satisfy the standards established in the Nuremberg Code and developed since.

In sum, before any risk-benefit analysis is implemented, minimal human rights standards must be met. The choice to participate or not to participate in a human subjects research project should not be a new kind of “prisoner’s dilemma.” In addition, in discussing risk-benefit analysis, “risk” and “benefit” must be generated solely from the perspective of the prisoner. In other words, any weighing of risks and benefits should look at risks to the prisoner and benefits to the prisoner, not risks to the prison or researchers, and not benefits to corporations or society as a whole. A document that purports to show the way forward in prison-based research must address these standards.

Until such a document exists, however, the 2006 IOM Report provides a basis for debate and conversation, as well as a roadmap for expanded oversight that Congress should legislate and the OHRP should implement. Congress should change the definition of “prisoner” in Title 45, so that the term incorporates a range of vulnerable populations under the supervision of the criminal justice system, from those on probation and parole to those housed within drug-addiction treatment programs. Congress and the OHRP should work together to create a national database documenting every experimental protocol—public or private; federal, state, or local—involving prisoners. The Title 45 regulations currently on the books should be rigorously enforced, and the effectiveness of the enforcement should be evaluated by some independent agency, such as the IOM. Prisoners who do participate in human subjects research should be assured adequate and humane prison conditions as well as

access to the courts. Once these many conditions are met, then Congress, the OHRP, and the IOM can debate again and reevaluate the frameworks, whether categorical or risk-benefit based, for allowing or disallowing prisoner participation in medical research.