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Who Shall Decide When Doctors Disagree? A Review of the Legal Development of Informed Consent and the Implications of Proposed Lay Review of Human Experimentation

Marian F. Ratnoff*

After surveying the historical development of informed consent, the author considers the current effect of the doctrine upon various categories of human experimentation. Against this background, the author analyzes recent federal legislation and administrative regulations directed toward problems in experimentation, focusing in particular upon the hotly debated issue of the role of laymen in the control of medical research.

Who shall decide, when Doctors disagree,
And soundest Casuists doubt, like you and me?¹

I. INTRODUCTION

THEY CAME up from Alabama, to Washington one March morning in 1973—two country people—to bear witness to some unhappy events of their lives. They were poor; they were black.² Their audience was with a number of United States Senators investigating the use of human subjects in medical experiments. Their attorney testified that for 40 years they had been unknowing participants in a long-term study conducted by the United States Public Health Service to determine the course of untreated syphilis.³ The investigation, which started at a time when treatment with arsena-

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1. A. POPE, *EPISTLES TO SEVERAL PERSONS (MORAL ESSAYS)* 114 (Epistle III) (J. Wellington ed., Univ. of Miami 1963).

2. *Hearings on S. 974, S. 878, and S.J. Res. 71 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare (Quality of Health Care—Human Experimentation, 1973)*, 93d Cong., 1st Sess., pt. 3, at 1036-42 (1973) [hereinafter cited as *1973 Hearings*].

3. *Id.* at 1033-35.

mine or its cogeners was well established, was continued even when a revolutionary therapy, the use of penicillin, became the standard of care.⁴ Ingenuously, these subjects of the so-called Tuskegee Study told the story of their recruitment and participation. "[T]hey said we had bad blood. After then they started giving us the shots . . . for a good long time."⁵ In fact, they received no antisyphilitic treatment.⁶

Despite their chilling testimony, both witnesses seemed only dimly aware of the extent of the deception that had been practiced upon them. They did appreciate, however, that they had been used in some manner,⁷ and, perhaps coached by their lawyer, they asked that compensation be given them so they could, in their words, "continue [their] health."⁸ The more sophisticated testimony of their attorney chronicled a frightening misuse of individual human experimental subjects⁹ emanating from what must surely have been the innocent intentions of the investigators to provide a greater good to a greater number. Yet, the evidence reads like an evil scenario.¹⁰ The subjects were enticed into and induced to remain in the study by promises of free medicine, burial assistance, free meals, and automobile trips to and from the hospital followed by opportunities to stop in town to visit friends.¹¹ Above all, they were never told they had syphilis. They did not understand the meaning of the euphemism "bad blood," nor were they told they were part of a study.¹² No one asked for their consent to remain untreated and none was given. A subsequent investigation of the study uncovered an absence of a written experimental protocol and a questionable statistical foundation for a meaningful long-term study.¹³

4. 10 *VENEREAL DISEASE INFORMATION* 53, 65-66 (1929), cited in G. ANDREWS, *DISEASES OF THE SKIN* 507 (2d ed. 1938); J. STOKES, H. BEERMAN & N. INGRAHAM, JR., *MODERN CLINICAL SYPHILOLOGY* ch. 7, at 210 (3d ed. 1944).

5. *1973 Hearings* pt. 3, at 1036.

6. *Id.* at 1035.

7. *Id.* at 1041.

8. *Id.* The participants filed suit in the Middle District of Alabama against various governmental agencies—federal and state—and certain doctors. The suit sought a \$3 million judgment. The case was settled, however, before trial with an award of \$37,500 to each survivor. *N.Y. Times*, Feb. 6, 1975, at 31, col. 8.

9. *1973 Hearings* pt. 3, at 1033-36.

10. *Id.* at 1033.

11. *Id.* at 1034.

12. *Id.*

13. Curran, *The Tuskegee Syphilis Study*, 289 *NEW ENG. J. MED.* 730 (1973).

Through the years, the men believed the injections they were receiving were therapeutic.¹⁴ During a campaign mounted in the late forties and early fifties to provide penicillin to all persons in the United States suffering from syphilis, they were specifically enjoined by the study's sponsors from seeking treatment.¹⁵ Thus, they were denied the basic freedom to choose whether to continue or to seek new help.

Could the Tuskegee experiment be conducted today? This article will consider a number of similar instances of human experimentation and the philosophical responses and legislative safeguards which are emerging as a result of their disclosure. Some examples are drawn from the testimony adduced at the aforementioned Senate Subcommittee hearings¹⁶ on the quality of health care in this country while many reach back into early case law.¹⁷ The cases and events chronicled here, however, are notable as exceptions to the conscientious work of thousands of physicians in whose debt we lie. Medical scientists, generally a self-critical group, recognized the dilemmas posed by the need for human experimentation long before the subject interested lawyers. However difficult the premise may be to accept emotionally, accretion of medical knowledge cannot progress without human subjects. Indeed, as a result of human experimentation, the state of the art of medicine changes with such rapidity that today's standard of care becomes tomorrow's malpractice. Americans who are so quick to demand the panacea of a simple injection to cure assorted aches and pains should be cautioned against the adoption of self-righteous attitudes toward physicians and human experimentation.

Appreciation of the complexities surrounding the use of human beings as experimental subjects requires an examination of the growth and development of modern medical science. Today, the organization and methodology of clinical investigation are taken for granted, yet medical research involving large scale clinical trials is a very recent development. Before the 1940's, organized hunts for causes and cures of disease were very few.¹⁸ Medical knowledge

14. 1973 *Hearings* pt. 3, at 1038.

15. *Id.* at 1034, 1042.

16. *See id. passim.*

17. *See* notes 33, 47-85 *infra.*

18. One notable exception at the turn of the century was Dr. Walter Reed's search for the cause of yellow fever. Carefully controlled tests were carried out in which heroic volunteers died. Dr. Reed was concerned that each volunteer should be made aware of the risks and possible fatal consequences of participation in the study. His work, done under the auspices of the United

was advanced by a small number of investigators working in modest university or hospital laboratories supported by the endowments of the institutions, individual private benefactors, or grants from philanthropic foundations.¹⁹ Such simple arrangements for those lucky enough to receive support were possible because of the comparatively simple state of the art. None of the sophisticated equipment or salary support which are integral to today's research was available or even conceived of before World War II. Today's principal sources of funds, the government and the drug houses, were not a part of the investigatory process.²⁰ Government support for research was confined to scattered laboratories of the Department of Agriculture for crop research and of the United States Public Health Service for intramural investigation.²¹ Although the Public Health Service had established the National Institutes of Health in 1937 and had begun to make a few grants,²² modern research and development began in earnest only in 1941 with the outbreak of World War II. Franklin D. Roosevelt provided the framework for an unheard-of collaboration between government and university by setting up the Office of Scientific Research and Development, an organization born of the war needs of the nation.²³ The Office had the task of determining the military needs of the country, including the medical needs of the

States Army, is an example worthy of imitation. For further description of this work, see Dowling, *Human Experimentation in Infectious Disease*, 198 J.A.M.A. 997 (1966). YELLOW FEVER, A COMPILATION OF VARIOUS PUBLICATIONS, S. Doc. No. 822, 61st Cong., 3d Sess. (1911), contains fascinating accounts by Drs. Reed, Carroll, and Agramonte, who worked at Camp Lazear in Cuba. Dr. Reed's reports describe experimental attempts to establish the fever in 16 individuals who gave "full consent." *Id.* ch. 5. Dr. Lazear, for whom the camp was named, died after contracting yellow fever as a self-experimenter.

For an example of United States Army requirements on the use of soldier volunteers, see Army Reg. No. 70-25 (Use of Volunteers as Subjects of Research) (1962).

19. NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, FEDERAL SUPPORT OF BASIC RESEARCH IN INSTITUTIONS OF HIGHER LEARNING 22 (1964) [hereinafter cited as FEDERAL SUPPORT]. By 1928, the foundations were acknowledged to be the principal support for science. *Id.* Gray, *Science and Profits*, HARPER'S MAGAZINE, Apr. 1936, cited in Fishbein, *Medical Patients*, 109 J.A.M.A. 1539, 1542 (1937), states: "Scientific research, as a recognized full-time occupation, is one of the youngest of the professions. It has come up out of the basements and garrets of the early experimenters, and has attained status among the most honored of the callings of man."

20. FEDERAL SUPPORT 22.

21. *Id.* at 17-18 (U.S. Dep't of Agriculture), 40 (U.S. Public Health Service).

22. *Id.* at 40.

23. *Id.* at 25.

military, and of finding research laboratories at the universities and in industries that could supply answers. Dealings between the Office and the various laboratories with which it worked were reduced to contracts that secured the services of the scientists in return for government support.²⁴ Provisions regarding costs, acquisition and disposition of equipment and other property, patents, and security were written into these contracts.²⁵ The pattern for support, therefore, was well established when the scientists, who had devoted their talents to the military application of scientific knowledge were ready to return to their universities following the end of the War.

It was the will of determined and farsighted men like James Forrestal and Vannevar Bush, who had helped to formulate the national science policy during the War, that this government "partnership with university scientists" should persist.²⁶ With their support and that of certain congressmen,²⁷ an explosion of medical research occurred. Age-old plagues of mankind were attacked, and in many cases conquered, with a vigor and enthusiasm that the large sums of available money enhanced.²⁸

When the Public Health Service established the prestigious National Institutes of Health (NIH) Clinical Center in 1953,²⁹ the partnership of the government and clinical medicine begun in the war years was cemented. The Clinical Center provided a new kind of organization for the study of disease. Many of the monumental strides and perceptions which marked the postwar medical research in the United States may be attributed to the Center.

Now, as then, people who come to the Center for study and treatment are those whose doctors have exhausted their knowledge and ability to help. Because of the unlimited resources, the many scientific disciplines represented, the pool of exceptional talent, and the superspecialization of NIH physicians, dramatically innovative therapy can be attempted there, sometimes with remarkable results. For many, the Center is the last refuge. For others, healthy people

24. *Id.* at 27.

25. *Id.*

26. *Id.* at 35.

27. *Id.* at 31-32.

28. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354, 1355 (1966).

29. Frankel, *The Public Health Service Guidelines Governing Research Involving Human Subjects: An Analysis of the Policy-Making Process*, in PROGRAM OF POLICY STUDIES IN SCIENCE AND TECHNOLOGY 9 (George Washington Univ. Monograph No. 10, 1972).

who come as normal volunteers,³⁰ the Center provides an opportunity to fulfill religious, moral, or civic duties.³¹

II. HISTORICAL REVIEW

This blossoming of medical knowledge following World War II was not unflawed. The ethical and legal problems raised by the existence of a facility like the NIH and, indeed, by the absolute need for human experimentation had troubled doctors for many years. Only in the last two decades have nonscientists as well become aware of the problems.³²

A. United States v. Karl Brandt

Perhaps the first glimmer of information about the problems of human experimentation came to nonscientists from an unusual source, the Nazi war crimes trials. No discussion of the legal and proper involvement of the human experimental subject should proceed without reflecting upon the demonic behavior documented in *United States v. Karl Brandt*,³³ the Medical Case heard by the Nuremberg tribunal following World War II. In his opening statement at trial, Brigadier-General Telford Taylor observed that the 23 Nazi doctor-defendants had received human subjects in wholesale lots—"200 Jews . . . , 50 gypsies, 500 tubercular Poles, or 1,000 Russians"³⁴—for diabolical experiments which "revealed nothing which civilized medicine can use."³⁵ A sampling of such experiments is a catalogue for death. Injections of live typhus virus merely to maintain the strain, intravenous injections of gasoline to determine

30. NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER, HANDBOOK ON THE NORMAL VOLUNTEER PATIENT PROGRAM iv (rev. ed. 1966). Normal volunteers are defined as persons possessing no demonstrable scientific contraindicatory abnormalities.

31. *Id.* at 3. "Current Sources of Volunteers" lists religious groups, college students, and civic groups that provide normal volunteers for the Center.

32. Two of the earliest discussions of the conflict raised by experimental medicine are Cady, *Medical Malpractice: What About Experimentation?*, 6 ANNALS OF W. MED. & SURGERY 164 (1952), and Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. PUB. L. 467 (1954). Ladimer, an attorney, has done much of the fundamental work, gathering much of the source material upon which others have built. The basic text on the subject of human experimentation was CLINICAL INVESTIGATION IN MEDICINE: LEGAL, ETHICAL AND MORAL ASPECTS (I. Ladimer & R. Newman eds. 1963).

33. 1, 2 Trials of War Criminals Before the Nuremberg Military Tribunals (The Medical Case) (Military Tribunal I, 1947).

34. 1 *id.* at 27.

35. *Id.* at 73.

how fast they would cause death, and forced ingestion of sea water to determine how long the subjects could survive, typify the experiments performed supposedly in the name of science.³⁶

B. The Codes

Brandt, an unusual and dramatic case, marked the beginning of modern formal guidance for the medical researcher. The opinion set out 10 principles for conducting human experiments that became known as the Nuremberg Code.³⁷ The Code may now appear some-

36. *Id.* at 46 (sea water), 50 (typhus), 73 (gasoline injections).

37. See Ladimer, *Human Experimentation: Medicolegal Aspects*, 257 *NEW ENG. J. MED.* 18, 22 (1957); Welt, *Reflections on the Problems of Human Experimentation*, 25 *CONN. MED.* 75, 76 (1961). The Nuremberg Code states:

1. The voluntary consent of the human subject is absolutely essential. . . .
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably [*sic*] cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

United States v. *Brandt*, 2 Trials of War Criminals Before the Nuremberg Military Tribunals (The Medical Case) 181-82 (Military Tribunal I, 1947).

Brigadier General Taylor, Chief Prosecutor at the Nuremberg Trials, states

what diffuse, but it remains basically sound. To this author's knowledge, it is the first expression of the absolute requirement of consent to nontherapeutic experimentation. Continued refinement of the Nuremberg precepts climaxed in the widely supported Declaration of Helsinki in 1964,³⁸ a document issued by the World Medical Association and adopted by many learned societies.³⁹ In essence, the Declaration of Helsinki requires an adequate experimental design, adequately trained medical personnel, the fully informed consent of the subject, and a risk not disproportionate to the knowledge to be gained.⁴⁰ More sophisticated than the Nuremberg Code, the Declaration recognizes the difference between a therapeutic experiment, in which clinical research is combined with professional care, and nontherapeutic clinical research, in which experiments are not expected to benefit the subject but are designed to add to the understanding of normal and disease states.⁴¹

In 1966, the American Medical Association (AMA) adopted ethical guidelines for research which expanded the Helsinki work.⁴² The AMA Guidelines and the Helsinki Declaration, both more detailed than the Nuremberg Code, require that definitive animal experimentation precede human experimentation and that the benefit to be derived be proportionate to the risk taken. The crux of both codes is concern with the subject's informed consent: Does the subject understand what is being done to him, what risks he faces,

that the Code was formulated by two American judges with the assistance of Dr. Andrew Ivy, a prominent medical investigator. See *Informed Consent in Drug Research*, 3 COLUM. J.L. & SOC. PROB., Oct. 24, 1966, at S-4, S-7 n.105.

Dr. Leo Alexander wrote the critical memorandum to the war crimes court on human experimentation. Alexander, *Psychiatry: Methods and Processes for Investigation of Drugs*, 169 ANNALS OF N.Y. ACAD. SCI. 344, 345 (1970).

In England there were expressions of ethical guidelines for physicians as early as 1803. In 1848, the American Medical Association issued a Code of Medical Ethics based on the 1803 document. Cf. Kidd, *The Problem of Experimentation on Human Beings: Limits of the Right of a Person to Consent to Experimentation on Himself*, 117 SCIENCE 211, 212 (1953). These guides, of course, did not address the problem of medical research as we know it today.

38. Edelson, *Human Guinea Pigs: A Curb*, World Journal Tribune, Sept. 25, 1966, at 34, col. 4.

39. *The Changing Mores of Biomedical Research: A Colloquium on Ethical Dilemmas from Medical Advances*, 67 ANNALS OF INTERNAL MED. supp. 7, app. IV, at 75 (1967).

40. Editorial, *The Experimental Use of Human Beings*, 65 ANNALS OF INTERNAL MED. 371, 372 (1966).

41. Lowe, *Pediatrics: Proper Utilization of Children as Research Subjects*, 169 ANNALS OF N.Y. ACAD. SCI. 337, 339 (1970). A delineation of the varieties of medical experiments appears in the text preceding note 45 *infra*.

42. *Changing Mores*, *supra* note 39, at 76.

and what benefit may be derived from his participation or even his sacrifice?

Unfortunately, these guidelines are flawed by the assumption that human beings in stressful situations can grasp the investigators' explanations. The codes are difficult to challenge because fully informed consent, like Plato's ideal of beauty, is unattainable. They condemn uninformed consent, but contain no blueprints for avoiding it. A 10-year experience with the codes has proven, sadly, that they are sometimes more honored by lip service than by fealty because of their imprecision.

C. The Evolution of the Legal Doctrine of Informed Consent

1. Three Types of Medical Experiments

If the codes have provided unsatisfactory guidance, legal principles have been equally inadequate. Old legal doctrines yield with the greatest reluctance or not at all to fit present day medical research. To understand the difficulty of trying to adapt legal precepts to clinical research, three types of modern medical experiments must be distinguished. First is the individual therapeutic experiment that occurs in the treatment of a critically ill person because, in his physician's judgment, he is not responding to the standard or prescribed treatment for his disease or because the physician feels the standard care is inadequate or hazardous in some way. Frequently, such experimentation involves a patient suffering a fatal disease to whom an untried or even potentially dangerous drug is administered as a last resort. Here the effect of the drug may be dramatically lifesaving or of no value at all. In either case the experiment may advance the state of medical knowledge without further jeopardizing the patient's life. These experiments often take place on an individual basis and in isolated instances. Here, doctor and patient are in their traditional relationship involving the patient's faith and the physician's fiduciary duty.

A second type of experiment involves the less critically ill patient to whom new or revised therapy is administered or, conversely, withheld for the purpose of establishing a control. The Tuskegee experiment⁴³ is an example of the latter endeavor. This second category of experiment may find the patient in his dependent role, but frequently the doctor administering the treatment may be unknown to him; the emphasis is upon the disease rather than the patient.

43. See text accompanying notes 2-13 *supra*.

The investigator in this situation is interested in the mechanism of disease and therapy; his goal lies beyond the individual.⁴⁴

The third type of experiment is purely manipulative. Subjects of these experiments may be healthy, mentally and physically, or they may be patients whose illnesses are under study to elucidate their disease state. Here, drug administration or manipulation of normal or diseased bodily functions may be undertaken to delineate the subject's physiological reactions, *e.g.*, the body's defenses or immune reactions. Manipulative experiments need not be medically oriented. College students have been frequent subjects of experiments involving dangerous alteration of their psychological and sociological environment to record their reactions.⁴⁵

2. *The Doctrine of Slater v. Baker*

The concept of informed consent has application to all three forms of experimentation since consent is a prerequisite to any act involving risk to a patient or subject except in certain emergencies. The quantity of the information that the doctor must provide, however, may vary according to the particular facts. For instance, if the traditional doctor-patient relationship exists and the treatment elected is a standard, well-established procedure involving risks which are minimal in most patients, the doctor may not have to impart as much information as he does when the risks are known to be greater. But the more the elements of a situation diverge from the routine, the more complete must be the patient's knowledge and understanding.

In the courts the doctrine of informed consent has come to embody three major elements: (1) competence of the subject, (2) his knowledge of the risk involved, and (3) voluntariness of the consent.⁴⁶ A historical review of familiar cases is essential to show the evolution of these concepts. Some of the cases involve innovative or experimental procedures conducted without informed consent; others involve standard procedures posing risks of which the patients are not informed. These cases are the only legacy which can be applied, by analogy, to the nontherapeutic experimental setting.

44. For a good description of this type of experimentation see *Medical Experimentation on Human Beings*, 152 *SCIENCE* 448 (1966).

45. For excerpts of published reports of such experiments with students see Ring, Wallston & Corey, *Disclosure of Manipulation*, in *EXPERIMENTATION WITH HUMAN BEINGS* 395 (J. Katz ed. 1972) [hereinafter referred to as Katz].

46. *Kaimowitz v. Michigan Dep't of Mental Health*, 42 U.S.L.W. 2063, 2064 (Cir. Ct., Wayne County, Mich. 1973).

*Slater v. Baker*⁴⁷ appears accepted universally as the earliest expression in our legal system of the need for consent to radically new medical treatment. The case involved the unauthorized use of an instrument of the surgeon's own design, one not used by other surgeons. The court opined that to act contrary to the common practice of surgeons was ignorance and "what no surgeon ought to have done."⁴⁸ The court said that a patient should be informed of any treatment he undergoes and that such a requirement is part of "the usage and law of surgeons . . ."⁴⁹ In *Slater* all three elements of consent were lacking. The decision, however, was more than a condemnation of this shortcoming. The court indicated that the defendants, in wishing to try an experiment, had committed a "rash action."⁵⁰

During the ensuing century, case law developed no further than the *Slater* doctrine. We hear *Slater* echoed in *Carpenter v. Blake*,⁵¹ a malpractice suit in which the court acknowledged the need to try new methods where the disease was newly discovered or the mode of treatment unsettled. Yet the court held that "when the case is one as to which a system of treatment has been followed for a long time, there should be no departure from it, unless the surgeon who does it is prepared to take the risk of establishing, by his success, the propriety and safety of his experiment."⁵² An opening wedge in permitting experimentation can be discerned about thirty years later in an interesting case, *Allen v. Voje*,⁵³ which still held that a physician generally could not experiment. Nevertheless, the court stated that there might be an exception to the rule prohibiting experimentation if the patient is *in extremis*.⁵⁴

47. 95 Eng. Rep. 860 (K.B. 1767). Stapleton, an apothecary, was called in by Slater, the plaintiff, to remove the bandages from his broken leg, which had been set weeks before and which was apparently healing properly. Stapleton insisted upon calling in Baker, a surgeon. Baker then sent for a toothed claw device of his own design, which he subsequently used on plaintiff without consulting him. The King's Bench took evidence indicating that this procedure varied radically from accepted medical procedure.

48. *Id.* at 862.

49. *Id.*

50. *Id.* at 863.

51. 60 Barb. 488 (N.Y. Sup. Ct. 1871), *rev'd on other grounds*, 50 N.Y. 696 (1872).

52. *Id.* at 524.

53. 114 Wis. 1, 89 N.W. 924 (1902).

54. "[A] physician of standing and loyalty to his patients will [not] subject them to mere experimentation, the safety or virtue of which has not been established . . . save possibly when the patient is *in extremis* and fatal results substantially certain unless the experiment may succeed." *Id.* at 22-23, 89

3. *The Early Approach to Experimentation: Malpractice and Battery*

Development of the doctrine of informed consent inched on through the 20th century.⁵⁵ Many of the cases in this slowly evolving body of law found the patient in a situation in which innovative therapy was undertaken for his benefit. These cases sounded in negligence, and occasionally in battery, and frequently penalized the doctor for straying too far from the standard of practice even though it might have been inadequate for the patient. Although consent was recognized as a major issue in these cases, the courts found that the mere presence of some form of consent was not enough. Even though the doctors' actions in these cases were taken to benefit the patient, the doctor had not provided the information that the hazardous nature of the procedure required or had exceeded the procedures actually consented to. Negligence forms the basis of an action in malpractice. The standard of care applied in malpractice cases is founded upon the law's regard for the physician as an individual of superior knowledge and skill. In Prosser's view, the law demands of him conduct consistent with his knowledge, which is greater than an ordinary man's.⁵⁶

In therapeutic experiments, the distinction between malpractice and battery should be recognized. In a malpractice action, the plaintiff is alleging that he consented to the services rendered but that the doctor performed negligently, *i.e.*, he failed to adhere to the appropriate standard of care. In a case of battery, the plaintiff alleges that he did not consent to the treatment or that the treatment exceeded his consent.⁵⁷ The theory of such cases is that an

N.W. at 932.

Neither *Carpenter* nor *Allen* actually mentions the issue of patient consent. But in *Carpenter*, by implication, consent to experimental procedures where an accepted mode existed would not excuse the physician. *Allen* is viewed as relaxing the harsh rule because an experiment may be permissible on a patient certain to die unless the experiment works. In such a case the patient may be presumed to consent to a procedure that represents his only chance at life. This is the first indication that a departure from accepted norms may be contemplated with the "consent" of the patient. See generally Katz 527-28.

55. *E.g.*, *Brinkley v. Hassig*, 83 F.2d 351 (10th Cir. 1936); *Salgo v. Leland Stanford Junior Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957); *Pratt v. Davis*, 224 Ill. 300, 79 N.E. 562 (1906); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 105 N.E. 92 (1914) (dictum), *overruled on other grounds*, *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3 (1957).

56. See W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* 161-66 (4th ed. 1971).

57. See, *e.g.*, *Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 432-34, 88

unconsented-to touching of the patient by the physician has occurred.⁵⁸

The concept of informed consent as it developed in malpractice cases would seem to apply by analogy to experimentation. The analogy is made more difficult however because many of the early 20th century American cases spoke of negligence when, far from possessing superior skill, the ministering individual possessed no skill at all. Frequently, the plaintiffs were victims of outright quackery. In *Graham v. Dr. Pratt Institute*,⁵⁹ for example, the plaintiff responded to an advertisement for the removal of smallpox scars. Finding the disastrous treatment not sanctioned by medical science, the court ruled that no legal right had existed to perform the operation. Malicious intent was absent, but the defendant would not be relieved of the imputation of malice even in the presence of consent for experimentation that ran beyond the bounds of "normal science."⁶⁰ In California, a child suffered irreparable harm when her physician, employing a diagnostic machine of his own invention, misdiagnosed her illness. Although her parents had agreed at first to the use of the machine, they later withdrew their consent. In spite of the original agreement, the court found against the doctor.⁶¹

Some courts did not rely on negligence but rather made findings of battery when the physicians' acts exceeded what the patients agreed to expressly. *Rolater v. Strain*,⁶² for example, held against the doctor who removed a toe bone when the patient gave permission for an operation on her toe but expressly forbade the removal of bone. A Canadian court similarly confirmed a finding of battery

N.W.2d 186, 189-90 (1958); *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905), *overruled on other grounds*, *Genzel v. Halvarson*, 248 Minn. 534, 80 N.W.2d 527 (1957).

58. See generally Annot., 29 A.L.R.2d 1028 (1961). Battery is a form of action anchored in the antiquity of English law, protecting the integrity of one's physical being.

59. 163 Ill. App. 91 (1911).

60. *Id.* at 93.

61. *Kershaw v. Tilbury*, 214 Cal. 679, 8 P.2d 109 (1932).

In both *Graham* and *Kershaw* the "innovation" patently involved quackery that took unfair advantage of the untrained and unsuspecting public. Judge and jury probably felt that some compensation was called for despite the fact of consent. In those cases such a result was probably justified. But application of the harsh result to modern-day physicians, who in good faith and with excellent training behind them engage in experimentation, may be stultifying to medical progress. The mere fact that a procedure departs from the accepted mode should not be a basis of liability when the patient has consented.

62. 39 Okla. 572, 137 P. 96 (1913).

when the doctor, acting in an emergency, failed to give a complete explanation of what he intended to do. The court said he had exceeded the consent he received to perform certain acts.⁶³ No American cases appear to have so penalized the physician who acted in an emergency.

By 1935, the concept that some experimentation must occur began to be expressed. In Michigan, a jurisdiction distinguished by its enlightened medicolegal opinions, *Fortner v. Koch*⁶⁴ acknowledged in dictum that the progress of medicine might be dependent upon a "certain amount of experimentation,"⁶⁵ but experimentation, cautioned the court, could not vary too radically from accepted procedures and could be undertaken only with the knowledge and consent of the patient.⁶⁶

4. *Evolution of Risk as an Element of Informed Consent*

How much knowledge should be imparted to the patient remained undefined until *Natanson v. Kline*,⁶⁷ a malpractice suit against a hospital and its radiologist for plaintiff's injuries resulting from cobalt radiation therapy. On the patient's first visit, the defendant doctor told her how long the treatments would take and which areas of her body would be irradiated. That day, he began

63. *Mulloy v. Hop Sang*, 1 W.W.R. 714 (Alta. App. Div. 1935). See generally *Gill v. Selling*, 125 Ore. 587, 267 P. 812 (1928).

The patient in *Mulloy*, a Chinese, specifically told the doctor not to amputate his hand because he wanted to consult his own physician. The doctor indicated he would be governed by the conditions as he found them after examination under anesthesia. The patient was silent, a response that the doctor took as consent. Taking these circumstances in conjunction with the fact that the patient did not speak English well, the court found a lack of consent despite the apparent emergency.

In neither *Rolater* nor *Mulloy* does the court expressly state that battery is the basis for liability. But the facts are comparable to those in *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905). In *Mohr* the plaintiff had consented to surgery on her right ear. During the operation the doctor discovered that the left ear was also diseased and immediately proceeded successfully to operate on it, although no emergency existed. The court found that by exceeding the consent given, the doctor had committed a technical assault and battery.

64. 272 Mich. 273, 261 N.W. 762 (1935).

65. *Id.* at 282, 261 N.W. at 765.

66. *Id.*

67. 186 Kan. 393, 350 P.2d 1093 (1960), *rehearing denied*, 187 Kan. 186, 354 P.2d 670 (1960). The first *Natanson* case contains an excellent discussion of the difference between battery and malpractice, an issue raised in the pleadings and briefs. *Id.* at 402, 350 P.2d at 1100. The court stated the former is intentional, the latter unintentional.

therapy,⁶⁸ but failed to tell her that the risks of cobalt radiation included the injury she eventually sustained.⁶⁹ Directly facing the issue whether informed consent is possible when the nature of the risks of treatment is not properly explained, the court asked:

What is the extent of a physician's duty to confide in his patient where the physician suggests or recommends a particular method of treatment? What duty is there upon him to explain the nature and probable consequences of that treatment to the patient? To what extent should he disclose the existence and nature of the risks inherent in the treatment?⁷⁰

The case was sent back for retrial with instructions to the lower court that the first issue for jury determination was whether the treatment had been given with Mrs. Natanson's informed consent and that if this question were answered negatively, a finding of malpractice must issue. In denying rehearing to the defendant,⁷¹ the court explained that a physician violates his duty and subjects himself to liability for malpractice when no immediate emergency exists and he fails to make reasonable disclosure of the risks involved.⁷² Unfortunately, the court's circular definition of "reasonable" as what a reasonable medical practitioner would do under similar circumstances⁷³ does not provide the practitioner with clear guidelines. The court did acknowledge, however, that under some circumstances the physician may be justified in withholding disclosure.⁷⁴ *Mitchell v. Robinson*,⁷⁵ decided within two days of *Natanson*, also held that a physician has a duty to inform his patient of *the risk* involved in treatment.⁷⁶

68. *Id.* at 401, 350 P.2d at 1100.

69. *Id.*

70. *Id.* at 403, 350 P.2d at 1101.

71. 187 Kan. 187, 354 P.2d 670 (1960).

72. *Id.* at 188, 354 P.2d at 672.

73. *Id.* at 191, 354 P.2d at 673.

74. *Id.*

75. 334 S.W.2d 11 (Mo. 1960).

76. Some courts have gone beyond the nebulous formulation in *Natanson* and have attempted to refocus the scope of information that must be given to the patient. Instead of considering what other practitioners might do, these courts consider what information is actually essential to the patient in order for him to make a rational judgment. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972), held that the doctor must impart all the information needed to make a decision if some of the information might lead the patient to refuse the treatment. *See also Berkey v. Anderson*, 1 Cal. App. 3d 790, 82 Cal. Rptr. 67 (1969); *Watson v. Clutts*, 262 N.C. 153, 136 S.E.2d 617 (1964).

D. *Consent to the Nontherapeutic Experiment:
The Hyman Case*

Not until 1965, when medical societies and thoughtful investigators were already wrestling with the problem, was the legal issue of informed consent raised in a nontherapeutic experimental situation. Interestingly, *Hyman v. Jewish Chronic Disease Hospital*⁷⁷ sounded neither in battery nor negligence; indeed, the latter was considered only obliquely in relation to a hospital trustee's duty. The basic question was the right of a hospital director in performing his legal duties to examine a patient's record.⁷⁸ Hyman, a hospital trustee, had been informed by several concerned physicians that a number of patients at the chronic disease hospital had received injections of live cancer cells to determine whether debilitated individuals could reject cancer cells as readily as healthy persons.⁷⁹ The study was part of an extensive investigation by a prestigious physician, a leading authority on cancer and the body's defenses against the disease.⁸⁰ Hyman wished to examine certain patients' records to determine whether they had received injections of live cancer cells without their knowledge or at best without their appreciation of the implication of the procedure to which they were subjected.⁸¹ The trial court upheld the director's right to inspect corporate records,⁸² but the appeals court reversed, denying that right to Hyman because, it argued among other things, the patient-physician privilege would be violated.⁸³ The Appellate Division noted that the doctors had attempted to justify their actions on the ground that a complete explanation would have stirred up unnecessary anxieties.⁸⁴ New York's highest court overturned the Appellate Division decision and held that as a matter of law the director of a hospital corporation is entitled to inspect records of the hospital to investigate alleged illegal and improper experimentation. It was suggested that confidentiality could be protected by withholding patients' names.⁸⁵

77. 42 Misc. 2d 427, 248 N.Y.S.2d 245 (Sup. Ct.), *rev'd*, 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964), *rev'd*, 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965).

78. 42 Misc. 2d at 428, 248 N.Y.S.2d at 246.

79. 21 App. Div. 2d at 497, 251 N.Y.S.2d at 821.

80. *Id.*; Langer, *Human Experimentation: New York Verdict Affirms Patient's Rights*, 151 SCIENCE 663 (1966).

81. 21 App. Div. 2d at 496, 251 N.Y.S.2d at 820.

82. 42 Misc. 2d at 429, 248 N.Y.S.2d at 247.

83. 21 App. Div. 2d at 499, 251 N.Y.S.2d at 822.

84. *Id.* at 497, 251 N.Y.S.2d at 820.

85. 15 N.Y.2d at 322, 206 N.E.2d at 339, 258 N.Y.S.2d at 399 (1965).

Hyman did not end with the New York Court of Appeals' decision. Applications for the revocation of the licenses of the two physicians involved were filed before the New York Board of Regents.⁸⁶ Addressing the problem of consent head-on, the Regents found the physicians guilty of fraud and deceit, suspended their licenses, but stayed execution, thus placing the doctors on probation but allowing them to practice.⁸⁷ The Regents' opinion was not shared by all. Shortly following his suspension, one of the physicians was elected president of the American Association for Cancer Research.⁸⁸

Thus, controversy swirled around *Hyman*. Researchers, Regents, reporters, legal scholars, ethicists—all had opinions about the case.⁸⁹ No legal guidance for the modern clinical investigator could be found in the meager legacy of negligence and battery which pre-*Hyman* cases had brought to the 20th century, but the court did not address the precise issue for which an answer was urgently required by the medical community. If it had, the subsequent developments and today's rancorous outcries from nonphysicians might never have occurred.

E. *The Treatment of Special Subjects*

The ethical issues in the *Hyman* case seem simple in comparison to the complexities of dealing with and trying to help certain other experimental subjects who are even less able to participate in the decisions affecting them than the *Hyman* subjects. In the case of these special subjects, the elements of competence and voluntariness are at issue, and frequently actual consent is absent also.⁹⁰ Nowhere does the problem of informed consent elude solution more than with those who suffer some legal disability. The child, the prisoner, the

86. Board of Regents of Univ. of St. of N.Y., *Licenses Suspended, Suspensions Stayed, Respondents Placed on Probation*, 34 J. MEETING OF BOARD OF REGENTS OF UNIV. OF ST. OF N.Y. 787 (1965). See also Katz 44-65, for materials related to the Board of Regents' action.

87. Board of Regents, *supra* note 86, at 787.

88. 10 PROCEEDINGS OF AM. ASS'N FOR CANCER RESEARCH 110-11 (1969), reprinted in Katz 65; Goodman, *Doctors Must Experiment on Humans: But What Are the Patient's Rights*, N.Y. Times, July 2, 1967, § 6 (Magazine), at 12, 33.

89. E.g., Langer, *Human Experimentation: Cancer Studies at Sloan-Kettering Stir Public Debate on Medical Ethics*, 143 SCIENCE 551 (1964); Lear, *Do We Need Rules for Experiments on People?*, SATURDAY REVIEW, Feb. 5, 1966, at 61; Board of Regents, *supra* note 86, at 787.

90. Cf. Behrman, *The Importance of Fetal Research*, N.Y. Times, June 9, 1974, § 4, at 17, col. 2.

mental retardate, and the mentally ill have been frequent participants in medical research.⁹¹

1. Children

The defenselessness of children—their inability to consent, their inability to comprehend procedures which they may undergo, and their lack of experience—makes their plight difficult to resolve. In addition, a problem exists about parents' competence to consent to their children's participation in experiments not for their direct benefit. In some nonbenefit experiments, an eminent pediatrician questions the practicality of securing consent from the parents alone. He suggests in these difficult circumstances a surrogate, *e.g.*, a court, should participate and be the final arbiter in the decision.⁹² In the end, no satisfactory resolution may be possible since obvious and valid medical reasons necessitate work with children. They are not miniature adults to whom the results of adult experimentation can be applied in small doses. Unfortunately, the medical literature does contain accounts of procedures of dubious value and questionable risks to which children have been subjected in the past.⁹³

One poignant example of work with children in which medical and lay opinion is divided by bitterness and accusations is the study of viral hepatitis begun in 1956 among juvenile mental retardates at New York's Willowbrook State School.⁹⁴ The crowding and unsanitary conditions, which are a fact of the institutionalization of retardates, and their sad inability to maintain personal hygiene, make fecally borne infectious hepatitis rage through custodial institutions.⁹⁵

91. The classic article documenting earlier abuses is Beecher, *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 1354 (1966).

92. Telephone Interview with Dr. Frederick Robbins, Dean of the Case Western Reserve University School of Medicine, Cleveland, Ohio, in Cleveland, Feb. 13, 1975. Dr. Robbins, a pediatrician, won the Nobel Prize for his work on poliomyelitis research.

93. See Katz 958-64 for examples of abuses in pediatric research.

94. Krugman, Ward, Giles & Jacobs, *Infectious Hepatitis: Studies on the Effect of Gamma Globulin and on the Incidence of Inapparent Infection*, 174 *J.A.M.A.* 823 (1960). For a brief insight into medical opposition and Dr. Krugman's work see Gillmor, *Wrestling With Ethical Dilemmas: How Much for the Patient, How Much for Medical Science? An Interview with Dr. Saul Krugman*, *MODERN MED.*, Jan. 7, 1974, at 30, 33. Gillmor describes the attack against Dr. Krugman by the Medical Committee for Human Rights. The Medical Committee for Human Rights was established by physicians interested in patients' rights. It now includes attorneys, engineers, and other members who are nonphysicians. Personal communication to the author from Virginia Snodgrass Cowart, Associate Editor, *Medical News*, *J.A.M.A.*, Nov. 1, 1973.

Hepatitis is frequently protracted and debilitating and sometimes fatal to the victim.⁹⁶ Children entering Willowbrook had for a number of years been exposed deliberately to the virus through inoculation with infected serum or ingestion of infected material.⁹⁷ Doctors involved in the long term study believe and have argued forcefully that the risk of being intentionally inoculated, with the hope of establishing a mild, attenuated form of the disease,⁹⁸ is less of a risk than that of living uninoculated under the prevailing institutional conditions.⁹⁹

Critics of the Willowbrook experiments are many.¹⁰⁰ Many parents alleged that they feared their children would be denied admission if they refused consent to participation in the study.¹⁰¹ Among physicians, controversy festers.¹⁰² Many believe the value of the not inconsiderable knowledge gained from the experiment is negated by the means by which it was attained. One esteemed physician, lamenting the ineffectiveness of the codes, pointed out that

95. Krugman, Giles & Hammond, *Infectious Hepatitis: Evidence for Two Distinctive Clinical Epidemiological and Immunological Types of Infection*, 200 J.A.M.A. 365 (1967).

96. Mosley & Galambos, *Viral Hepatitis*, in DISEASES OF THE LIVER, 410, 456-61 (3d ed. Schiff 1969). Dr. Krugman believes hepatitis is not as debilitating in children as in adults. See Gillmor, *supra* note 94, at 30.

97. Krugman, Ward, Giles, Bodansky & Jacobs, *Infectious Hepatitis: Detection of Virus During the Incubation Period and in Clinically Inapparent Infection*, 261 NEW ENG. J. MED. 729, 731 (1959) (innoculation with infected serum); Ward, Krugman, Giles, Jacobs & Bodansky, *Infectious Hepatitis: Studies of its Natural History and Prevention*, 258 NEW ENG. J. MED. 402, 412-14 (1958) (ingestion of infected material).

98. Smadel, *Smallpox and Vaccinia*, in VIRAL AND RICKETTSIAL INFECTIONS OF MAN 314, 323-32 (T. Rivers ed. 1948).

99. Krugman, Ward, Giles, Bodansky & Jacobs, *Infectious Hepatitis: Detection of Virus During the Incubation Period and in Clinically Inapparent Infection*, 261 NEW ENG. J. MED. 729, 730 (1959) (innoculation with infected serum); Krugman & Giles, *Viral Hepatitis, New Light on an Old Disease*, 212 J.A.M.A. 1019 (1970).

100. See, e.g., Beecher, *supra* note 91; Ingelfinger, *Ethics of Experiments on Children*, 288 NEW ENG. J. MED. 791 (1973).

Dr. Krugman had also tested measles vaccine in its experimental development. In a recent interview with Dr. Krugman it was observed, "By no coincidence, critics of the ethical standards for his Willowbrook hepatitis investigation never seem to find fault with his measles studies." Gillmor, *supra* note 94, at 33.

101. *Hearings on S. 974, S. 878, and S.J. Res. 71 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare (Study of Quality of Health Care—Human Experimentation, 1973)*, 93d Cong., 1st Sess., pt. 1, at 179 [hereinafter cited as *1973 Hearings*] (remarks of Senator Hubert H. Humphrey in offering S. 974, 93d Cong., 1st Sess. (1973)).

102. See, e.g., Ingelfinger, *supra* note 100.

the Nuremberg Code, which had been formulated by the time the Willowbrook experiment began, interdicted this very use of the patient who could not consent.¹⁰³ Yet neither adherence to the Nuremberg Code nor the Helsinki Declaration could ever protect children specifically because informed consent by definition excludes them. So, arguably, informed consent is not the issue at Willowbrook.

Even with regard to normal children, who do not suffer the mental impairment of the Willowbrook inmates, consent remains a most difficult problem. In the physician-patient context Prosser commented that those below the age of 21 are generally considered incapable of consenting to medical procedures.¹⁰⁴ Current statutory revisions in many states have lowered this age to 18.¹⁰⁵ A 1941 case, *Bonner v. Moran*,¹⁰⁶ is generally cited as the leading case embodying the concept that a physician's duty to protect his patient overrides a consent freely given by one of tender years. Fifteen-year-old Bonner was persuaded by his aunt to become a skin graft donor for her badly burned child. The urgency and appeal of the situation are easily imagined. Without his mother's knowledge, young Bonner agreed to be the donor. Unfortunately, through his participation on the experiment, the young boy himself suffered injury and was forced to spend two months in the hospital. The trial court found for the defendant, but the appellate court remanded because the jury had not been instructed that parental consent was re-

103. *Id.*

104. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* 102-03 (4th ed. 1971).

105. *See, e.g.*, OHIO REV. CODE ANN. § 3109.01 (Page Supp. 1974); *see Pohlman, Developments in the Law: The Physician and the Minor Patient*, 70 OHIO ST. MED. J. 41 (1974), containing an interesting analysis of proposed statutory and judicial exceptions to the requirement of parental consent for those under the age of 21. There have been corresponding changes in hospital consent forms as a result; *e.g.*, University Hospitals of Cleveland, Official Memorandum No. 1289, Revised Operative Consent Policy (1973).

Contravening Prosser's statement are several cases in which minors in their middle teens have been adjudged capable of giving consent. In *Bishop v. Shurley*, 237 Mich. 76, 211 N.W. 75 (1926), for instance, a 19-year-old boy was adjudged capable of choosing a local anesthetic over a general anesthetic in a tonsillectomy despite the contrary preference of his parents. The real issue turned on whether the choice proximately caused his death. Similarly, in *Gulf & S.I.R.R. v. Sullivan*, 155 Miss. 1, 119 So. 501 (1928), the court held that a 17-year-old boy employed by the railroad was legally capable of consenting to smallpox vaccination given to him in the course of his employment. *See Curran & Beecher, Experimentation in Children: A Reexamination of Legal Ethical Principles*, 210 J.A.M.A. 77 (1969).

106. 126 F.2d 121 (D.C. Cir. 1941).

quired before an operation on a minor. There was some question that the mother had ratified her son's consent and the appellate court held that if on retrial she was found to have ratified the boy's consent, that would be sufficient.¹⁰⁷

Bonner is particularly interesting because by implication it approves a minor's participation in a nontherapeutic procedure, provided the consent of the parent has been assured.¹⁰⁸ But even with parental consent can the physician proceed in the nonbenefit setting?¹⁰⁹ A measure of the uncertainty can be found in companion cases involving the first kidney transplant operations.¹¹⁰ In these cases, each involving pairs of minor twins, parents consented to the transplantation of the healthy twin's kidney to his critically ill sibling.¹¹¹ The parents and the minor donors were anxious for the transplant, which in each instance was the only hope for the desperately ill twin. Because there was no law on the issue in Massachusetts, or indeed anywhere, the hospital and surgeons were advised to seek declaratory judgments.¹¹² In each case the judge received evidence from a psychiatrist that there would be an adverse emotional effect on the healthy twin if the operation were not performed and the sick twin died.¹¹³ Curran points out that the court felt obligated to look for and find a benefit to the donor as well as the donee.¹¹⁴

The view that parents cannot consent to procedures not directly benefiting the child has a considerable following.¹¹⁵ Philosophers

107. *Id.* at 123.

108. Curran & Beecher, *supra* note 105, at 79.

109. The absence of a firm legal basis for parental consent to participation in research on behalf of the incompetent subject is discussed in 38 Fed. Reg. 31737, 31739, 31741 (1973).

110. *Foster v. Harrison*, No. 68674 Eq. (Mass. Sup. Jud. Ct., Nov. 20, 1957), *Huskey v. Harrison*, No. 68666 Eq. (Mass. Sup. Jud. Ct., Aug. 30, 1957), and *Masden v. Harrison*, No. 68651 Eq. (Mass. Sup. Jud. Ct., June 12, 1957), as reported by Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. Rev. 891 (1959).

111. Curran, *supra* note 110, at 892.

112. *Id.* at 892.

113. *Id.* at 892-93.

114. See Curran & Beecher, *supra* note 105, at 79-80. Curran and Beecher believe these cases have been misinterpreted to mean a minor cannot participate in a medical procedure, including an experiment, unless it provides a benefit to him.

115. Dr. Charles V. Lowe, scientific director of the National Institutes of Child Health and Human Development states: "[T]here is no legal basis for parental consent" to nontherapeutic research on children. Britain, in fact, prohibits nontherapeutic research on children under the age of 12. *Medical News*, 227 J.A.M.A. 13, 14 (1973).

might argue that a measure of civilization is the extent to which a society protects its helpless members. A physician has an obligation to protect his patients, but where the physician-patient privilege does not exist, as it did not at Willowbrook, attempts to experiment with minors place the experimenter on treacherous legal ground. In commenting upon the anomalous position of children in research, one writer has remarked that the law is no help to a child unless he is a donee of property.¹¹⁶ Nevertheless, the dialogue about children has helped us progress beyond the dark times under the common law when children were chattels.

2. Prisoners

Other members of society much used as research subjects are those in prison. Much has been written about this easily accessible pool of human "volunteers."¹¹⁷ Voluntariness, the quintessence of consent,¹¹⁸ is difficult to achieve and highly unlikely in prison. The conclusion has been reached many times that no matter how altruistically the prisoner may approach his participation as a volunteer, no matter how he or others may rationalize an opportunity for meaningful service to society, he cannot avoid the thought that his sacrifice will be viewed favorably by the parole board. Less philosophically, material advantages tempt him. He may receive money which he needs desperately or an opportunity to be released from the grinding misery and fear of prison life.¹¹⁹

Lasagna notes that current concern for the use of prisoners reflects our changing social attitudes.¹²⁰ Prisoners have probably been used in medical experimentation since man conceived prisons.¹²¹ Of particular interest is a 1967 report by two physicians on their use

116. Lowe, *Pediatrics: Proper Utilization of Children as Research Subjects*, 169 ANNALS OF N.Y. ACAD. SCI. 337 (1970).

117. E.g., Beecher, *Experimentation in Man*, 169 J.A.M.A. 461 (1959); *Ethics Governing the Service of Prisoners as Subjects in Medical Experiments*, 136 J.A.M.A. 457 (1948); Hodges & Bean, *The Use of Prisoners for Medical Research*, 202 J.A.M.A. 513 (1967).

118. Beecher, *Consent in Clinical Experimentation: Myth and Realty*, 195 J.A.M.A. 34 (1966).

119. Lasagna suggests, however, that to suppose that looking only to the temptations of the prisoner is overly simplistic, since the impoverished student who volunteers for money is equally the captive of poverty. Lasagna, *Special Subjects in Human Experimentation*, in EXPERIMENTATION WITH HUMAN SUBJECTS 262, 271 (P. Freund ed. 1970).

120. Lasagna, *supra* note 119, at 262.

121. *Id.*

of prisoners for research.¹²² The doctors reported that they had had no difficulty in securing the cooperation of the prisoners and prison officials until the state attorney general ruled that it was not legal to accept prisoners for medical research. The physicians then sought and obtained passage of a statute permitting the use of prisoners.¹²³ The statute provides that a prisoner must volunteer his consent in writing and that he may withdraw this consent at any time.¹²⁴ It appears to be the only such statute dealing with prisoner research.

Much concern has been expressed about the reduction of sentences in return for volunteering. A well-known study by a committee appointed by Illinois Governor Green during World War II observed that a prisoner's participation in medical experimentation might be viewed as a form of good conduct and that reduction of sentence under the parole system might be a reward for good conduct.¹²⁵ Nevertheless, the report cautioned that reduction of sentence must not be excessive because it would become a form of coercion inconsistent with the concept of voluntariness.¹²⁶ A strong statement by the American Medical Association expressed its disapproval of participation by persons accused of violent crimes and its view that none of the prisoners participating in experimentation should be considered for pardon.¹²⁷

Most recently, a vigorous exchange occurred between a professor of medicine and a prisoner. Dr. Bach-Y-Rita stated that what may be perceived as an acceptable risk for a person outside a prison may be totally unacceptable for the same person inside because the lack of unimpeded access to information, absence of advice from a physician friend, lack of legal counsel, and the isolation from changing ideas of society restrict the prisoner's ability to assess the risk he undertakes.¹²⁸ A written response from a prisoner attacks what the prisoner terms the stance of liberals who pose as friends of con-

122. Hodges & Bean, *supra* note 117.

123. *Id.* at 514.

124. IOWA CODE ANN. § 246:47 (1964).

125. *Ethics Governing the Service of Prisoners as Subjects in Medical Experiments*, 136 J.A.M.A. 457, 458 (1948); see Freund, *Ethical Problems in Human Experimentation*, 273 NEW ENG. J. MED. 687 (1965).

126. *Ethics Governing the Service of Prisoners as Subjects in Medical Experiments*, 136 J.A.M.A. 457, 458 (1948).

127. House of Delegates of the American Medical Ass'n, *Resolution on Disapproval of Participation in Scientific Experiments by Inmates of Penal Institutions*, from *Digest of Official Actions*, in Katz 1025.

128. Bach-Y-Rita, *The Prisoner As An Experimental Subject*, 229 J.A.M.A. 45 (1974).

victs.¹²⁹ He states that participation in medical research is one of the few free choices a man has in prison.¹³⁰ Similar vocalization by other prisoners may be more helpful than judgments made by members of the outside world looking in.

3. *The Mentally Infirm*

In the unending colloquy about proper experimentation a third category of volunteers requires special attention—the mentally infirm,¹³¹ perhaps better described as those with behavioral disturbances. About these individuals, the observation has been made that “[P]ersons encumbered with the economic or custodial responsibility for the mentally infirm might not be sufficiently objective to make judgments which are fully in the best interest of the institutionalized person.”¹³² Work with the mentally ill is surely enveloped with even greater uncertainty than work with children or prisoners. Abuse of children is not generally tolerated by society and prison sentences may be finite, but the terrible fact of confinement of unknown duration increases the vulnerability of those exhibiting mental infirmity. Frequently their families and guardians are driven to desperate measures by the disruption which their condition or illness can create.¹³³

a. *Psychosurgery*. One recent focus of attention in experimentation to aid the mentally ill has been the quandary engendered by the difficulty of obtaining truly informed consent from patient, parent, or guardian for the experimental surgical alteration in behavior, termed psychosurgery.¹³⁴ The controversy over this highly technical procedure has become increasingly rancorous.¹³⁵ Those who use the technique believe that specific diseased sites in the brain are responsible for undesirable behavior. To eliminate unwanted

129. Letter from Frank Hatfield to the Editor, 229 J.A.M.A. 1720 (1974).

130. *Id.* at 1721.

131. Protection of Human Subjects, 39 Fed. Reg. 30648, 30652 (1974).

132. Protection of Human Subjects, 38 Fed. Reg. 31738, 31745 (1973).

133. See note 101 *supra* and accompanying text.

134. B. BROWN, L. WIENCHOWSKI & L. BROWN, *PSYCHOSURGERY: PERSPECTIVE ON A CURRENT ISSUE* (U.S. Dep't of Health, Education, and Welfare Pub. No. [HSMHA] 73-9119, 1973).

135. For perceptive reporting and an excellent status report see *Medical News*, 225 J.A.M.A. 1035 (1973).

A measure of the antipathy toward psychosurgery may be seen in the “Butcher of the Year” Award given to a well-known neurosurgeon for his activity. Albertson, *Psychosurgery Hits Back Against Racism Charges*, *Hospital Tribune*, Jan. 21, 1974, at 2, col. 1.

destructive behavior, they argue, the diseased or abnormal cells of the brain must be eliminated.¹³⁶

Psychosurgery employs surgical excision or deliberate destruction of brain tissue by means of an electrical current applied to the suspect tissues or nerve cells within the brain. Current is directed to the diseased site by means of electrodes implanted in the brain through burr holes drilled into the skull.¹³⁷ The electrodes can be left in place as long as 6 weeks while neurophysiologic data are assembled.¹³⁸

Once surgery is performed, the treated portion of the brain is permanently altered or destroyed.¹³⁹ Through the use of sophisticated medical instrumentation, such as stereotaxic machines and x-ray beams,¹⁴⁰ and demanding techniques, an attempt is made to pinpoint the exact locus in the brain responsible for undesirable behavior and hopefully the destruction of "only those tissues and nerve cells [will ensue] leaving other functions and behaviors of the patient unaffected."¹⁴¹ Unfortunately if healthy or nonaffected brain tissue is also destroyed it will not regenerate, for the effect of psychosurgery is irreversible.

Ideally, psychosurgeons hope by these direct or mechanical means to free severely disturbed individuals from the tyranny of their compulsive, uncontrolled behavior.¹⁴² The bitterness of the controversy, however, is seen in conflicting reports in the medical literature about the efficacy of the results obtained. Typically, advocates of the procedure maintain that psychosurgery is performed upon individuals whose aberrant or violent behavior torments them or their families.¹⁴³ Case histories present a repetitive pattern of aggressive, wild actions, expressed as self-mutilation, attempted suicide, or even homicide.¹⁴⁴ The desperation which their uncontrollable deeds

136. 1973 *Hearings* pt. 2, at 349; V. MARK & F. ERVIN, *VIOLENCE AND THE BRAIN* 70 (1970) [hereinafter cited as MARK & ERVIN].

137. Sweet, *Treatment of Medically Intractable Mental Disease by Limited Frontal Leucotomy—Justifiable?*, 289 *NEW ENG. J. MED.* 1117 (1973).

138. *Medical News*, 225 *J.A.M.A.* 914, 915 (1973).

139. 1973 *Hearings* pt. 2, at 360.

140. MARK & ERVIN 71-85. See also *PSYCHOSURGERY: PERSPECTIVE ON A CURRENT ISSUE*, *supra* note 134, at 1.

141. Testimony of Dr. Bertram Brown, Director of National Institute of Mental Health, 1973 *Hearings* pt. 2 at 344.

142. Mark & Nevelle, *Brain Surgery in Aggressive Epileptics*, 226 *J.A.M.A.* 765 (1973).

143. 1973 *Hearings* pt. 2, at 349, 350.

144. *Id.*

cause such patients, their families, and their psychiatrists cannot be minimized. Sometimes these patients have suffered organic brain disease such as encephalitis; sometimes they have sustained a severe head injury; but more frequently the cause of their behavior is not known.¹⁴⁵

The growing number of advocates for the technique, believing that the brain is structurally abnormal in these people, stress that drug therapy or other generally accepted modes of psychiatric treatment do not control them. Relief, they believe, can be obtained only through techniques which deal directly with the "structural" anomaly.¹⁴⁶ Exponents of a middle-of-the-road philosophy believe that despite the stab in the dark which characterizes psychosurgery, the core personality of the patient remains unchanged by the process.¹⁴⁷

Countering the zeal of the psychosurgeons are opinions like those expressed by Dr. Bertram Brown, Director of the National Institutes of Mental Health, that the procedure falls short of the goals expressed by its advocates and "even the best research in this field is not able to achieve . . . precision."¹⁴⁸ Critics of psychosurgery are disturbed because the treatment is used when the nature of the patient's illness is far from clear. Despite the claims of its proponents, psychosurgery is, in fact, performed in the absence of direct evidence of the structural brain disease of which they speak.¹⁴⁹ Basic to the opposition to psychosurgery is the belief that it is nothing more than mind control. Critics believe that the step from controlling the mind of one believed to be mentally ill to controlling any human behavior is very short.¹⁵⁰

A particularly strong critic of the technique has been Dr. Peter Breggin,¹⁵¹ who characterizes the process as "a pacifying operation which blunts the emotions and subdues behavior regardless of the presence or absence of any brain disease or any particular psychiatric problem."¹⁵² Breggin argues that psychosurgery "partially destroys

145. *Medical News*, 225 J.A.M.A. 916-17 (1973) (encephalitis; unknown causes); *Medical News*, 226 J.A.M.A. 19-20 (1973) (head injury).

146. *E.g.*, 1973 *Hearings* pt. 2, at 349.

147. *Medical News*, 225 J.A.M.A. 1037, 1041 (1973).

148. 1973 *Hearings* pt. 2, at 344.

149. *Id.* at 339.

150. MARK & ERVIN 125; 118 CONG. REC. 11396 (1972); Letter from Peter R. Breggin to the Editor, in 226 J.A.M.A. 1121 (1973).

M. CRICHTON, *TERMINAL MAN* (1972) is a popular novel about the control of a violent individual by the implantation of an electronic device in his brain.

151. Dr. Breggin is a practicing psychiatrist in Washington, D.C.

152. 1973 *Hearings* pt. 2, at 439.

a human being."¹⁵³ He alleges that the most frequent candidates are not psychotics but hyperactive children and women suffering from neuroses manifested as depression, anxiety, or obsession.¹⁵⁴ Whether the technique is employed upon mere neurotics, as Breggin argues, or upon those whose behavior is actually beyond control,¹⁵⁵ experience indicates that the subjects of psychosurgery have case histories of intractable illness. By and large they have been under psychiatric treatment long enough to determine that nonsurgical therapy has not been effective. Breggin testified during Senate Subcommittee hearings that neurosurgeons practicing psychosurgery fail to obtain the consent of affected persons.¹⁵⁶ But, since such unfortunate individuals are always in stressful situations, the validity of their consent is always debatable.

The issue of consent to this drastic procedure was the precise question which gave rise to the first court decision on psychosurgery; the patient involved in the case was in fact a prisoner. In *Kaimowitz v. Michigan Department of Mental Health*,¹⁵⁷ an alleged murderer and rapist had been confined to a state hospital because of his homicidal rages. He alleged he had no hope of release until he "volunteered" to participate in a program comparing the effects of drug therapy and psychosurgery. An attorney, a member of the Medical Committee for Human Rights,¹⁵⁸ hearing of the case petitioned the court to enjoin the procedure. The court ordered the inmate released, stressing the legal inability of an involuntarily detained mental patient to consent to psychosurgery.¹⁵⁹ The court stated that psychosurgery should never be performed on an involuntarily confined person. *Kaimowitz* is a strongly worded opinion, reflecting the judge's horror at the prospect of physical intervention in the brain by irreversibly destroying part of it. Echoing Breggin, the court said:

Experimental psychosurgery, which is irreversible and intrusive often leads to the blunting of emotions, the deadening of memory, the reduction of affect, and limits the ability to generate new ideas. Its potential for injury to the creativity of the individual is great, and can impinge upon the

153. *Medical News*, 225 J.A.M.A. 916 (1973).

154. *1973 Hearings* pt. 2, at 360.

155. *Medical News*, 225 J.A.M.A. 1036 (1973).

156. *1973 Hearings* pt. 2, at 363.

157. 42 U.S.L.W. 2063 (Cir. Ct., Wayne County, Mich. 1973).

158. *Medical News*, 225 J.A.M.A. 1035, 1036 (1973).

159. 42 U.S.L.W. at 2064.

right of the individual to be free from interference with his mental processes.¹⁶⁰

In the court's view three elements are necessary for consent: (1) competence, (2) knowledge, and (3) voluntariness.¹⁶¹

Noting the law's vigilance against inequality of bargaining power in many legal relations and the inherently coercive nature of a mental institution, the court turned its attention to the depersonalizing effect of institutions and the resulting inequality of mental patients who cannot reason as equals with doctors and administrators.¹⁶² The court did not rely solely on informed consent arguments, but also found that under the first amendment the government has no power or right to control men's minds.¹⁶³ Thus, an involuntarily detained person may not consent to psychosurgery. The language in *Kaimowitz* is usually forceful, and the case is another example of Michigan's well-reasoned stand on medicolegal problems.

Two unreported cases on psychosurgery have also considered the issue of the informed consent to psychosurgery.¹⁶⁴ In Virginia a deeply disturbed patient's acts of self-mutilation led his parents to agree to psychosurgery. The Virginia Attorney General's office, learning of the proposed procedure, intervened in behalf of the patient. The court stayed the surgery on the ground of the patient's inability to give consent.¹⁶⁵ In the second case, which was settled before trial, the plaintiff, blinded from psychosurgery, recovered settlement on the ground that she was inadequately informed of the risk in the procedure.¹⁶⁶

b. *Aversive Therapeutic Techniques.* Another example of judicial antipathy to tinkering with the mental processes may be found in a second case involving a prisoner, *Mackey v. Procunier*.¹⁶⁷ The Court of Appeals for the Ninth Circuit reversed and remanded to the district court on the ground that the lower court had treated plaintiff's complaint as one alleging malpractice when, in fact, his

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. *Medical News*, 225 J.A.M.A. 1035, 1036, 1044 (1973).

165. *Id.* at 1044.

166. *Id.* A third case, *Kille v. Mark*, No. 681998 (Mass. Super. Ct., filed Dec. 3, 1973) has drawn a great deal of attention. See MARK & ERVIN (for an exposition of their views on psychosurgery); Dietz, *Hub Psychosurgery Draws 2 Million Suit*, Boston Globe, Dec. 10, 1973, at 3, col. 4.

167. 477 F.2d 877 (9th Cir. 1973).

case went far beyond such claim.¹⁶⁸ Plaintiff, a state prisoner, alleged he consented to electroshock therapy as a behavior modification technique. Instead of receiving shock therapy, the plaintiff was given succinylcholine, a drug generally used as an adjunct to electroshock and given while the patient is unconscious.¹⁶⁹ Succinylcholine is a terrifying drug. It stops the patient's breathing and produces feelings of imminent death.¹⁷⁰ The administration of succinylcholine was part of an experiment designed to test aversive therapy for prisoners.¹⁷¹ By exposing the prisoner to this painful and frightening experience accompanied by psychological suggestion, alteration of a criminal behavior pattern was sought.¹⁷²

*Knecht v. Gillman*¹⁷³ presents another example of the questionable value of aversive therapy for prisoners. In the Iowa Security Medical Facility, a drug, apomorphine, was administered for "pieces of behavior" such as refusing to get up, giving cigarettes against orders, talking, swearing, or lying, and other violations of prison protocol. Apomorphine causes vomiting and changes in cardiovascular balance. Once administered, its effect is irreversible.

In *Knecht*, the drug was administered by nursing personnel without their personal observation of the inmate's prohibited behavior but upon the report of other prisoners and without specific authorization of doctors. Holding the "treatment" an instance of cruel and unusual punishment, its administration was enjoined except with written consent from the prisoner which could be withdrawn at any time. Each injection was required to be authorized by a physician upon personal observation by the professional staff. No attention was given in the case to the questionable morality of the treatment shown in the face of "informed consent." Curiously, Iowa is the state which by statute permits experimentation on prisoners with their consent only.

F. *The Evolution of Federal Guidance for the Researcher*

A number of the problems which have been reviewed in the pre-

168. *Id.*

169. *Id.*

170. *Id.*

171. *Id.*

172. A Cleveland newspaper has given an account of the use of hypnosis and electric shock in the treatment of child molesters. Twice a week 12 inmate volunteers viewed slides of nude children. Each slide was accompanied by an electric shock to the prisoner's groin. *Plain Dealer* (Cleveland), Dec. 6, 1973, at 9-G, col. 6.

173. 488 F.2d 1163 (8th Cir. 1973).

ceding sections began to be identified very soon after World War II. As early as 1952, a few astute observers pointed out that some of the research being undertaken involved the unconsidered use of human beings.¹⁷⁴

Although, in general, public and private granting agencies scrutinized grant requests for originality of thought, validity of methodology, and expectation of success, the matter of securing consent was left to the conscience of the individual investigator. Some inquiries about securing consent were made by Dr. Louis Welt,¹⁷⁵ and a pioneering conference on the Legal Environment of Medical Science was held at the University of Chicago under the leadership of attorneys Irving Ladimer and William Curran.¹⁷⁶ By and large, however, until a number of events occurred almost simultaneously, "there was a general skepticism toward the development of ethical guidelines, codes, or sets of procedures concerning the conduct of research."¹⁷⁷ It was not that doctors were unconcerned but that they believed the ethical judgment of each physician would lead him to the deepest consideration for his subjects.¹⁷⁸

1. *Development of Peer Review*

The NIH, however, was not satisfied with the vague reliance upon the conscience of the investigator. From the beginning, the NIH administrators believed (and there was evidence that much legal consideration was given to this point) that the traditional doctor-patient relationship prevailed and thereby protected those ill subjects who came to the Center for study.¹⁷⁹ They were uncertain, however,

174. See, e.g., Bean, *Testament of Duty: Some Strictures on Moral Responsibilities in Clinical Research*, 39 J. LABORATORY MED. 3 (1952); Cady, *Medical Malpractice: What About Experimentation?*, 6 ANNALS OF W. MED. & SURGERY 164 (1952).

175. Welt, *Reflections on the Problems of Human Experimentation*, 25 CONN. MED. 75, 78 (1961) (results of poll of university departments of medicine in 1961).

176. See *Report on the National Conference on the Legal Environment of Medical Science*, reprinted in CLINICAL INVESTIGATION IN MEDICINE: LEGAL, ETHICAL, AND MORAL ASPECTS 138 (I. Ladimer & R. Newman eds. 1963). The conference was held on May 27-28, 1959 in Chicago. Dr. Irving Ladimer served as Secretary of the Conference. *Id.* at iv. Curran, *Governmental Regulations of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, in EXPERIMENTATION WITH HUMAN SUBJECTS 402, 408 (P. Freund ed. 1970).

177. *Id.*

178. See, e.g., Page, *Medical Ethics*, 152 SCIENCE 1 (1966); Welt, *supra* note 175, at 78; *When Is Consent?*, THE LANCET, Oct. 14, 1967, at 813.

179. Frankel, *The Public Health Service Guidelines Governing Research*

about the legal status of normal volunteers and the Government's responsibility for them. In response to this uncertainty, in 1953 the NIH issued guidelines for the protection of normal volunteers.¹⁸⁰ The guidelines were entitled "Group Consideration of Clinical Research Procedures *Deviating From Accepted Medical Practice or Involving Unusual Hazard.*"¹⁸¹ Departure from medical practice, the touchstone of the old malpractice cases, was thus squarely confronted in the nontherapeutic situation. Investigators were directed that written consent of the normal volunteer was required in the face of unusual hazard.¹⁸² Most important in the guidelines was the initiation of a system of review of the ethics of the investigator by his colleagues.¹⁸³

At first this review by the researcher's peers and the guidelines for his activities were internal and not applicable to the large number of investigators working outside the NIH who were funded by the United States Public Health Service.¹⁸⁴ That the need for securing the informed consent of experimental subjects was also being considered by such outside workers seems certain. Study sections and other advisory groups which reviewed grant applications for the Public Health Service were composed of first-rate investigators who were members of the scientific societies whose journals provided a forum for discussion of the issue.¹⁸⁵ In 1960, two years after the conference on the Legal Environment of Medical Science conducted by Ladimer,¹⁸⁶ the NIH funded the Law-Medicine Research Institute of Boston University Law School for the purpose of studying legal, moral, and ethical issues involved in clinical investigation in the United States.¹⁸⁷ In 1964 and 1965, especially at the time of

Involving Human Subjects: An Analysis of the Policy-Making Process, in PROGRAM OF POLICY STUDIES IN SCIENCE AND TECHNOLOGY 10 (George Washington Univ. Monograph No. 10, 1972).

180. *Id.*

181. *Id.* at 10-11 (emphasis added).

182. *Id.* at 12.

183. *Id.* at 11.

184. *Id.* at 12.

185. *Id.* at 13. For examples of the discussions in medical journals, see Beecher, *Experimentation in Man*, 169 J.A.M.A. 461 (1959); Freund, *Ethical Problems in Human Experimentation*, 273 NEW ENG. J. MED. 687 (1965) (*The New England Journal of Medicine* is the official journal of the Massachusetts Medical Society); Wolfensberger, *Ethical Issues in Research with Human Subjects*, 155 SCIENCE 47 (1967).

186. See note 176 *supra* and accompanying text.

187. Frankel, *supra* note 179, at 18; cf. Curran, *supra* note 176, at 406 n.21. Curran says the Institute was established in 1958.

Hyman, James A. Shannon, the NIH director, pressed his staff to develop a mechanism for peer review of proposed research at institutions outside the NIH.¹⁸⁸

Thereafter, in 1966, Surgeon General William Stewart issued a written policy which imposed upon the research institutions supported by the Public Health Service a peer review system similar to that used by the NIH Clinical Center.¹⁸⁹ The review was to assure independent determination of the rights and welfare of individuals involved in clinical studies, the appropriateness of methods used to secure their informed consent, and an assessment of the risk-benefit ratio, *i.e.*, was the benefit consonant with the risk to the subject?¹⁹⁰ Five months later, a revised policy required further assurance from the funded institution of the propriety of its policies, procedures of review, and decisions regarding plans for human experimentation.¹⁹¹ Still later that year, a further clarification was issued indicating that the policy was also to be applicable to the behavioral and social sciences,¹⁹² fields in which, to this author's mind, many damaging experiments had proceeded unchecked.¹⁹³

Concurrent with its policy statements and the establishment of the peer review system, the NIH Clinical Center issued the *Handbook of the Normal Volunteer Patient Program of the Clinical Center*, in which informed consent in the experimental situation was de-

188. Frankel, *supra* note 179, at 19-31.

189. Surgeon General, Public Health Service, Clinical Research and Investigations Involving Human Beings, Feb. 8, 1966 (memorandum to the heads of institutes conducting research with Public Health Service grants), *accompanying* PPO No. 129, Clinical Investigation Using Human Subjects, Feb. 8, 1966 (available through HEW).

190. *Id.*

191. Surgeon General, Public Health Service, Revised Procedure on Clinical Research and Investigations Involving Human Subjects, July 1, 1966 (memorandum to heads of institutions receiving Public Health Service grants), *accompanying* PPO No. 129, Revised Policy July 1, 1966, *superseding* PPO No. 129, Clinical Investigation Using Human Subjects, Feb. 8, 1966 *and* PPO No. 129 Supp., Apr. 7, 1966 (available through U.S. Public Health Service, Division of Research Grants).

192. Surgeon General, Public Health Service, Clarification of Procedure on Clinical Research and Investigation Involving Human Subjects, Dec. 12, 1966 (memorandum to heads of institutions receiving Public Health Service grants).

193. See Katz 358-69, 436-51 (for reports of behavioral studies); *Privacy and Behavioral Research: Preliminary Summary of the Report of the Panel on Privacy and Behavioral Research*, 155 SCIENCE 535 (1967). For an excellent survey of controversial behavioral studies, see Marcus, Book Review, N.Y. Times, Jan. 13, 1974, § 7, at 1, which reviews MILGRAM, OBEDIENCE TO AUTHORITY: AN EXPERIMENTAL VIEW (1973).

fined.¹⁹⁴ It was to be "[a] formal, explicit free expression of willingness to serve as a subject for research after the *values* and effects of such participation have been explained by the investigator and are sufficiently understood for the volunteer to make a mature judgment."¹⁹⁵ The definition, obviously not perfect, represents considerably more guidance than researchers had secured from the *Hyman* court, and parallels what is being expressed in the most recent malpractice cases. A revision of the definition added a requirement for explaining any attendant risk or discomfort.¹⁹⁶

Another example of the growing attention to the protection of human subjects was found in the *Grants Administration Manual* of the Department of Health, Education, and Welfare, in the section discussing the protection of human subjects.¹⁹⁷ First issued in 1959, it contained a detailed exposition of the criteria for determining risk and protection. One of the best definitions of informed consent appeared therein.¹⁹⁸ Briefly, it required that the patient or his representative be given a fair explanation of the procedures to be followed, a description of possible discomforts and risks, a description of possible benefits, a disclosure of alternative procedures, an offer to answer all inquiries, and a clear enunciation of the patient's freedom to withdraw from the study at any time.

These formal expressions of the ethics of human experimentation by the NIH and the Public Health Service were exemplary of the growing sensitivity of concerned investigators to the problems they faced.

III. FOOD AND DRUG LEGISLATION

For those outside the NIH and the Public Health Service, 1962 might be deemed the crucial year. At the same time the Helsinki

194. NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER, HANDBOOK ON THE NORMAL VOLUNTEER PATIENT PROGRAM (rev. ed. 1966).

195. *Id.* at iv.

196. NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER, HANDBOOK ON THE NORMAL VOLUNTEER PATIENT PROGRAM OF THE CLINICAL CENTER (rev. ed. 1967).

197. U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, GRANTS ADMINISTRATION MANUAL pt. I, chs. 1-40, *Protection of Human Subjects* (1971) [hereinafter cited as GRANTS ADMINISTRATION MANUAL]. The *Grants Administration Manual* was issued as GRANTS AND AWARD PROGRAMS OF THE PUBLIC HEALTH SERVICE, POLICY & INFORMATION STATEMENT IN RESEARCH GRANTS (1959). This information was kindly provided by Dr. Robert Akers of the NIH.

198. GRANTS ADMINISTRATION MANUAL 2.

Declaration was being considered,¹⁹⁹ the Senate held hearings to investigate drug industry monopolies.²⁰⁰ At this time the heartbreaking thalidomide catastrophe in Germany also came to light.²⁰¹

Curiously, testimony about thalidomide and the heroic intransigence of Dr. Frances Kelsey of the Food and Drug Administration, who refused to allow the drug on the market, was never recorded at the hearings.²⁰² The horrifying details of the drug's effects,²⁰³ however, must surely have impressed Congress, because it quickly passed the Drug Amendments of 1962, which made profound changes in the regulation of the pharmaceutical houses.²⁰⁴

Too often corrective legislation comes only after a predictable tragedy has occurred and drug legislation is no exception. A pattern for drug testing was started in 1938 when the Federal Food, Drug, and Cosmetic Act²⁰⁵ was promulgated after hundreds died because of an industry error in which sulfanilamide was compounded as an elixir with a deadly poison.²⁰⁶ During the next 25 years, limited control

199. See, e.g., Bukantz, *The Helsinki Declaration*, 2 HOSPITAL PRACTICE 24 (Jan. 1967); *Declaration of Helsinki*, 271 NEW ENG. J. MED. 473 (1964), reporting British views on human experimentation and the work of the World Medical Association.

200. *Hearings on S. Res. 276 Before the Subcomm. on Reorganization and International Organizations of the Senate Comm. on Government Operations*, 87th Cong., 2d Sess., pt. 1 (1962).

201. Beachboard, *Investigational Drugs: Experimentation or Medical Practice*, 20 FOOD DRUG COSM. L.J. 256, 268 (1965).

202. Curran, *supra* note 176, at 409.

203. Ten thousand babies were born in Germany and Great Britain suffering phocomelia, i.e., the misshapeness and absence of limbs. The defects were traced to their mothers' ingestion of thalidomide, a tranquilizer, during the critical second and third months of pregnancy when the fetus develops arms and legs.

204. The Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, amending Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-92 (1970).

205. *Id.* § 355.

206. *Deaths Due to Elixir of Sulfanilamide—Massengill Report of Sec'y of Agriculture Submitted in Response to H. Res. 352 of Nov. 18, 1937 and S. Res. 194 of Nov. 16, 1937*, 109 J.A.M.A. 1985 (1937). "[T]he only basis of action under the Food and Drugs Act against the interstate distribution of the 'elixir' was the allegation that the word implies an alcoholic solution whereas the product was a diethylene glycol solution." *Id.* at 1987. The Department of Agriculture, under whose aegis the Food and Drugs Act was administered, recommended legislation. The first recommendation was licensing of control of new drugs to insure they would not be distributed until experimental and clinical tests had shown them to be safe for use. Exemptions would be made for new drugs distributed to competent investigators for experimental work. The second recommendation was prohibition of drugs dangerous to health when administered in accordance with manufacturer's directions for use. This would provide a more appropriate basis of action than that on which pro-

over drug manufacture and sale was attempted. Under FDA regulations,²⁰⁷ drugs had first to be tested in animals, then in selected volunteers,²⁰⁸ and then marketed under restricted conditions before general release. Unfortunately, the FDA merely required drug manufacturers to apply for an investigational-use exemption. By labeling the medicine as a new drug and one limited to investigational use, the manufacturer was free to distribute it.²⁰⁹

A. *The 1962 Drug Amendments*

Thus, although well intentioned, the 1938 regulations were sadly inadequate. The 1962 amendments tightened the requirements for introduction of drugs into commerce by requiring prior evidence of the drug's safety and efficacy, a description of its components and method of manufacture, and the submission of specimen labeling to the Secretary of Health, Education, and Welfare.²¹⁰ The most important part of the amendments, however, lay in the Investigational New Drug²¹¹ provisions, which exempted from restricted interstate movement those drugs intended solely for investigational use by experts qualified by scientific training and experience. As a condition for exemption, the investigator had to certify that he had informed his human subjects, both patients and controls, of the investigatory nature of the drug unless it was not feasible or the investigator judged consent would be contrary to the subject's interests.²¹²

Although the safeguards for patient and subject written into the 1962 amendments were regarded as drastic when introduced,²¹³ the feasibility provision nevertheless permitted some unethical practices to proceed unchecked.²¹⁴ The FDA regulations on consent had

ceedings were instituted against the "elixir." Third, it was proposed that drug labels bear appropriate directions for use and warnings against probable misuse. Last, the Department recommended prohibition of secret remedies by requiring that labels disclose fully the composition of drugs. *Id.* at 1988.

207. 21 C.F.R. §§ 130 *et seq.* (1962).

208. See Beachboard, *supra* note 201, at 260.

209. Curran, *supra* note 176, at 410.

210. The Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, amending Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-92 (1970). The thalidomide experience was the precipitating event for the tightened regulations. See Alshire, 13 GROUP PRACTICE 433, 434 (1964).

211. 21 C.F.R. § 130.3 (1962).

212. U.S. Dep't of Health, Education, and Welfare, Food and Drug Administration Form FD 1572, ¶ 6(g), in 21 C.F.R. § 130.3 (1962). See also 1973 Hearings pt. 1, at 36-37.

213. *Informed Consent in Drug Research*, 3 COLUM. J.L. & SOC. PROB., Oct. 24, 1966, at S-4, S-7 n.105.

214. Curran, *supra* note 176, at 419.

merely repeated the language of the Act²¹⁵ but in 1966 the FDA promulgated new regulations that defined the scope of the exceptions to the consent requirements.²¹⁶ The feasibility exception was limited to cases in which consent could not be obtained because the patient could not communicate, *e.g.*, because he was comatose.²¹⁷ The exception for cases in which securing consent would be contrary to the best interests of the subject was made strictly applicable to situations in which communication of the information to obtain consent would seriously affect the patient's disease state.²¹⁸ Another amendment passed in 1970 provided a further brake to untrammelled, unauthorized experimentation by interposing a 30-day waiting period between the time a proposed work was approved and the start of clinical trials, in order to verify that animal investigation had preceded the proposed human studies.²¹⁹

Despite careful honing of the regulations to control use of new drugs without the proper restraint, they may still allow experimentation to take place without FDA supervision in some instances. Once a new drug has been shipped in interstate commerce for its approved use, a physician may lawfully prescribe that new drug for an unapproved use when that prescription is part of the practice of medicine.²²⁰ Thus, a higher dosage, use in an unapproved subject, or use in a different disease may occur. Here, the burden of recognizing the investigational aspect of such use and consideration of the attendant moral and ethical obligations it imposes are placed upon the doctor.²²¹ The FDA, however, has various means for controlling this unapproved use. It may stop such usage or require relabeling when it determines it may endanger patients or create a public health hazard or conversely that a benefit has been created.²²²

B. *Unethical Practices in Drug Research Despite Regulation*

Even with the increasing attention focused on safety and consent, the FDA has found instances of unethical practices which raise the question whether ethical judgments can be assured by regulations.

215. *Id.* at 417.

216. 21 C.F.R. § 130.37 (1967) (consent for use of investigational drugs in humans; Statement of policy).

217. *Id.* § 130.37(f).

218. *Id.* § 130.37(g).

219. 1973 *Hearings* pt. 1, at 37-38.

220. Proposed HEW Reg. § 130(a)(3), 37 Fed. Reg. 16504 (1972).

221. *Id.*

222. *Id.* § 130(b), 37 Fed. Reg. 16504 (1972).

In 1967 the FDA established a six-man Scientific Investigations Group headed by Dr. Frances Kelsey, the thalidomide heroine, to determine the truth of data submitted by drug investigators.²²³ To date, her committee has investigated 50 physicians in private practice, of whom 16 are said to have supplied false data.²²⁴ In May 1973, one physician was indicted by a grand jury for having submitted false data on two drugs to two drug companies.²²⁵ Part of the problem is that investigators are frequently paid by drug houses for their investigations. One scientific journal comments:

A sophisticated study of two dozen patients for 2 weeks may net an investigator \$6500. If the investigator should elect to submit the same data to another sponsor, he will receive \$13,000 for his 2 weeks' work. Several clinical investigators are known to gross more than \$1 million a year from their testing programs.²²⁶

Another fraud uncovered by Dr. Kelsey's committee was the reporting of information about prisoners and mental patients as present data, weeks after the subjects had been released. The committee found that in some cases consent consisted of obtaining "X" marks from senile patients and that some consents were "executed" posthumously. Upon questioning, the patients were frequently unaware that they were part of a medical experiment.²²⁷ The resemblance to *Hyman* is worthy of mention.²²⁸

These examples show that regulations, no matter how precisely drawn, do not automatically enhance the ethical sensitivity of those involved in research. The work of Dr. Kelsey's committee demonstrates that peer review can be a very effective weapon.

C. Codification by the HEW

Undoubtedly influenced by the drug falsification experiences of

223. *Physicians Who Falsify Drug Data*, 180 SCIENCE 1038 (1973).

224. *Id.* Falsification of drug research results is not a new phenomenon. In 1966, FDA inspectors reported that two doctors had filed false data on Regimen tablets. *Unsavory Aspects of the Clinical Trial*, 275 NEW ENG. J. MED. 1198 (1966).

225. *Physicians Who Falsify Drug Data*, *supra* note 223, at 1038.

226. *Id.*

227. *Id.*

228. *Hyman v. Jewish Chronic Disease Hosp.*, 42 Misc. 2d 427, 248 N.Y.S. 2d 245 (Sup. Ct.), *rev'd*, 21 App. Div. 2d 495, 251 N.Y.S.2d 818 (1964), *rev'd*, 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965). See text accompanying notes 77-89 *supra*.

the FDA, by events like the *Mackey v. Procunier*²²⁹ case, by the growing sense that the NIH guidelines lacked the force of law, and by the looming certainty of federal legislation, the Department of Health, Education, and Welfare (HEW) codified the existing NIH policies for the protection of human subjects.²³⁰ The basic policy of the regulations provides that no activity that is supported by an HEW grant or contract and that involves placing human subjects at risk shall be undertaken unless a committee of the organization applying for funds has reviewed and approved the proposed activity. The organization must furnish certification of that review and approval to HEW.²³¹ "Subject at risk" is defined as an individual exposed to the possibility of physical, psychological, or social injury as a result of participation in a research project or a related activity that departs from the accepted methods necessary to meet his needs or that increases the ordinary risks of daily life, including those inherent in the subject's occupation.²³² When the review committee decides that a subject is at risk, it must then determine:

- (1) if the risk is sufficiently outweighed by the sum of the potential benefit to the subject and the importance of the knowledge to be gained, so as to warrant the decision to allow the subject to accept the risk;
- (2) if the rights and welfare of the subject will be adequately protected; and
- (3) if legally informed consent is being obtained by appropriate methods.²³³

The applicant organization must assure HEW that the supported research activity will be reviewed at timely intervals and that the or-

229. 477 F.2d 877 (9th Cir. 1973). See notes 167-71 *supra* and accompanying text.

230. 45 C.F.R. §§ 46.1-.22 (1974). Technical amendments to these regulations were promulgated as this issue went to press. The amendments substituted the words "institutions" and "Institutional Review Board" for existing references to "organizations" and "committees" respectively. The amendments eliminate the inconsistent terminology between the National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342, and HEW regulations. The reader is asked to read "organizations" as "institutions," and "committee" as "Institutional Review Board." Wherever the terms "application" or "proposal" appeared singly in the final regulations, both terms now appear together. Other changes were minor and may be found by consulting 40 Fed. Reg. 11854 (1975).

231. *Id.* § 46.2(a). For certification requirement see § 46.11.

232. *Id.* § 46.3(b).

233. *Id.* § 46.2(b).

gанизation will assume responsibility for the subjects involved.²³⁴ No delineation of the organization's responsibility for the subject is provided, however. Presumably the regulations mean that the organization will provide medical care if adverse results obtain, but the regulations do not expressly so state, nor do they give guidance about the extent or duration of such care. The responsibility of organizations engaging in behavioral research is even less certain. Does the responsibility, for example, encompass psychotherapy if the subject is harmed by the experiment? No answers are provided by the Department.

An applicant organization with a significant number of HEW supported activities must file a general assurance with the Department that HEW policies will be met in proposed ongoing research.²³⁵ A special assurance must be given for a single project or activity, but it is not solicited if a general assurance is on file with the Secretary.²³⁶ A general assurance must take the form of a statement of the principles respecting the rights and welfare of experimental subjects.²³⁷ It must describe the procedures by which initial and continuing review of research shall be conducted and the procedures which the review committee will adopt to advise and counsel the investigator of the applicant institution. Procedures for the prompt reporting of proposed changes in research activities, of unanticipated results, and of adverse effects must also be detailed.²³⁸

The crux of the regulations appears in the requirements for the composition and activities of an organizational review committee.²³⁹ This critical committee, charged with the task of protecting experimental subjects by initial and continuing review must be composed of not less than five persons of diverse backgrounds, who must possess the professional competence to review specific research activities to ascertain the acceptability of the research in terms of organizational commitments, applicable law, standards of conduct, and community attitudes.²⁴⁰ The committee "must therefore include persons whose concerns are in this area."²⁴¹

234. *Id.* § 46.2(c).

235. *Id.* § 46.4(a). General assurances are applicable to all HEW-supported activities of the applicant institution. Special assurances are applicable to a single activity or project.

236. *Id.* § 46.5(b).

237. *Id.* § 46.5(a).

238. *Id.* § 46.7(e).

239. *Id.* § 46.6(b)(2).

240. *Id.* § 46.6(b)(1).

241. *Id.*

The regulations do not specify the occupations or interests of these individuals, but Dr. Donald Chalkley, a principal drafter of the regulations, has suggested that, in addition to persons competent to make scientific judgments, lawyers, ministers, and representative members of the community served by the applicant organization, such as members of hospital auxiliary boards or board members of health organizations like the American Cancer Society, would be the most appropriate members.²⁴² Citizen members need not bring professional expertise to the deliberations of this committee, but would convey community attitudes to the group. Ideally, the lawyers, ministers, and other professional members would bring the knowledge of their own disciplines.²⁴³ Nothing in the regulations however, prohibits the lay members of the committee from making scientific judgments, *e.g.*, assessing the importance of the knowledge to be gained.

Very detailed instructions are given regarding the organizational review committee's duty to assure that legally effective consent of experimental subjects is obtained.²⁴⁴ The phrase, "legally effective" is undefined. The regulations do not make clear whether it is the duty of a lawyer-member to make that legal judgment or whether the judgment shall be the product of the labors of the committee as a whole. The definition of informed consent, however, is set out in the very terms so painstakingly worked out over the years in the *Grants Administration Manual*²⁴⁵ by the NIH scientists and staff, people not now considered competent under the regulations to make the judgment unaided by laymen.

Informed consent is defined as the knowing consent of the subject or his legally authorized representative exercised freely in the absence of undue inducement, force, fraud, or coercion.²⁴⁶ The information that must be imparted to the subject includes a fair explanation of what procedures are to be followed, what the purposes of the procedures are, and what experimental aspects are involved

242. Telephone interview with Dr. Donald Chalkley, Chief of the Institutional Relations Branch, Division of Research Grants, National Institutes of Health, Dec. 5, 1974 [hereinafter cited as Telephone Interview].

243. *Id.*

244. See 45 C.F.R. § 46.9 (1974), for mention of legally effective consent; *id.* § 46.3(c) for a definition of informed consent.

245. See text accompanying notes 184-86 *supra*; Frankel, *The Public Health Service Guidelines Governing Research Involving Human Subjects: An Analysis of the Policy-Making Process*, in PROGRAM OF POLICY STUDIES IN SCIENCE AND TECHNOLOGY 42 (George Washington Univ. Monograph No. 10, 1972).

246. 45 C.F.R. § 46.3(c) (1974).

in the procedure. The subject must also be given a description of the attendant risks and discomforts associated with the proposed procedures, a description of the benefits reasonably to be expected, and a disclosure of appropriate alternative methods. An offer to answer any inquiries and instruction that the subject is free to withdraw at any time are also required.²⁴⁷ Documentation of the participant's consent may be accomplished in one of two ways: a written consent may be secured which embodies all of the aforementioned elements.²⁴⁸ Sample copies of such written consent must be kept with the committee records.²⁴⁹ Oral consent may be obtained from the subject or his legally authorized representative, provided written summaries of what is said to the subject are approved by the committee.²⁵⁰ A short-form written consent must be signed by the subject or his legal representative and by an auditor-witness documenting that the basic elements of informed consent have been presented.²⁵¹ To permit modification of the written or oral consent procedures, the committee must establish that the risk to the subject is minimal, that the use of the prescribed oral or written consent procedures would invalidate objectives of considerable importance, and that alternative means of securing consent would be less advantageous to the subject.²⁵² A grave omission in the regulations is their failure to explain how nonprofessional members of the review committee shall make a judgment about whether the risk to a subject is minimal or whether experimental objectives will be invalidated. Scientific judgments by persons unfamiliar with scientific disciplines may pose the possibility of greater harm to the experimental subject than judgments made by ethically oriented investigators.

Whether oral or written, the consent may not contain any exculpatory language through which the subject is made to waive or appear to waive any of his legal rights. Any attempted release of the organization or its agents from negligence is also prohibited.²⁵³ Unexpected consequences may result from this portion of the regulations. General assurances submitted to HEW must be signed by an individual authorized to act and assume the obligations of the regula-

247. *Id.* § 46.3(c)(1)-(6).

248. *Id.* § 46.10(a).

249. *Id.*

250. *Id.* § 46.10(b).

251. *Id.*

252. *Id.* § 46.10(c).

253. *Id.* § 46.9.

tions;²⁵⁴ special assurances must be signed by each individual member of the institutional review committee.²⁵⁵ Yet, in return for their signed assurances, these individuals are not given the reciprocal assurance of their immunity from liability even for judgments made in good faith. The regulations thus could make committee members vulnerable to a variety of legal actions.

Dr. Chalkley suggests that physicians who serve on the organizational review committee will be protected by their professional malpractice insurance in much the same manner they are protected when serving on professional standards review organizations.²⁵⁶ Many states have passed immunity statutes specifically protecting physicians from liability in the exercise of their duties on these professional standards review groups.²⁵⁷ Such statutes have been said to codify the legally recognized privilege that permits physicians in reviewing the work of colleagues to make remarks that in another context might be considered defamatory.²⁵⁸ Attorneys and ministers, he believes, can also be protected by their professional liability coverage.²⁵⁹ Nowhere, however, is the question of protection of the citizen representative addressed realistically. He has neither the umbrella of professional liability insurance nor statutory immunity. The comments to the regulations suggest that the applicant organization's liability insurance will cover these lay persons so exposed,²⁶⁰ but not all institutions have such coverage. Further contradiction arises in the specific statement that the committee must not be composed entirely of persons who are employees of the organization.²⁶¹ The comments suggest that such persons should be considered "employees" for the purpose of coverage.²⁶² Do the citizen or lay mem-

254. *Id.* § 46.4(b).

255. *Id.* § 46.7(a).

256. Telephone Interview, *supra* note 242.

257. B.J. Anderson, *Legal Considerations and Peer Review*, in 1 PEER REVIEW MANUAL 3 (1971), published and distributed by the American Medical Association, Division of Medical Practice, Department of Insurance on Practice Management.

258. These statutes protect physicians from liability for remarks made about other physicians in fulfilling the function of the review committees, which are supposed to improve the quality of medical care. Individuals who provide information to review committees are also protected when communications are published in good faith without malice. *Id.*

259. Telephone Interview, *supra* note 242.

260. Protection of Human Subjects, Comment D, 39 Fed. Reg. 18914, 18915 (1974).

261. 45 C.F.R. § 46.6(b)(4) (1974).

262. Protection of Human Subjects, Comment D, 39 Fed. Reg. 18914, 18915 (1974).

bers then become "employees" only for purposes of coverage? The willingness of insurers to cover persons of such uncertain legal relationship to the insured is difficult to imagine.

For material failure to comply with these complex regulations, the HEW Secretary may exercise his judgment and terminate a grant or contract or suspend it.²⁶³ In evaluating present and future proposals from the applicant, the regulations empower the Secretary to consider whether the applicant has been subject to termination, whether deficiencies have existed in the past, and whether corrective steps have been taken.²⁶⁴ The Secretary is given further authority to impose additional conditions prior to awarding a grant.²⁶⁵ Thus, the power of the Secretary alone to terminate and his authority to impose further conditions seem to subvert the very purpose of the regulations. Ironically, the regulations permit the free exercise of the subjective judgment of the Secretary while purporting to eliminate the subjective judgment of the scientist by involving the laity in the process of scientific research. No such safeguards for the investigator are written into the regulations to protect him against the vagaries or caprices of a Secretary who may reflect the attitudes of an administration hostile to science.²⁶⁶

1. *Lay Representation v. Peer Review*

The gravity of the penalties proposed in the HEW regulations for the protection of human subjects forebodes a difficult time of adjustment both for medical researchers and ultimately, the public. In a sense, the regulations taint the climate of investigation by raising suspicion and distrust of the scientist. Not only is the assessment of the subject's comprehension of the experiment and his consent to it passed beyond the physician, but also beyond the scope of existing legal principles on consent. The regulations, thus, reflect the current ground swell for the involvement of the laity in medical ethics. Whether the lay public is able to grapple more effectively with the complex moral and scientific judgments about human experimentation is questionable.

263. 45 C.F.R. § 46.21(a) (1974).

264. *Id.* § 46.21(b).

265. *Id.* § 46.22.

266. See the legislative history of the National Research Service Award Act of 1974, Pub. L. No. 93-348, § 103, 88 Stat. 342, for a description of administrative hostility to scientific research. S. REP. No. 93-960, 93d Cong., 2d Sess. 2163-66 (1974).

IV. LEGISLATIVE PROPOSALS

A. *The Influence of the Tuskegee Panel*

Even before the issuance of regulations for the protection of human subjects, faith in the laity had been exemplified in the HEW's appointment of the Ad Hoc Panel to investigate the Tuskegee experience after its details were made public.²⁶⁷ Although the Panel included doctors, other professionals—lawyers, ministers, labor leaders, educators, and health administrators—also served.²⁶⁸ The Panel, comparable to a blue-ribbon jury, concluded that the Tuskegee study lacked the statistical validity and reliability necessary for a long term investigation, and had an experimental goal of questionable value.²⁶⁹ Thus, scientific and statistical judgments were made by individuals whose training was not in these areas. Were the observations of the Panel made more perceptive by the presence of laymen? Were their judgments different from those that a panel composed of doctors alone might have reached? The works of Doctors Welt, Beecher, and Lasagna, for example, would seem to belie such a conclusion.²⁷⁰ What is striking is that the Panel did not say that the experiment was begun over 40 years ago, was probably maintained through bureaucratic oversight, and would probably be impossible today. The Panel's report purports to be a blueprint for assuring that Public Health Service grants are conditioned upon complete attention to ethics.²⁷¹ The Panel, it seems, did not take cognizance of what had been going on down the hall at the NIH since 1953, when guidelines for the protection of the individual were first issued.²⁷²

Aside from specific recommendations to indemnify the Tuskegee subjects,²⁷³ the Panel's major suggestion was the promulgation of a

267. Curran, *The Tuskegee Syphilis Study*, 289 NEW ENG. J. MED. 730 (1973).

268. *Id.*

269. *Id.*

270. *E.g.*, L. LASAGNA, *THE DOCTORS' DILEMMAS* (1962); Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966); Welt, *Reflections on the Problems of Human Experimentation*, 25 CONN. MED. 75 (1961).

271. U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, *FINAL REPORT OF THE TUSKEGEE STUDY AD HOC ADVISORY PANEL* (1973).

272. Frankel, *supra* note 245, at 10.

273. Dr. Irving Ladimer has been a strong advocate of such monetary protection. *E.g.*, Ladimer, *Social Responsibility in Clinical Investigation*, 18 MEDICAL SCIENCE 32, 39 (1967). Further, United States Army research is covered by the Federal Tort Claims Act. See Army Reg. No. 70-25 (Use of Volunteers as Subjects of Research) (1962).

statute which would empanel a permanent body to regulate all HEW research and possibly all research, whether publicly or privately supported.²⁷⁴ The Panel suggested a superstructure, fashioned after our court system, with separate peer and lay review groups from whose decisions the right of appeal is granted to higher authorities.²⁷⁵ The Panel has even recommended that the decisions of these groups be published in learned journals.²⁷⁶ In this writer's view, any proposed

274. Curran, *supra* note 267, at 734.

275. Precisely these types of suggestions may be found in the work of several social scientists, *see, e.g.*, note 276 *infra*. Bernard Barber, a social scientist at Barnard College, views physicians as "men of power" who possess mediocre ethics." *See* Barber, *Some "New Men of Power": The Case of Biomedical Research Scientists*, 169 ANNALS OF N.Y. ACAD. SCI. 51 (1970). To the knowledge of this author, Professor Barber has not commented upon the ethics of social scientists.

276. Curran, *supra* note 267, at 734. The work of the Panel echoes the type of thinking expressed by social scientists who have lately entered the discussion about human experimentation. *See* B. BARBER, J. LALLY, J. MAKARUSHEKA & D. SULLIVAN, RESEARCH ON HUMAN SUBJECTS: PROBLEMS OF SOCIAL CONTROL IN MEDICAL EXPERIMENTATION (1973). Barber et al. state that their work is the first attempt to obtain systematic empirical estimates on expressed ethical standards compared with actual behavioral practices. *Id.* at 5. The Barber study quite literally suggests that an appeals system is required to maintain "control" over physicians. The conclusion of the group is that a new profession should be created—that of the "informed outsider," *i.e.*, a retired doctor or nurse or perhaps a social scientist who would have the ability to judge the ethical merits of proposed experimentation. *Id.* at 197. The basic flaw in this proposal is that the informed outsider cannot remain the impartial evaluator once he becomes part of an institution. In addition to exhibiting an unseemly, strong, and perplexing hostility to doctors and little faith in attorneys, the book demonstrates an unclear understanding and many misconceptions about the conduct of medical research. For example, the test constructed by the group includes in the definition of clinical research the concept of the patient's being "at risk" when the collection of human substances—presumably blood or excreta—is undertaken. Physicians and institutions were asked to "agree or disagree" on a series of premises, many of which were framed in the "fallacy of the complex question," "Have you stopped beating your wife?" For a discussion of this well recognized principle of faulty logic *see* BARKER, ELEMENTS OF LOGIC 178-79 (1965). Many of the conclusions were based upon an "interview" study of two institutions receiving Public Health Service grants, when by the authors' count in 1969, 1600 institutions in the United States were receiving such Public Health Service money. *Id.* at 12.

No *a priori* reason exists, as the authors suggest, for believing that the addition of individuals not a part of the research institution would improve the effectiveness of a local research review committee. Lay participation by patients, as suggested *id.* at 194-95, demonstrates an insensitivity to the emotional fragility of persons during any illness.

An example of the hostility toward physicians which pervades the work is in the discussion of the abuse of power that knowledge gives. Here the reader is free to infer that knowledge gained by physicians is withheld from patient and community in order to preserve the doctors' power. *Id.* at 186.

procedure involving human subjects that occasions such a difference of opinion that appeal to a higher authority is required should probably not be conducted at all.

Further difficulty with recommendations like those of the Tuskegee Panel is that they are soon echoed by others.²⁷⁷ Ideas rise and fall in fashion like modes in clothing. The hard reality is that decisions about human experimentation are difficult. Perhaps their difficulty has made onlookers impatient.

Finally, the major difficulty with the thinking advanced by the Tuskegee Panel and with the new NIH regulations discussed earlier is the abolition of that flexibility which is critical to making an ethical judgment. Sometimes, in Hippocrates' words, the occasion is fleeting;²⁷⁸ a patient's illness may require an unanticipated immediate experimental deviation from accepted practice. The sweep of NIH guidelines from 1953 up until the present codification demonstrates how accommodations can be made to the exigencies of experimentation as they arise.²⁷⁹ Such flexibility becomes impossible when ethics become entrapped in statute.

B. Legislation

The risk of rigidity did not discourage the 93d Congress, which passed the National Research Service Award Act after the introduction and consideration of a lengthy list of bills dealing with human experimentation.²⁸⁰ The Act is a consolidation of bills dealing with

277. The legislative history of the National Research Service Award Act makes clear that the report of the Panel was highly influential. S. REP. No. 93-960, 93d Cong., 2d Sess. 2174 (1974).

278. 4 HIPPOCRATES, WORKS, Aphorisms § 1 (W. Jones transl., G.P. Putnam's Sons 1927).

279. Frankel, *supra* note 245, at 5-30.

280. The list of bills introduced in both Houses during the 93d Congress is impressive.

The bills introduced in the House covered a number of areas in the experimentation area. In H.R. 10403, 93d Cong., 2d Sess. (1974), Protection of Human Subjects Act, the proposal to establish an 11-man commission to regulate projects supported by the Department of Health, Education, and Welfare particularly reflects the growing interest in lay review. H.R. 9341, 93d Cong. 2d Sess. (1974), was a proposed amendment to the Public Health Service Act to provide for a new program to support the training of public and community health personnel and to raise the programs of assistance under Title VII of that Act. H.R. 11539, 93d Cong., 2d Sess. (1974), was a bill to improve the Public Health and National Health Service Corps scholarship training program. H.R. 11339, 93d Cong., 2d Sess. (1974), proposed to amend the Federal Food, Drug and Cosmetic Act by requiring that patients not be treated with investigational new drugs without their consent.

the ethical, social, legal, and moral implications of advances in biomedical and behavioral research and the funding of grants for the training of medical scientists and other health professionals. Through the legislative process, the training of future investigators— young doctors and Ph.D candidates—has become inextricably bound with cumbersome bureaucratic proposals for insuring ethical experimentation.²⁸¹

In brief, Title I of the National Research Service Award Act of

Three Senate bills particularly emphasized lay review. First, S. 878, 93d Cong., 2d Sess. (1974), "To amend the Public Health Service Act to provide for restrictions on funds for experimental use," provided for an organizational committee composed of individuals of varying backgrounds to review federally funded projects involving human subjects "at risk." The organizational committee was to determine if subject's rights were protected and to insure that risks did not outweigh benefits anticipated. Informed consent was carefully detailed, including provisions designed to produce full disclosure of experimental procedures, risks, and alternatives. The subject was expressly to be given the right to withdraw at any time. Documentation of consent was provided for, and exculpatory language was banned. Like existing FDA and Public Health Service requirements, S. 878 provided an exception to consent requirements when it was not feasible to obtain consent.

Second, S. 974, 93d Cong., 2d Sess. (1974), offered by Senator Jacob Javits, was designed to amend the Public Health Service Act in order to increase emphasis on ethical, social, legal, and moral implications of research.

Third, S.J. Res. 71, 93d Cong., 2d Sess. (1974), a joint resolution, was to provide for study and evaluation of the ethical, social, and legal implications of advances in biomedical research. A commission was to be composed of individuals drawn from medicine, law, theology, physical, social, and biological sciences, philosophy, humanities, health administration, and government. The commission was to make a complete analysis of scientific advances, their implications, and the codes, laws, and principles relating to the area. In addition consideration was to be given to the public's understanding of these issues.

A number of other bills were also introduced in the Senate. S. 934, 93d Cong., 2d Sess. (1974), was to create a National Human Experimentation Standards Board composed of persons selected from disciplines concerned with clinical investigation. The Board would have created guidelines for ethical research and reviewed experiments to enforce compliance with the guidelines. S. 2071, 93d Cong., 2d Sess. (1974), dealt with training grants to enable young physicians to become medical scientists. S. 2368, 93d Cong., 2d Sess. (1974), was aimed at requiring informed consent for testing medical devices. S. 2072, 93d Cong., 2d Sess. (1974), suggested a National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research to set up rules for ethical research, procedures for review boards, and rates for compensating injured subjects.

A consolidation of S.J. Res. 71, S. 2071, S. 2072, and H. 9341 produced S. 724, 93d Cong., 2d Sess. (1974), that combined provision of training grants to young doctors with bureaucratic proposals designed to insure ethical research.

281. Culliton, *Training Grants; Tied Up in Congress with Ethics Bills*, 182 SCIENCE 265 (1973).

1974 provides support for predoctoral and postdoctoral training in biomedical and behavioral research by amending the Public Health Service Act to provide National Research Service awards.²⁸² In return for 3 years of financial support, a recipient of an award has a number of options for service. He may serve for a specified period by engaging in health research or teaching, by serving in the National Health Service Corps, by practicing his medical specialty in an area of shortage, or by working for a health maintenance organization.²⁸³ The Act's legislative history states that Title I "was prepared in response to [a] drastic change in National policy proposed by the [Nixon] administration with regard to the support of training for the nation's biomedical researchers. It arose out of the conviction that the proposed changes would significantly change this nation's biomedical research activities, activities which are currently preeminent in the world."²⁸⁴

If Title I was enacted in opposition to the administration's proposed policy changes regarding the training of young doctors, Title II was enacted in response to a recital of carefully selected horror tales of which the Tuskegee study was one. At no time during the Senate hearings dealing with the ethical, moral, social, and legal dilemmas of medical advances was testimony given detailing the active and ongoing protection of human subjects by conscientious physicians and biomedical researchers. No evidence was offered about researchers' evergrowing sensitivity to the problems of human research.²⁸⁵ Instead, having listened to several days of testimony about lapses in ethics, the Committee on Labor and Public Welfare could only conclude, as it did, that in too many cases the subjects of biomedical and behavioral research were inadequately protected. The consensus that legislation was needed "with no 'ifs' and 'ands' and 'buts'"²⁸⁶ reflected, with somewhat lesser intensity, the generally hostile attitude toward medical research exhibited by the administration.

The Act establishes a National Advisory Council for the Protec-

282. National Research Service Award Act of 1974, Pub. L. No. 93-348, tit. I, § 103, 88 Stat. 342 [hereinafter cited as NRSAA].

283. *Id.* § 103(c)(1)(C)(2).

284. S. REP. NO. 381, 93d Cong., 2d Sess. 22 (1974).

285. *E.g., id.* at 12-19. See also *Hearings on S. 974, S. 878, and S.J. Res. 71 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare (Quality of Health Care—Human Experimentation, 1973)*, 93d Cong., 1st Sess., pts. 1-3 (1973).

286. S. REP. NO. 381, 93d Cong., 2d Sess. 24 (1974).

tion of Subjects of Biomedical and Behavioral Research. The membership consists of the Secretary of HEW and no less than seven nor more than fifteen distinguished individuals in the fields of medicine, law, ethics, the biological, physical, and social sciences, philosophy, humanities, health administration, government, and public affairs who are to serve for a period of 4 years beginning July 1, 1976.²⁸⁷ Displaying the now familiar infatuation with the laity, the Act provides that no more than three individuals may be persons who have engaged in biomedical and behavioral research.²⁸⁸ The Council's duty is to advise the Secretary concerning the protection of human subjects, reviewing the policies, regulations, and other requirements of the Secretary governing research to determine whether basic ethical principles are being observed.²⁸⁹ It must also determine the effectiveness of these regulations and make recommendations for revisions, if needed, and periodically review changes, scope, purpose, and type of research and the impact of these changes upon the policies, regulations, and other requirements of the Secretary.²⁹⁰

One of the most important aspects of the Act is the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to serve until the Council is seated in 1976.²⁹¹ The Commission, which has now been selected by the Secretary of HEW, is composed of distinguished individuals in medicine, law, ethics, theology, the biological, physical, and social sciences, philosophy, the humanities, health administration, government, and public affairs.²⁹² Once again, reflecting a generalized distrust of the scientist, the Act provides that only five of the eleven members may be research scientists.²⁹³ On August 23, 1974, the Secretary of HEW announced his approval of the charter providing for the operation and functioning of the Commission and directed, in accordance with the Act's provisions, that the Commission shall cease

287. NRSAA tit. II, pt. B, § 211, 88 Stat. 342.

288. *Id.* § 211(a).

289. *Id.*

290. *Id.*

291. NRSAA tit. II, pt. A, § 201, 88 Stat. 342.

292. *Id.* The Secretary has now appointed the Commission. It is composed of a professor of behavioral research, a university vice chancellor for health sciences, the president of a national Negro women's group, a professor of bioethics, three professors of law, a professor of Christian ethics, a gynecologist-obstetrician, a professor of internal medicine, a pediatrician, and a professor of physiological psychology. *Ethics Commission Named*, 186 SCIENCE 38 (1974).

293. NRSAA tit. II, pt. A, § 201(b)(1), 88 Stat. 342.

to exist 30 days following the submission of its final report, which will be due sometime in 1976.²⁹⁴

The Commission's major function is to conduct a comprehensive investigation to identify the basic ethical principles which should underlie the conduct of experimentation.²⁹⁵ It must develop guidelines to assure that these ethical principles are met and recommend appropriate administrative action to apply these guidelines to HEW supported research. In carrying out these tasks, the Commission must discern the boundaries between biomedical and behavioral research and the accepted routine practice of medicine. It must consider appropriate guidelines for the selection of human experimental subjects and the nature and definition of informed consent.²⁹⁶ The Commission must consider ways to evaluate and monitor performance by the Institutional Review Boards and the methods for carrying out the Boards' decisions.²⁹⁷ Through the mechanism of these Institutional Review Boards, Title II, dealing with the protection of human subjects, is closely tied to Title I, providing support for trainees in biomedical and behavioral research. Section 212 amends the Public Health Service Act by requiring that each entity applying for a training grant provide assurance to the Secretary that an Institutional Review Board has been established to review the research at the institution and to protect the human subjects thereof.²⁹⁸ Further concern for ethics may be found in the Commission's obligation under the Act to study the appropriateness of applying its guidelines to the delivery of health care to patients under HEW supported programs and to consider the protection of subjects in research efforts not under the regulation of the Secretary of HEW.²⁹⁹ The Commission is also directed to study the requirement for informed consent to participation in research involving children, prisoners, and the institutionalized mentally infirm.³⁰⁰

A further monumental task assigned to the Commission embraces an analysis of the scientific and technological advances in past, present, and projected biomedical and behavioral research, and the implication of those advances for individuals and society. Pursuant to

294. 39 Fed. Reg. 32172 (1974).

295. NRSAA tit. II, pt. A, § 202(a)(1)(A), 88 Stat. 342.

296. *Id.* § 202(a)(1)(B).

297. *Id.* § 202(a)(1)(B)(ii). The phenomenon of the Institutional Review Board first appeared in the Public Health Service Act, 42 U.S.C. §§ 284(c), 287c(b)(c), 288c(c)(f) (1944).

298. NRSAA tit. II, pt. B, § 212, 88 Stat. 342.

299. *Id.* pt. A, §§ 202(a)(1)(C).

300. *Id.* § 202(a)(2).

this duty, it must analyze the laws and moral and ethical principles governing the use of technology in medical practice and the public understanding of such laws.³⁰¹

Fetal research, one of the most controversial branches of medical research, is dealt with in two parts of the Act. The Commission is directed to study the nature and extent of fetal research and, within 4 months after all Commission members have taken office, to recommend policies to the Secretary defining the circumstances under which such research should be undertaken.³⁰² During this period, the Act also prohibits HEW support of research on a living human fetus before or after induced abortion unless the research is done for the purpose of assuring the survival of the fetus.³⁰³ Pursuant to this statutory limitation HEW instructed all its agencies to discontinue fetal research until the Secretary determines the moratorium should be lifted.³⁰⁴

Another section of the Act treats the critical issue of psychosurgery, directing the Commission to study the use of psychosurgery for the 5-year period ending in 1972 to determine the appropriateness and need for its use and to recommend to the Secretary under what circumstances it should be performed.³⁰⁵ Hopefully, the Commission may be able to provide some guidance in this troublesome area.

Finally, the most important part of the Act lies in a short section dealing with the duties of the Secretary. Despite the elaborate mechanism for study, analysis, advice, and ethical guidance to be supplied by the distinguished Commission, ultimate authority for the future of American research is placed in the hands of the Secretary, who is empowered to determine whether the actions proposed by the Commission are appropriate to assure the protection of human subjects. If he concludes that the suggested action is inappropriate, he has merely to publish his determination in the Federal Register with a statement of the reasons for his decision.³⁰⁶ Like the NIH regulations, then, the Act places the ultimate moral judgment with the Secretary, with no assurance that his judgments will be "more moral" than those of physicians consulting together. The Act creates the

301. *Id.* § 203.

302. *Id.* § 202(b).

303. *Id.* pt. B, § 213.

304. Letter from Charles C. Edwards, Department of Health, Education, and Welfare, to the Editor, 185 SCIENCE 900 (1974).

305. NRSAA tit. II, pt. A, § 202(c), 88 Stat. 342.

306. *Id.* § 205.

same kind of imbalance that exists in the NIH regulations; laymen are included in the Commission to protect subjects from arbitrary researchers, but nothing is done to assure that researchers are protected from arbitrary decisions of the Secretary.

C. ADDITIONAL PROPOSED REGULATIONS FOR THE PROTECTION OF SPECIAL SUBJECTS

Earlier, this article pointed out the difficulties of working with subjects who suffer a legal disability which necessitates special solicitude for their care.³⁰⁷ Responding in part to their needs, a companion set of regulations³⁰⁸ to the now effective regulations for the Protection of Human Subjects was proposed.³⁰⁹ The proposed regulations purport to afford additional protection to special subjects—fetuses, abortuses, prisoners, and the mentally disabled.³¹⁰ Issuance of rules for the protection of children has been delayed.³¹¹

The proposed regulations dealing with these subjects, for whom emotions run so high, acknowledge the enactment of the National Research Service Award Act and express the hope that the proposed rules will continue the current public dialogue and that the rules will be available to the Commission in its discussions.³¹² Characterization of the reaction to the regulations as “dialogue” is a pallid description of the controversy they engendered. Five hundred responses were received about the original version of Protection of Human Subjects.³¹³ Four hundred and fifty responses were received about the first offered regulations on special subjects. Perhaps as a result of this tumultuous reception, both the enacted regulations and the proposed regulations for special subjects are a considerable retreat from the original posture of HEW.³¹⁴ Nevertheless, exemplifying the force of an idea whose time has come, the proposed regulations on special subjects not only interpose the laity between the researcher

307. See text accompanying notes 91-173 *supra*.

308. Proposed HEW Reg. §§ 46.301-.310, .401-.407, .501-.507, .601-.607, 39 Fed. Reg. 30648 (1974).

309. 45 C.F.R. § 46.1-.22 (1974).

310. Proposed HEW Reg. §§ 46.301-.310, .401-.407, .501-.507, 39 Fed. Reg. 30648 (1974).

311. *Id.*

312. *Id.*

313. *Id.*

314. See 38 Fed. Reg. 27882, Protection of Human Subjects: Proposed Policy (1973) (the first set of proposed regulations); 38 Fed. Reg. 31738, Protection of Human Medical Subjects (1973) (a second draft of proposed regulations).

and his subject, they also require the formation of a Consent Committee,³¹⁵ adding another level of surveillance to the organizational review committee of the basic regulations³¹⁶ and to the Institutional Review Boards of the Public Health Service Act.³¹⁷

Applications to HEW for support of research dealing with fetuses, abortuses, prisoners, and the institutionalized mentally disabled must be reviewed by a fourth group, an Ethical Advisory Board established within the NIH to advise the funding agency about the acceptability of such activities from an ethical view. Members of this Board shall be competent to deal with medical, legal, social, and ethical issues and shall include physicians, research scientists, lawyers, clergymen, and ethicists as well as members of the general public.³¹⁸

In addition to the guidance of the Ethical Advisory Board, serving at a national level, and the organizational review committee serving at the institutional level, the regulations require the establishment of a Consent Committee, which will be even more deeply involved in the research activity. Specifically the Consent Committee must:

- 1) participate in the actual selection of subjects and the securing of consent to assure that legally effective consent is secured. Depending upon the activity involved, this duty could require approval of an individual's participation or simple verification of the procedures used in the selection process.
- 2) monitor the progress of the activity according to the requirements of the Secretary. This supervision could include visits to the activity site, identification of members who might be available for consultation with those involved in the consent procedures, continuing evaluation of the activity to determine if unanticipated risks have arisen, periodic contact with participants to ascertain their continued willingness to remain in the activity, and the authority to terminate participation *with or without* the consent of the participant.³¹⁹

The size and composition of the Consent Committee must be approved by the Secretary, who is also authorized to determine the adequacy of the committee, considering the scope and nature of the acti-

315. Proposed HEW Reg. §§ 46.305, .405, .506, 39 Fed. Reg. 3053, 3055, 3056 (1974).

316. 45 C.F.R. § 46.4(b) (1974).

317. NRSAA tit. II, pt. B, § 212, 88 Stat. 342.

318. Proposed HEW Reg. § 46.304, 39 Fed. Reg. 30653 (1974).

319. *Id.* § 46.305.

vity it will oversee and the particular subjects with whom it shall be involved.³²⁰ The Secretary shall determine if the committee is objective, if it has sufficient members not involved in research and development, and if it is competent to deal with the legal, moral, social, and ethical issues involved.³²¹

1. *Research Involving Fetuses and Abortuses*

One of the first assignments reserved by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research is the study of the nature, extent, and purposes of fetal research and the consideration of alternatives.³²² The moratorium on fetal research declared by the Secretary as a consequence of the strictures of the National Research Act³²³ places the proposed special-subjects regulations dealing with the fetus and abortus in limbo. Perhaps the cooling-off period will be helpful in an area full of bitter disputes, conflicting moral values, and lack of understanding.

In the proposed special-subjects regulations a fetus is defined as a product of conception from the time of implantation to the time of delivery.³²⁴ An abortus is defined as a fetus which is expelled whole prior to viability, whether spontaneously or as the result of surgical or medical intervention.³²⁵ The term does not apply to the placenta, cells, tissues, or organs excised from a dead fetus.³²⁶ No activity involving fetuses in utero or pregnant women may be undertaken unless the activity is for the purpose of benefitting the health needs of the fetus or its mother, or the activity, conducted as part of a procedure to terminate a pregnancy, is for the purpose of improving prenatal diagnosis, preventing premature birth, or studying and preventing birth defects or injury.³²⁷

Additionally, the proposed regulations provide that fetal research may not proceed without the consent of legally competent parents.³²⁸ The father's consent is excused if he is not identifiable or available or if the purpose of the activity is to respond to the mother's health

320. *Id.* § 46.305(b), 39 Fed. Reg. 30653.

321. *Id.*

322. NRSAA tit. II, pt. A, § 202(b), 88 Stat. 342.

323. *Id.* § 213.

324. Proposed HEW Reg. § 46.303(d), 39 Fed. Reg. 30653 (1974).

325. *Id.* § 46.303(f), 39 Fed. Reg. 30653.

326. *Id.*

327. *Id.* § 46.306(a), 39 Fed. Reg. 30654.

328. *Id.* § 46.306(b), 39 Fed. Reg. 30654.

needs.³²⁹ Once again, the regulations are inconsistent. The United States Supreme Court held in *Roe v. Wade*³³⁰ that a woman has an absolute right to abortion in her first trimester and a conditional right to it beyond that interval. Since the regulations insist upon her consent, it seems illogical to deny her the incontrovertible right to say what shall be done with her fetus. Indeed, some attorneys have likened the fetus to any other portion of her body that she may donate to science.³³¹

In general, the regulations applicable to fetuses are applicable to abortuses, but additionally they state that the vital functions of the abortus may not be artificially maintained except where the purpose is to develop new methods for helping abortuses to survive.³³²

2. Prisoner Research

A prisoner is defined in the proposed regulations as any individual involuntarily confined in a penal institution under a criminal or civil statute or any individual confined to any other type of institution which provides alternatives in incarceration in a penal institution.³³³

In addition to the duties prescribed for the organizational review committee by the already enacted regulations,³³⁴ the proposed regulations require the organizational review committee to determine that no undue inducement is offered to prisoners, taking into account their earnings, living conditions, medical care, food, and the amenities offered to the participants that would be better than those generally available to prisoners.³³⁵ The committee must also determine whether all aspects of the activity would be acceptable if the subjects were not prisoners or whether the activity involves a negligible risk to the subjects and is for the purpose of studying the effects of incarceration.³³⁶ The review committee must decide whether the application for funds contains adequate procedures for the selection of subjects and for securing consents and monitoring the activity.³³⁷ It must also determine that the rates of

329. *Id.*

330. 410 U.S. 113 (1973).

331. Goldston, *Fetal Research in the Balance*, 4 MALPRACTICE X-POSURE REPORTS 4 (1974).

332. Proposed HEW Reg. § 46.307(d), 39 Fed. Reg. 30654 (1974).

333. *Id.* § 46.403(b), 39 Fed. Reg. 30654.

334. 45 C.F.R. § 46.6 (1974).

335. Proposed HEW Reg. § 46.404(a)(1), 39 Fed. Reg. 30654 (1974).

336. *Id.* § 46.404(a)(2), 39 Fed. Reg. 30654.

337. *Id.* § 46.404(a)(3), 39 Fed. Reg. 30654.

remuneration are consistent with the activity but not in excess of that generally available to inmates of the penal institution and that withdrawal from the project for medical reasons will not result in a punitive loss of anticipated income.³³⁸

A Consent Committee also must be established for prisoner research; significantly, it must include a prisoner or a representative of a prisoner's organization in its membership.³³⁹ Special restrictions are placed upon persons detained in a correctional facility pending arraignment, trial, or sentencing or those in a hospital for observation prior to arraignment, trial, or sentencing.³⁴⁰

3. *Research Involving the Institutionalized Mentally Disabled*

The term "mentally disabled" includes the mentally ill, the mentally retarded, the emotionally disturbed, and the senile.³⁴¹ The stated purpose of the proposed regulations on the institutionalized mentally disabled is to provide additional safeguards where the freedom and rights of the subjects are potentially subject to limitation and the subjects may be unable to comprehend sufficient information or be legally incompetent to give informed consent to their participation.³⁴²

The term "institutionalized" includes persons confined voluntarily or involuntarily in a residential institution for the care of the mentally disabled.³⁴³ The definition includes public and private hospitals, community mental health centers, halfway houses, nursing homes, and general hospitals where the mentally disabled are patients.³⁴⁴

The most important aspect of these proposed regulations is the provision limiting research using such individuals to the etiology, pathogenesis, prevention, diagnosis, or treatment of mental disability or the management, training, or rehabilitation of the mentally disabled.³⁴⁵ The research must also seek information which cannot be obtained from those not institutionalized and mentally disabled.³⁴⁶ The organizational review committee must ascertain that the general

338. *Id.* § 46.404(a)(4), 39 Fed. Reg. 30655.

339. *Id.* § 46.405(b), 39 Fed. Reg. 30655.

340. *Id.* § 46.406, 39 Fed. Reg. 30655.

341. *Id.* § 46.503(b), 39 Fed. Reg. 30655.

342. *Id.* § 46.502, 39 Fed. Reg. 30655.

343. *Id.* § 46.503(c), 39 Fed. Reg. 30655.

344. *Id.* § 46.503(d), 39 Fed. Reg. 30655.

345. *Id.* § 46.504(a), 39 Fed. Reg. 30655.

346. *Id.*

requirements of the regulations are met and that no undue inducements will be offered other than those generally available to the mentally disabled at the institution.³⁴⁷

V. CONCLUSION

This article posed the question whether the Tuskegee experiment could be conducted today. The increasing intensity of concern about human experimentation exhibited in scientific and legal disciplines makes the possibility seem remote. No formula, however, can guarantee that decisions that appear proper today will remain morally correct in future decades. The only certainty is that attitudes will change, but decisions about human experimentation will remain as difficult as they have always been for the scientific investigator and his peers who shared the decisionmaking process. Past errors in judgment by physicians have created an understandable desire among those on the outside looking in for some kind of control—particularly because a major source of funding has been the tax dollar.

Unfortunately, the seductive but erroneous impression has arisen that what has been lacking has been the folk wisdom and democratizing influence of the laity. The current regard for the importance of lay opinion is exemplified by the proliferating array of statutes and regulations seeking to involve lay persons in scientific decisions.³⁴⁸ Yet lay thinking on such matters appears to have added little to the moral rectitude sought. Some examples of the dangerous consequences of lay meddling may be useful.

Both the National Research Service Award Act and the proposed regulations for the protection of special subjects ban all research on abortuses and fetuses unless it is related to fetal development or the maintenance of fetal or maternal health.³⁴⁹ Strong evidence suggests that the legislation was a response to lay opinion about fetal research.³⁵⁰ The regulations and statutes thus accommodate lay opin-

347. *Id.* § 46.505(a)(2), 39 Fed. Reg. 30656.

348. *See, e.g.*, NRSAA tit. II, pt. A, § 202(b), 88 Stat. 342; Protection of Human Subjects, 39 Fed. Reg. 18913 (1974), effective July 1, 1974; Protection of Human Subjects, 39 Fed. Reg. 30647 (1974) (a new set of proposed regulations designed to give additional protections in biomedical research, development, and related activities involving fetuses, abortuses, pregnant women, in vitro fertilization, prisoners, and the mentally disabled).

349. *See, e.g.*, NSRAA tit. II, pt. A, § 213, 88 Stat. 342; Proposed HEW Reg. §§ 46.306-309, 39 Fed. Reg. 30654 (1974).

350. *See, e.g.*, Goldston, *supra* note 331, at 3.

ion but ignore scientific fact and human necessity. Fetuses are essential to medical research because fetal tissue is used for studying poliomyelitis, measles, cancer, and cholera.³⁵¹ Under the Act, which declares a moratorium on such research until the Commission issues guidelines on fetal research,³⁵² no work using fetal tissue can proceed on those diseases. Yet the public clamors for cancer cures and correctly laments the death of children from measles.

In Boston, four physicians have been criminally indicted under an old grave robbing statute because of their study of dead fetuses.³⁵³ The doctors were engaging in much needed research to determine the effect of two commonly used antibiotics which they were considering for use in the treatment of syphilis of the fetus in utero.³⁵⁴ They wanted to know whether a particular antibiotic was able to cross the placental barrier to eliminate the syphilis organism in the fetus.³⁵⁵ With the rising incidence of venereal disease in the United States, the need for this information and possible mode of treatment is critical.³⁵⁶ The subjects of the experiments were women who were scheduled to have legal abortions, their consents had been secured, and the research procedure had been approved by the review committee of the hospital in which the investigation was to proceed.³⁵⁷ Although the subjects had consented to participation in the part of the experiment which affected them directly, they had not specifically "consented" to the study of the tissues of the fetus after the abortion.³⁵⁸ In routine practice, the disposition of all surgical and pathological specimens which are removed from patients is the province of the hospital. Presumably the fetuses studied by the Boston doctors would have been disposed of if they had not been used for research.³⁵⁹ Until recently, no one has suggested that consent be secured for such disposal, but today, under the pressure of the informed consent regulations, hospitals are beginning to require

351. *Id.* at 4. See also Behrman, *The Importance of Fetal Research*, N.Y. Times, June 9, 1974, § 4 at 17, col. 2.

352. NRSAA tit. II, pt. B, § 213, 88 Stat. 342.

353. Culliton, *Grave Robbing: The Charge Against Four from Boston City Hospital*, 186 SCIENCE 420 (1974). On February 15, 1975, one of the physicians, Dr. Kenneth Edelin, was found guilty of manslaughter. N.Y. Times, Feb. 16, 1975, at 1, col. 3.

354. Culliton, *supra* note 353, at 421.

355. *Id.*

356. *Venereal Disease Remains Major Health Problem*, 221 J.A.M.A. 14 (1972).

357. Culliton, *supra* note 353, at 421.

358. *Id.* at 420.

359. *Id.*

consent from patients to use their sweat, urine, and feces in the vital biological materials banks in which substances are stored to be available for experimental purposes.³⁶⁰

The regulations on abortuses portend even stranger consequences since they state that the vital functions of the abortus may not be artificially maintained except where the purpose is to develop new methods for helping abortuses to survive.³⁶¹ Incongruously, then, this regulation would permit a woman to have an abortion at the same time permitting the physician to keep the abortus alive outside her body.

When the pioneer discussants of the moral issues in human experimentation began to marshal instances of poor judgment,³⁶² their purpose was to raise the consciousness of physicians to the possibility of abuse. Clearly their purpose was not to raise the surrealistic bureaucracy which has resulted from the National Research Service Award Act and the HEW regulations. In fact, the efforts of doctors like Welt, Beecher, Lasagna, and Shannon increased medical scientists' sensitivity to the problem and fostered for their profession a revolutionary concept—peer review³⁶³—which was unknown to other disciplines and which has proven a powerful force for good. Little reason exists to believe that other disciplines have added significantly to the ethical basis laid down by physicians.

The danger of the present regulations and statute is that they will inhibit scientific investigation, and a dead and stale science will ensue in which "obedience to artificial precepts takes precedence over rational assessment."³⁶⁴ Scientists will be "bombarded by criticisms, suits and penalties."³⁶⁵ Such a time did indeed exist in the dark medieval period of the history of medicine when the dicta of Galen, a physician of ancient times, were venerated by the laity and new practices and procedures were abhorred.³⁶⁶ Because of Galen's dic-

360. *E.g.*, N.Y. Times, Apr. 30, 1974, at 35, col. 1.

361. Proposed HEW Reg. § 46.307, 39 Fed. Reg. 30654 (1974).

362. *E.g.*, L. LASAGNA, *THE DOCTORS' DILEMMA* (1962); Beecher, *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 1354 (1966); Welt, *Reflections on the Problems of Human Experimentation*, 25 *CONN. MED.* 75 (1961).

363. *See* text accompanying note 185 *supra*.

364. DeBakey, *Medical Research and the Golden Rule*, 203 *J.A.M.A.* 574, 576 (1968).

365. Moore, *Therapeutic Innovation: Ethical Boundaries in the Initial Clinical Trials of New Drugs and Surgical Procedures*, 98 *DAEDELUS* 502, 521 (1969).

366. F. GARRISON, *AN INTRODUCTION TO THE HISTORY OF MEDICINE* 143 (4th ed. 1929).

tum that "surgery is only a mode of treatment" and therefore, by implication, not worthy of study by reputable physicians, surgery was left in part in those days to the unskilled and the charlatan.³⁶⁷ Those surgeons who were skilled advised their colleagues to avoid operative treatment of difficult or incurable cases.³⁶⁸ "[W]hen they attempted the major operations, their custom was to require a written guarantee that no harm should come to them in the event of a fatal termination."³⁶⁹ A similar release from liability is neither available nor desired by present-day investigators. Nevertheless, physicians may be forced into inactivity by the apprehension which the present legislation engenders.

Too often history has proved lay judgments about scientific matters not only incorrect but damaging ultimately to mankind. Two physicians recalled recently the vilification of Galileo, who dared to espouse the concept of a universe in which the earth was not the center, and the trial of a Tennessee schoolteacher, who taught his classes that man had evolved from lower forms of life.³⁷⁰ Czapek and Dykes state correctly, "No matter how strongly any group of citizens may cleave to a certain belief on moral grounds that belief may ultimately prove false."³⁷¹

No one need question that restraints are needed against the scientist victimized by ambition, inexperience, or insensitivity to perform dangerous experiments. But who is in the better position to judge those factors than his fellow scientists?

Policing medical experimentation, preferably before it is carried out, is without doubt a necessity. The question remains how this is to be done—by those who are intimately knowledgeable about the risks and gains or by those who stand on the outside and are governed by folk wisdom concerning morality and health needs. One interesting example of this conflict may be found in the actions of protesters against the Willowbrook experiment, who accused the investigators of performing vile experiments and at the same time withholding the benefits derived from those experiments.³⁷²

367. *Id.* at 144.

368. *Id.*

369. *Id.*

370. Dykes & Czapek, *Regulations and Legislation Concerning Abortus Research*, 229 J.A.M.A. 1303 (1974).

371. *Id.*

372. Gillmor, *Wrestling With Ethical Dilemmas: How Much for the Patient, How Much for Medical Science? An Interview With Dr. Saul Krugman*, MODERN MEDICINE, Jan. 7, 1974, at 30, 32.

The unreasoned faith in the ability of the laity to make a reasoned judgment is the disturbing premise of contemporary thinking. Lay opinion all too often supports the glamorous results of unverified experimentation. Thus, the danger inherent in the use of lay opinion is twofold: through ignorance laymen may inhibit and stifle justified high risk experiments and at the same time permit unjustifiably risky projects because of the glamor of the potential results. The unthinking physician may avoid appropriate control studies because he believes to do so would withhold from his patients what he conceives to be new and lifesaving procedures.

On the one hand, we hear a cry for improved delivery of health care. People are encouraged, as they should be, to rely upon medical help from conception onward. They are encouraged to put their faith in doctors. On the other hand, the intrusion of lay opinion into the rectitude of proposed research implies that physicians are, in fact, not to be trusted. By some mysterious power the laity can make a judgment that is better informed and more moral than that provided by experts. This kind of conflict fosters a national schizophrenia about life-and-death matters which we can ill afford.