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Some Legal Problems in Medical Treatment and Research, Human Laboratory Animals: Martyrs for Medicine

Cover Page Footnote

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HUMAN LABORATORY ANIMALS: MARTYRS FOR MEDICINE

MARIAN F. RATNOFF* & JUSTIN C. SMITH**

ON December 3, 1967, doctors in a Capetown hospital opened a man's chest, removed his heart and replaced it with the heart of an individual recently pronounced dead.¹ Few happenings in medicine have so captured the interest of the public or aroused as many conflicting emotions as the rash of heart transplants which have occurred in the past few months. The press has begun to raise moral and ethical questions about the new procedures.² This current interest attracts attention to the larger problem of human experimentation, an issue in which lawyers will become increasingly involved. A delineation of the ethical and legal rights of individuals who, willingly or not, serve society by being laboratory animals is of critical importance.

Contemporary interest in the ethics of human experimentation began in 1947.³ Stunned by the trial record in *United States v. Karl Brandt*,⁴ which recounted medical experiments of doubtful importance, doctors and lawyers involved in the Nuremberg Trials promulgated a code of behavior to guide medical researchers torn by sometimes conflicting desires to conquer disease and at the same time to respect the integrity of the individual patient. The product of that medical-legal collaboration, the Nuremberg Code,⁵ was admirable in intent, but has been criticized as be-

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1. An Unexpected Difficulty, Details of Heart Transplant Reported, 202 J.A.M.A. No. 12, at 23 (Dec. 18, 1967).

2. See, e.g., Time, Jan. 19, 1968, at 50-51.

3. For an excellent discussion of the interrogation of former Nazi leaders held in the Nuremberg Prison following the cessation of hostilities in 1946, including the work of Dr. Professor Hurt of the Strassburg Anatomical Institute see, Musmanno, Witness Against Eichman, Averbach & Price, *The Verdicts Were Just* 89 (1966).

4. 1 & 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10 (1949).

5. 2 id. at 181-82. 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.

ing at once too restrictive and too ambiguous in language to provide significant and workable guidelines.⁶ Furthermore, it did not address itself to the need for the advancement of medicine.

The imprecisions of that Code may be due to the fact that people, particularly attorneys, dislike discussions of the problems of human experimentation. Their reticence may reflect an appreciation of the risks of exposing ethical questions which are not easily answered by the metaphysician, let alone by the legal scholar working within the confines of established precedent. The problem is compounded by the tendency of doctors and lawyers to view the problem in fundamentally different ways. Law tends to build on experience, while medicine uses experience only as a guide for the evolution of new ways to deal with unsolved problems. Put another way, a lawyer works from society to his client, while the physician works through his patient upon society. The legal community must free medical research to proceed, without permitting abridgement of the legal rights of the patients.

The purpose of this paper is to examine, for the benefit of lawyers, the moral and legal dilemmas faced by doctors—a problem more discussed in medical and scientific journals than legal ones—and to describe some of the attempts of the medical community to deal with the conflict which arises when the good of society and the good of the individual clash.

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5. No experiment should be conducted when 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 probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

6. See, e.g., Beecher, *Some Fallacies and Errors in the Application of the Principle of Consent in Human Experimentation*, 3 *Clinical Pharmacology and Therapeutics* 141 (1962) (editorial); Welt, *Reflections on the Problems of Human Experimentation*, 25 *Connecticut Medicine* 75 (1961).

Hopefully this paper will help foster the "interchange between law and medicine" called for by a recent writer.⁷

I. THE PHENOMENON OF MEDICAL RESEARCH

Until recently, medical research was a semi-private affair, conducted by lone investigators supported by individual patrons or foundations interested in health problems. Since World War II, however, medical research has become institutionalized in a way difficult for the layman to understand. The end of the war marked the entrance of the federal government into medical laboratories and the beginning of a program as accepted a part of social welfare as is social security. Since that time, much of the progress of American medical science has become an extension of national policy. One writer's explanation of the phenomenon is probably accurate:

The extraordinary growth of the federal role in medical research had as its base a historical confluence of forces in the post-war period. First the "payoffs" from research in the physical sciences during the war—radar, the Bomb—gave basic research new respectability in political circles. Second, the end of the war left the nation with unemployed scientists and more money. Third, the medical societies concerned with specific diseases such as polio and cancer were taken over from the doctors by civilians and turned toward promotion to raise money and educate the public.⁸

Currently, even on an international level, American advances in the field of medicine have become part of our foreign policy. This country has undertaken to improve public health in underdeveloped countries through our knowledge of vaccines, nutrition and sanitation. President Johnson's offer of contraceptive information and supplies to overpopulated nations is but one recent example of the extent to which medicine and medical researchers are being employed by the government.

The American people have not been unaffected by the involvement of their government in medicine. One has only to note the use of the word "research" today as a noun, adjective and verb. The virtual isolation and obscurity in which medical research formerly functioned have been shattered. Newspapers abound with material on heart and kidney transplants, wonder drugs and miraculous vaccines and serums. The public, through its broad financial support of organizations like the American Heart Association and the American Cancer Society, demonstrates its faith that doctors will "find the way." But at the same time, a curious change in the public's attitude is clearly discernible. On a recent television program, a minister commenting upon the heart transplants used the following

7. Freund, *Ethical Problems in Human Experimentation*, 273 *New England J. Med.* 687 (1965); Freund on *Human Experimentation*, *id.* at 774 (editorial).

8. Drew, *The Health Syndicate/Washington's Noble Conspirators*, *The Atlantic*, Dec. 1967, at 75.

words: "I think we have to be very careful about what we are doing. We must maintain the life of the patient."⁹ The inference of these words seems clear. They indicate that the public is now looking over the doctor's shoulder. Before the public becomes too free with its advice, it must realize that the effectiveness of the new procedures has been bought at a price; the inevitable cost is the inescapable risk to those on whom the innovations were first tried.

II. THE DEFINITION OF HUMAN EXPERIMENTATION

In a sense, every time a doctor elects a course of treatment for his patient, a human experiment takes place; no matter how routine a particular treatment may be, the individual reactions of patients are unpredictable. What is beneficial for one may be disastrous for another. The law recognizes this variability of response among individuals. Thus, a physician who has exercised reasonable care in treating a patient is protected by the classical tort test of "the standard practice."¹⁰ Under this doctrine, he will not be liable for an honest mistake in judgment or for an untoward reaction by the patient to accepted therapy.¹¹ Ironically, this same legal standard can be a hindrance to the development of new procedures, new techniques and new drugs. Although it is the duty of a physician to keep up with the advancements made by his profession, he must not forge too far ahead.¹² For the physician, the admonition of Alexander Pope, "Be not the first by whom the new are tried/Nor yet the last to cast the old aside"¹³ is a puzzling reality.

A. *Differentiation between Therapeutic and Manipulative Experiments*

Obviously, some physicians must move away from the established drug or practice. One physician had to be the first to undertake an organ transplant. In this regard, two types of innovation must be distinguished—those experiments designed for the treatment or cure of a particular person, who is the patient-subject of the experiment, and those experiments designed to add to our understanding of normal and abnormal functioning of the body, including the effect of drugs and various techniques. This second type of research, in which the subject has ordinarily nothing to gain either diagnostically or therapeutically, creates the principal problem and the one which concerns us here. Ideally, such experiments are conducted upon volunteers and are ordinarily carried out with the sub-

9. City Camera News, Station WJW-TV, CBS Affiliate, Cleveland, Ohio, Jan. 11, 1968, 11 P.M. E.S.T. (emphasis added).

10. W. Prosser, *Torts* 166 (3d ed. 1955) [hereinafter referred to as Prosser].

11. *Id.* at 165.

12. 41 Am. Jur. *Physicians & Surgeons* § 86 (1942).

13. A. Pope, *Essay on Criticism*, pt. II, ll. 132-33.

ject's express consent with a view to advancing the state of medical knowledge. In this second type of experiment lies the nub of the moral issue. As Dr. Walsh McDermott has put it: "When the needs of society come in head-on conflict with the rights of an individual, someone has to play God."¹⁴ Most medical scientists would shrink from such a role, but the moral issues they must face are certainly not commonplace. Most physicians begin with the question of whether an experiment, dangerous or potentially lethal for the subject, should be performed because the benefit to so many will be so great. Theoretically, the answer should be easy for the physician whose Hippocratic Oath¹⁵ requires him to strive for his patient. This principle of dedication to the individual rather than society is not alien to the law.¹⁶

B. *Individual Questions of Morality*

Despite these sentiments, to which a majority of lawyers and doctors would heartily subscribe, it is naïve to believe that medical triumph can be secured without life-threatening risk to individuals. Assuming the medical scientist has satisfied himself that although the risk to his subject exists, he acts with the subject's full and knowing acquiescence, his task is not over. There remains the question of whether the experiment seeks an answer which will serve humanity or only academic curiosity. An experiment encompassing grave risk in return for an answer not honestly needed is one described by Dr. Henry Beecher, a professor at Harvard Medical School.¹⁷ In the criticized study, an examination of the toxic effects upon the blood of an antibiotic, chloramphenicol, was undertaken. Although a well known complication of the use of the drug is severe and often fatal aplastic anemia,¹⁸ the stated aim of the study was to define further the toxicology of chloramphenicol.¹⁹ In this study of 41 patients who did not require the drug for their own therapy, 20 developed toxic symptoms

14. McDermott, Opening Comments, 67 *Annals of Internal Medicine*, Supp. 7, at 39 (1967).

15. The Hippocratic Oath, reprinted in F. Garrison, *History of Medicine* 102 (4th ed. 1929).

16. It is noteworthy that over the years the law has never seen fit to justify the taking of one or more lives in order to preserve the lives of others. Perhaps this is best exemplified by the holding of the English court in *The Queen v. Dudley*, 14 Q.B.D. 273 (1884), one of the two lifeboat cases, and *United States v. Holmes*, 26 F. Cas. 360 (E.D. Pa. 1842), the American counter-part decided some years earlier. The rule in the latter case is said to have prompted Justice Cardozo to comment that there is no law of human jettison.

17. Beecher, *Ethics and Clinical Research*, 274 *New England J. Med.* 1354 (1966).

18. Scott, Cartwright & Wintrobe, *Acquired Aplastic Anemia: An Analysis of Thirty-nine Cases and Review of the Pertinent Literature*, 38 *Medicine* 119 (1959).

19. Beecher, *supra* note 17, at 1357.

after its administration.²⁰ Beecher and those sharing his concern²¹ are, however, not without vocal and competent critics.

A further question is whether an adequate theoretical basis exists for the proposed undertaking, derived from sound, established knowledge. Often, in the scientist's anxiety to accomplish his goal, his actions may be too hastily conceived. Sometimes the help gained from a careful study of animal models may not yet be available, but the investigator, conscious of his mission, proceeds with his human studies nonetheless. Typical of such a situation is the current vogue for heart transplantation, daring in concept, magnificent in skill, but undertaken at a stage in knowledge about immunity which is inadequate to afford most patients the protection needed against rejection of the donated organ.²²

A final question concerns the practicality of the experiment. Can it be designed to give a reasonable answer, considering safety, time, expense and the possibility that the observation can be made without bias? Typical of this problem is the continuing medical controversy over the role of anticoagulant drugs in the treatment of patients who have suffered heart attacks.²³ Since the anticipated benefit of treatment is small, medical investigators have had to rely on data obtained from many patients. The inevitable variations in the quality of medical care and accuracy of observations has brought about confusion. A clear answer comes only when the question can be posed in such a way that relatively few subjects need to be studied. Unfortunately, as in the case of anticoagulant therapy, the uncertainties of diagnosis and the vagueness with which therapeutic results can be judged have made it difficult to pose the simple question of practicability.²⁴

III. THE MEDICAL VIEW OF THE PROBLEM: THE CODE PERIOD: 1947-1967

Researchers tackling these moral decisions have not lacked guidance from their profession. Doctors as a group maintain a rigid inter-professional discipline in order to insure the adequacy of patient care.

Since the days of the Greeks, doctors have sworn aloud: "I will follow that method of treatment which according to my ability and judgment I

20. *Id.*

21. M. Pappworth, *Human Guinea Pigs: Experimentation on Man* (1967). For criticism of Beecher, see, e.g., *Medical World News*, April 9, 1965, at 43.

22. See, e.g., Rusk, *Organ Transplant*, *N.Y. Times*, Jan. 14, 1968, at 86, col. 1; *The Heart: Miracle in Cape Town*, *Newsweek*, Dec. 18, 1967, at 86; *Heart Transplants: Treatment or Experiment*, 159 *Science* 374 (1968) (letter to the editor).

23. Merskey & Drapkin, *Analytic Review: Anticoagulant Therapy*, 25 *Blood* 567 (1965).

24. *Id.*

consider for the benefit of my patients and will abstain from whatever is deleterious and mischievous." The Hippocratic Oath thus articulates the morality of Western medicine²⁵ and provides the touchstone for all expressions of medical ethics.

A. *Medical Codes of Ethics*

In 1803, an English doctor formulated a statement of "Medical Ethics" upon which was modeled the first code of ethics promulgated by the American Medical Association in 1848.²⁶ During the next hundred years, the medical profession expressed itself formally and informally on the proper conduct of the physician.²⁷ In contrast to physicians in the United States, apparently a somewhat liberal attitude prevailed on the European continent. "Americans who studied at Vienna, Leipzig, and other medical centers in Europe before the first world war admired the skill of the doctors but were shocked at treatment administered and operations performed which would never have been undertaken had the welfare of the patient been the sole consideration."²⁸

It was not until the Nuremberg Code was enunciated in 1947 that a modern-day expression of the ethics of medical experimentation was articulated. Numerous attempts have been made since the Nuremberg Code to develop other workable codes of ethics. In 1957, the American Medical Association, which had issued a formal statement, *Principles of Medical Ethics*, expanded it to make it applicable to the research situation.²⁹ The Law Department of the American Medical Association advised its members:

In order to avoid legal liability for use of experimental procedures in treatment of a patient, the following requirements must not vary too radically from the accepted methods of procedure; and (3) usual and accepted procedures must have been tried previously without success. Medical ethics prohibit human experimentation except (1) with the voluntary informed consent of the person on whom the experiment is to be performed; (2) after the danger of the experiment has been investigated previously by animal experimentation; and (3) under proper medical protection and management.³⁰

In 1963, the Medical Research Council to Parliament made an official statement on responsibility in investigations in human subjects.³¹ Finally,

25. Beecher, *Experimentation on Man*, 169 J.A.M.A. 461 (1959).

26. *Id.*

27. *Id.*

28. 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).

29. A.M.A., *Principles of Medical Ethics* (1957) (pamphlet).

30. *Id.*

31. *Responsibility in Investigations on Human Subjects*, 2 *Brit. Medical J.* 178, 179 (1964).

in 1964, the World Medical Association issued the Declaration of Helsinki:³²

DECLARATION OF HELSINKI

RECOMMENDATIONS GUIDING DOCTORS IN CLINICAL RESEARCH

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words, "The health of my patient will be my first consideration"; and the International Code of Medical Ethics which declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. *Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.*

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and clinical research the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. *Basic Principles*

1. Clinical research must conform to the moral and scientific principles that justify medical research, and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.
5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. *Clinical Research Combined With Professional Care*

1. In the treatment of the sick person the doctor must be free to use a new therapeutic measure if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

32. 67 *Annals of Internal Medicine*, Supp. 7, at 74-75 (1967) (emphasis added).

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. *Non-Therapeutic Clinical Research*

1. In the purely scientific application of clinical research carried out on a human being it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.
2. The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.
- 3a. Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured.
- 3b. The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.
- 3c. Consent should as a rule be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject, even after consent is obtained.
- 4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.
- 4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued. The investigator or the investigating team should discontinue the research if in his or their judgment, it may, if continued, be harmful to the individual.

Of all the codes, this Declaration is the most significant because it was adopted in 1967 by at least nine élite medical societies in this country.³³ In their endorsement of the Declaration, these medical bodies noted that its principles of medical ethics supplemented ethics to which every American physician already subscribes.³⁴ The American Medical Association endorsed the Declaration but issued additional guidelines enlarging on the fundamental concepts.³⁵

B. *The Essence of the Codes*

Almost all official pronouncements and commentaries state unequivocally that human experimentation must be preceded by animal experimentation. These declarations also pose such questions as: will the proposed trial meaningfully advance the state of medical knowledge? Is the danger to which the investigator submits the patient-subject commensurate with the benefit which might ensue to him, or is the danger so minimal that the investigator may ask him to accept it although no personal benefit is foreseen? Is the patient-subject fully informed and has he given his fully voluntary consent?

33. *Id.* at 75.

34. *Id.*

35. *Id.* at 76.

It is significant that none of the declarations speak to any form of control by groups other than doctors and scientists. The possibility that lay control may be imposed upon medical research workers could cause much apprehension to physicians.

C. *Interdisciplinary Help for Doctors*

In addition to formal guidelines, doctors often seek prior approval for their proposed studies from colleagues. Informal consultation with other research scientists and formal review committees (which exist in most medical schools) are two methods of exploring the efficiency of a contemplated experiment. More and more the investigator is advised to seek guidance from medical school department heads or from the editors of medical journals.³⁶ Often scientific journals will refuse to publish reports of research which appears to be immoral or hazardous to the subjects.³⁷ In addition, most research scientists belong to specialized societies which pass informal judgment upon the ethics of work presented at society meetings, as well as upon the merits of the study. Medical scientists as a group, like lawyers, are strongly self-disciplining.

IV. THE LEGAL VIEW OF THE PROBLEM

Tracing the legal history of medical experimentation has been the work of Ladimer.³⁸ All writers in this field are indebted to him for his difficult work in gathering source material. Many of the materials in the next two sections can be found in their entirety in his anthology on the subject of clinical investigation.³⁹

Historically, the law has dealt harshly with the medical experimenter. Although physicians had been experimenting with man and other animals for centuries,⁴⁰ there was an absence of decisional law on experimentation until the eighteenth century. In 1767, one Slater brought suit against a surgeon and an apothecary for undertaking to rebreak his improperly

36. Responsibility in Investigation on Human Subjects, 2 *Brit. Medical J.* 178, 179 (1964); Ladimer, Social Responsibility in Clinical Investigation, *Medical Sci.*, Oct. 1967, at 33.

37. Letter from Dr. Russell Elkington, Editor, *Annals of Internal Medicine*, to the author.

38. See, e.g., Ladimer, Ethical and Legal Aspects of Medical Research on Human Beings, 3 *J. Pub. L.* 467 (1954). Ladimer, Human Experimentation: Medicolegal Aspects, 257 *New England J. Med.* 18 (1959); Ladimer, Medical Experimentation: Legal Considerations, 1 *Clinical Pharmacology and Therapeutics* 674 (1960).

39. *Clinical Investigation in Medicine: Legal, Ethical, and Moral Aspects* (I. Ladimer & R. Newman ed. 1963).

40. It was the practice in ancient times for the king to hand over condemned criminals for experimental purposes in science. Later the Ptolemies did the same in Egypt. Beecher, Experimentation in Man, 169 *J.A.M.A.* 461 (1959).

healed leg and attempting to straighten it by attaching a claw of iron to hold the bone in place.⁴¹ Most legal scholars invoke this case as the first expression of the legal maxim that experimentation is at the physician's peril.⁴² Concluding that the treatment was a rash action, the King's Bench said, "It seems as if Mr. Baker wanted to try an experiment with this new instrument."⁴³ The case specifically addressed the problem of consent: "It is reasonable that a patient should be told what is about to be done to him"⁴⁴ In view of the crucial nature of consent in medical experimentation, the old English judges seemed prescient.

A. *The Physician's Peril Doctrine*

Scattered early American cases speak of the perils of departure from the accepted mode of practice,⁴⁵ but the American counterpart of *Slater* did not appear until 100 years later in *Carpenter v. Blake*.⁴⁶ Blake used an untried method to set Carpenter's elbow. The court held it "incumbent on surgeons called to treat such an injury, to conform to the system . . . established; and if they depart from it, they do it at their peril."⁴⁷

American cases following *Carpenter* reinforced the *doctor's peril* principle. These cases present vignettes of quackery, leaving little doubt as to why the courts held steadfastly to their prejudice against experimenting. Witness the plight of a young man who in 1911 presented himself at the Dr. Pratt Institute for the purposes of having his smallpox scars removed. Noting that the treatment proved to be more disfiguring than the defect which it sought to cure, the court held that the defendant should have known the treatment was not sanctioned by medical science and that therefore the doctors had no right to perform the procedure.⁴⁸

In *Kershaw v. Tilbury*,⁴⁹ a nine-year-old girl suffered permanent damage because the defendant-physician, using a radio diagnostic machine of his own invention diagnosed her ailment as meningitis and caused a delay in securing proper treatment for her true illness, osteomyelitis.

Typically, these cases involved some radical departure from the ac-

41. *Slater v. Baker*, 95 Eng. Rep. 860 (K.B. 1767).

42. See, e.g., Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. Pub. L. 467 (1954).

43. *Slater v. Baker*, 95 Eng. Rep. 860, 862 (K.B. 1767).

44. *Id.*

45. E.g., *Landon v. Humphrey*, 9 Conn. 209 (1832).

46. 60 Barb. 488 (N.Y. 1871), rev'd on other grounds, 50 N.Y. 696 (1872).

47. *Id.* at 514.

48. *Graham v. Dr. Pratt Institute*, 163 Ill. App. 91 (1911).

49. 214 Cal. 679, 8 P.2d 109 (1932).

cepted standard in the community. They were branded by the courts as experimentation, but they appear to have been simple instances of quackery.⁵⁰ Very often, the fact situations presented breaches of well-recognized legal duties, such as want of knowledge and skill, failure to conform to an established school of medicine, or departure from accepted practice. Much of the confusion which permeates this area is directly attributable to the fact that medical research as we know it today did not exist 100 years ago when our courts were preoccupied with defining the liability of a physician to his patient. It is unfortunate that the judges of this period chose the word "research" when in reality what they meant to describe were either ill-considered innovations or deviations from standard practices.

B. *Legal Recognition of the Necessity for Experimentation*

Not until the 1930's and the introduction of the sulfonamides did the courts begin to take a less jaundiced view of untried procedure and to show an appreciation of the necessity for trial. *Fortner v. Koch*⁵¹ recognized, albeit in dictum, that "if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on"⁵² But once again there was the admonition to the doctor not to stray too far.

C. *The Development of the Consent Doctrine*

Significantly, the cases which helped to build the law's chariness of experimentation were concerned with the problem of therapeutic innovation directed toward the patient's own disease. Attention must be drawn to another factor developing along with the *physician's peril* doctrine, which on occasion altered the intransigence of the courts. This was the concept of *consent*. "[The] Anglo-American law starts with the premise [that] . . . each man is considered to be master of his own body"⁵³ Logically extended, this concept of self-determination leads to the premise that a man may give his consent to any act which may affect his body, although it can be shown that this conclusion is not wholly true. Many of the earlier cases, especially those dealing with malpractice suits against surgeons, addressed this problem of consent.⁵⁴ It has always been possible to give consent sufficiently general in its terms to cover

50. Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. Pub. L. 467, 479 (1954); see also notes 53-56 *infra*.

51. 272 Mich. 273, 282, 261 N.W. 762, 765 (1935).

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

53. Annot., 79 A.L.R.2d 1028 (1961).

54. Smith, *Antecedent Grounds of Liability in the Practice of Surgery*, 14 Rocky Mt. L. Rev. 233 (1942).

the particular operation or authorize a surgeon to do whatever he must to remedy what he finds.⁵⁵ Such a policy, in the absence of blatant malpractice, might protect the therapeutic innovator, but in the past failure to obtain *proper* consent rendered a surgeon liable in assault and battery, even in the absence of negligence.⁵⁶ Furthermore, the patient could attach conditions to his consent,⁵⁷ or tie the hands of a surgeon even in the face of an emergency.⁵⁸ Once again, the legal admonitions of this period did not cover the physician's liability for innovation not related to patient care.

D. *Consent by Parents for Minors*

A unique situation involving both the consent of parent and minor presented itself in the case of *Bonner v. Moran*.⁵⁹ Here for the first time, in 1941, was a "case of a surgical operation not for the benefit of the person operated on but for another. . . ."⁶⁰ Further, its involved technique required a mature mind to understand precisely what the donor was offering to give. Fifteen-year-old Bonner consented to the removal of a large flap of skin from his side to provide a skin graft for his cousin. The boy was hospitalized for three months, suffering great pain and disfigurement. His mother, living in a different city, unaware that the boy had given consent to the operation, later ratified his consent. The court nevertheless held the physician liable for proceeding on the child's consent alone, judging him incapable of understanding the consequences of his act. The court rejected the view of the Restatement which allows consent by an intelligent, informed, older minor, and relied on the common law view that only parental consent is effective.⁶¹

In practice, despite the Restatement's stand, hospitals more often than not require consent of the parents before any treatment is undertaken, except in demonstrated emergencies.⁶²

In 1956, a case arose in which the hospital had parental consent to the treatment of a minor but was reluctant to proceed.⁶³ Doctors at the Peter Bent Brigham Hospital in Boston contemplated the performance

55. Prosser 104-06.

56. Smith, *supra* note 54, at 234.

57. *Rolater v. Strain*, 39 Okla. 572, 137 P. 96 (1913).

58. *Mulloy v. Hop Sang*, [1935] 1 W.W.R. 714 (Sup. Ct. Alta.).

59. 126 F.2d 121 (D.C. Cir. 1941).

60. *Id.* at 123.

61. *Id.* at 122, citing Restatement of Torts § 59 (1934).

62. See Prosser 104.

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

of the first kidney transplant in identical twins, one of whom faced certain death from severe renal disease.⁶⁴ Hospital officials were uncertain that even the parents' fully informed consent was legally effective for such a dangerous and novel proceeding. Disturbed over the moral and legal dilemma, the Hospital sought a declaratory judgment from the Massachusetts Supreme Judicial Court before performing the contemplated transplant.⁶⁵ Testimony from the parents and the donor-twin led the court to conclude that everyone concerned was fully aware of the hazardous nature of the operation. In this and two subsequent transplant cases, the Massachusetts court relied heavily upon testimony from psychiatrists that a brutal emotional blow would fall upon the healthy twin if he refused to donate his kidney and his ailing twin's death was hastened by the refusal. Finding in the psychiatrist's testimony a basis for a benefit to the healthy child, the court assented to the operations.⁶⁶

E. *Consent by the Incompetent*

Many physicians feel that even with full and knowing parental consent the use of minors is never justified.⁶⁷ Beecher's condemnation⁶⁸ contains several frightening examples of the use of children as experimental subjects. Many doctors have stated categorically that minors, the aged, the debilitated, the weak and the incompetent should never be used as experimental subjects.

The most recent case involving such consent is *Hyman v. Jewish Chronic Disease Hospital*.⁶⁹ The litigation arose when doctors injected living cancer cells into "volunteer" patients at a New York hospital, as part of an experiment to determine the existence of inherent immunity to cancer. A lay director of the hospital, learning of the experiment, enlisted the aid of the courts to compel the hospital to give him access to patients' charts in order to determine whether the patients had given intelligent consent. The director found it necessary to take his plea through three courts before his inspection rights as a corporate director were held superior to the physician-patient privilege which the hospital invoked.⁷⁰ *Hyman* is the first case to touch the right of doctors to perform experiments not for the immediate benefit to the patient but rather for the advancement of medical knowledge.

64. *Id.* at 892.

65. *Id.*

66. *Id.* at 893.

67. Gross, *The Doctors* 312 (1966).

68. Beecher, *Ethics and Clinical Research*, 274 *New Eng. J. Med.* 1354, 1356-58 (1966).

69. 15 *N.Y.2d* 317, 206 *N.E.2d* 338, 258 *N.Y.S.2d* 397 (1965).

70. *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 (2d Dep't 1964), *rev'd*, 15 *N.Y.2d* 317, 206 *N.E.2d* 338, 258 *N.Y.S.2d* 397 (1965).

In deciding *Hyman* on appeal, the New York Court of Appeals avoided the question of the impropriety of the experiments. Since that court refused to speak to this issue, the New York Board of Regents, the licensing authority for doctors in the State of New York, had to face it directly. The Board both disciplined the doctors⁷¹ involved in the experiment and issued an opinion addressing the question of what form actual consent must take and "how far . . . the physician . . . [may] exercise his physician's authority when he is acting in the role of experimenter. . . ."⁷² As one writer points out, the pronouncements by the Board of Regents, although "not legal precedents . . . represent a major attempt to put some precision into the vague ethical concepts now governing experimentation with human subjects."⁷³

V. STATUTES AND REGULATIONS AFFECTING THE USE OF THE HUMAN VOLUNTEER

In actual practice, certain groups have attempted more than vague pronouncements on medical experimentation. Notably, where prisoners and soldiers have been experimental subjects, those responsible for their care have attempted to formulate workable guidelines.

A. Prisoner Regulations

During World War II, federal and state convicts were used in many experimental studies on malaria, hepatitis, blood substitutes and new drugs.⁷⁴ Cancer injections of the type given to the patients in the *Hyman* case were first given to prisoners at the Ohio State Penitentiary.⁷⁵ In 1948 an advisory committee to the governor of Illinois set forth guiding principles for the selection of prisoner-volunteers.⁷⁶ These regulations required consent of the subject and absence of coercion. The experiment also had to yield results unprocurable by other methods of study, and be necessary for the good of society.⁷⁷ Although the regulations attempted to be specific, such concepts as the "good of society" lead to ambiguities.

A recent article on the use of prisoners for medical research in Iowa sets forth a procedure followed there.⁷⁸ When the researcher decides upon

71. The order of the Board of Regents suspended the license of these physicians for one year, but execution was suspended because the doctors were first offenders and they were placed on probation. Langer, *Human Experimentation: New York Verdict Affirms Patient's Rights*, 151 *Science* 663 (1966).

72. *Id.*

73. *Id.*

74. Beecher, *Experimentation in Man*, 169 *J.A.M.A.* 461, 465 (1959).

75. Langer, *Human Experimentation: Cancer Studies at Sloan-Kettering Stir Public Debate on Medical Ethics*, 143 *Science* 551 (1964).

76. *Ethics Governing the Service of Prisoners as Subjects in Medical Experiments*, 136 *J.A.M.A.* 447 (1948).

77. *Id.*

78. Hodges & Bean, *The Use of Prisoners for Medical Research*, 202 *J.A.M.A.* 513 (1967).

a project, his proposal is submitted for approval to a research committee at his medical school. The dean of the medical school then communicates with the director of penal institutions in the Board of Control of the state who sends a message about the proposed work to the warden of the prison. After the warden explains the type of study to be conducted to the group of volunteers, the prison authorities select men who are not emotionally ill, habitually unreliable or otherwise unsuited.⁷⁹

B. *Army Regulations*

Since the days of Walter Reed and his investigation of the etiology of yellow fever, the United States Army has used soldier volunteers, and therefore has very specific regulations dealing with the use of the medical volunteer.⁸⁰ The regulations are applicable all over the world, wherever an Army research program is conducted, and extend to all volunteers, military and civilian. The Army requires that "certain basic principles be observed to satisfy moral, ethical and legal concepts."⁸¹ Consent is required to be in writing and approved through channels to the Secretary of the Army.

In the case of the civilian volunteer, provision is made for claims to be submitted to the Bureau of Employee Compensation, United States Department of Labor, if disability or death results from participation in experimental studies.⁸²

An opinion of the Judge Advocate General accompanies the regulation setting forth legal implications of volunteer programs. Under the present laws, "no additional rights against the Government will result from the death or disability of military and civilian personnel participating in experiments by reason of the hazardous nature of the operations."⁸³ To assure that there is no ulterior motivation to seek compensation it is the policy of the Government to prohibit acceptance of gratuitous services when they may provide a basis of future claims against the Government.⁸⁴ Where the Army contracts out research and development, the Judge Advocate General has stated that the contractor's employees may prosecute claims under the Federal Tort Claims Act.⁸⁵

In 1964, the Department of the Army issued additional regulations concerning the use of investigational drugs, *i.e.*, any substances intended

79. *Id.* at 514.

80. See Research and Development, Use of Volunteers as Subjects of Research, Dep't of the Army, A.R. 70-25 (Washington, March 26, 1962).

81. *Id.*

82. *Id.* at 3.

83. *Id.* at 4 (Appendix, Legal Implications).

84. 31 U.S.C. § 665(b) (1964).

85. A.R. 70-25, *supra* note 80, Appendix at 4.

to affect the structure and function of the human body.⁸⁶ The Army reiterated the necessity for securing the understanding of the subject to whom a drug is to be administered. When the purpose of administering an investigational drug is not to benefit the individual, approval for its use must be secured by the up-through-channels method described in a preceding paragraph. "Benefit to the individual is defined as the administration of a drug to an individual expected to result in the diagnosis, mitigation, treatment, cure, or prevention of disease or injury of the same individual."⁸⁷ The Air Force has similar regulations on the use of investigational drugs.⁸⁸

C. United States Public Health Regulations

One other governmental agency, the United States Public Health Service, has seen fit to adopt guidelines for dealing with human subjects. In 1966, the United States Public Health Service's National Institute of Health spent \$1,248,000,000 to support medical research conducted by laboratories in medical schools and hospitals throughout the country.⁸⁹ Strict compliance with Public Health Service requirements is a prerequisite for continued support for meritorious research. It is particularly significant, therefore, that the Public Health Service has adopted the essence of the Nuremberg Code⁹⁰ as a guide to be followed in conducting experiments involving human subjects. In addition, applications for funds from the Public Health Service must contain a "statement of assurance" with words such as: "The investigations encompassed by this application have been or will be approved by a committee of associates of the investigator in accordance with the institution's assurance on clinical research."⁹¹

D. The Investigational Drug Amendment: An Application to the Food and Drug Act

The first statute to protect the general public was promulgated in 1962.⁹² The drug amendments to the Federal Food, Drug and Cosmetic

86. Clinical Use of Investigational Drugs, Dep't of the Army, A.R. 40-7 (Washington, Nov. 13, 1964).

87. *Id.* at 3.

88. A.F.R. 169-6 (Washington, 10 Apr. 1963), cited in Hartman, *Human Volunteers in Biomedical Research*, 130 *Mil. Med.* 674, 676 (1965).

89. *Washington News*, 196 *J.A.M.A.* 27 (1966).

90. Hartman, *supra* note 88, at 678; *News in Brief*, 153 *Science* 401 (1966).

91. Administration Report, Division of Research Grants, National Institutes of Health, U.S. Public Health Service, Washington, 1966.

92. Hearings on S. 1552 Before the Senate Comm. on the Judiciary, S. Rep. No. 1744, 87th Cong., 2d Sess. (1962).

Act⁹³ were enacted in response to the thalidomide tragedy.⁹⁴ They concern investigational drugs, not experimental medical or surgical procedures or tests.

Through the device of the "Statement of the Investigator"⁹⁵ the clinician is made subject to the requirements of the Investigational Drug Regulations. He agrees that the investigation will be conducted by him or under his supervision, that he will keep adequate records of the use of the drug and return any unused supply, that he will prepare and maintain accurate and adequate records and give immediate notice of any alarming adverse effects, and that he will make available on request to authorized scientific personnel of the FDA certain records.⁹⁶ The signed statement of the investigator requires him to outline the plan of the experiment, the clinical uses of the drug, the kind of clinical observations and laboratory tests to be undertaken.⁹⁷ This plan must be amended if a significant change in the direction of the investigation occurs.⁹⁸ Under the 1962 amendments, as well as later amendments,⁹⁹ an investigator must certify to the Department of Health, Education and Welfare that he "will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered . . . that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where [he] deem[s] it not feasible or, in his professional judgment, contrary to the best interests of such human beings."¹⁰⁰ This provision of the law has aroused sharp comment.¹⁰¹ Critics ask the purpose of requiring elaborate supervisory mechanisms within the bill when the consent provisions give the investigator such a comfortable leeway.¹⁰² One answer may be that consent is obviously difficult to define and would seem to vary from

In 1900, a physician-senator attempted to promulgate legislation which would regulate the use of human beings as experimental subjects. The legislation was conceived for the benefit of citizens in Washington, D.C., and is described in Ladimer, *supra* note 42, at 497-98.

93. Federal Food, Drug and Cosmetic Act § 505, as amended, 21 U.S.C. § 355 (Supp. III, 1967).

94. Note, Drug Liability, 16 W. Res. L. Rev. 392 (1965).

95. Statement of Investigator, Form F.D. 1573, 21 C.F.R. § 130.3 (1967).

96. *Id.*

97. *Id.*

98. *Id.*

99. Federal Food, Drug and Cosmetic Act § 505(i), 21 U.S.C. § 355(i) (Supp. III, 1967).

100. *Id.* (emphasis added).

101. See, e.g., Boyer, Medical Liability in Drug Trials, 270 New Eng. J. Med. 777 (1964); Schreiner, Limb to Limbo—The Moral and Legal Entanglement of the Clinical Investigator, 11 Clinical Research 127, 130 (1965).

102. Informed Consent in Drug Research, 3 Colum. J.L. & Soc. Probs. 54 (1966).

situation to situation. In the *Hyman* case, the doctors did not tell the patients they were receiving cancer cells because in their professional judgment they felt the information would needlessly frighten the patients, and that it would therefore not have been in the best interests of the patients to tell them.¹⁰³ Since the injection of cancer cells did not constitute use of an investigational drug, the Food and Drug Act amendments would not have been relevant in any case.

E. *Municipal Regulation*

One municipal pronouncement on human experimentation speaks with the utmost clarity but seemingly curtails research.¹⁰⁴ A 1949 directive of the Department of Hospitals, City of New York, interdicted clinical and laboratory research using a patient in any municipal hospital *unless a specific benefit to the patient was involved*.¹⁰⁵ The directive required further that any "proposed clinical or laboratory investigations in any hospital or institution . . . be submitted for review and approval by the Executive Committee of the Medical Board of the hospital concerned."¹⁰⁶ New York has always exhibited militant concern for the rights of patients in its hospitals.¹⁰⁷ In light of this, it might not be an unreasonable prediction that as a result of the *Hyman* case, New York lawmakers will attempt to promulgate state legislation much like the 1949 municipal directive. The "sensational charges and accusations" which appeared in New York newspaper accounts¹⁰⁸ of the *Hyman* imbroglio portends wide public support for such legislation.

VI. CONSENT: THE PIVOTAL ISSUE

A. *Legal Precedent*

Beecher has pointed out that the most obvious flaw of all the codes is that they start out with the bland assumption that a patient's consent can be secured by the doctor just for the asking.¹⁰⁹ Neither in medicine nor in law is consent a simple issue. The fundamental premise of Anglo-American law that each man is the master of his own body is expressed in the equally venerable common law principle—*volenti non fit injuria*.

103. Langer, *supra* note 75, at 552.

104. New York City Dep't of Hosps., General Order 462, Concerning Research Proposals, Oct. 27, 1949, cited in Beecher, *supra* note 25, at 478 n. 23.

105. *Id.*

106. *Id.*

107. See, e.g., *Hyman v. Jewish Chronic Disease Hosp.*, 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965); *Munzer v. State*, 41 N.Y.S.2d 98 (Ct. Cl. 1943).

108. Langer, *supra* note 75.

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

Prosser comments that where no public interest is involved the courts have been willing to accept the maxim and have left each man free to work out his own destiny within its framework.¹¹⁰ Thus, consent would seem to negate the wrongful element of the defendant's act in intentionally invading the plaintiff's interest.¹¹¹ We know nonetheless that an individual really cannot consent to a serious harm. Even in the rowdy days of 1693, an English court believed that mutual consent had its limits: "If a man licence [sic] Another to beat him, such licence [sic] is void as it is against the peace."¹¹² In this country, a person cannot give legal consent to his own death;¹¹³ indeed, in England an attempted suicide is a criminal act.¹¹⁴ In most states, consent to abortion will not bar an action against the doctor who performs it.¹¹⁵ A 1904 court summed up the general feeling on the subject by pointing out that the state has a direct interest in the lives and health of all its citizens.¹¹⁶ Consequently, the investigator not only owes that person a duty but he has an obligation to the state to use care and to do nothing that will endanger the lives and health of its citizens.¹¹⁷

B. *Religious Views on Consent*

The Catholic Church, recognizing that "sometimes medical research must work on its immediate object, the living man in the interest of science,"¹¹⁸ has taken a strong stand on consent in contradiction to the "every man is the master of his body" maxim. Pope Pius XII reasoned: "[T]he doctor can take no measure or try no course of action without the consent of the patient. . . . On his side, the patient cannot confer rights he does not possess. . . . As for the patient, he is not absolute master of himself, of his body or of his soul Because he is a user and not a proprietor he does not have unlimited power to destroy or mutilate his body and its functions."¹¹⁹

A Protestant has said: "A person can prudently permit a few limited

110. Prosser 102.

111. *Id.*

112. *Matthew v. Ollerton*, (1693) *Comberbach* 218, cited in *Bohlen, Consent as Affecting Civil Liability for Breaches of the Peace*, 24 *Colum. L. Rev.* 819, 825 (1924).

113. *Kidd, Limits of the Right of a Person to Consent to Experimentation on Himself*, 117 *Science* 211, 212 (1953).

114. *Roxburgh, Experiments on Human Subjects*, 3 *Med. Sci. & L.* 132, 135-36 (1963).

115. *George, Current Abortion Laws: Proposals and Movements for Reform*, 17 *W. Res. L. Rev.* 371, 375-84 (1965).

116. *Spead v. Tomlinson*, 73 *N.H.* 46, 59 *A.* 376 (1904).

117. *Id.*

118. *Symposium, Human Experimentation—a World Problem From the Standpoint of Spiritual Leaders*, 7 *World Med. J.* 80 (1960).

* 119. *Id.*

experiments upon himself after a careful study of all elements involved, that is, the avoidance of too great imprudence, with previous and sufficient animal experiments in order to reduce the risks to a minimum."¹²⁰ In sum, "[T]he moral and spiritual competence of the doctor remains the most important factor."¹²¹

A Jewish view realizes that "a certain element of experimentation is inherent in every medical activity. . . ."¹²² In securing the patient's consent, "the doctor-investigator has to take into consideration not only the attitude of the individual and his capacity to grasp the meaning of what is being asked of him but also the general attitude of the group, the social community and even the nation to which the volunteers belong."¹²³

C. *Informed Consent*

One article has said that informed consent presupposes that permission has been fully granted and that the party who consents to medical procedure is aware of some of the consequences of the treatment.¹²⁴ In discussing treatment, the article states: "Where possible, disclosure of the information on which consent is based should precede treatment by enough time so that the patient or person giving consent has time to ponder possible alternative courses of action. Further, informed consent should result from a deliberation based on objective disclosure of the situation as viewed by the physician."¹²⁵ Other legal writers have sought to discuss gradations of consent. Informed consent can be measured by the assurance that the patient completely understands the contemplated procedure, that he acknowledges in writing the risks involved and that he has had explained to him the various possible complications.¹²⁶

No matter how carefully legal scholars may delineate the elements of informed consent, there still remains the problem of how to protect the volunteer against the subtle forms of coercion of which even the most benevolent doctor or lawyer may be unaware. A medical student, for example, may give his fully informed consent to an experiment through a desire to please his professor or worse, a subtle fear that failure to consent will influence his professional future. Although prisoners are

120. de Senarclens, *id.* at 81.

121. *Id.* at 82 (emphasis omitted).

122. Groen, *id.* at 83.

123. *Id.*

124. Smith & Schroeder, *Legally Effective Consent for the Physician*, 32 *Postgraduate Med.*, Dec. 1962, at A-42, A-44.

125. *Id.*

126. Cady, *Medicolegal Facets of Clinical Experimentation*, 31 *G.P.* Feb. 1965, at 187, 188-89.

repeatedly told that volunteering for medical experiments will in no way influence their privileges, how are we to say that there still does not exist the hope that a parole board might conclude that the volunteer has paid his debt to society?

Furthermore, there is the inescapable provision of the drug amendments to the Food and Drug Act that the doctor must secure the consent of the subject—*if it is feasible to do so*. Very often in performing experiments of a psychological nature, it is extremely important that the subject not know he is part of an experiment.

The law allows the physician treating a fatally ill patient to refrain from making a full disclosure of his condition to the patient, if the doctor feels it is in the best interests of the patient to be silent. Such inconsistencies in the law make it very difficult to formulate legal guidance for the physician-investigator. Might not a doctor argue that disclosure is not always in the best interest of the patient? It is clear that if the law is to help, it must formulate new doctrines. The old concepts of malpractice and negligence appear to be only partially relevant.

VII. CONCLUSION

The dilemma is simply this: presupposing broad public support for medical research, should medical advances be treated on a piecemeal basis, or should legislative bodies come forth at this time and define the parameters of acceptable experimentation? It appears that society stands at the hinge of time and that private decisions, while appropriate in some areas, are not entirely adequate in others. The Nuremberg Code, the Declaration of Helsinki, and the recommendations of the Medical Research Council of Parliament provide a framework for broad public discussions and suggest a need for enlightened attitudes on the part of the general public, particularly the law, if society is to benefit from the recent advances in experimental medicine.