Experimentation on Human Beings

I. Introduction

In July 1963 Drs. Chester M. Southam and Emanuel E. Mandel injected live cancer cells into 22 debilitated patients at the Jewish Chronic Disease Hospital of Brooklyn without the patients' voluntary and informed consent. The experiment, financed by the United States Public Health Service[1] and the American Cancer Society, was part of a project aimed at discovering ways to build up immunities against cancer. The experiment was designed to test Southam's hypothesis that bodies racked by serious but noncancerous diseases would reject implanted live cancer cells as rapidly and completely as healthy bodies and more quickly than bodies already suffering from cancer. The experiment confirmed Southam's hypothesis.

Dr. Southam's work had been recognized as among the most promising of all lines of cancer research.[2] In his opinion, the project presented "no risk of harm" to the patients,[3] and apparently no patients suffered any ill effects from the experiment.[4] Nevertheless, because Dr. Southam and his colleague Dr. Mandel failed to inform the patients that the injections contained live cancer cells and were in no way related to their normal therapeutic programs, the Board of Regents of the University of the State of New York found the two doctors guilty of fraud and deceit and of unprofes-

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1. *See* 2 U.S. Pub. Health Serv., Research Grants Index 1459 (1965); Lear, *Do We Need New Rules for Experiments on People?*, Saturday Rev., Feb. 5, 1966, at 61, 67.

2. 151 Science 663 (1966); 143 Science 551 (1964). At the time of this experiment Dr. Southam was a full member of the distinguished Sloan-Kettering Institute for Cancer Research and the head of its sections of clinical virology and oncogenic virology. He was an associate professor of medicine at the Cornell University College of Medicine, associate attending physician at Memorial Hospital for Cancer and Allied Diseases (New York City), and associate visiting physician at James Ewing Hospital (New York City). He was a special consultant to the United States Public Health Service and the National Cancer Institute, a member of the panel that recommends recipients of research grants from the American Cancer Society, a member of the scientific advisement committee of the Damon Runyon Fund, and a research advisory panelist for both the World Health Organization and the International Union Against Cancer. Dr. Mandel was the director of medicine and medical education at the Jewish Chronic Disease Hospital (New York City). Lear, *supra* note 1, at 65.

3. According to Southam, "[W]ithin any reasonable definition of the words 'no risk' there was no risk." 143 Science 551, 552 (1964). On the other hand, Bernard Pisani, past president of the Medical Society of the County of New York, testified in a New York supreme court proceeding involving the Southam-Mandel episode: "The known hazards of such experiments include the growth of nodules and tumors and may result in a metastasis [spreading of cancer] if the patient does not reject the cells." *Quoted in* Letter from William A. Hyman, 152 Science 865 (1966). In a previous part of the project, Southam had injected live cancer cells into healthy inmates of the Ohio State Penitentiary with their consent. He said he did not use himself and his colleagues because it would have served no useful purpose. "[I] did not regard the experiment as dangerous. But, let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk." *Quoted in* 143 Science 551 (1964).

4. Two of the patients died soon after the injections, but they were already seriously ill. The committee investigating the experiment did not challenge the assertion of Drs. Southam and Mandel that the injections did not cause or contribute to the deaths. *See* Lear, *supra* note 1, at 68; 143 Science 551 (1964).

sional conduct in the practice of medicine. Their medical licenses were suspended for one year, but the suspensions were stayed and the doctors were placed on probation for one year.[5]

The Southam-Mandel project is not an isolated example of abusive practices in experimentation on human beings. Testimony at their hearing before the board of regents indicates that many medical and surgical tests, some quite risky, are routinely made on hospital patients with no purpose other than to satisfy medical curiosity or to teach students how to conduct medical tests.[6] A recent article by Dr. Henry K. Beecher of the Harvard Medical School documents 22 cases in which the rights of patients or experimental subjects have been abused by medical researchers.[7] In one case 25 subjects contracted rheumatic fever, while in another 23 subjects died after contracting typhoid fever; none of the subjects knew he was participating in an experimental project.

Although most laymen would undoubtedly question the ethical basis for conducting medical experiments on uninformed and nonconsenting subjects, the medical profession is apparently divided on the issue. Many medical researchers indicated that they considered the practices of Southam and Mandel unethical,[8] but several distinguished scientists supported the two doctors.[9] Further, only 57 percent of the doctors surveyed by the Pharmaceutical Manufacturers Association said that they always obtained a patient's consent before treating him with experimental drugs.[10]

Research on human beings is necessary to advance medical and scientific knowledge.[11] Although experiments on animals are useful, they cannot provide a researcher with satisfactory answers to many relevant questions. Furthermore, every medical treatment, no matter how simple or well accepted, is experimental in nature in that it is applied in a new context each time. Even no treatment at all can be a form of experimentation.[12] Experimentation on human beings is, therefore, both valuable and unavoidable. This Note is an attempt to ascertain some standards and safeguards that

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5. The board's action was taken under N.Y. EDUC. LAW §§ 6514(2)(a), (g) (McKinney 1953). *See* Regents Comm. on Discipline, Univ. of the State of N.Y., Report on the Matter of Southam and Mandel, Nos. 158, 159 (undated).

6. Lear, *supra* note 1, at 69.

7. Beecher, *Ethics and Clinical Research*, 274 NEW ENGLAND J. MEDICINE 1354 (1966). For reasons of space, Dr. Beecher omitted 28 other examples originally compiled. A modified form of this article, entitled *Documenting the Abuses*, appears in SATURDAY REV., July 2, 1966, at 45.

8. 143 SCIENCE 551, 553 (1964).

9. *See* Lear, *supra* note 1, at 66; 151 SCIENCE 663, 666 (1966).

10. TRIAL, Oct.-Nov. 1966, at 35. *See also* Washington Post, July 19, 1966, at 10, col. 5 (reporting that 57% of those *responding* to the questionnaires distributed in the survey obtained a patient's consent before treating him with experimental drugs).

11. *See* Guttentag, *The Problem of Experimentation on Human Beings: The Physician's Point of View*, 117 SCIENCE 207, 208 (1953); Shimkin, *The Problem of Experimentation on Human Beings: The Research Worker's Point of View*, 117 SCIENCE 205 (1953).

12. *See* Ivy, *The History and Ethics of the Use of Human Subjects in Medical Experiments*, 108 SCIENCE 1 (1948); Shimkin, *supra* note 11, at 205.

will permit useful medical and scientific research, yet protect the safety, privacy, and dignity of experimental subjects.

Research on human beings takes place under a variety of circumstances in the medical, psychological,[13] and, lately, space-research fields.[14] Experiments differ from each other in the objective of the research, the degree of sophistication of the person who is the subject of the experiment, and the extent to which the nature of the experiment can be disclosed to the subject. In the following discussion, these three factors will be the basis for suggested distinctions in the standards to be applied.

The objectives of experiments on human beings cover a wide spectrum, but may be classified roughly as therapeutic or nontherapeutic.[15] Many experiments are intended to benefit the subject (therapeutic experimentation). Frequently a doctor must treat a patient with an untried method because no "accepted" treatment exists. A doctor may also use a new method of treatment where other procedures are regarded as "standard practice," thinking that the new method will prove more beneficial to his patient or be equally beneficial to his patient but lead to improved treatment for other sufferers of similar disorders. On the other hand, many experiments are not intended to benefit the subject (nontherapeutic experimentation), but are conducted solely in the pursuit of new knowledge. The subject might be a patient under a doctor's care for an unrelated ailment (as were the subjects of Southam and Mandel's experiment) or he might be a healthy volunteer. Different standards should govern therapeutic and nontherapeutic experimentation. The therapeutic purpose itself serves to justify a doctor's exposing a terminal leukemia patient to substantial risk in an effort to prevent or postpone imminent death, while a stronger independent justification should be required for allowing a researcher to expose a healthy volunteer to a similar risk simply to gain new knowledge.

Both therapeutic and nontherapeutic experiments can be conducted on subjects who vary in knowledge and sophistication, from the hospital patient who is unaware he is receiving experimental treatment to the highly trained astronaut or test pilot who makes his living exposing himself to the risks of scientific investigation. Obviously, for the less sophisticated

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13. For commentaries on the conflict between behavioral research and the individual's right of privacy see Panel on Privacy and Behavioral Research, *Privacy and Behavioral Research: Preliminary Summary of Report*, 155 SCIENCE 535 (1967); Ruebhausen & Brim, *Privacy and Behavioral Research*, 65 COLUM. L. REV. 1184 (1965).

14. *See generally* Wolf, *Human Beings as Experimental Subjects*, in THE CLINICAL EVALUATION OF NEW DRUGS 85 (S. Waife & A. Shapiro eds. 1959).

15. *See* Freund, *Ethical Problems in Human Experimentation*, 273 NEW ENGLAND J. MEDICINE 687, 689 (1965); Schreiner, *Liability in Use of Investigational Drugs*, 185 A.M.A.J. 259, 260 (1963); Wolfensberger, *Ethical Issues in Research with Human Subjects*, 155 SCIENCE 47 (1967). A revised version of Freund's article, entitled *Is the Law Ready for Human Experimentation?*, appeared in TRIAL, Oct.-Nov. 1966, at 46.

subject stricter safeguards are needed to guarantee his safety, privacy, and dignity from abuse by an overzealous researcher.

The extent to which a researcher is able to inform a subject of the details and risks of an experiment varies with the type of research as well as the sophistication of the subject. The success of an experiment will sometimes depend upon the nondisclosure of certain facts. More frequently a researcher will be unable to inform a subject adequately because the subject is incapable of understanding all the complexities of the project or because full disclosure might produce excessive worry.

II. Informed Consent

A. *The Need for Informed Consent*

The concept of informed consent is central to any standard regulating research on human beings. Southam and Mandel were punished not because they conducted an experiment that harmed their patients but because they failed to obtain informed consent before injecting their patients with live cancer cells.

The requirement of informed consent was most strongly articulated in the code adopted by the United States Military Tribunal at Nuremberg as a standard against which to judge 25 German scientists accused of medical atrocities.[16] This code is considered "the most highly publicized and carefully developed set of precepts specifically drawn to meet the problem of human experimentation."[17] The code is particularly relevant in the United States. Unlike the International Military Tribunal at Nuremberg, which was composed of judges from four different nations and which operated pursuant to procedures established by international agreement, the United States Military Tribunal was composed of American judges and operated according to American procedural rules.[18] In addition, the principles in the code on human experimentation, which was the substantive law applied by the United States Military Tribunal, are consistent with the ethics governing American medical practice.[19] Therefore, while the code does not have the authority of an American statute, decisions of the United States Military Tribunal based upon it should be considered the

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16. Seven of the defendants were acquitted, nine were imprisoned, and nine were sentenced to death. *See generally* R. Gallagher, Nuremberg: The Third Reich on Trial 159–205 (1961); A. Mitscherlich & F. Mielke, Doctors of Infamy: The Story of the Nazi Medical Crimes (1949).

17. Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. Pub. L. 467, 487 (1954).

18. *See* R. Woetzel, The Nuremberg Trials in International Law 222 (1962).

19. *Cf.* Judicial Council of the Am. Medical Ass'n, *Supplementary Report*, 132 A.M.A.J. 1090 (1946). Dr. A.C. Ivy, the prosecution's expert medical witness, was appointed by the board of trustees of the American Medical Association. *See* Ivy, *Nazi War Crimes of a Medical Nature*, 139 A.M.A.J. 131 (1949).

primary American articulation of standards governing human experimentation. As expressed by the tribunal:

> 1. The voluntary consent of the human subject is absolutely essential.
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> This means that the person involved should have legal capacity to consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved so as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
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> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.[20]

The tribunal further required that the human subject be at liberty to bring the experiment to an end should he reach the physical or mental state where continuation of the experiment seemed to him to be impossible.

The only federal or state statute dealing with research on human beings also requires informed consent. Section 505(i) of the Federal Food, Drug, and Cosmetic Act,[21] which applies only to experimental drugs,[22] provides that the Secretary of Health, Education, and Welfare shall promulgate regulations concerning "drugs intended solely for investigational use." The statute requires a sponsor of research to procure certification from investigators that the investigators will obtain the informed consent of all human beings to whom they will administer experimental drugs "except where they deem it not feasible or, in their best professional judgment, contrary to the best interests of such human beings."

Although this statute would appear to give investigators a disturbing amount of freedom,[23] the Commissioner of Food and Drugs, as the Secretary's delegate,[24] has recently promulgated strict regulations[25] under the

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20. United States v. Brandt (The Medical Case), 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, at 181–82 (1949).

21. 21 U.S.C. § 355(i) (1964).

22. For a discussion of the role of the Food and Drug Administration in regulating drugs see Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 954–70 (1964).

23. Soon after the passage of § 505(i), the National Health Federation declared that the exception in the section left a loophole which would enable "human guinea pig" experimentation on unsuspecting subjects to continue. MODERN MEDICINE, Feb. 4, 1963, at 14. This loophole was inserted because of "[m]assive criticism from organized medicine and individual practitioners of high stature as well as from the drug industry" of a requirement of fully informed consent in *all* cases. Rheingold, *supra* note 22, at 1012.

24. 21 C.F.R. § 2.90 (1966).

25. 31 Fed. Reg. 11415 (1966), *adding* 21 C.F.R. § 130.37. *See* Editorial, 276 NEW ENGLAND J. MEDICINE 115 (1967).

statute. These regulations distinguish between therapeutic and nontherapeutic experimentation. Informed consent must be obtained in *all* cases in which "drugs are being administered primarily for the accumulation of knowledge." In cases in which patients are "under treatment with investigational drugs," informed consent is required in all but "exceptional cases." The exception allowed by section 505(i) is thus limited to instances of therapeutic experimentation. Furthermore, informed consent is "not feasible" only when the patient's inability to communicate renders consent impossible—for example, when the patient is unconscious and when it is imperative to administer the drug before the patient's representative can be reached. Informed consent is "contrary to the best interests" of the subject only "when the communication of information would seriously affect the patient's disease status . . . ." In addition, the regulations require the investigator to obtain the patient's consent in writing and to inform the subject fully and clearly of all the facts prior to obtaining that consent. This disclosure must include the existence of any alternative form of treatment and "the fact, where applicable, that the person may be used as a control."

An absolute requirement of informed consent to nontherapeutic experiments also appears in other governmental regulations. Air Force Regulation No. 169–8 (Use of Volunteers in Aerospace Research) states: "The voluntary informed consent of the human subject is essential."[26] The subject must have the legal capacity to consent and must be able to revoke his consent at any time during the research project. Research centers of the National Aeronautics and Space Administration (NASA) appear to follow similar procedures. For example, in research projects conducted at the NASA-Ames Research Center, Moffett Field, California,

> [n]o person may serve as a subject of human research until he has been fully apprised of the nature, purpose, and risks of such research and has freely manifested his consent . . . and in no event may any person serve as a subject of human research unless such person has legal capacity to give his voluntary informed consent.[27]

NASA employees must witness both the briefing of the subject and the signing of the consent form.[28]

Informed consent is also an important factor in experiments conducted within the doctor-patient relationship. The physician who treats a patient is guided by the professional maxim, *primum non nocere* ("first of all, do

26. Use of Volunteers in Aerospace Research, Air Force Reg. No. 169–8, § 1, Oct. 8, 1965.

27. J. Henry Glazer, Memorandum, Management Instruction: Use of Persons in Aerospace Research attachment at 3–4, Nov. 28, 1966 (proposed instruction to employees of NASA-Ames Research Center).

28. Interview with J. Henry Glazer, Chief Counsel, NASA-Ames Research Center, at Moffett Field, Cal., Feb. 20, 1966. In its research projects, the simulation sciences division of the Center uses test pilots, government employees drawn from a hazardous-duty-test panel, and volunteers. The formalities noted above are not required when the subjects are test pilots, because consent to hazardous projects can be inferred from their profession. *Id.*

no harm"), which dates back at least to the Hippocratic Oath.[29] Since the doctor's dedication to this principle may be sufficient to protect the interests of the patient in cases of therapeutic experimentation, informed consent, while desirable, is not necessarily vital. Nevertheless, the law, recognizing the desirability of consent within the doctor-patient relationship, imposes civil liability for battery on any doctor who performs a therapeutic operation without the express or implied consent of the patient, even if the operation benefits the patient.[30] The recent Declaration of Helsinki, published by the World Medical Association and officially endorsed by the American Medical Association, states that in instances in which clinical research is combined with professional care informed consent may be dispensed with where full disclosure is not "consistent with patient psychology."[31]

In nontherapeutic experiments, however, the doctor may be more concerned with advancing the state of medical knowledge—and perhaps gaining fame—than with his patient's recovery.[32] In these situations, informed consent is essential to protect the subject's welfare. The Declaration of Helsinki requires informed consent in *all* cases in which the research is not intended to be therapeutic.[33] No doctor, in short, should have the "godlike ability to choose martyrs."[34]

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29. "I will use that method of treatment which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous." Quoted in Ladimer, *supra* note 17, at 487.

30. *See, e.g.*, McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381 (1957); Smith, *Battery in Medical Torts*, 16 CLEV.-MAR. L. REV. 22 (1967); sources cited note 75 *infra*.

Despite the rule that operations without consent will render a doctor liable for battery, the law usually does not require formal consent in the doctor-patient relationship. Consent to ordinary procedures can usually be inferred from the patient's seeking out the physician for diagnosis and treatment. A doctor must obtain consent to a therapeutic procedure only if the average physician in the community (or a reasonable medical practitioner) would have done so. *See, e.g.*, Dunlap v. Marine, 242 Cal. App. 2d 162, 177, 51 Cal. Rptr. 158, 167 (2d Dist. 1966); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, *opinion clarified*, 187 Kan. 186, 354 P.2d 670 (1960). Consent is not required in emergencies if the patient is unconscious and the delay incurred in getting his consent or that of a close relative might cause the patient's death. *See, e.g.*, Jackovach v. Yocom, 212 Iowa 914, 237 N.W. 444 (1931); Luka v. Lowrie, 171 Mich. 122, 136 N.W. 1106 (1912). Finally, physicians must sometimes suppress relevant facts lest excessive worry destroy all hope of recovery. *See, e.g.*, Natanson v. Kline, *supra* at 406, 350 P.2d at 1103 (dictum); Hunt v. Bradshaw, 242 N.C. 517, 88 S.E.2d 762 (1955).

31. Art. II, § 1. The English translation of the official French text is printed in [1964] 2 BRITISH MEDICAL J. 177.

32. *See* Bean, *A Testament of Duty: Some Strictures on Moral Responsibilities in Clinical Research*, 39 J. LABORATORY & CLINICAL MEDICINE 3, 5 (1952).

33. The Nuremberg Code is widely regarded as too absolute to provide final answers today. Because it was drafted in response to abuses in experiments not intended to benefit the subjects, it failed to deal adequately with research designed to help the patient. "The Code separated right from wrong more easily than can be done with the nuances of modern research . . . ." Editorial, 270 NEW ENGLAND J. MEDICINE 1014 (1964). The Declaration of Helsinki was intended to provide a more modern and realistic code. Nevertheless, it continues to require informed consent in all cases of nontherapeutic research.

Several commentators have said that the practices of medical research institutions generally accord with the codes discussed above. *See, e.g.*, Ladimer, *Medical Experimentation: Legal Considerations*, 1 CLINICAL PHARMACOLOGY & THERAPEUTICS 674 (1960). *But see* Rheingold, *supra* note 22, at 957 n.53: "Not only are these guidelines voluntary, but there also is not much evidence that they are subscribed to by a significant section of the medical profession in practice."

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

A member of the Armed Forces who refuses medical treatment is subject to court-martial if the

B. *Inadequacies of Informed Consent*

While informed consent is an important prerequisite to conducting research on human beings, it may be insufficient to protect the subject. The complexities of modern research often make "informed" consent virtually impossible to achieve.[35] The subject is ordinarily not qualified to evaluate the true risks and expected benefits of any experimental drug or procedure.[36] In addition, an investigator who is eager to confirm some hypothesis might, in informing the subject, minimize, either consciously or unconsciously, experimental risks and uncertainties.[37] Indeed, the investigator may not know all the risks, and conflicting opinions are hardly unknown.[38] "Consent" is an equally troublesome factor. Many experiments are performed on medical students and on prisoners. The desire to please a professor or a parole board might preclude these individuals from giving truly voluntary consent.[39] The special relationship of trust between a patient and his physician undoubtedly induces many patients to consent to any medical practices their doctors propose.[40]

Requiring the informed consent of every experimental subject raises problems for investigators. Disclosure of enough facts to enable the subject to make an informed choice may in some cases hinder legitimate scientific inquiry.[41] For example, physicians sometimes give patients placebos (inert "medications") to test whether an experimental drug is an improvement over the use of no drugs at all. The use of placebos can be effective only if the patient thinks he is receiving a powerful medication. If the patient knows that he is being or might be used as a control, the results of the research may be vitiated.[42] Investigators cannot evade this dilemma by securing the subject's consent to a new drug while actually giving him a

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Surgeon General and a review board of medical officers decide that the treatment is necessary to enable such person to perform his military duties. However, no one can be required to submit to any treatment that is not "universally accepted" by the medical profession as a "complete cure" and that is not necessary to make one physically fit to perform one's duties. *See* Johnson, *Civil Rights of Military Personnel Regarding Medical Care and Experimental Procedures*, 117 SCIENCE 212 (1953). Thus, military personnel can be compelled to submit to therapeutic procedures, but not to nontherapeutic ones.

35. *See* Beecher, *supra* note 34; Beecher, *Experimentation in Man*, 169 A.M.A.J. 461, 473 (1959); Guttentag, *supra* note 11, at 209–10.

36. "It is possible that the whole consent requirement in medical practice is inserted more to insulate the doctor from suit than to inform the patient. The medical profession tends to feel that no layman can really be told what a drug is and what it is being used for." Rheingold, *supra* note 22, at 1012 n.355.

37. *See* Editorial, 270 NEW ENGLAND J. MEDICINE 1014–15 (1964).

38. *See* Beecher, Editorial, 3 CLINICAL PHARMACOLOGY & THERAPEUTICS 141 (1962).

39. *See* Freund, *supra* note 15, at 691; Committee Appointed by Gov. Dwight H. Green of Illinois, *Ethics Governing the Service of Prisoners as Subjects in Medical Experiments*, 136 A.M.A.J. 457 (1948).

40. *See* Medical Research Council, *Responsibility in Investigations on Human Subjects*, [1964] 2 BRITISH MEDICAL J. 178, 179.

41. *See, e.g.*, Finland, *Ethics, Consent, and Controlled Clinical Trial*, 198 A.M.A.J. 637 (1966); Comment, *Legal Implications of Psychological Research With Human Subjects*, 1960 DUKE L.J. 265, 267.

42. *See* Spivak, *Drug Tests on Men*, Wall Street Journal, Nov. 18, 1966, at 16, col. 4.

placebo, for the subject has not consented to take sugar pills in the name of science. The nonuse of a new drug which the subject thinks is being administered for his benefit is as much "experimentation" as is the use of the new drug itself.[43]

Investigators face an additional problem when they must use minors as subjects. As a general rule, the consent of the legally incompetent is no defense to civil tort liability. Some courts have carved out an exception so that the consent of a mature minor capable of understanding the consequences of his act will protect a physician from liability not based on negligence;[44] but this exception has been held to be inapplicable where the operation is nontherapeutic. In *Bonner v. Moran*[45] a 15-year-old youth consented to a skin graft intended to help his cousin, a burn victim. The youth was adversely affected but could not prove negligence. The court allowed him to recover damages from the doctor because the operation was not for his benefit.

Since minors too frequently lack the judgment necessary to a decision to incur risks in the name of science, the *Bonner* rule should apply in the human research area. The researcher should, therefore, be required to obtain the consent of the minor's guardian. Such consent would usually be sufficient to protect the minor's interests. Whenever the minor is old enough to be capable of intelligent consideration of the issues involved, his consent should be obtained as an additional precaution.[46]

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43. Researchers have frequently objected to external restraints, such as the new food and drug regulations, on the ground that these can unduly hinder legitimate research; they have pointed to the problems relating to placebos as one example. *See id.* However, the amount of legitimate research that depends on nondisclosure is probably very small. In any experiment in which full disclosure is truly impossible, other stringent precautions are necessary for the protection of both the subject and the investigator.

44. *See* Bakker v. Welsh, 144 Mich. 632, 108 N.W. 94 (1906); Lacey v. Laird, 166 Ohio St. 12, —, 139 N.E.2d 25, 31 (1956) (Taft, J., concurring); RESTATEMENT (SECOND) OF TORTS § 59 (1965).

45. 126 F.2d 121 (D.C. Cir. 1941).

46. Declaration of Helsinki § II(1), in [1964] 2 BRITISH MEDICAL J. 177, requires the consent of the minor subject as well as that of his guardian whenever the minor is mature enough to comprehend the issues.

Even the consent of both minor and guardian may not be sufficient. The Supreme Judicial Court of Massachusetts in 1957 rendered three advisory opinions (not officially published) allowing kidney transplants between minor twins. The court found that each of the donors had consented and that each (two were aged 14; one, 19) was mature enough to understand the consequences of his act. Their guardians also consented. Nevertheless, in approving the transplants the court felt constrained to find some sort of benefit to the donors, and relied on the testimony of psychiatrists that each donor would suffer "grave emotional impact" if he were not allowed to donate a kidney in an effort to save his brother's life. *See* Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. REV. 891 (1959); Freund, *supra* note 15, at 691; Lieberman, *Caveat—Medical Treatment of Minors*, ILLINOIS CONTINUING LEGAL EDUCATION, Oct. 1966, at 99. The court evidently found no authority in point and gave no reason why benefit should be necessary when both the minor and his parents give their informed consent.

A better rule would be that the guardian's approval is sufficient if the subject also consents or, should he be too young to comprehend the issues, the circumstances are such that the consent of a competent subject could be presumed. *See* Kloss, *Consent to Medical Treatment*, 5 MEDICINE, SCI. & L. 89, 95 (1965); Ladimer, *supra* note 33, at 680. Doctors are likely to ignore any rule that purports to ban entirely all nontherapeutic research on minors.

III. Other Safeguards

Because the requirement of informed consent alone is not an adequate standard for permitting legitimate scientific inquiry while protecting the interests of experimental subjects, other safeguards are required. However, there is no consensus as to what these additional precautions should be. Indeed, the attorneys for Southam and Mandel argued that the two doctors were "stumbling through a signless desert."[47]

Certainly the primary safeguard of a subject's interests is and must continue to be the investigator's sense of professional responsibility. Unfortunately, this is not always enough. "Research on human beings is too hazardous and implies too many responsibilities to be undertaken by lone investigators."[48] Additional safeguards for the experimental subject should include prior group review of proposed human research and the inclusion in any research team of a "monitor" concerned solely with the subject's welfare. "Other physicians whose careers are not advanced by the experiment are best able to weigh the public benefits against the undue hazards to the patients involved . . . ."[49]

Prior group review of nontherapeutic experimentation is currently required by several governmental agencies. The Air Force requires that all human research projects have the prior review and clearance of both a research committee and the United States Surgeon General.[50] Also, the director of the simulation sciences division of the NASA-Ames Research Center has proposed that where doubt exists as to whether the value of a project is outweighed by foreseeable risk to a subject, the matter be referred for advice to an intra-agency board, and if doubt remains on the part of the board, then to a "jury" composed of persons outside of the agency.[51]

Prior group review is even more necessary to safeguard subjects of nontherapeutic research conducted within the doctor-patient relationship, since they are likely to be trusting hospital patients rather than paid volunteers. The Southam-Mandel episode is one illustration of the abuses possible in this area.

Most group review today takes place inside the institution conducting the research. For example, the United States Public Health Service requires institutions receiving any of its grants to certify that all decisions to use

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47. 151 Science 663 (1966). The United States Public Health Service has recently announced a $100,000 grant to the American Academy of Arts and Sciences to finance a series of conferences on the moral and ethical aspects of human experimentation. The results of the conferences, which will include the views of physicians, sociologists, psychologists, lawyers, and others, will be published in *Daedalus*, the Academy's quarterly. Washington Post, July 19, 1966, at A10, col. 5.

48. Shimkin, *supra* note 11, at 206.

49. Spivak, *supra* note 42.

50. Use of Volunteers in Aerospace Research, Air Force Reg. No. 169–8, § 4, Oct. 8, 1965.

51. Interview with Dr. George Rathert, Director, Simulation Sciences Division, NASA-Ames Research Center, at Moffett Field, Cal., Jan. 30, 1967.

humans as experimental subjects, as well as the appropriateness of the methods used to secure informed consent, are subject to prior review by the "institutional associates" of the investigator.[52] These associates, however, are apt to be less than completely objective; "they have a professional identification with the investigator, owe a common loyalty to their joint institution, and share, at least indirectly, in the glory (and money) that research brings."[53]

The problems attendant on intra-institutional group review can be avoided by requiring that the reviewing group include individuals in no way associated with the sponsoring institution. One doctor has suggested that reviewing groups include individuals from all walks of life, appointed by some public body, because "the issues they must grapple with go far beyond the confines of medical science."[54] This proposal, however, creates the possibility of bureaucratic complications and unwarranted public interference with useful scientific research. The problem of explaining the complexities of modern research projects to laymen would seem to make this proposal more political than practical.

A second means of safeguarding experimental subjects would be to require that all research projects be conducted by a minimum of two persons, at least one of whom is a medical doctor solely concerned with the subject's welfare.[55] The doctor would act as a check against any undue hazards to which the investigator might be willing to expose the subject. This investigator-monitor system is presently in use in the simulated sciences division of NASA-Ames Research Center. Both a monitor and an investigator must attend any research project judged to be at all hazardous, and either individual (as well as the subject) has the power to stop the experiment at any time.[56]

The investigator-monitor system would also be useful when nontherapeutic experimentation is conducted within the doctor-patient relationship. The investigator should, if possible, be an outside physician, while the monitor should be the doctor already responsible for the patient's care. Forbidding a doctor to conduct nontherapeutic experiments on his own patient would increase the patient's likelihood of knowing when medical treatment was not intended to have curative value for him. Further, the patient's doctor would be less likely to confuse treatment administered for the welfare of the patient with that administered out of scientific curiosity.[57]

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52. Washington Post, July 19, 1966, at A1, col. 8. These rules were not in effect at the time of the Southam-Mandel experiment.

53. Alderman, *Medical Experiments on Humans*, NEW REPUBLIC, Dec. 3, 1966, at 10, 11.

54. *Id.* at 12.

55. Dr. Guttentag says this would be similar to providing a defense attorney for the individual and a prosecuting attorney for the state. Guttentag, *supra* note 11, at 210.

56. Interview with Dr. George Rathert, *supra* note 51.

57. Guttentag, *supra* note 11, at 210.

However, when research within the doctor-patient relationship is also designed to help the immediate subject involved, both prior group review and the investigator-monitor system may be impractical. As noted earlier, all medical treatment is a form of experimentation;[58] a requirement of group review or the use of the investigator-monitor system might seriously affect the normal doctor-patient relationship. In cases of therapeutic experimentation, therefore, society may be forced to rely upon the doctor's recognition of his professional responsibility to safeguard the interests of his patients, aided somewhat by his realization that drastic therapeutic experimentation exposes him to a charge of malpractice.

Some consideration should also be given to methods of encouraging postexperimentation review of research projects. The Southam-Mandel case illustrates the importance of such review. Mandel, the director of the Jewish Chronic Disease Hospital, had discussed the project with three staff members, who told him not to conduct the experiment because the patients were incapable of giving informed consent. This informal prior review did not deter Mandel.[59] After the experiment, the three staff members resigned in protest. An ad hoc medical grievance committee appointed by the hospital supported and even commended Southam and Mandel, as did the majority of the hospital's board of directors. Only Director William Hyman objected.[60] The resulting publicity brought the matter to the attention of the Regents of the University of the State of New York, whose medical grievance committee found the two doctors guilty of fraud and deceit and of unprofessional conduct in the practice of medicine.[61]

Finally, some commentators have suggested that medical journals screen all articles submitted to them for possible violations of the rights of patients or subjects.[62] Another has suggested that all research grants carry a requirement that an investigator who submits his findings for publication include the results of any experiment he has conducted on human beings.[63]

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58. *See* text accompanying note 12 *supra*.

59. Regents Comm. on Discipline, *supra* note 5, at 10.

60. Hyman sued to force the hospital to show him the patients' records. He succeeded in the New York supreme court, lost in the appellate division, and finally triumphed in the court of appeals. Hyman v. Jewish Chronic Disease Hosp., 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965), *rev'g* 21 App. Div. 2d 495, 251 N.Y.S.2d 818, *rev'g per curiam* 42 Misc. 2d 427, 248 N.Y.S.2d 245 (Sup. Ct. 1964).

61. *See* text accompanying note 5 *supra*. Although Hyman was one of the founders of the Jewish Chronic Disease Hospital and had been on its board of directors since its foundation in 1926, the nominating committee of the board of directors of the hospital refused to place his name on the ballot for reelection to a new term in 1966. *See* Lear, *supra* note 1, at 67. The approval of the Southam-Mandel experiment by the hospital's ad hoc grievance committee and most of its board of directors indicates the importance of including on any review board some members who are not associated with the institution involved.

62. *See* Beecher, *supra* note 7, at 1359–60. Dr. Beecher examined "100 consecutive human studies published in 1964, in an excellent journal; 12 of these seemed to be unethical." *Id.* at 1355. *See also* Use of Volunteers in Aerospace Research, Air Force Reg. No. 169–8, § 5, Oct. 8, 1965: "All printed papers or articles that pertain to the use of human volunteers will contain the following footnote: 'The voluntary informed consent of the subjects used in this research was obtained as required by AFR 169–8.' "

63. *See* Freund, *supra* note 15, at 690.

Such a requirement might combat the tendency to omit from published reports the untoward results of an experiment in order to avoid possible criticism.[64] Neither of these requirements would prevent dishonest researchers from modifying their reports, but both would serve the salutary purpose of keeping the rights of subjects in the minds of researchers.

IV. Researcher's Liability

A more thorough articulation of standards and safeguards in the field of human research is necessary not only to guide investigators but also to provide criteria for tribunals judging alleged abuses of the rights of experimental subjects. The propriety of experimental conduct could be tested in three different contexts—a licensing authority might invoke professional sanctions, the subject (or his estate) might sue the researcher or his employer for civil damages, or the state might file criminal charges.

A. *Professional Sanctions*

In fact, only professional sanctions have ever been applied to an investigator for conduct in the field of human research, and these only rarely. The case of Southam and Mandel was exceptional. In professional disciplinary proceedings the licensing authority has the duty to establish the standards that a physician must meet to practice in the jurisdiction. While customary medical practice may be a satisfactory guide for determining questions of a doctor's failure to use proper skill,[65] standards for human research must incorporate ethical considerations not dependent upon community practice. Thus, although expert testimony on standard medical practice is admissible in establishing these standards, the licensing authority itself must decide what is proper. The decision of the New York regents in the Southam-Mandel case illustrates the role a licensing authority can play in establishing standards in the area of human experimentation.[66]

B. *Civil Liability*

A more difficult question arises when an injured subject attempts to impose civil liability on an investigator.[67] Prior case law is of little help here:

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64. *See* Shimkin, *supra* note 11, at 205.

65. *See* S. Shindell, The Law in Medical Practice 53 (1966).

66. "We trust that this measure of discipline will serve as a stern warning that zeal for research must not be carried to the point where it violates the basic rights and immunities of a human person." Regents Comm. on Discipline, *supra* note 5, at 12, quoted in 151 Science 663, 666 (1966).

67. The remedies available to a subject injured in a research project may be limited by statute. A prime example is research connected with the national space program, where the claimant is likely to be a federal employee. The Federal Employees' Compensation Act, 5 U.S.C. §§ 751–56, 757–91, 793 (1964), is the exclusive remedy of any government employee suing the United States. It is also the exclusive remedy of any nongovernment employee donating his services to a government agency, such as NASA. Federal Employees' Compensation Act § 40(b)(2), 5 U.S.C. § 790(b)(2) (1964); *see*

> Research, as such, has not been the subject of any reported court decisions, considering it squarely in terms of the rights and liabilities of a trained professional, utilizing a living patient or a normal subject, to discover new knowledge not necessarily of benefit to that patient or subject . . . . None involved a recognized scientist observing proper precautions.[68]

All cases in which courts have purported to discuss human experimentation have involved conventional malpractice issues. The plaintiffs had gone to physicians for treatment, had been dissatisfied with the results, and had accused the doctors of departing from accepted methods of treatment.[69] In concluding that these physicians were guilty of malpractice, the courts have said that all experimentation on human beings is "outside the law" and that "the doctor experiments at his own peril."[70] The opinions appear to say that a doctor who experiments is always liable for any resulting injury, no matter how proper and well conducted the research.[71] For example, a Wisconsin court said: "We have little doubt that, if the first case

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McNicholas v. United States, 226 F. Supp. 965 (N.D. Ill. 1964). Negligence is irrelevant here. The employee's compensation is determined by the amount of his medical expenses, the extent of his injury, the number of his dependents, and the amount of his salary.

Nongovernment employees can recover against the United States under the Federal Tort Claims Act, 28 U.S.C. §§ 1346, 2671–80 (1964), if they can prove negligence by an agent of the Government acting within the scope of his employment. Causes of action based on absolute liability for ultrahazardous activities, breach of warranty, and the like, are not allowed. *See, e.g.*, Dalehite v. United States, 346 U.S. 15, 44–45 (1953); United States v. Page, 350 F.2d 28 (10th Cir.), *cert. denied*, 382 U.S. 979 (1965); Strangi v. United States, 211 F.2d 305, 308 (5th Cir. 1954). Even where a claimant can prove negligence, however, the Federal Tort Claims Act contains various exclusions which might preclude recovery against the Government. These include the "discretionary function" exemption, 28 U.S.C. § 2680(a) (1964), and the exclusion of liability based on misrepresentation, deceit, assault, or battery, 28 U.S.C. § 2680(h) (1964). *See generally* United States v. Neustadt, 366 U.S. 696 (1961); United Air Lines, Inc. v. Weiner, 335 F.2d 379 (9th Cir.), *cert. dismissed*, 379 U.S. 951 (1964); Hungerford v. United States, 307 F.2d 99 (9th Cir. 1962) (misrepresentation and deceit); Moos v. United States, 225 F.2d 705 (8th Cir. 1955); Lane v. United States, 225 F. Supp. 850 (E.D. Va. 1964) (assault and battery); Annot., 99 A.L.R.2d 1016 (1965) (discretionary function).

Section 213(b)(13) of the National Aeronautics and Space Act of 1958, 42 U.S.C. § 2473(b)(13) (1964), provides another potential source of redress against the United States. This section gives NASA authority to settle claims up to $5,000, without regard to the enforceability of the claim through other channels. NASA can also recommend that Congress compensate claimants in amounts higher than $5,000 through private laws. *Id.*

Workmen's compensation statutes would cover many employees of private contractors. These statutes, which make negligence irrelevant, are an employee's exclusive remedy against his employer, and usually against any fellow employee. Many of these acts do, however, allow an injured employee to sue a third party whose negligence caused or contributed to the injury. *See generally* 2 A. LARSON, WORKMEN'S COMPENSATION LAW §§ 71–72 (1961); Page, *The Exclusivity of the Workmen's Compensation Remedy: The Employee's Right To Sue His Employer in Tort*, 4 B.C. IND. & COM. L. REV. 555 (1963).

The Federal Tort Claims Act does not allow suit against both the Government and a government employee for the same injury. 28 U.S.C. § 2676 (1964). However, a claimant who is a government employee can collect his Federal Employees' Compensation Act award and still sue the scientist whose wrongful conduct caused his injury, whether or not the scientist is a government employee. *See* Allman v. Hanley, 302 F.2d 559 (5th Cir. 1962); Marion v. United States, 214 F. Supp. 320 (D. Md. 1963).

68. Ladimer, *supra* note 17, at 471.

69. *See id.* at 480–81; 40 CALIF. L. REV. 159 (1952).

70. Ladimer, *supra* note 17, at 480–81. The statement that "the doctor experiments at his own peril" implies that if the patient is not harmed, the doctor escapes all liability. As the Southam-Mandel experience shows, this is not always true.

71. *See, e.g.*, Carpenter v. Blake, 60 Barb. 488 (N.Y. Super. Ct. 1871), *rev'd on other grounds*, 50 N.Y. 696 (1872); Slater v. Baker, 95 Eng. Rep. 860 (K.B. 1767); 41 AM. JUR. *Physicians & Surgeons* § 86 (1942).

of vaccination had proved disastrous and injured the patient, the physicians should have been held liable. Nor do we believe a physician of standing and loyalty to his patients will subject them to mere experiment . . . ."[72]

Since research on human beings is today recognized as being a legitimate and useful activity, the older cases, which equate experimentation with quackery, are not persuasive precedent. Hence a court will probably look to the conventional malpractice area for guidance and analogies. A patient alleging lack of skill must usually provide expert medical testimony that his doctor failed to act as a typical medical practitioner in the community would have acted under similar circumstances. The patient can succeed without such testimony only in those exceptional cases where the negligence and harmful results are sufficiently obvious to be within common knowledge.[73] A patient suing for malpractice, battery, or trespass because his doctor failed to inform him of all the risks involved in an operation or course of treatment is similarly required by most courts to provide expert medical testimony. Generally, a doctor's failure to inform a patient of all possible consequences of a therapeutic procedure is actionable only if the average medical practitioner in the community would have acted differently.[74] This standard appears to be founded on the recognition that disclosure of all relevant information might cause the patient excessive worry.[75]

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72. Allen v. Voje, 114 Wis. 1, 22–23, 89 N.W. 924, 932 (1902).

73. *See, e.g.*, Gin Non Louie v. Chinese Hosp. Ass'n, 249 Adv. Cal. App. 891, 901, 904, 57 Cal. Rptr. 906, 913, 915 (1st Dist. 1967); W. PROSSER, TORTS § 32, at 167 (3d ed. 1964).

74. *See, e.g.*, Shetter v. Rochelle, 2 Ariz. App. 358, 409 P.2d 74 (1965), *modified*, 2 Ariz. App. 607, 411 P.2d 45 (1966); Di Filippo v. Preston, 53 Del. 539, 549–50, 173 A.2d 333, 339 (1961), *noted in* 75 HARV. L. REV. 1445 (1962); Dowling v. Mutual Life Ins. Co., 168 So. 2d 107 (Fla. Ct. App. 1964); Williams v. Menehan, 191 Kan. 6, 10–11, 379 P.2d 292, 295 (1963); Mayor v. Dowsett, 240 Ore. 196, 400 P.2d 234 (1965); Govin v. Hunter, 374 P.2d 421 (Wyo. 1962).

75. Most courts, however, have applied this community standard even where the doctor did not claim that nondisclosure was necessary to protect the patient. *See* cases cited note 74 *supra*. On the other hand, a few courts have held that under the circumstances of a particular case the doctor was guilty of malpractice as a matter of law for not disclosing to the patient facts necessary for intelligent consent. *See* Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, *opinion clarified*, 187 Kan. 186, 354 P.2d 670 (1960); Mitchell v. Robinson, 334 S.W.2d 11 (Mo. 1960), *disapproved*, Aiken v. Clary, 396 S.W.2d 668, 673–75 (Mo. 1965); Woods v. Brumlop, 71 N.M. 221, 377 P.2d 520 (1962); Di Rosse v. Wein, 24 App. Div. 2d 510, 261 N.Y.S.2d 623 (1965) (mem.) (*semble*); *cf.* Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 154 Cal. App. 2d 560, 578, 317 P.2d 170, 181 (1957).

The extent of the physician's duty to disclose facts to his patient has been the subject of much commentary, as well as inconsistent and unclear court opinions. The more recent articles include Gelfand, *Surgeon's Liability for Unauthorized Operations*, ILLINOIS CONTINUING LEGAL EDUCATION, July 1966, at 103; Hirsh, *Consent to Medical Treatment—With Forms*, 1961 TRIAL LAWYERS' GUIDE 51, 55–62; Karchmer, *Informed Consent: A Plaintiff's Medical Malpractice "Wonder Drug,"* 31 Mo. L. REV. 29 (1966); Kloss, *supra* note 46, at 97–99 (1965); Levin, *Consent to Medical Procedures*, 1963 INS. L.J. 711; Comment, *Surgery Without Consent—Malpractice or Battery*, 29 ALBANY L. REV. 342 (1965); Comment, *Informed Consent: Malpractice*, 18 BAYLOR L. REV. 137 (1966); Note, *Informed Consent to Medical Treatment*, 11 CLEV.-MAR. L. REV. 249 (1962); Note, *Consent to Medical and Surgical Treatment*, 14 DRAKE L. REV. 101 (1965); Comment, *Valid Consent to Medical Treatment: Need the Patient Know?*, 4 DUQUESNE U.L. REV. 450 (1965–66); Comment, *Medical-Surgical Consent*, 20 N.Y.U. INTRA. L. REV. 144 (1965); Note, *Physician and Patient: Some Problems of Consent*, 2 WASHBURN L.J. 158 (1962); 75 HARV. L. REV. 1445 (1962).

Where medical treatment is designed solely to cure the patient and is "experimental" only in the sense that it is not universally accepted, the standards of skill and disclosure required in the normal medical malpractice case are still appropriate. The patient should be required to present expert testimony to establish a violation of community practice. Where medical treatment is administered by a doctor who is also attempting to increase scientific knowledge, however, more safeguards are necessary. When the doctor is no longer concerned *solely* with the patient's best interests, but is simultaneously pursuing a personal interest in medical research, he should be required to obtain the patient's consent after full disclosure, unless such disclosure would not be in the patient's best interests.[76] Thus, a plaintiff-subject proving nondisclosure or a failure to secure consent should prevail unless the physician can establish that nondisclosure was necessary for the patient's welfare. Expert testimony would be relevant not to establish existing community practices but to assist the factfinder in determining whether full disclosure would have been detrimental to the patient.

When research is in no way intended to benefit the subject involved, expert testimony on the propriety of securing informed consent should never be required. No investigator should have the power to dedicate a person's life to the advancement of science without that person's informed consent—even if the average practitioner in the community might do so. Protecting the subject from excessive worry is hardly a relevant consideration when the welfare of the subject is not a motive for the research.

Because informed consent is frequently not an adequate safeguard for the interests of a subject,[77] his consent should not in itself insulate the investigator from civil liability. The subject should be entitled to allege that the investigator negligently failed to secure prior group review or to take steps to protect the subject's interests throughout the experiment. An important consideration in these instances is the sophistication of the subject—his ability both before and during the experiment to comprehend and evaluate the risks involved. For example, an investigator conducting experiments on students, prisoners, or his own patients should have a responsibility to safeguard his subjects beyond the mere securing of informed consent. Indeed, some courts might regard the consent of even a knowledgeable subject as insufficient.

Civil liability may serve a punitive as well as a compensatory function.[78] Courts interested in deterring what they consider to be excessively hazardous research projects might rule that the consent of a legally competent and

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76. *See, e.g.*, Declaration of Helsinki, art. II, § 1, *supra* note 31; 21 C.F.R. § 130.37 (1967).
77. *See* text accompanying notes 35–40 *supra*.
78. *See* W. PROSSER, TORTS § 4 (3d ed. 1964).

knowledgeable subject does not bar him from recovering damages from the investigator, just as a consenting female injured by an illegal abortion is in many states allowed to recover against the abortionist.[79] By requiring more than informed consent, courts would be encouraging investigators to seek prior group review and to establish methods of protecting the subject's interests throughout the experiment. None of these safeguards would deter legitimate scientific inquiry.

Finally, a court might hold an investigator conducting nontherapeutic research to a standard of liability without fault. It is the investigator who initiates nontherapeutic research and has the principal interest in its successful outcome. Therefore it can be argued, by analogy to the doctrine of strict liability for ultrahazardous or inherently dangerous activities and to notions of "enterprise liability" generally, that an investigator should bear all losses caused by his experiment, regardless of negligence.[80] This rule would have the added virtue of avoiding the difficult proof problems concomitant to a negligence standard in this area. A person injured because he agreed to incur risks in the name of science should not be left to bear the loss simply because of the intractability of proving that the investigator did not take all reasonable precautions.[81] Thus the old "human experimentation" decisions may indicate the correct result, not because nontherapeutic experimentation is "outside the law," but because principles of equitable loss distribution dictate that the investigator, his employer, and their insurance companies should bear the loss.

A great deal of nontherapeutic human experimentation already takes place under such a system. Most of the human research involved in the nation's space program is performed on government employees, who are covered by the Federal Employees Compensation Act when injured in the line of duty. They can recover against the Government without having to prove any breach of duty. Many other research subjects are covered by workmen's compensation statutes, which perform the same function.[82]

Absolute liability should not extend to experimentation which is strictly therapeutic—intended solely for the subject's welfare. Here the doctor has no personal interest in the success of the treatment distinct from the interest of the subject. Indeed, because all medical treatment is to a degree experimental, imposition of absolute liability on a physician for injuries stemming

79. A large minority of states allow a consenting female or her representative to sue an abortionist for injuries or death caused by an abortion, even where the abortionist was not negligent. *See, e.g.*, Martin v. Hardesty, 91 Ind. App. 239, 163 N.E. 610 (1928); Joy v. Brown, 173 Kan. 833, 252 P.2d 889 (1953); Milliken v. Heddesheimer, 110 Ohio St. 381, 144 N.E. 264 (1924). *See generally* W. PROSSER, TORTS § 18, at 109 (3d ed. 1964); C. STETLER & A. MORITZ, DOCTOR AND PATIENT AND THE LAW 98–99 (4th ed. 1962).

80. *See generally* Ehrenzweig, *Negligence Without Fault*, 54 CALIF. L. REV. 1422 (1966).

81. *See* Rheingold, *supra* note 22, at 1014; 1960 DUKE L.J. 265, 274; 13 STAN. L. REV. 645, 651–52 (1961).

82. *See* note 67 *supra*.

from therapeutic experimentation would go far toward extending it to all forms of medical treatment.

Imposing absolute liability for nontherapeutic experimentation while retaining common malpractice standards for therapeutic experimentation would create serious definitional problems. To what extent would a doctor have to be concerned with objectives other than the cure of his patient before absolute liability attached? Should a doctor's "primary concern" govern? Even if the courts could establish a standard to characterize experiments with combined therapeutic and nontherapeutic objectives as being in one category or the other, how would a patient previously suffering from an illness prove that the experiment contributed to his illness or aggravated an existing condition? Thus, absolute liability, while avoiding the morass of deciding the question of "negligence," would create problems of potentially equal magnitude.

C. *Criminal Liability*

An investigator engaged in hazardous experiments on human beings might be subject to criminal liability even if he obtains the voluntary and informed consent of the subject. No one can consent to his own death or serious injury—the perpetrator is still guilty of murder, manslaughter, or mayhem.[83] However, all reported criminal cases have involved either persons who maimed themselves for selfish motives,[84] or doctors or pseudo-doctors guilty of quackery and extreme foolhardiness.[85] No state has ever brought criminal charges against a scientist for conducting experiments on a subject who has given his informed consent. No researcher who follows stringent safeguards to guarantee that the experiment promises very valuable results, that the experiment is conducted as safely as possible, and that the subject is fully informed of all the risks and volunteers without any form of coercion or duress[86] should face criminal prosecution for con-

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83. Kidd, *Limits of the Right of a Person to Consent to Experimentation on Himself*, 117 SCIENCE 211, 212 (1953). Manslaughter requires only a form of negligence, usually characterized as gross, aggravated, culpable, or reckless. *See* 1 R. ANDERSON, WHARTON'S CRIMINAL LAW AND PROCEDURE § 291 (1957). Murder requires "malice aforethought," a term of art which is usually deemed to include "recklessness." *See* MODEL PENAL CODE § 2.02(2)(c) (Proposed Official Draft 1962): "A person acts recklessly with respect to a material element of an offense when he consciously disregards a substantial and unjustifiable risk that the material element exists or will result from his conduct. The risk must be of such a nature and degree that, considering the nature and purpose of the actor's conduct and the circumstances known to him, its disregard involves a gross deviation from the standard of conduct that a law-abiding person would observe in the actor's situation." Thus, one can have the mens rea requisite to murder without specifically intending to kill anyone. However, all doctors or pseudo-doctors held criminally liable in the treatment of a patient have been found guilty of manslaughter, not murder.

84. *See, e.g.*, State v. Bass, 255 N.C. 42, 120 S.E.2d 580 (1961), *noted in* 47 IOWA L. REV. 1122 (1962). The classic examples are persons who injured themselves to avoid military service and the man who cut off his hand to make himself a more successful beggar. *See* Kidd, *supra* note 83, at 212.

85. *See, e.g.*, Commonwealth v. Pierce, 138 Mass. 165 (1884); State v. McFadden, 48 Wash. 259, 93 P. 414 (1908).

86. The Nuremberg Code sets forth these standards as those which an investigator must meet to avoid criminal liability. *See* text accompanying note 20 *supra*.

ducting an experiment he knows to carry a substantial likelihood of death or disabling injury.[87] When Walter Reed and his men injected themselves with mosquito extract to find a cure for yellow fever they were considered heroes, not criminals. Even the Nuremberg Code recognized that extra-hazardous research projects might be permissible if the physician were to show his good intentions and his concern for the welfare of his subjects by serving as a subject himself.[88]

It is hardly probable that a researcher would be so unethical that criminal charges would be filed. Even so, one safeguard of the welfare of an experimental subject is the researcher's knowledge that he is, at least in theory, criminally liable if he totally disregards the rights of his subjects.

Conclusion

Research on human subjects is vital to medical and scientific progress. Abuses have occurred, however, and will continue to occur as long as standards and safeguards are insufficiently articulated. The greatest need today is for a wider public airing of the standards involved in the area lest a recurrence of such abuses as were involved in the Southam-Mandel case arouse the public into forcing unwarranted restrictions on the legitimate and necessary activity of human research.

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87. *See* Kidd, *supra* note 83, at 212. *But cf.* Address by Pope Pius XII, First International Congress of the Histopathology of the Nervous System, Sept. 14, 1952, entitled "The Moral Limits of Medical Research and Treatment," in 51 Catholic Mind 305 (1953) (man cannot agree to excessively perilous experiments on himself, because he is not the complete master of his body but only its guardian and steward); Lynch, *Human Experimentation in Medicine: Moral Aspects*, 1 Clinical Pharmacology & Therapeutics 396 (1960).

88. *See* United States v. Brandt (The Medical Case), 1 & 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10 (1949).

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