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Leonard V. Kaplan

University of Nebraska College of Law

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EXPERIMENTATION—AN ARTICULATION
OF A NEW MYTH

Leonard V. Kaplan*

An eminent legal scholar convincingly tells us "the law cannot be expected at this time to yield precise answers to the ethical problems of medical experimentation." An equally eminent physician assures us "experimentation in man for scientific purposes is as old as recorded history." Experimentation in man evokes a scheme of scientific methods, controls and scrupulous ethics. The world was shocked by the denouement at Nuremberg that dedicated and honored medical men had "experimented" on live human subjects, adding to the sum of medical knowledge inter alia, the fact that phenol or gasoline injected intravenously will kill a man inexpensively and within sixty seconds. This and a few other "advances" are all in the field of thanatology.

It will do well to cite from the closing statement of one of the Nuremberg defendants:

[E]vidence has now proved that in recent decades and even earlier, numerous experiments were carried out on human beings, and, moreover, on persons who did not volunteer for such purpose . . . . The only conclusion which can be drawn from these facts is that during recent decades views on this question have changed in the same way as the relations between the individual and the community in general have changed . . . . It is a fact, that at least in Europe, the state and the community have taken a different attitude toward the individual. However differently one may write about the change in these relations in detail, one thing is certain, namely, that the state has more and more taken possession of the individual and limited his personal freedom. This is evidently one of the accompanying facts of technics and the modern mass-state. It must be added that the development of medicine in the course of the last decades has led to discriminating formulations of questions which can no longer be solved by means of the laboratory and animal experiments.

* LL.B., 1965, Temple Law School; LL.M., 1966, Yale Law School; Assistant Professor of Law, University of Nebraska.


2 Beecher, Henry K., Tentative Statement Outlining the Philosophy and Ethical Principles Governing the Conduct of Research on Human Beings at the Harvard Medical School.

3 From the opening statement of the Chief Prosecutor Telford Taylor at the Nuremberg Military Tribunals reprinted in DONELLY, GOLDSTEIN, & SCHWARTZ, CRIMINAL LAW 68 (1962).

4 Id. at 69. (Emphasis added.)
Nuremberg did, in fact, give rise to a code of ethics for experimentation on man:

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

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

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparation 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 continua-
tion of the experiment is likely to result in injury, disability, or death to the experimental subject.\(^5\)

The American Medical Association has promulgated its own code,\(^6\) as has the British Medical Association, the American Psychological Association,\(^7\) and the World Medical Association\(^8\) inter alia. Article Seven, Draft Covenant on Civil and Political Rights, adopted by the Third Committee of the General Assembly of the United Nations 1958 provides: "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation involving risk, where such is not required by his state of physical or mental health." His Holiness Pope Pius XII addressing a body of the medical profession admonished:

Although one must recognize in the "interests of science" a true value that the moral law allows man to preserve, increase and widen, one cannot concede the following statement: "Granted, obviously, that the doctor's intervention is determined by scientific interest and that he observes the rules of his profession, there are no limits to the methods for increasing and deepening medical science." Even on this condition, one cannot just concede this principle.\(^9\)

With this explicit recognition of the need for ethical codes, after the scepter of Nuremberg, what problem does experimentation present to the individual and the community, and if problems

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\(^7\) Approved by the Board of Directors of the American Psychological Association, 1959. Principle 16 is particularly significant: "Only when a problem is significant and can be investigated in no other way is the psychologist justified in giving misinformation to research subjects or exposing research subjects to physical or emotional stress. a. When the possibility of serious after-effects exists, research is conducted only when the subjects or their responsible agents are fully informed of this possibility and volunteer nevertheless. b. The psychologist seriously considers the possible harmful after-effects and removes them as soon as permitted by the design of the experiment. *Ethical Standards of Psychologists*, 14 Amer. Psychologist 279, 282 (1959).


do exist, why do they defy legal control? Before analyzing the ethical interaction of doctor and patient and experimenter and subject, we should first recognize that experimentation as a concept is descriptive of legal and social operations as well. We do, in fact, "engineer" consent in areas wholly outside of the medical. This is true in such an example as the "loud fanfare for a heroic crew of astronautical volunteers to attempt some ultrahazardous exploit." Moreover, "we can calculate approximately the loss of life in any large-scale job of highway construction, tunneling, or the building of skyscrapers, and yet we deliberately elect to take the known risk of loss of life."

The law does not and cannot yield scientific answers; rather it balances, makes value judgments; the law is, in fact, experimenting when it intercedes encouraging or more often proscribing certain conduct. Legal outcomes may vary also according to the particular legal institutions put into action or quieted, e.g., courts, administrative tribunals, discretionary powers of various public officials such as public prosecutors. Certainly legal intervention and resultant proscription can yield results ultimately more dangerous and more at variance with the stated goals to be rectified, than if the proscribed conduct had been left unregulated.

Keeping in mind then the fact that legal intervention may be nugatory, ineffective, harmful, or oppressive we turn to the definition of medical experimentation. Freund includes within the scope of the experimentation concept,

... the practice of therapy where there is no generally-accepted mode of treatment; next, the use of drugs or injections or other procedures on patients, not for immediate therapy at all but for the sake of observation of the results with a view to the eventual improved treatment of sufferers, who may or may not include the particular patient. Finally, at the other end of the spectrum, the use of non-patients as experimental subjects.

This range of medical activity is certainly wide but a true picture of medical experimentation would be even more expansive. In fact all medical intervention, i.e., treatment or calculated omission is experimental in that results at best are only probable. We know, for instance, that much of the efficacy of drugs flows from

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10 Experimenter and subject is obviously subsumed under doctor and patient; obviously the experimenter remains a doctor.
11 If your jurisprudential definition of law is broad all social interaction will fall within the ambit of "the law."
13 See note 1 supra at 47.
14 Ibid.
the psychological faith the patient has either in the drugs themselves, in his physician or in the combination of the two. We have all heard the television commercial for a leading headache remedy wherein a layman on questioning responds to the effect that "I don't know why they work, just that they work." For this very reason drug experiments often employ double blind tests; i.e., not only is the subject uninformed as to the drug he is taking but the administering physician is also uninformed as to the drug he is using. It is not an overgeneralization to state then that all medical treatment is experimental. The problem posed here is to determine (1) whether or not different ethical issues are invoked in the more typical doctor-patient relationship than in the experimenter-subject relationship and (2) if differences do or do not exist whether the two relationships are susceptible to the same controls.

More typically the doctor-patient relationship is practiced in the physician's office. The emphasis in such a relationship is the treatment of a specific disturbance either brought to the attention of the physician by the patient himself or discovered while the patient is undergoing an examination for other reasons. This is certainly not to say that this relationship is not experimental. In fact, the physician may be using a totally new or as yet unproved therapeutic method to attempt "cure" or "amelioration" of the disturbance in question. A whole body of law, in malpractice and battery, describes the duty of the physician to inform his patient of the particular treatment planned and of the probable dangers in such treatment. The patient comes to the physician generally expecting the exercise of good medical judgment; often, moreover, it should be indicated that the patient affirmatively wishes to allow the physician a free hand, and does not want to be informed and is perhaps frightened by the physician's explanation; in short this type of patient wishes only reassurance and cure and sometimes only reassurance. Normally, the physician because of his expertise exercises the dominant position as between himself and his patient; this position is increased by the patient's faith in his doctor, and his need for reassurance engendered by fear. We have all seen or experienced that the sick want pampering and reassurance, that very often they become more dependent and enjoy this dependency and the added attention from physician, family and friends that go with their debilitated state. To further increase the difficulty of determining to what extent a patient should be informed as to the danger of the particular treatment

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15 This phenomenon is known as secondary gain when the patient, in fact, holds on to the debilitated state because he is enjoying such attention and affection.
projected is the psychological factor which often determines the success or failure of therapeutic intervention. A frightened or unconfident patient may very well have less chance for a successful intervention be it by drugs, operation, or mere talk.

Malpractice as a rule is based on negligence theory—that the physician was guilty either of a negligent act or of an omission. Among the questions subsumed under medical malpractice are what duty does the physician owe his patient to inform him of the usual and unusual results which might result from an intervention, what method or methods are available for the condition to be remedied and which method does the physician propose to employ. The concept of experimentation takes on particular relevance to the question of the use of new or unproved methodology or drugs. Old methods, however, may be equally experimental in that results are far from certain. In fact, as in any working science, medical methods are constantly discarded as outmoded, inefficient, and in some cases actually harmful. One writer in the area has expressed the opinion that our civilization explicitly “accepts medicine as an experimental discipline.”

It is my feeling that Western civilization accepts medicine as an experimental discipline and that, in expecting it to continue to grow, to be a progressive science, as against the attitudes of the medicine man whose incantations and medicaments were not expected to nor designed for change, an acceptance of the trial of the new and the search for the better is implicit. I also think that when society confers the degree of physician on a man it instructs him to experiment on his fellow. I think that when a patient goes to a modern physician for treatment, regardless of whether he consciously consents to it, he is also unconsciously presenting himself for the purpose of experimentation.

Both the criminal law and the tort law have established

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17 Ibid.
(1) In General. The consent of the victim to conduct charged to constitute an offense or to the result thereof is a defense if such consent negatives an element of the offense or precludes the infliction of the harm or evil sought to be prevented by the law defining the offense.

(3) Ineffective consent. Unless otherwise provided by the code or by the law defining the offense, assent does not constitute consent if:
(a) it is given by a person who is legally incompetent to authorize the conduct charged to constitute the offense; or
(b) it is given by a person who by reason of youth, mental disease or defect or intoxication is manifestly unable or known by the actor to be unable to make a reasonable judgment as to the nature or harmfulness of the conduct charged to constitute the offense; or
standards of consent necessary for infringement of bodily integrity. Despite consent, indeed, the physician can sometimes be held criminally or tortiously liable in cases of (1) nontherapeutic intervention, (2) unnecessary intervention (3) legally questionable procedures involving criminal liability and public policy.  

**Bonner v. Moran** involved a skin graft from a fifteen year old boy to his severely burned cousin. The court indicated: ""[T]he question here is different from that in any of the cases to which our attention has been drawn, for here we have a case of surgical operation not for the benefit of the person operated on but for another...""  

Cases of operations without cause fall under unnecessary intervention.  

The third group involves such areas as nontherapeutic abortion or sterilization. The criminal law is not generally invoked since the ""interests of society will be subsumed by holding a physician civilly liable in damages for ignorance and incompetence.""  

An early English case indicated that liability can arise by deviating from an accepted to an innovative medical procedure.  

**Langford v. Kosterlitz** is an American case recognizing a different standard of liability for an alteration in customary technique. Ladimer quotes from Dr. H. W. Smith on this issue:

""There is scant legal authority on this intriguing problem. It would seem true, as a basic proposition, that a patient who submits to treatment, does not thereby authorize more than application of methods currently approved by some school of medical practice. On that ground, alone, it may well be an unconsented act and thus a battery, for a surgeon to subject him to the risk of some novel and experimental method without advance disclosure of his intention and of the material risks involved. Abundant expert testimony is usually available to show that subjecting a patient to experimentation without disclosure and consent is contrary to the customs of surgeons, and thus negligent even though there be no technical

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(c) it is given by a person whose improvident consent is sought to be prevented by the law defining the offense; or

(d) it is induced by force, duress or deception of a kind sought to be prevented by the law defining the offense.

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20 126 F.2d 121 (D.C. Cir. 1941).
21 Id. at 123. (Emphasis added.)
23 See note 20 supra at 502, citing State v. Schulz, 55 Iowa 628, 8 N.W. 469 (1881).
25 107 Cal. App. 175, 290 Pac. 80 (Dist. Ct. App. 1930).
slip in actual performance of the experiment."26

But even without an innovative technique the courts are starting to recognize the duty of physicians to obtain an “informed consent” before therapeutic intervention. The Missouri Supreme Court in *Mitchell v. Robinson*27 stated:

In the particular circumstances of this record, considering the nature of Mitchell's illness and this rather new and radical procedure with its rather high incidence of serious and permanent injuries not connected with the illness, the doctors owed their patient in possession of his faculties the duty to inform him generally of the possible serious collateral hazards; and in the detailed circumstances there was a submissible fact issue of whether the doctors were negligent in failing to inform him of the dangers of shock therapy.28

However, the same court in *Aiken v. Clary*29 cut back on the *Mitchell* doctrine indicating the need for medical testimony on the “informed consent” issue. Informed consent depends on a contextual analysis varying from “full disclosure of all risks which had any reasonable likelihood of occurring” to a narrower disclosure. In any event the determination as to whether or not the consent obtained was informed would be a medical determination.30 To similar effect the Kansas Supreme Court stated:

In our opinion the proper rule of law to determine whether a patient has given an intelligent consent to a proposed form of treatment by a physician . . . compels disclosure by the physician in order to assure that an informed consent of the patient is obtained. The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances.31

The California court specifically recognized the potential danger in informing an “unduly apprehensive” patient:

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. At the same time, the physician must place the welfare of

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27 334 S.W.2d 11 (Mo. 1960).
28 *Id.* at 19.
29 396 S.W.2d 668 (Mo. 1965).
his patient above all else and this very fact places him in a position in which he sometimes must choose between two alternative courses of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; this may well result in alarming a patient who is already unduly apprehensive and who may as a result refuse to undertake surgery in which there is in fact minimal risk; it may also result in actually increasing the risks by reason of the physiological results of the apprehension itself. The other is to recognize that each patient presents a separate problem, that the patient’s mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with full disclosure of facts necessary to an informed consent.32

The majority rule as to informed consent is without doubt that expert medical testimony is necessary to determine whether the information given was proper medical practice for the particular case at hand.33 Thus the questions earlier raised as to the duty to inform of variance in technique from ordinary medical practice, as to alternative methods and as to indicated dangers implicit in a specific mode of treatment are answered according to the instant situation and how that situation has been and will be appraised by the called medical experts. Much has been written about the so-called “conspiracy of silence” in the medical profession; suffice it to say that it is often difficult to obtain expert medical testimony in any malpractice situation. Of more import is the abdication to the medical profession of the task of establishing criteria more generally applicable to the issue of informed consent. Certainly the decision to inform a particular patient of indicated dangers to a particular treatment is often made by the physician qua human being. The nonmedical community would seem quite capable of understanding and determining fine ethical decisions of whether a physician was or was not justified in failing to inform a patient of particular dangers if the circumstances of the case are fairly presented. Recognizing our preferred value in law for bodily integrity we should articulate to a greater degree the dimensions of ethical decision-making as to informed consent. If one of our societal goals is, in fact, to establish individual dignity and responsibility the rule should be weighted toward complete disclosure of


33 See note 30 supra at 55. This article and a comment, Informed Consent: Malpractice, 18 BAYLOR L. REV. 137 (1966), survey the leading cases in this area. Wood v. Brumlop, 71 N.M. 221, 377 P.2d 520 (1962), remains the leading case not requiring medical experts for an “informed consent” determination.
the nature of the ailment and the recognized dangers of the proposed treatment. Extraordinary or improbable dangers would not have to be explained unless the patient specifically inquired. I concur with Professor Freund on the value of "wider airing." In fact, we must educate the medical profession that we expect and want information. I would place the burden then initially on the doctor to inform the patient as to the inherent dangers in the proposed treatment.

If the patient does not want to hear, he can so inform the physician and "waive" any further disclosure. I think it quite possible for a physician to reduce his information to terms which can be understood by the patient, to sympathetically reassure the patient without unduly frightening him, and to allow and encourage the patient to understand and share in the decision-making concerning his own bodily integrity. Certainly this is the ideal situation, but should we postulate the ideal? A proper informing rather than creating further anxiety in the patient may very well reassure the patient, make him feel confident that he has at least some control over his destiny, and that he is respected as a fellow human and an equal of his physician.

If my paradigm is the standard we wish to achieve in this situation, how do we go about structuring in this direction? The courts at best handle very few cases and have only speculative impact on educating in ethical standards. To reiterate, the legal standard should be one of full disclosure of known risks; the patient should have the responsibility of asking or attempting to clarify all misunderstanding or omission after such a full disclosure. Education in the medical schools and journals would appear to have greater chance for impact than court decisions. I would propose separate courses in problems of medical ethics as part of the basic medical school curriculum. Doctors are part of the larger society and their attitudes often reflect the dominant community attitudes so that community education is important to the whole problem of medical intervention and experimentation.


We can speculate that often a patient if adeptly informed will have increased respect for the physician. He may very well reason that a physician who so undertakes to inform has confidence in his knowledge and can be relied upon. The purported great length of time it takes to inform a patient may very well be thereby reduced by effective explanation at the outset.

A seminar on medical experimentation offered last year at the Yale Law School by Dr. Jay Katz and the late Prof. Richard Donnelly is an
Do different problems arise when we characterize the physician as an experimenter and the patient a subject, or if we move from the physician's private office into clinics or hospitals? If the issues remain the same do possibilities of effective control differ?

The experimenter still remains a physician and perhaps does not even conceive himself to be an experimenter. The patient may be a subject since he is, in fact, worked upon; or a subject may be one who for a variety of reasons volunteers or is enlisted for purposes of the study of certain medical procedures or drugs the benefits of which will not redound to any condition he presently may have. This article is concerned with the analysis of the problem of actual physical medical intervention or experimentation. Psychological and psychiatric experiments involve similar ethical issues but are of even greater difficulty for analysis because of the state of our knowledge in the psychic area. Walter Sullivan has reported one psychological experiment where forty subjects, men of various ages and vocations from New Haven, participated for a nominal sum in a study designed ostensibly "to bring to light the effect of punishment on learning." The subjects were seated one at a time at a console lined with thirty switches, each progressively marked as administering a more severe shock to a volunteer sitting in an "electric chair." The "learner" actually was an accomplice and was not "shocked" at all but reacted as though in pain when the "danger: severe shock" button was pushed by the teacher who, in fact, was the real subject of the experiment. "At this point [when the learner started to demand that the teacher stop administering pain] there remained 10 switches, each of which seemed to inflict more pain. Only 14 of the 40 subjects defied orders and stopped before completing the sequence." One of the "teachers" became "so violently convulsive that the experiment had to be halted." Others displayed "bizarre laughter" and one businessman who had entered the laboratory "smiling and confident" was "within 20 minutes . . . reduced to a twitching, stuttering wretch, who was rapidly approaching a point of nervous collapse." One research psychologist explicitly recognized and expressed great concern for the ethical issues implicit in this type of experiment:

But do researchers, for purposes of experimentation, have the right to provide such potentially disturbing insights to subjects who

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38 Ibid.
39 Ibid.
do not know that this is what they volunteered for? And yet, this same research illustrates the complexity of the issues raised by the use of deception. These studies of obedience have produced significant and challenging findings which have posed some basic questions about human behavior and social life. Without deception this line of investigation could probably not have been pursued.41

The same author cites studies where male college students were induced to believe that they had homosexual reactions to photographs of men; another study gave disturbing information about their levels of masculinity or femininity supposedly based on psychological tests that they had taken. In these studies the deception was explained at the end of the experiments. But wounds certainly may have been opened. Dr. Kelman challenges the basic hypothesis that deception is necessary. He argues that, in fact, subjects frequently realize that some deception is being practiced. Moreover, "in institutionalizing the use of deception in psychological experiments we are contributing to a historical trend that threatens the values most of us cherish."42 Kelman further suggests that the subject can be informed that information is being kept from him at the outset and throughout the experiment.43 Minimally all subjects should certainly be checked to ascertain that they are leaving the experiment with at least as much equilibrium as when they entered. Hornbook tort law holds that the tortfeasor takes his victim as he finds him.

Assuming a "fiduciary" relationship between the experimenter and his subject it would seem that blanket consent without at least knowing that information is being withheld is certainly not informed, if consent at all. One letter44 to the editor corroborating Kelman's view indicates the core issue here:

Are there limits to such experimentation even when it is admittedly in the interests of science and truth? Are those limits reached whenever the experiment becomes a threat to the moral as well as the psychic integrity of the person? Dr. Kelman develops a "yes" answer to both questions. Interestingly enough, the "yes" is supported, not only by the knowledge and experience of the scientist who voiced it but by a Pope of Rome!

The so-called "interests of science" may or may not serve sci-

41 Id. at 22.
42 Id. at 23.
43 Ibid. Kelman also suggests that it may be possible to conduct more experiments in a natural non-laboratory setting in which, with the full cooperation of the subjects, specific experimental variations are introduced. The advantages of dealing with motivations at a real-life level of intensity might well outweigh the disadvantages of subjects knowing the general purpose of the experiment.
44 Letter of Mary J. McCormick to Editor of Transaction, Nov. 1966, p. 55.
ence. In the long run, the practice of deception will destroy faith in those disciplines exercising it. The law, however, must balance the values of this scientific search for truth and protect the individual from the operations of this "truth." Returning to the level of physical, medical intervention we find equally disturbing examples of gross abuse of any "informed consent" criterion for experimentation.\(^{45}\)

"Human experimentation beyond the boundaries of medical ethics is being carried out to an alarming and dangerous degree by clinical investigators more concerned with furthering the interests of science than with the good of the individual patient, an eminent Harvard physician has claimed." This eminent physician, Dr. Henry K. Beecher, Director of the Anesthetic Laboratory of Harvard Medical School at the Massachusetts General Hospital reported in the prestigious New England Journal of Medicine fifty examples of unethical experimentation.\(^{46}\) Each example was corroborated by the Journal editors. To cite a few examples of Beecher's findings:

In a rheumatic fever test, doctors tried to find out if some of the complications of acute streptococcal pharyngitis would be reduced by the drugs used to control the infection itself. Though it was well known that penicillin and other antibiotics would do this, investigators withheld the drugs from 500 Air Force men without their knowledge or consent. Result: some 5.4 per cent of the men treated with drugs got rheumatic fever; 4.2 per cent of those in the control group denied both sulfas and penicillin, contracted the infection.

Even though chloramphenicol was known to fight off typhoid fever effectively, some 157 patients of a group of 408 charity patients were denied it. Result: of those who received the drug, only 20—some 7.97 per cent,—died. Of those who did not, 36—some 22.9 per cent—died.

Healthy patients were used along with sick ones in testing a new technique for injecting a needle into the heart through the bronchus. The technique's risks were quite unknown. All of the subjects had normal hearts—with nothing to gain and everything to lose.\(^{48}\)

Beecher places the responsibility on the profession, and recognizes the goal of informed consent, but believes the ultimate re-

\(^{45}\) Experimentation includes, to repeat, all medical intervention but most particularly the use of innovative or unproved techniques or the use of subjects who are not being treated in the usual mode of treatment if for any "ailment" at all.

\(^{46}\) Trials, Aug.-Sept. 1966, p. 18.

\(^{48}\) Ibid.

\(^{48}\) Ibid.
sponsibility and means of control rests with the responsible investigator. Speaking before a seminar on experimentation conducted at the Yale Law School by Dr. Jay Katz and the late Prof. Richard C. Donnelly, Beecher indicated that the responsible medical journals publish experimental findings where ethical standards have been partially ignored. He suggested that if these journals assumed their responsibility and refused such articles much of the incentive for such publication of research would be removed. He analogized the underlying rationale of such a policy on the part of the journals to the Mapp exclusionary rule. Beecher seemed to believe that the medical profession with added education could mend its own house and further that legal intervention could unduly undermine lay faith in the profession to the bane of both physicians and society. What place then does the law have or should the law take in this area?

We have often heard the rubric that medicine is an art and not a science. Every dispensation of a drug can be characterized as an experimentation; every random use of alternative remedies can be likewise characterized; every use of volunteers to study for particular results which are not intended to accrue to the direct benefit of those subjects is again within the purview of experimentation. The term experimentation is subject to such semantic difficulties as to void the utility of its use without full definition. As a starting point I will characterize even the classical doctor-patient relationship as experimentation.

The physician is constantly open to attack on his basis of operation. When should he inform the patient or subject, and to what degree? In Hyman v. Jewish Chronic Disease Hospital, esteemed experimenters grafted live cancer cells onto ward patients, obtaining consent for this action without informing the patients that the cells involved "cancer." The experimenters were sure of the lack of possible danger and can only have feared that the use of the word "cancer" would prejudice the potential volunteer against the procedure. The experimenters arguendo can be taken truly to have thought the term cancer to have been irrelevant to the patient in terms of "informed consent." Other esteemed colleagues later attested to the correctness of the procedure. The experimenters were censured.

49 The relevant facts can be found in Hyman v. Jewish Chronic Disease Hosp., 21 A.D.2d 495, 251 N.Y.S.2d 818 (2d Dep't 1964), where a trustee of the hospital sought discovery of the hospital records to ascertain if any liability could possibly attach to the hospital. In the argument before the New York Regents Committee on Discipline one lawyer remarked, "If the whole profession is doing it how can you call it unprofessional conduct." Langer, 151 Science 663 (1966).
On the other hand, Jacob Markowitz, a New York trial judge, recently berated the medical profession for "'shifting the burden of its responsibilities to the courts'" in a situation where physicians were attempting to get a court order for a leg amputation. "Neither a physician nor a hospital" wrote the judge, "'should be deterred from the exercise of sound medical judgment with respect to necessary treatment merely by threat of possible legal action.'"

The physician on the one hand should not (or cannot justifiably) "arrogate unto himself" the position of ethical decision maker superior to societal dictates nor should he go to the courts thereby abdicating a responsibility implicit in his societal role. The physician is to be the paradigm of the existential man who dares not mistake the values of his society.

The problem of experimentation then requires a resolution of the conflict between individual responsibility, and environmental encroachments on that autonomy; it must attempt to safeguard individual rights without shattering societal precepts. Any distinction between experimentation and therapeutic intervention must revolve more on procedural methods for effectuating desired control than on inherent distinctions in the two concepts. Every intervention is necessarily experimental as to results at least; moreover, the entire range of human interrelationships can be conceptualized as experimentation. An adequate treatment of the problem requires an assessment of values which society is determined to uphold despite individual predilection. Conversely, a democratic government mythically is attempting to encourage notions of individual responsibility.

I start from a value premise then that all experimentation and intervention is permissible given informed consent. The burden of proving the right to intercede and "protect" is then made a heavy one for the government. It becomes blatant hypocrisy to extoll the virtues of physical and mental courage in almost all work and play aspects of society and then to proscribe the less "safe" side. Implicit within the recognition of complete responsibility is the ability to decide when to act in a manner which does not accord with society's general view of benefit. It is illusory to believe that government can remove the general impingement on the autonomy of perhaps a majority of the population. Yet we perpetuate the myth of personal responsibility. For equal protection reasons alone then, I hold that each man can commit his own personal brand of suicide as long as he does not encroach on the individual rights of others. When an experiment or intervention

might redound to the benefit of either the individual and/or the society, it becomes the individual's responsibility to decide whether or not to "volunteer" for such an experiment. Therefore, all adults prima facie can agree to any experiment. The only limitation I would place on an experiment is that it be carefully conceived and thought to be of potential benefit. The more serious the possible harm to the individual, the more searching the experimenter should be in undertaking the experiment or intervention, since his is a responsibility on a higher level. The experimenter, all legal liability aside, has the personal responsibility for the well-being of each subject or patient; he cannot be allowed to rationalize that he abdicates responsibility because of informed consent. Responsibility is a two way street.

The categories of subjects for experimentation include inter alia psychotics, mental defectives, the aged and infirm, prisoners, employees on experimental teams, and children. The key to a societal evaluation of the responsibility for experimentation or intervention purposes should not be the label attached to a particular class or individual but the ability of that individual to understand and consent to the experimentation upon him. Some psychotics, notably paranoid schizophrenics, probably are more self-protective and capable of resisting inducement toward experimentation than the so-called normal. The investigator should be charged with the duty of affirming the responsibility of any individual whose capacity is put into question prior to and after experimentation. This responsibility would continue into necessary aftercare for the subject. All doubts should be resolved against the experimenter whenever a challenge may accrue despite the results of an experiment. This is already an encroachment on the responsibility of the subject; however, it is a recognition of a higher responsibility on him who has conceived the experiment. Also the burden of showing

51 A New York State Senator recently made the following allegations on the senate floor. "Willowbrook State Hospital on Staten Island 'took 500 mentally retarded children, 3 to 9 years old, and injected them with a live hepatitis virus because officials wanted to start a hepatitis research program.'

"A 23 year old pregnant woman at Harlem Hospital recently underwent a hysterectomy to demonstrate the operative procedure to interns (sic) and residents.

"Harlem Hospital provides therapy for youngsters with congenitally deformed limbs 'except when interns and residents are being taught surgical procedure—they then the children are sent to surgery for removal of the limbs.'

"Five out of 1,000 alcoholics and derelicts taken to Bellevue Hospital died after the hospital took liver biopsies for its research program." N.Y. Times, Jan. 11, 1967, p. 1 col. 3.
responsible for the selection of subjects. All statements of consent to experimentation should be in writing, notarized, countersigned by the experimenter and one colleague not involved in the experiment, and witnessed by two other individuals (whose characteristics will be discussed in detail later on), all in the presence of the subject.

I would entirely disregard the issue of extreme rewards either in financial recompense or to prisoners in terms of good leave time, on the basic assumption of individual responsibility. Volunteering may be an act of courage or cowardice; it is undertaken by the consenting subject for motivations which he has a right to choose if he is at all capable of choice. The question of rehabilitation should be ignored as speculative at best and probably a red herring. We should frankly acknowledge that we are indulging constantly in a system of rewards, tangible or psychic, in encouraging any type of human action. Certainly dangerous prisoners can and should be precluded from bargaining for time off for experimentation. The only objection I can see to inducement of prisoner consent is that it may impede any movement toward shorter terms so as to "protect" a potential group of volunteers. Recognizing no rational justification for many prison terms anyway, I would proceed a step further and allow the convict an opportunity to volunteer for experimentation prior to imprisonment; any reward money which the experimenter may offer I would apply to any damage caused by the crime. Surplus money, which would be rare, would go to the convict's family or if he has no family to the state toward its expense for the administration of justice. The convict so released could still be kept under ambulatory supervision.

The aged and infirm present a difficult question not because of any imputed reduction in capacity but because of problems of communication. I would do away with any concept of "dying patients" because of the inherent difficulty of definition, because I would allow dangerous experiments even on normal consenting subjects and to "save" the experimenter from having to determine when the dying state could be invoked. This removes the dying patient somewhat as bait; it does not mean that he cannot volunteer. Again I would apply a strict standard of responsibility on the investigator.

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52 In the one case we speculate the fact of volunteering is evidence of rehabilitation, in the other we deem the act of volunteering one for reward; such reward thwarts the working of rehabilitative machinery on the involved prisoner.
with the same written, notarized and witnessed consent.

I must acknowledge the strong value judgment implicit in allowing dangerous experiments leading even to death with a strong caveat that the experiment potentially should be beneficial to the subject. First, I believe as stated in the individual right to suicide and that a man can be responsible, integrated and still choose this path. Euthanasia presents no problem either in the case of chronic, ceaseless pain. I do not see how serious experimentation can be undertaken without the possibility of death or severe deprivation. I do not state therefore that experiments should be designed so that death is inevitable, only possible. As a value judgment, however, I encroach upon my theme of responsibility and allow the subject to volunteer for such dangerous experimentation only where a physical benefit can accrue to him as a result of the experimentation. This is an explicit recognition of the value of life as held by society. It does not negate my stand on suicide or euthanasia in that such choice should remain a personal choice as much as possible removed from added inducement of societal benefit or personal rationalization. Society can recognize the individual right for self-destruction and even the possibility of dignity implicit within such an act. Society and medicine, however, must be committed to life, not to the further structuring of death. War would seem sufficient homage to Thanatos. Moreover, the logic of taking life to save life as part of a societally countenanced act escapes me. We can understand risk even of death where a tangible physical benefit can accrue. I do feel, however, that a good portion of the reason for restricting volunteering for death or serious bodily injury type of experiments lies in society's feeling of guilt and repugnance. I wonder furthermore whether those subject victims who have been extolled in the past are not lionized because of an innate societal uneasiness. The sacrifice to societal or my own personal uneasiness does not seem balanced.

The case of children presents yet another restriction on the hypothesis of responsibility. Undoubtedly some children do and can exercise as much judgment as an adult. Nevertheless, I would draw an arbitrary age of sixteen under which an infant could be used as a subject for experimentation only when he or someone in like condition could benefit physically or psychically as a result of the experiment, e.g., an experiment on retarded children designed to understand and ameliorate retardation. I would certainly not

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53 This would discard any relevant law which now proscribes euthanasia by competent medical practitioners for experimental purposes. The question of euthanasia presents ethical difficulties which I do not propose to explore for the purposes of this article.
MEDICAL EXPERIMENTATION

object to observational studies on children where no physical agent was introduced or no psychological trauma could occur. Here, I would demand consent from the responsible adult, i.e., a parent if the experiment were in school. My objection to general experimentation on children rests on the rather pedestrian assumption that children already living with a different reality, i.e., fantasies, may be particularly prone to trauma from experimentation. Moreover, by definition and clinical experience children have not sufficiently developed ego to withstand external pressure even granting sufficient insight. Further, we must acknowledge that children are most often drawn from institutions as subjects for experimentation. We want to circumscribe the potential abuse of these subjects through blanket permission from institutional authorities.

With these modest exceptions, there is a rather large population from which to draw volunteers. However, without statistical documentation I would assume that a disproportionate number of volunteers are drawn from classes not up to the mythical standard of responsibility which I am assuming to be rule rather than myth. If I carried the argument of universal responsibility to the logical conclusion there would be little need for state intervention. This would be particularly true since we must assume the competency and honesty of the medical profession. The one element which must be safeguarded above all else, if we are to give more than lip service response to the responsibility concept is consent. But consent as an extension of responsibility is just as much a myth as responsibility.

Consent to be viable must be a response to an understood action or explanation. Without understanding one cannot responsibly act. The significant differentiation I would make between experimentation and intervention would be in procedural aspects of acquiring informed consent. I would require the physician to whom a patient comes for treatment to inform the patient of the nature of the ailment and the risk of pain or harm in treating the ailment. The burden of responsibility would then shift to the patient to ask whatever questions he desired; all questions should be honestly answered. I require no greater burden upon the physician in this situation since I assume responsibility on the patient's part in selecting his doctor and I further assume that any lack of questions after the initial explanation of the nature of the illness and risk of harm and pain of the treatment can only mean that the patient does not want further information, a choice which is entirely his. The physician would still be answerable for negligence or malpractice for choosing a poor alternative treatment; this is to bolster the physician's medical responsibility. Serious innovative intervention
even in this situation should be submitted to a board which I will shortly describe. By serious I include only innovations (experimental interventions) which could lead to physical harm or suffering. Methods generally remain then the physician’s prerogative if not challenged by the patient. A failure to make even the initial explanation of the nature of the illness and risk of harm and/or suffering from the proposed treatment should be subject to tort sanction and professional reprimand apart from any negligence issue.

Whenever the patient-subject is sought as a volunteer for an experiment (and within this group I include any group of patients which is subdivided into a control group) I would increase the burden of procuring consent. I would include the control group type of experiment even where benefit is sought for the particular complaint of that group of patients to preserve a modicum of responsibility in the respective patient. In such a case an educated guess is at best involved. When the physician-experimenter is only guessing, the patient should have the right to make his own choice. Responsibility is not based on random numbers. We thereby somewhat safeguard institutional manipulation of patients into endless “experimental” situations. To repeat, even the division of a group into two sections using accepted alternatives and equally accepted procedures, using random numbers, would be an experiment.

I have already stated several times that I would require a signed, notarized, witnessed writing as an indication of consent. Such writing would not be probative of consent but merely a prerequisite for any experimental intervention on the patient. This signed writing shall state in nontechnical terms briefly the purpose of the experiment and the degree of harm mental or physical which can potentially be expected. Any judicially proved misrepresentation would be sanctionable in tort and by professional reprimand or licensing supervision with the writing being prima facie evidence of misrepresentation. Such misrepresentation would, of course, have to include such a concept as avoidance of knowledge, simple negligence as well as willful fraud. Moreover, oral explanation of the experiment should be made to the patient-subject before the signing witnesses and notary immediately prior to the signing. Any reward the patient-subject might be receiving should be indicated both orally before the witnesses and in the written consent. A subject can with only pro rata loss of reward withdraw from any experiment whenever he wishes unless he would be thereby endangered. A misrepresentation as to such danger would of course be sanctionable in tort and through licensing authorities.
The oral explanation to the patient-subject volunteer should include the purpose of the experiment in layman's terms so that the subject comprehends the purpose, e.g., "This experiment will help us to determine the efficacy of a particular remedy for streptococcal infection of the throat." I do not feel that there exists any potential experimental purpose which cannot be explained to a layman. If necessary, simple diagrams of human anatomy should be used. Moreover, the witnesses must indicate on the writing that they understand every aspect that the patient understands. At least one of the two witnesses should be in a subgroup in the following order of preference when possible: (1) an adult member of the patient's immediate family, (2) a relative, (3) a personal friend, (4) a private court-appointed attorney who has no connection with either the experimenter or the institution in which the experiment is to be undertaken. This would help to prevent any further duress, or loss of responsibility as through emotional reliance, as well as to apprise the experimenter of the fact of his own possible prejudice.

The oral examination and written report should include in addition to the purpose of the experiment a brief description of the method to be used and the risk of physical harm and personal discomfort. I would allow no experiment which was intentionally based on a misrepresentation necessary for the experimental outcome unless the patient-subject was apprised prior to the experiment that psychic trauma could result and that the experiment was dependent upon methods which might be based on deception. It would be up to the experimenter to correct the results for the effect of this prior disclosure. This could perhaps be somewhat alleviated by allowing one such consent for a sequence of psychological experiments. The subject-patient should be informed in such a case of any possible harm or discomfort from the total group planned. Again, of course, the subject-patient could withdraw at his volition. I would, moreover, require the use of any label as to disease or method which is popularly known with either good, bad or neutral connotation, e.g., cancer. This, I would require despite the fact that the experimenter may personally feel that the experiment is safe and that the popular label has only an emotional ring. I maintain that in any case where the patient subsequently discovered that he took part in an experiment which held a loathsome connotation to him, such discovery possibly causing great psychic anguish as well as perhaps psychosomatic symptoms, the subject-patient has the right to exercise any personal prejudices no matter how unfounded in fact.

Once the experimenter has framed his experiment I would require the submission of his protocol to a selected board which I
will immediately outline. The submitted protocol should include the purpose of the experiment, the method to be used, the number(s) and type(s) of proposed subjects and the expectations for results on which the experiment is based. Also included on the protocol should be a summary of similar types of experiments, results and differences between past experiments and the instant experiment. This information could be obtained by the experimenter through a federal clearing house office similar to the Patent Office to which all protocol must be submitted. The function of the federal agency would be confined to categorization and dissemination upon request of submitted protocol. Failure to submit a protocol either to the board or the federal clearing house would be sanctionable.

The prime function of the board would be educational, i.e., to apprise the experimenter of any perceived difficulties, shortcomings or necessary alterations in the protocol. The board shall make a recommendation and keep protocol, changes in the protocol by the experimenter if any, and the board's own report on file as public records. The entire file will be admissible into evidence in any subsequent action either in the court or before a professional discipline committee; the file shall not carry any prescription for or against the experimenter except for its inherent persuasiveness. In this way I feel that the experimenter can be apprised of any defects, e.g., failure to provide adequate after-care in his protocol, and still continue after the board's rejection if he is willing to assume complete responsibility. Moreover, the experimenter cannot escape responsibility through the board's unreserved acceptance although undoubtedly the report will have weight depending on its thoroughness, fairness and competency.

The board shall be composed of members of the following description: (1) an expert in the particular field of the experiment (even if he must be drawn from a different locale), (2) a medical doctor from each institution in the area, (3) a court-appointed attorney, (4) a court-appointed layman from an academic field, i.e., board of education or university official, (5) a psychiatrist from one institution in the area sequentially. Each board member will serve a two year term with no more than two new members in a given year. Each board member will be charged with the obligation of writing an individual report indicating reasons for and against the experiment in any necessary respect and a conclusion as to the justifiability of the experiment in the last form submitted to the board.

I would not make board members sanctionable generally in tort or criminal law for faulty reports. Of course, conspiracy statutes would be applicable. Board members would be open to dis-
medial experimentation for incompetent reports on review of the courts from a peti-
tion by an interested party, including the other board members, the experimenter, the subject-patient's kin and any other petition on discretion of the court, e.g., hospital attorney, district attorney. Board members, moreover, would be open to professional sanctions, i.e., disbarment, license suspension. Any movement against a board member, of course, would have no effect per se on the responsibility or lack thereof of the experimenter.

The board then assumes the delicate task of educating the experimenter with particular emphasis on ethical considerations. The investigator, of course, can be discouraged by board action, but the final decision of whether or not to proceed belongs to him. Since individual reports will be presented by the board members, the experimenter will be able to weigh the various criticisms according to his own value judgments and thereby determine the validity of the majority position (rather than being subject to a mere majority-minority vote). By keeping records we safeguard any future remedies of patients who have not consented as explained before as well as any official judgment concerning the merits of the experiment. We have, moreover, opened up the greater possible number of experimental volunteers who, dependent upon individual capacities rather than group labels, can derive benefits psychic or financial from experimentation which may now be blocked to them. Certainly abuses will continue. The presence of reviewable records, however, will after a time allow the firming up of any flaws in the system and hopefully minimize the real potential flaw—human perspective and operation.