THE ROLE OF LAW IN MEDICAL PROGRESS

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Medical science expands at an ever accelerating rate. Kidney transplants are now almost commonplace; over 1000 of them have been performed in the last dozen years. Liver and heart transplants are making current headlines; the lung may be next. Radioisotopes are used for both diagnosis and therapy. The mechanism of human heredity is increasingly an open book. Cardiac catheterization is everyday business, and management of malignancy is constantly on the upgrade. Medical research has opened these and other new vistas, and better things are doubtless just around the corner. Modern medicine is indeed frontier business.

At the same time legal science—or should it be called an “art”?—is also constantly encountering new frontiers created by the continuing scientific and technological revolution. Nuclear substances are giving rise to new legal problems. Supersonic transports will soon carry us from New York to Tel Aviv in three hours, and their sonic booms are certain to have impact on the law. Electronic devices are leaving us with diminishing privacy and ultimately may penetrate the inmost thoughts of man. Modern medicine gives birth to new legal problems. The law and lawyers will be forced to play a significant role as the new order continues to unfold.

In this article we propose to examine one of these frontiers—medicine and law—to attempt an evaluation of the possibilities of law-medicine cooperation in finding helpful solutions for the future. Such interprofessional cooperation, while seemingly an obvious prerequisite of progress, cannot be taken for granted, for much disharmony and mutual mistrust exists between the professions. Medical malpractice suits in courts of law, the agonies of the expert medical witness on the stand, the federal restrictions on the use of investigational drugs, and various other encounters with the law have created in the minds of many doctors an image of law and lawyers that is far from complimentary. On the other hand, members of the legal profession are well aware of some of the medical profession's less appealing aspects—for example, some doctors' violent antipathy to “Medicare” and the problem sometimes characterized as the “conspiracy of silence” which makes it so difficult to get professional expert testimony in a malpractice suit against a defendant doctor. As a consequence of these and other abrasive contacts between the two professions, and notwithstanding the many thousands of fine personal friendships and much

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The author acknowledges with appreciation the assistance of the editors, who have added to this article, written in the late summer 1967, the many more recent decisions and other developments in the fast moving field of medico-legal relations.

mutual admiration, there is found in each profession an unfortunately high degree of disrespect for the other calling, which seriously handicaps the necessary processes whereby the law impinges on medical practice.¹

In the course of a recent lecture, Dr. Charles G. Child III, Professor of Surgery and Chairman of the Department of Surgery in the Medical School of the University of Michigan, approached this problem of professional dichotomy with candor and perspicacity.² After psychoanalyzing the two professions and identifying their differences, Dr. Child pointed out basic disparities in the personality and education of members of the two professions. Then he observed:

In my opinion, the adversary method of administering justice may very well be the single most important deterrent to cooperation between law and medicine in the conduct of malpractice actions. This procedure is so ill-suited to any reasonable medical ends that its use engenders not only hostility but also reflects as well a conscious withdrawal amongst the medical profession. Few indeed have been the important issues in medicine that have been resolved by controversy and dispute.³

Dr. Child further contrasted medicine, with its scientific method and objective inquiry into facts, and the law, with its Socratic method which etches clearly things supposed to be derived from the past by rational beings. The thought processes of the two professions, he said, are so different that they do not readily merge in attack upon specific problems. Finally, Dr. Child noted that the slow pace and the delays in legal proceedings keep the doctor, whether a party or a witness, away from his patients and that even life itself may be adversely affected. In short, Dr. Child offers much food for thought for one seeking to explore "the role of law in medical progress," as we are doing in this article.

Notwithstanding the difficulties that Dr. Child suggests, we now proceed to look more closely at the various facets of the law-medicine relationship. Law and medicine meet in many areas. The role of law will, we safely predict, be one of increasing significance in the future of medicine.

I

POSSIBLE AREAS OF CONTACT BETWEEN LAW AND MEDICINE OF THE FUTURE

To approach our task of considering the role of law in the medical future we will help orient ourselves by first surveying the larger scene. This will give an

¹ The American Medical Association has taken a constructive interest in medical professional liability. Since 1954 the Law Department of the Association has made a continuing study of the subject. In 1957 a series of twenty-one articles was published in the *Journal of the American Medical Association*, dealing with nearly all aspects of the matter. A bi-weekly publication, *The Citation*, is currently issued by the Law Department. Now in its fourteenth volume, this publication acquaints the medical profession with the many pitfalls of the law.

² Child, *Lawyers, Doctors and Medical Malpractice: A Surgeon Reacts*, in *MEDICAL MALPRACTICE* 43 (Institute of Continuing Legal Education, Ann Arbor, Mich., 1965).

³ *Id.* at 47.

impression of the wide dimensions of the matter before we get down to the task of more careful examination of the role of law in dealing with a few subjects we have chosen for closer inspection.

Areas of interaction between law and medicine in the future will include at least the areas delineated in the fourteen ensuing paragraphs:

(1) *Psychiatry and the law.* The understanding of psychiatrists concerning mental illness and its treatment do not mesh satisfactorily with the rather more primitive precepts of the criminal law. The debate goes on not only over the various possible definitions of criminal responsibility, but also over the procedures whereby mental incompetents are committed for treatment and the sufficiency of the treatment given such persons to justify deprivation of their liberty in the absence of due process of law. The future holds the potential for unlimited development in this field as psychiatric techniques improve, as more funds are channeled into this needy area, and as law adapts its rather clumsy institutions to the subtle problems of coping with mental illness in an increasingly anxiety-inducing society.

(2) *Alcoholism.* Alcoholism has been called the nation's fourth most serious health problem, affecting some 6,000,000 persons, many of whom are potentially highly productive but are handicapped by compulsive drinking. Courts are beginning to hold that chronic alcoholism is not a crime but a disease.⁴ Doctors must participate in working out changes in the laws and in setting up centers for the treatment of alcoholism.⁵

(3) *Narcotics offenders.* A "pusher" is a criminal; a user of narcotics may not be a criminal but a person needing medical aid whom the medical profession should be free to treat.⁶ The law and medicine must cooperate to provide the opportunity and the means for effective treatment.⁷

(4) *Population control.* This is a controversial matter. The Supreme Court has provided protection from legislative intrusion for families wishing to practice birth control.⁸ The more difficult and pressing problem is how the population explosion is to be kept within bounds. Family planning and birth control advice and equipment are a small step, it would seem, though religious pressures still inhibit full efforts in these areas. Economic disincentives to reproduce may be utilized in the future as well.

⁴ Compare *Driver v. Hinnant*, 356 F.2d 761 (4th Cir. 1966) and *Easter v. District of Columbia*, 361 F.2d 50 (D.C. Cir. 1966) with *Application of Spinks*, 61 Cal. Rptr. 745 (Ct. App. 1967).

⁵ See generally Kupferman, *Treatment of Alcoholism Must Change With Times*, TRIAL, Aug.-Sept. 1966, at 49-50.

⁶ A statute punishing the "status" of drug addiction is cruel and unusual punishment in violation of the eighth and fourteenth amendments. *Robinson v. California*, 370 U.S. 660 (1962). California courts have found involuntary commitment imposed on the addict for purposes of treatment, as opposed to punishment, to not constitute cruel and unusual punishment. *In re Trummer*, 60 Cal. 2d 658, 381 P.2d 177, 36 Cal. Rptr. 281 (1964).

⁷ See generally W. ELDRIDGE, *NARCOTICS AND THE LAW* 118-25 (1962).

⁸ *Griswold v. Connecticut*, 381 U.S. 479 (1965).

(5) *Genetics*. A gradual movement toward premarital genetic testing and counselling may be expected as a means of minimizing birth defects and other hereditary maladies. Presumably the day is much farther off when law will attempt in any direct way to control the eugenic development of the population.

(6) *Artificial insemination*. Changes in the law will be necessary to assure legitimacy of births resulting from such procedures. Also, damage suit possibilities are present in the absence of informed consent, as well as in instances of breach of secrecy. Finally there are innumerable questions raised concerning relations in the family, such as grounds for divorce, child support, and inheritance rights.⁹

(7) *"Medicare."* This was one of the most controversial pieces of legislation of the decade because of the alleged trend toward "socialized" medicine, but seemingly the bureaucratic machinery is in fair working order today and is increasingly approved by laymen and by doctors. The influence of this law on the practice of medicine and quality of medical care is as yet incalculable. The guidance of the new administrative influences in the right directions is one of the paramount challenges in medical-legal affairs today.

(8) *"Medicaid."* This is the important extension of Medicare to low-income families under Title XIX of the Social Security Amendments of 1965.¹⁰ It has disturbed many doctors and the budget makers in many states, but it is likely to be with us for a long time and to influence greatly the over-all quality of medical care provided in this country, where, incidentally, high infant mortality among the poor is a national disgrace.

(9) *"Good Samaritan" laws*. These are widely sought by the medical profession and are already on the books in thirty-two states. They limit malpractice actions against physicians who offer to help injured persons under emergency conditions, especially on the highways. Carefully collected statistics indicate that seldom does a good Samaritan action succeed and that there is not too much for doctors to fear.¹¹ But apprehension persists, and legal protection may be justified to prevent needed assistance from being withheld. The argument for legislation might be even stronger if the law were construed to create an affirmative duty to render such assistance.

(10) *Computers*. It may happen a decade hence, but someday diagnosis and treatment that does not include retrieval of relevant data from the memory of a computer will be deemed to fall short of the familiar standard, the practice of reputable physicians in the community.¹² Other uses of computers will likewise speed medical progress and improve the quality of medical care.

⁹ See generally Verkauf, *Artificial Insemination: Progress, Polemics, and Confusion—An Appraisal of Current Medico-Legal Status*, 3 HOUSTON L. REV. 277 (1966).

¹⁰ §§ 121-22, 79 Stat. 343 (codified in scattered sections of 42 U.S.C.).

¹¹ Plant, *"Good Samaritan" Laws in Legal Dilemma*, TRIAL, Oct.-Nov. 1966, at 34.

¹² See generally McGraw & McGraw, *Automating Medicine*, SATURDAY REVIEW, Oct. 7, 1967, at 66-69. See also Freed, *Legal Aspects of Computer Use in Medicine*, in this symposium, p. 674.

(11) *Homotransplantation*. The process of removing a part from one human body and implanting it in another is among the most dramatic of medical feats. Blood, skin, bone, and kidneys have been transferred from one living person to another, and corneas, kidneys, the liver, and, most dramatically, the heart have been salvaged from the dead. The legal questions are many.

(12) *Abortion*. Most abortion laws date from the nineteenth century. They contain prohibitions that conflict with the twentieth century's demands and with the judgment of most members of the medical profession.

(13) *Patient consent to therapy*. Informed consent is a new facet of malpractice and assault and battery now emerging in legal actions to add to the medical profession's exasperation with the law.

(14) *Subject consent to human experimentation*. The vast increase of medical research is assuredly for the benefit of mankind, but the necessarily increasing use of human research subjects is creating special problems with respect to which improved cooperation and understanding between law and medicine are clearly needed.

In the remainder of this article we shall direct more detailed attention to only the last four of the topics named, namely homotransplantation, abortion, patient consent to therapy, and subject consent to experimentation. From these we will try to draw some conclusions concerning the role of law in medical progress.

II

TRANSPLANTATION OF HUMAN TISSUES¹³

A. Technical Aspects

What will be the role of law in homotransplantations? Human bodies and human tissues are used in many aspects of medical science, and the use increases year by year, especially as knowledge advances with respect to immunology and rejection of foreign tissues. Human bodies and parts thereof are used in teaching, research, and transplantation. Whole bodies or their parts are dissected in teaching and research laboratories. Transplantation of parts under existing surgical procedures frequently involves skin, bone, blood, corneas, arteries, kidneys, and in recent months even the human heart. The pituitary glands are removed to recover hormones for medical uses. Even the liver has been transplanted, and in the future the lung and other vital parts may be subject to transfer from one body to another. Both living and nonliving donors are used.

These procedures are becoming increasingly numerous and important as medical science progresses from year to year. It is reported, for example, that there have been over 1000 kidney transplants performed in the world in the last thirteen years, with seventy-five per cent of them in the last five years. Transplants from living

¹³ For a wider ranging treatment of legal and medical issues involved in organ transplants, see Stickel, *Organ Transplantation in Medical and Legal Perspectives*, in this symposium, p. 597.

relatives have been sixty-five to seventy per cent successful. Cadaver transplants have been about forty per cent successful.¹⁴ Unfortunately there is a shortage of available kidneys. It is said that renal transplants may, in due course, if sufficient supply becomes available, save from 6,000 to 10,000 lives per year in the United States alone.

The potential supply of transplantable parts would actually exceed the demand if full utilization could be made of nonliving donors, but there are problems to be solved. There is the matter of logistics, which is indeed formidable. With a living donor in the next room, there is no great problem, but with a nonliving donor, time is of the essence. For a few minutes after death cellular metabolism continues throughout the majority of the body cell mass. Certain tissues are suitable for removal only during this brief interval, although improvements in storage and preservation may permit a short delay in actual implantation in the recipient. Cadaver tissues are divided into two groups according to the speed with which they must be salvaged. First, there are "critical" tissues, such as the kidney and liver, which must be removed from the deceased within a matter of thirty to forty-five minutes after death.¹⁵ On the other hand, certain "noncritical" tissues may be removed more at leisure. Skin may be removed within twelve hours from time of death. The cornea may be taken at any time within six hours. The fact is, however, that in all cases action must be taken promptly to make use in a living recipient of the parts of a nonliving donor, and this gives rise to legal problems. There is but little time to negotiate with surviving relatives, and waiting for the probate of the will is out of the question.

B. Legal Aspects

As previously noted, transplantation may take place either from one living person to another living person or from a dead person to the living. In the former case, all that is required is the appropriate written and witnessed "informed consent," which will be discussed later in this article, authorizing the surgical removal from the donor and the implantation in the recipient. If utilization of all or any part of the body after death is intended, the matter becomes more complicated both in fact and in law.

The complications arise from the variety of interests in the dead body. The deceased naturally had an interest in his body during his lifetime, and any expression of his wishes as to its post-mortem disposition may or may not be effective, depending upon the local law. After death, the surviving spouse or, if none, the surviving

¹⁴ Murray, Barnes & Atkinson, *Fifth Report of the Human Kidney Transplant Registry*, 5 *TRANSPLANTATION* 752, 774 (1967).

¹⁵ After removal, the tissues can be preserved for six hours or so when stored at 5°C., and for even longer periods if continuously perfused with a proper blood and salt solution. This and other technical aspects of transplantation are discussed in Couch, Curran & Moore, *The Use of Cadaver Tissues in Transplantation*, 271 *NEW ENG. J. MED.* 691 (1964).

child or parent or other relative has an interest that must be recognized and dealt with. Primarily this is an emotional interest connected with the dignity of the disposition of the body. Finally, the public has an interest, as, for example, in finding the cause of death by autopsy when suspicious circumstances are involved.¹⁶ Also, the public interest includes having available a sufficient number of bodies and parts of bodies to satisfy the needs of teaching, research, and therapy.¹⁷

These various interests in the body, some of which conflict with others to a greater or lesser extent, give rise to a number of troublesome points of law. The first revolves around the possession of rights in the dead body. Who possess such rights and what are they? Common law principles, originated in the seventeenth century in the English ecclesiastical courts, announced the concept that there are no "property rights" in the ordinary sense in the dead human body. This principle was carried into the common law courts in the latter part of the seventeenth century.¹⁸ In general, the private rights, such as they are, that exist respecting a dead body involve the assurance of a dignified treatment of the body and a decent burial. The rights belong first to the surviving spouse, then to the children, and finally to the next of kin, in that order, unless the statutes specifically provide otherwise.¹⁹ Moreover, the person who has the right to possession is entitled to receive the body in the same condition as when death occurred, unless this right is modified in some manner as provided by law. He can recover damages from anyone who performs an unauthorized autopsy on the body, or who mutilates it, or dissects it, or removes or keeps parts without his consent.²⁰ In view of the foregoing it is clear that any interest possessed by the survivors must be reckoned with. Before the surgeon undertakes a transplant, he must, unless the deceased has made a valid ante-mortem gift, negotiate with them to obtain consent. Moreover, time for so doing is limited.

A second legal question of significance in connection with human transplants is whether or not a person during his lifetime can make a legally effective gift of his body or a portion thereof to be carried out after his death, either by giving it to a named donee or to a specified hospital or to any person in need. Will such gift be

¹⁶ Statutes in all states provide for autopsies by the coroner or medical examiner, who is given authority to proceed even against the wishes of the relatives.

¹⁷ This interest of the public has been manifested by the adoption of statutes in about 80% of the states providing for the delivery of unclaimed bodies to medical schools for dissection in the teaching of anatomy and physiology and for medical research. There is always an inadequate supply of such bodies, especially at the present time with the generous burial provisions available through public bounty. In any event, since these bodies are usually embalmed and are normally released long after death, they are of no value for organ transplantation purposes.

¹⁸ See generally Vestal, Taber & Shoemaker, *Medico-Legal Aspects of Tissue Homotransplantation*, 18 U. DET. L.J. 271, 273 (1954). The authors have set forth an extensively documented statement of the legal background.

¹⁹ *Larson v. Chase*, 47 Minn. 307, 310, 50 N.W. 238, 239 (1891).

²⁰ The monetary damages may not be great. \$3,000-5,000 seems to be about enough to assuage the usual plaintiff's grief, although some verdicts are larger. See *Patrick v. Employers Mut. Liab. Ins. Co.*, 233 Mo. App. 251, 118 S.W.2d 116 (1938); *Phillips v. Newport*, 28 Tenn. App. 187, 187 S.W.2d 965 (1945). The principal damage often takes the form of injury to the public repute of the defendant surgeon. This can be serious.

a nullity if survivors object, or will it take precedence over the wishes and burial rights of the survivors? According to the common law any such attempted ante-mortem gift could be repudiated by the next of kin, and this is still the law in at least a dozen states.²¹ In certain other states there is at least uncertainty with respect to the application of the common law. Therefore it is clear that if transplants are to be facilitated on any reasonably satisfactory and universal basis, there must be specific statutory authorization of such ante-mortem donations, which must prevail over contrary desires of survivors. The doubt must be eliminated, and those who act in good faith in reliance upon an antemortem authorization must be protected.

Because of the desirability of removing all doubt with regard to the effectiveness of ante-mortem consents, upwards of thirty states have in recent years, especially since about 1950, adopted statutes dealing with the subject in some manner, the majority of these laws being to some extent inadequate; several states have adopted statutes authorizing donation of corneas or eyes alone.²² Because of this lack of uniformity in the statutes, there is a choice of law problem which may arise when the domiciliary of one state dies in another state, having made a gift of his organs in one or the other or even in a third state prior to his death.²³ Few of the statutes cover the details of execution, delivery, and possible revocation of agreements of gift, and some of them fail to include specific exculpatory provisions protecting surgeons, hospitals, and others from embarrassing complications if some of the survivors are dissatisfied.²⁴

²¹ Couch, Curran & Moore, *supra* note 15, at 693.

²² The Law Revision Commission of New York has recently presented a report to the New York State Legislature recommending a comprehensive statute to replace the present statute which authorizes only gifts of eyes. The report includes an analysis of the laws of all the states. See N.Y. LEGIS. DOC. (1964) No. 65D.

²³ If the donor dies outside his state of domicile, a conflict in the choice of state law may arise when the law of the state of death is contrary to the law of the donor's domicile. One example would be where the law of the state of death authorized the donation, and the law of the state of domicile did not. Practically speaking, the question would be whether the next of kin could sue the doctor removing the donated organ contrary to their wishes, and thus effectively prevent the removal in the state of death.

Traditional application of the law of conflicts on testamentary disposition might result in application of the law of the domiciliary state. If, however, the interests served by the respective statutes in this problem are analyzed, the law of the state of death should prevail. Recipients benefited by such donations will reside in that state, and by enacting an authorization statute, the legislature has expressed a concern for their benefit and a desire to encourage progress in medical science. The state of domicile, on the other hand, is concerned with the interests of next of kin and wants to prevent the practice of organ removal by the medical profession through the prospect of a civil action being filed by the next of kin against the physician.

As a practical factor, physicians should not be responsible for compliance with the law of innumerable jurisdictions and for the resolution of conflicts with the law of their own state. A standard which consistently applies the law of the state in which death occurs will enable the doctor to act with the necessary promptness, provided, of course, that the state has enacted the requisite authorization statute.

²⁴ Gift of human tissue statutes are found on the books of the following states: Alabama, Alaska (eyes only), Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine (eyes only), Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey (eyes only),

From the foregoing discussion it becomes apparent that the proper shape of a state statute authorizing and effectuating ante-mortem gifts of human tissue should, among other things, make provision for the following:

1. Who may execute a valid ante-mortem gift of his own body or a portion thereof? Many statutes provide that anyone "competent to make a will" may do so.

2. Who among the survivors may make a gift, either post-mortem or just prior to death? The statute should set up the authorized order of priority among survivors.

3. To whom may human tissues be donated? Black-market tissue banks are not to be desired, and therefore potential donees must be carefully identified.

4. What is to be the manner of execution of gifts? Is it to be by will or by some other document? And what are to be the formalities of execution? Provision should be made for a simple form of document, with preference for a small card to be carried on the donor's person evidencing the gift.

5. Gifts should be permitted either to a specific donee or to a specific hospital or, in general terms, to anyone in need for an authorized purpose.

6. Since time is of the essence, probate should be expressly eliminated. If a specific donee is named and is not reasonably available, the attending physician at death or immediately thereafter should be authorized to act in reliance upon the card evidencing the gift. He should act as the agent of the donee with all of the powers of the donee to use the gift for any authorized purpose as he deems best.

7. Revocation of the gift should be permitted in case the donor changes his mind at the last minute.

8. Liability for damages should be negated in every case of good faith reliance upon a gift without notice of revocation.

The National Conference of Commissioners on Uniform State Laws is currently engaged in drafting a Uniform Anatomical Gift Act that will meet the foregoing specifications. It will, when approved in final form, probably during 1968, be promulgated as a uniform act and recommended for adoption by all of the states. The act is currently being drafted with the cooperation and assistance of many doctors and their organizations as well as the lawyer members of the National Conference. The cooperative review by both professions should assure a satisfactory solution.

The uniform act should meet with ready acceptance by state legislatures, and, when adopted, it will certainly clarify many of the doubtful legal aspects with

New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, Washington, West Virginia (eyes only), and Wisconsin. For purposes of comparison the following are interesting: Ontario, Stats. 1962-63, ch. 59; Italy, Presidential Decree of June 26, 1967, [1967] *Gaz. Uff.* 3478; France, Decree No. 472057 of Oct. 20, 1947; and Regulations of United Kingdom, Human Tissues Act 1961.

respect to transplantation. It will facilitate taking advantage of modern medical and surgical developments for the benefit of those in need of corneas, kidneys, or other spare parts. Finally, the act will illustrate one aspect of the role of law in medical progress: an influential national legal organization will have undertaken to adjust the statutory law of the fifty states to accommodate a significant medical frontier—homotransplantation.²⁵

III

ABORTION

A. State Statutes Dealing with Abortion²⁶

Abortion is another area of medical concern where the law plays an important role. Most state abortion laws are highly restrictive. They were enacted in the nineteenth century and have been largely unchanged even in those states that have recently enacted new criminal codes. Although the statutory language differs slightly from state to state, the practical effect in most states is that abortion is a felony except when necessary to save the life of the mother. There are many detailed variations in the laws. For example, some states permit only a physician or surgeon to terminate a pregnancy; others permit anyone to do it if under legally justified circumstances. Many statutes purport to require that the abortion be absolutely necessary to save the life of the pregnant woman, while others, such as New York's,²⁷ are satisfied if the surgeon has a reasonable belief that such a necessity exists; other states, including Massachusetts, New Jersey, and Pennsylvania,²⁸ simply prohibit performing an abortion in broad terms qualified by language like "unlawfully" or "without lawful justification." Some states require consultation with one or more other physicians before operating. The statutes of Alabama, Maryland, New Mexico, and the District of Columbia²⁹ legalize abortions if necessary to protect the health, as well as to save the life, of the mother. In short, the statutes in the several states purport to set up an almost nationwide barrier to abortion. However, as in other areas, the law encounters the frailties of human nature, and the intentions of the framers of the statutes are not fulfilled.

²⁵ The first draft of the proposed Uniform Anatomical Gift Act was given a careful review at the 1967 Annual Meeting of the National Conference held in Honolulu, July 30-August 5. After revision, the measure will be reconsidered and possibly adopted at the 1968 Annual Meeting to be held in Philadelphia in August 1968. The Chairman of the National Conference committee who is the principal draftsman of the uniform act is the author of this article.

²⁶ See generally George, *Current Abortion Laws: Proposals and Movements for Reform*, 17 W. RES. L. REV. 371 (1965). In this article Professor George analyzes all of the state statutes in detail and with extensive citations.

²⁷ N.Y. REVISED PENAL LAW §§ 125.05, .40, .45 (McKinney Supp. 1965).

²⁸ MASS. GEN. LAWS ANN. ch. 272, § 19 (1956); N.J. STAT. ANN. § 2A:87-1 (1953); PA. STAT. ANN. tit. 18, § 4718 (1963).

²⁹ ALA. CODE tit. 14, § 9 (1958); MD. ANN. CODE art. 27, § 3 (1957); N.M. STAT. ANN. §§ 40A-5-1, -3 (1953); D.C. CODE ENCYCL. ANN. § 22.201 (1967).

Notwithstanding the generally uncompromising prohibitions of the law, there are estimated to be up to 1,000,000 abortions performed each year in this country,³⁰ most of them being illegal and carried out under hazardous conditions. There are, of course, no available sources for accurate statistical count. Some say that the total falls substantially short of the number stated though it is obvious that the activity is widespread. It is also frequently claimed that as many as 10,000 deaths occur each year from illegal abortions, although again some say that this figure is probably far too high and that the actual number may be as low as 500. Again accurate statistical information is not available.

It is known, however, that about 10,000 abortions are performed each year in ostensible accordance with the law. These abortions are carried out in hospitals with proper surgical supervision and for more or less proper medical reasons. There is no record of a criminal conviction as a result of an abortion carried out under these conditions even though there are reasons to believe that physicians have not strictly observed the statutory tests of legality.³¹

Professor B. James George, Jr., a codraftsman of the proposed revised criminal code in Michigan, has conducted a comprehensive survey of all of the state statutes on the subject.³² He takes note of the fact that the present statutory restrictions force many women to turn to unqualified operators with all of the hazards inherent in their procedures. He comments on the over-all effect of the present laws in the following manner:

To continue the present restrictive laws on abortion is to purchase the illusion of security at considerable human loss. Enforcement of criminal statutes in their present form may accomplish about all the protection possible against untrained abortionists, but with corresponding disadvantages which perhaps more than offset the gains. These disadvantages are the harassment of the medical profession by zealous prosecutors, and the creation of intolerable tension in the doctor who is torn between his desire to perform an abortion, which he believes to be necessary on humanitarian grounds, and his fear of performing it because it is illegal.³³

The doctor's dilemma noted here is the central factor in the tentative reforms that have been accomplished in recent months.

³⁰ Sands, *The Therapeutic Abortion Act: An Answer to the Opposition*, 13 U.C.L.A.L. REV. 285 (1966). But cf. *Rewriting the Law on Abortion*, MEDICAL WORLD NEWS, Sept. 29, 1967, at 46, 52.

³¹ See generally Sands, *supra* note 30; *The Law of Therapeutic Abortion: A Social Commentary on Proposed Reform*, 15 J. PUB. L. 386, 393-95 (1966). For a critical discussion of therapeutic abortions performed for "psychiatric reasons," see White, *Induced Abortions: A Survey of Their Psychiatric Implications, Complications, and Indications*, 24 TEX. REPORTS OF BIOLOGY AND MEDICINE 531 (1966). The California Board of Medical Examiners reprimanded one physician and placed a second on professional probation for violations of the state's law, which, even after a recent liberalizing amendment, does not legalize an abortion performed because of probable fetal deformity. N.Y. Times, Feb. 15, 1968, at 32, col. 8.

³² George, *supra* note 26.

³³ *Id.* at 402.

B. Views of the Medical Profession

The medical profession is divided on abortion, but the great majority of doctors currently favor liberalization of the laws. In February and March of 1967, *Modern Medicine* conducted a survey of the profession in which 40,089 questionnaires were returned. Liberalization was favored by 94.6 per cent of the psychiatrists, by 83.7 per cent of the obstetricians and gynecologists, and by 86.9 per cent of all categories.⁸⁴ The Roman Catholic Church has been consistently opposed to liberalization, but 49.1 per cent of the doctors responding who identified themselves as Catholics answered that they were in favor of broadening the grounds for abortion.

All doctors subscribe to the Hippocratic oath, the relevant section of which appears to frown upon tampering with the processes of nature: "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong doing. . . . I will not give to a woman a pessary to cause abortion. . . ." Notwithstanding the oath and the legal limitations in the statutes, members of the medical profession, who necessarily come into close contact with the tragic side of pregnancy as well as the happy side, are strongly committed to liberalizing the existing restrictions of the law.

C. Philosophical and Legal Views on Abortion

Mention has been made of the opposition of the Roman Catholic Church. It is widely believed that abortion has always been forbidden by the Church, but this is not borne out by history. Down to the reign of Pope Sixtus V (1585-90) termination of pregnancy was permitted within the first eighty days of pregnancy. Sixtus banned all abortions, but was reversed following his death by Pope Gregory XIV, who declared abortion illegal only after the fetus quickens. Not until 1869 did the Church, through Pope Pius IX, revive the strict doctrines of Sixtus, and these doctrines remain in effect to the present day. The Church is currently the most effective opponent of liberalization, though many Protestants take equivalent positions. Curiously, public opinion surveys indicate that lay Catholics and non-Catholics are not far apart in their views on abortion.⁸⁵

As of the present time views concerning liberalization of abortion laws range throughout a wide spectrum. There are at least three widely divergent views, with many minor variations of each. The three views are these:

1. *Abortion is a form of murder.* First, there are those who line up with the Catholic Church and regard any interruption of a pregnancy as a crime, as murder. This position is grounded upon the view that the fetus is a human life from the

⁸⁴ 29.1% favored abortion for illegitimacy, and 26.6% favored abortion for socioeconomic reasons. *Abortion: The Doctor's Dilemma*, MODERN MEDICINE, April 24, 1967, at 12, 13.

⁸⁵ Brody, *Abortion, Once a Whispered Problem, Now a Public Debate*, N.Y. Times, Jan. 8, 1968, at 28, col. 5.

moment of conception and that to destroy it wilfully cannot be justified except when the mother's life is clearly jeopardized.³⁶

2. *Abortion should be a matter of free choice.* At the opposite extreme are those who believe that the doctor should be given freedom to act subject only to the usual professional restraints; such a position would, of course, license the would-be mother as well, since she would have no difficulty locating a willing doctor. An especially radical position is that of the American Civil Liberties Union of Southern California, which contends that under the constitutional right of privacy established by the Supreme Court in *Griswold v. Connecticut*,³⁷ the birth control case, it is for each individual to determine when and whether to produce offspring.³⁸ Thus they would argue that the present laws outlawing abortion are unconstitutional.

3. *The Model Penal Code provision on abortion.* In between the foregoing extremes are those who take an intermediate position along the lines of the provisions of the Model Penal Code, which was drafted by the American Law Institute after ten years of study and is now ready for consideration by state legislatures. The Code penalizes as a felony an unjustified termination of pregnancy and defines the occasions for justification as belief that

there is substantial risk that continuance of the pregnancy would gravely impair the physical or mental health of the mother or that the child would be born with grave physical or mental defect, or that the pregnancy resulted from rape, incest or other felonious intercourse. All illicit intercourse with a girl below the age of 16 shall be deemed felonious.³⁹

Under the Code the operation must be performed by a licensed physician in a licensed hospital, and at least one other physician must join in a written certificate setting forth the justifying circumstances.

This proposed liberalization of the abortion laws is a rather conservative compromise position that would, in fact, have but little effect on changing the present status of illegitimate pregnancies or those of married couples who merely wish relief for social or economic reasons. It is possible that it would do little more than codify current practices of legitimate medical practitioners.

D. Impact of the Model Penal Code

The Code is already having substantial effect on current thinking in regard to abortion laws. First, we note that the American Medical Association House of Delegates, on June 21, 1967, voted to approve an official Association position allowing abortions substantially in accord with the recommendations in the Model Penal

³⁶ See, e.g., Harrington, *Is Abortion a Crime?*, TRIAL, June-July 1967, at 42.

³⁷ 381 U.S. 479 (1965).

³⁸ This conclusion was reached by the Southern California A.C.L.U. after a year of study by a special committee of lawyers, sociologists, and doctors. See TRIAL, June-July 1967, at 40. The constitutional argument is derived by extension of *Griswold*, which held that a state could not constitutionally prohibit married couples from using, or obtaining advice on the use of, contraceptive devices.

³⁹ MODEL PENAL CODE § 230.8 (Proposed Official Draft 1962).

Code.⁴⁰ This was the first policy change on the subject by the AMA in ninety-six years. In 1871, the Association had issued a policy statement to the effect that it would be deemed unethical for a physician to induce abortion "without the concurrent opinion of at least one other physician, and then always with a view to the safety of the child if that be possible." The AMA House of Delegates now calls this announcement "antiquated and inadequate" for the purposes of 1967.

Until 1967, however, there had been no noticeable impact in legislative halls. The draftsmen of the proposed Illinois Criminal Code advocated abortion provisions paralleling the Model Code,⁴¹ but the legislature would have none of it. The draftsmen of the proposed Minnesota Criminal Code included a somewhat similar provision in its revision, but the legislature rejected it.⁴² During 1967 similar legislation died or was pigeonholed in a number of states, including Connecticut, Nevada, Michigan, Iowa, Maryland, New Mexico, New York, and Tennessee, largely because of vigorous opposition from the churches. In Indiana, the legislature passed a liberalization bill, but the governor vetoed it.

The year 1967 was, however, the year of change. Three states adopted abortion laws in substantial accord with the American Law Institute proposal. In April, after stormy consideration, the Colorado legislature adopted, and on April 25 Governor John A. Love signed, an act substantially similar to the Model Penal Code,⁴³ allowing abortions where a three-member doctor board in an accredited hospital agrees unanimously that (1) the pregnancy would result in the death of the mother or serious, permanent impairment of her physical or mental health, or (2) the child would likely be born with grave and permanent physical deformity or mental retardation, or (3) the pregnancy resulted from forcible rape or incest or statutory rape of a girl under sixteen years of age.⁴⁴ The law contains no residency requirement. If the request is made by a married woman, the husband must concur.

⁴⁰ J.A.M.A., July 10, 1967, at 27, 38.

⁴¹ Proposed ILL. REV. CRIM. CODE § 32-1 (Burdette-Smith ed. 1961).

⁴² Proposed MINN. STAT. ANN. § 609.345 (West ed. 1963), and MINN. STAT. ANN. § 617.18 (1964).

⁴³ COLO. REV. STAT. ANN. ch. 40, art. 2, § 50 (1967). See N.Y. Times, April 26, 1967, at 48, col. 8.

⁴⁴ The question may be raised as to whether a statute legalizing abortion because of the likelihood that the child may be born with physical defect, may create a duty in the physician to warn the expectant mother of the defect, and if she so desires, to abort her. In *Gleitman v. Cosgrove*, 49 N.J. 22, 227 A.2d 689 (1967), an expectant mother had German measles during her pregnancy, and her child was born blind, deaf, and mute. The mother alleged that her physicians had failed to warn her of the 20% chance that her child would be physically defective, and the court assumed for purposes of discussion that had she known of this risk she could and would have obtained a lawful abortion. The mother sought damages because an abortion would have freed her from the emotional problems caused by raising a child with birth defects, and the father sought damages because it would have been less expensive to abort rather than raise the child. The court denied recovery because "[t]he right of their child to live is greater than and precludes their right not to endure emotional and financial injury." *Id.* at 31, 227 A.2d at 693. But cf. *Custodio v. Bauer*, 59 Cal. Rptr. 463 (Ct. App. 1967), where the court would allow recovery in an action showing a negligent failure to sterilize which resulted in pregnancy, even when the mother would suffer no harm, if there was a measurable economic loss to the family resulting from the necessity of supporting and raising an additional child. *Id.* at 476.

In *Gleitman*, a claim brought on behalf of the child against the physician for damages resulting

Some of the reactions to the Colorado law were violent. "It's a law against motherhood," said one state legislator. "It's legalized state murder," said a minister. "The whole world now finds Colorado available," said a doctor. "My fear is that Colorado will become the abortion Mecca of America," said a state senator. The pathway to liberalization is a thorny one.

The Colorado action was followed by the North Carolina legislature, which disposed of the possibility of an "abortion Mecca" by adopting a four-month residency requirement "except in the case of emergency where the life of the said woman is in danger."⁴⁵ California has recently changed its statute to legalize an abortion when the pregnancy threatens the physical or mental health of the mother, or when the pregnancy resulted from forcible rape, incest, or statutory rape of a girl under fifteen years of age.⁴⁶ Unlike the statutes of Colorado and North Carolina, the California act does not legalize an abortion performed because of probable fetal deformity. The California Supreme Court may soon determine whether a pregnancy terminated because of fetal deformity is to be considered violative of the existing law.⁴⁷

In New Jersey, action was taken not by the legislature, but by an organization of county prosecutors. In a policy declaration with reference to the 118-year-old statute which penalizes abortions performed "without lawful justification,"⁴⁸ the prosecutors stated that an abortion should be considered legally justified when performed by a physician "in good faith" and in accord with "accepted medical standards."⁴⁹ Further, the New Jersey Supreme Court has recently stated "it may well be that when a physician performs an abortion because of a good faith determination in accordance with accepted medical standards that an abortion is medically indicated, the physician has acted with lawful justification within the meaning of our statute and has not committed a crime."⁵⁰ Thus, reform may begin in some states whose legislatures have remained silent, through more liberal administrative and judicial construction of existing laws.

from his physical defects was reduced to a claim "[t]hat he should not have been born at all." 49 N.J. at 28, 227 A.2d at 692. No recovery was allowed because the privilege to live was thought to outweigh the harm suffered by the child because of his defects. Presumably the same policy considerations could govern a tort claim filed by a party raped, and upon whom an abortion is not performed, as well as any claim filed by the resulting illegitimate child. See *Williams v. State*, 46 Misc. 2d 824, 260 N.Y.S.2d 953 (Ct. Cl. 1965), *rev'd*, 18 N.Y.2d 481, 223 N.E.2d 343, 276 N.Y.S.2d 885, *aff'd*, 25 App. Div. 2d 906, 221 N.E.2d 181, 269 N.Y.S.2d 786 (1966).

⁴⁵ N.C. GEN. STAT. § 14-45.1 (Advance Legislative Service 1967).

⁴⁶ CAL. BUS. & PROF. CODE § 2377 (West Supp. 1967); CAL. HEALTH & SAFETY CODE §§ 25950-54 (West Supp. 1967); CAL. PENAL CODE §§ 274-76 (West Supp. 1967). The California act is discussed in Leavy & Charles, *California's New Therapeutic Abortion Act: An Analysis and Guide to Medical and Legal Procedure*, 15 U.C.L.A.L. REV. 1 (1967).

⁴⁷ See Leavy & Charles, *supra* note 46, at 25-27. For a favorable commentary on the California statute, see generally Giannella, *The Difficult Quest for a Truly Humane Abortion Law*, 13 VILL. L. REV. 257 (1968).

⁴⁸ N.J. STAT. ANN. § 21A:87-1 (1953).

⁴⁹ N.Y. Times, June 24, 1967, at 31, col. 3.

⁵⁰ *Gleitman v. Cosgrove*, 49 N.J. 22, 31, 227 A.2d 689, 694 (1967).

Preliminary reports from Colorado indicate that the new legislation did not significantly increase the number of legal abortions performed in the state,⁵¹ and the view has been expressed that nationwide liberalization of the law would result in only perhaps 1,000 more legal abortions per year, roughly a ten per cent increase.⁵² If experience bears out these indications, several important conclusions would have to be drawn: first, that physicians had been allowing their medical judgments to override the old legal inhibitions to a most surprising degree; second, that the benefits of adopting the Model Penal Code approach will accrue not so much to patients in need of abortions as to the law itself, by improving physician's respect for it; and, third, that the Model Penal Code approach would have practically no impact on the large number of illegal abortions now being performed.

This final conclusion means that it is possible that the current abortion reform movement will not be enough. One should not minimize the importance of relieving physicians of the conflict between their sensed professional responsibility and the law's proscription, but abortion will remain an important social problem. The proposed reform is desirable in bringing the law into accord with medical practice and medical ethics, but the law has an additional responsibility to accord with societal mores. It may be that this additional responsibility will come to be more and more felt.

Abortion reform is not confined to the United States. Of particular interest is the English abortion law, approved by the House of Commons on October 26, 1967.⁵³ An abortion will be legal if any two doctors agree that (1) the life of the mother is threatened, (2) the mother's physical or mental health might be injured, (3) any existing children might be mentally or physically injured, or (4) the child born might suffer from such physical or mental abnormalities as to be seriously handicapped. It is said that a major purpose served by the new law will be to sanction abortion in cases where the family is large and over-crowded, or where the strain on the mother which would be caused by raising an additional child would be too great.⁵⁴ As can be seen, the English reform legislation is more liberal than its counterparts in the United States.

⁵¹ Brody, *supra* note 35, col. 2.

⁵² Helleger, *Abortion, the Law and the Common Good*, MEDICAL OPINION & REVIEW, May 1967, at 76.

⁵³ N.Y. Times, Oct. 26, 1967, at 1, col. 2.

⁵⁴ *Id.* at 17, col. 1. Other countries have encountered the abortion problem and have taken action of a more or less liberal nature. In Sweden and Denmark, where abortion is much more easily obtained than in most places in this country, the operation must still meet certain standards. The limits of permissible abortion are about the same as those of the Model Penal Code, with the added stipulations that in cases of "weakness" of the mother or when economic hardship could cause disintegration of the family unit, the authorities would permit abortion. Contrary to common belief in the United States, abortions are not obtained merely for the asking by the pregnant female.

In Japan, Hungary, and the U.S.S.R., there is even greater liberality, the primary function of abortion in Japan being birth control. There it is deemed in the national interest to control the birth rate and therefore legal abortions are performed upon the request of the mother, often at state expense. There is no legal, medical, religious, or social pressure upon her decision. In Japan it is said that one out of every two pregnancies is interrupted by abortion.

At any rate, the corner toward liberalization in the United States has been turned. Some thirty states are currently reconsidering their abortion laws, and, despite opposition, many of them will soon adopt liberalizing measures.⁵⁵ Even though the moderate liberalization proposed by the Model Penal Code and now adopted by Colorado, California, and North Carolina does not solve all problems presented by the widespread demand for pregnancy termination, it does open the door to rationalizing the performance of abortions in a manner consistent with a certain measure of domestic contentment. Moreover, it resolves for the conscientious doctor the dilemma created by his normal desire to render medical assistance in case of need, on the one hand, and his countervailing concern over violation of state criminal laws. The process of modernizing the law in an area of vital concern to doctors has thus begun. It is notable that it was an organization of lawyers, the American Law Institute, that provided the impetus for this long-needed reform. Completing the process of reform requires the efforts of both professions.

E. The Legislature's Role in Controlling Abortion

The existing gap between the legal standard on abortion and actual medical practice demonstrates the severe limitations placed on the medical profession by legislation which inhibits the doctor in exercising his medical judgment. Serious questions can be raised about the extent to which legislatures should, as doctors often put it, "come between" the physician and his patient, prescribing the type of medical care that should or should not be given. Recently, for example, the New York legislature heard conflicting medical testimony on the therapeutic values and dangers of abortion in the process of deciding whether to amend the state's abortion law,⁵⁶ and it seems fair to question the competence of a legislature to weigh these matters. Similar problems of delineating the proper legislative function exist in other areas, such as euthanasia, sterilization, and the administration of drugs.

Interestingly, the Supreme Court, in *Griswold v. Connecticut*,⁵⁷ has created a constitutional limit on legislative interference in the dispensing of medical advice. While this case turned on the specially private interests of the recipients of the birth control information, one can envision extensions of the principle to other areas where a professionally qualified physician's relationship with the patient is encroached upon.

⁵⁵ The change will not come easily, for the opposition is potent and determined. The principal arguments are that modern science regards the moment of conception as the beginning of a new life; that the law owes a duty to protect this life; that its destruction should be prevented; that abortion constitutes a condemnation to death without a trial; that the possibility of deformed babies is negligible; and that the real solution lies in eliminating the causes of illegitimate pregnancies. See Harrington, *supra* note 36. The Georgia legislature has recently passed a liberalized law legalizing abortion if the mother's health is threatened, when probable fetal deformity would result, and in cases of rape. The bill was waiting for the approval of the governor at the date this issue went to press. N.Y. Times, Feb. 27, 1968, at 32, col. 8.

⁵⁶ See, e.g., N.Y. Times, Feb. 4, 1967, at 24, col. 2; N.Y. Times, Feb. 11, 1967, at 18, col. 1.

⁵⁷ 381 U.S. 479 (1965).

We have already noted that the case has been cited by some as establishing the unconstitutionality of abortion legislation.⁵⁸

There are recent indications that legislatures might elect repeal rather than amendment of existing abortion laws as the most desirable means of accomplishing the needed reform. For example, an official of the Minnesota Council for the Legal Termination of Pregnancy was recently quoted as saying, "I wouldn't be surprised if several states including Minnesota soon repealed their abortion laws and left the matter to physicians and their patients."⁵⁹ And a leading Catholic authority, the Reverend Robert F. Drinan, dean of the Boston College Law School, has recently argued that repeal is morally preferable to amendment, since the latter course puts the state in the position of deciding "who shall live and who shall die."⁶⁰ Repeal would at least leave the moral question in private hands. The case for repeal of all laws affecting the performance of abortions by licensed physicians is just beginning to be made, but it is becoming increasingly clear that the Model Penal Code is not the final answer.

Abortion laws thus bring sharply into focus the problem of the role of law in medical progress. A strong argument can be made that legislatures should confine their efforts to (1) setting minimum standards for admission to medical practice, (2) freeing doctors from unwarranted legal risks in providing for their patients (as is the object of the Model Penal Code's provisions on abortion), while maintaining standards of care and the legal remedies needed to protect the public, and (3) providing money to guarantee sound medical training and the best facilities and to extend care to more citizens. It may be unrealistic, given the public's intense interest in medical care, to expect legislatures to curb their own involvement, although hope for repeal of abortion laws is rising, or to rely on the courts to restrict the law's role in this way. Still, in any given legislative or judicial determination, the demonstrated integrity of the medical profession will militate against extending legal interference. Any demonstrated lack of integrity will, by the same token, be likely to produce a legal response.

IV

PATIENT CONSENT TO THERAPY: THE PROBLEM OF INFORMED CONSENT

Over fifty years ago in *Schloendorff v. Society of New York Hospital*,⁶¹ Judge Benjamin Cardozo commented, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."⁶² These words, written by a distinguished jurist, reveal

⁵⁸ See text accompanying notes 37 & 38 *supra*.

⁵⁹ Brody, *supra* note 35, col. 2.

⁶⁰ *Id.*, col. 6.

⁶¹ 211 N.Y. 125, 105 N.E. 92 (1914).

⁶² *Id.* at 129-30, 105 N.E. at 93 (1914).

one side of a coin, the possibility of the legal action for assault and battery; if the case had called for it, Judge Cardozo probably would also have said that, if the patient were a minor, or of unsound mind, any purported consent by him would have been ineffective, and again there would have been an assault and battery. A recent court, citing the *Schloendorff* opinion, stated that "If the consent given to the operation in question was ineffectual, every phase of the operation . . . was a continuing battery for which recovery should be allowed, *even if the operation had been successful*."⁶³

On the other side of the legal coin there is something else, namely liability in damages for negligence. We know that if a physician, having undertaken to render medical service for a patient, in the course of treatment fails to utilize the degree of skill and care that would be exercised by reputable practitioners of the same school of practice in the community under similar circumstances, and injury follows, he is liable in damages for breach of the prescribed standard of care—in short, for negligence. This is the familiar action for medical malpractice.

Recent judicial decisions, utilizing language on both sides of the legal coin, have brought forth the doctrine of "informed consent." Even if the physician has obtained the patient's expressed consent to an operation or similar procedure, yet he may have failed to furnish sufficient information about hazards, or alternative forms of treatment, to enable the patient to give a meaningful reasoned or "informed" consent. Because of this omission, the physician may become exposed to liability. Under the traditional doctrine of assault and battery, the consent may be held ineffective and the physician is liable to the patient for any damage incurred by the unpermitted operation.⁶⁴ Under the more recently evolved standard of malpractice, or negligence, the physician is said to have a duty to disclose the risks inherent in the operation or treatment. This duty is presupposed by the standard of what other reasonable medical practitioners in the community would have disclosed under similar circumstances. Liability will follow if the patient can show that the harm resulted from the breach.⁶⁵

⁶³ *Shetter v. Rochelle*, 2 Ariz. App. 358, 366, 409 P.2d 74, 82 (1965), *modified on other grounds*, 2 Ariz. App. 607, 411 P.2d 45 (1966). However, if the operation is beneficial or harmless, only nominal or very limited damages can be recovered. *Lacey v. Laird*, 166 Ohio Rep. 12, 139 N.E.2d 25 (1956); *Keister v. O'Neil*, 59 Cal. App. 2d 428, 138 P.2d 723 (1943).

⁶⁴ Conceptually it could be argued that failure to disclose a particular risk invalidates the patient's consent for all purposes and that the operation is therefore an assault and battery, regardless of whether the undisclosed risk actually materialized. Nevertheless, lack of informed consent seems to result in liability only for injuries resulting from risks which should have been but were not disclosed.

⁶⁵ In applying these two theories, the courts appear to be either confused or little concerned with distinguishing the grounds of recovery. Thus in one leading case, *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093 (1960), *rehearing denied but opinion explained*, 187 Kan. 186, 354 P.2d 670 (1960), it was charged that the court in its first opinion had confused malpractice with assault and battery, "giving rise to a hybrid action which is neither one of negligence nor of assault and battery, but may be a combination of the two." 187 Kan. at 187, 354 P.2d at 671. It has been stated, "Unfortunately, the leading cases dealing with the failure of a surgeon to warn of inherent risks do not always make it clear as to what theory supports recovery, when recovery is permitted." *Shetter v. Rochelle*, 2 Ariz. App. 358, 363, 409 P.2d 74, 79 (1965), *modified on other grounds*, 2 Ariz. App. 607, 411 P.2d 45 (1966).

From the foregoing it is clear that a proper informed consent is an important defense—an insulation from legal liability—available to physicians and surgeons, but that, in the absence of such consent, any invasion of the body or mind of another person, even though accompanied by the utmost in medical skill, may become an actionable wrong. This doctrine relating to consent is important to the medical profession in two principal contexts: (1) in professional therapy for sick patients and (2) in clinical research involving the use of human subjects in seeking new medical knowledge. Many volumes of case law have been written through the years involving malpractice for failure to exercise the required skill and care in rendering medical services, but there are comparatively few cases involving liability for failure to inform and obtain the required consent from the patient receiving medical treatment, and none at all concerned with the human subject in medical research.

We shall develop further the requirement of informed consent—which, when it is met, will serve to insulate doctors from the hardships of the courtroom. Possibly we can see how the concept can be sharpened and its use facilitated for the benefit of both lawyers and doctors. In the remainder of this section we shall be considering only those aspects of informed consent that apply to cases of therapy for sick patients. In the following section, we shall turn to its use in connection with experimentation on human subjects.

As already indicated, the law on consent to treatment is of recent vintage and is not fully developed. An ill person who calls upon a doctor for treatment is entitled, except in certain emergencies, to a diagnosis, a prognosis, and a statement of the proposed therapy, together with a statement of the hazards, if any, and the expected results or effect upon health or person to be anticipated from the treatment of his medical problem.⁶⁶ The patient's request for medical services carries with it implied consent to all conventional, nonoperative procedures indicated for his diseased condition.⁶⁷ But if the physician finds that such procedures will not effect a cure, he may in the exercise of his own professional judgment decide that an operation is needed, or he may wish to try some new and unconventional treatment or drug in which he has confidence. Before doing either of these things he

A cause of action asserting an assault and battery does not preclude recovery based upon malpractice for failure to disclose risks. See *Woods v. Brumlop*, 71 N.M. 221, 377 P.2d 520 (1962) (plaintiff's claim was based upon two theories: failure to inform of danger in electroshock treatment, and lack of consent because of not being informed of the danger); *Mayor v. Dowsett*, 240 Ore. 196, 400 P.2d 234 (1965) (when an action for assault and battery was barred because the statute of limitations had run, the court treated the action as one for malpractice: "[T]he operation might constitute a technical battery, but it would still be a violation of the established standard of care and actionable as malpractice." *Id.* at 233, 400 P.2d at 251); *Wilson v. Scott*, 412 S.W.2d 299 (Tex. 1967) ("Regardless of what some earlier informed consent cases suggest, such an action need not be pleaded as one for assault and battery." *Id.* at 302.) See also *Gravis v. Physicians & Surgeons Hosp.*, 415 S.W.2d 678 (Tex. Civ. App. 1967).

⁶⁶ Morse, *Legal Implications of Clinical Investigations*, 20 VAND. L. REV. 747, 749 (1967) (especially the cases cited in nn.8-10).

⁶⁷ B. SHARTEL & M. PLANT, *THE LAW OF MEDICAL PRACTICE* § 1-06 (1959).

must, unless the circumstances are exceptional, obtain the patient's expressed and informed consent to the operation or to the use of an experimental drug or treatment.

There are certain exceptions. Occasionally, the doctor may deem it desirable to withhold distressing information, as from a critically ill cancer patient. This may be justifiable, and in such cases informed consent may be omitted. The same is true if full explanation of the material facts is impossible because of emergency conditions, or if the facts are deemed emotionally so upsetting under the circumstances as to prejudice the treatment. Otherwise, before the doctor tries either ordinary operative measures or some unconventional treatment or procedure, the law requires that the consent be obtained and that it be preceded by informing the patient of the essential material facts, including in reasonable detail the means and methods of the proposed treatment, the inconveniences and risks involved, and the possible effects upon his health or person. Sometimes the doctor goes ahead without requesting a consent to the procedure involved, creating a potential lawsuit.⁶⁸

Judicial decisions are attempting to fill in the foregoing general outline of the law on informed consent. One important question is whether the information furnished the patient must, in order to make the consent valid, include *all* of the facts and risks which the patient contends that he should have known, or whether it will suffice to give him *only* those that would be supplied by other reputable and reasonable physicians in the community under the same or similar circumstances. Is the latter a necessary standard against which to judge the physician's disclosure?

The Kansas Supreme Court in *Natanson v. Kline*⁶⁹ threw light on this matter. The court was confronted with an action for damages against a radiologist and the hospital in which he was giving radioactive cobalt treatments. The plaintiff received such treatments in connection with a mastectomy operation and damage ensued. The doctor was not chargeable with failure to exercise proper professional skill in the treatments, but negligence was claimed because of his failure to inform her of the hazards. The court in its two opinions charted some new ground. It held that the duty to disclose existed but qualified it by saying:

⁶⁸ On occasion, absent express consent, an implied consent may be derived from the peculiar facts. See *Haywood v. Allen*, 406 S.W.2d 721 (Ky. Ct. App. March 25, 1966, as modified on denial of rehearing, Oct. 14, 1966), where suit was brought against a physician for damages for the allegedly unauthorized tying off of the patient's Fallopian tubes in the course of a Caesarean section. The patient did not expressly consent to the tubal ligation, but there was discussion of its possibility as a "package deal" and there was a tacit understanding that the ligation should be done unless the patient should affirmatively tell the surgeon that she did not want it done. It was held that the surgeon was entitled to act on the basis of implied consent. Compare *Carroll v. Chapman*, 139 So. 2d 61 (La. Ct. App. 1962) and *Shulman v. Lerner*, 2 Mich. App. 705, 141 N.E.2d 348 (1966) with *Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 88 N.W.2d 186 (1958).

⁶⁹ 186 Kan. 393, 350 P.2d 1093 (1960), rehearing denied but opinion explained, 187 Kan. 186, 354 P.2d 670 (1960).

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. How the physician may best discharge his obligation to the patient in this difficult situation involves primarily a question of medical judgment.⁷⁰

A subsequent Kansas case involved a claim of malpractice by the parents of a minor who had undergone cardiac catheterization. In response to the allegation by plaintiffs that they had been told that in previous cardiac catheterizations there had not been any trouble, the court again held that the standard of the reasonable medical practitioner governed disclosure.⁷¹

It is clear that in an action for negligence or malpractice, the standard of disclosure elaborated upon by the Kansas court is the prevailing view,⁷² and is substantially the same standard as that applied in a case of failure to exercise the proper degree of professional skill. On the other hand, the question may be raised as to whether this standard should be utilized in the action alleging lack of valid consent to an assault and battery. In this legal area there is less of a theoretical basis for looking to what other doctors similarly situated might have done.

Strictly speaking, an action for assault and battery raises only the issue of the patient's awareness, yet we do not expect the physician to suggest every risk factor nor do we demand a complete explanation of his medical decision, based as it is on various alternative modes of treatment and their relative probabilities of success. The courts have attempted to solve the problem in at least three ways: (1) by requiring only a general awareness of the risks on the part of the plaintiff,⁷³ (2) by simply submitting the question of consent as a fact issue to the jury without formulating any express standard,⁷⁴ or (3) by applying the negligence or malpractice standard of the reasonable practitioner.⁷⁵ It would seem that there must be some standard of reasonableness applied to determine the risks of which the patient must be informed and that questions of medical judgment are intimately involved in determining the fact of risk itself. The courts ought not to insist too rigidly on following the assault and battery rationale⁷⁶ and should apply the standard of the reasonable medical practitioner in all cases involving consent issues.

⁷⁰ 186 Kan. at 409, 350 P.2d at 1106.

⁷¹ *Williams v. Menihan*, 191 Kan. 6, 379 P.2d 292 (1963); *accord*, *Collins v. Meeker*, 198 Kan. 390, 424 P.2d 488 (1967).

⁷² *See, e.g.*, *Wilson v. Scott*, 412 S.W.2d 299 (Tex. 1967); *Shetter v. Rochelle*, 2 Ariz. App. 358, 409 P.2d 74 (1965), *modified on other grounds*, 2 Ariz. App. 607, 411 P.2d 45 (1966); *Aiken v. Clary*, 396 S.W.2d 668 (Mo. 1965); *Roberts v. Young*, 369 Mich. 133, 119 N.W.2d 627 (1963); *Govin v. Hunter*, 374 P.2d 421 (Wyo. 1962).

⁷³ "[A] consent to a surgical procedure is effectual if the consentor understands substantially the nature of the surgical procedure attempted and the probable results of the operation . . ." *Shetter v. Rochelle*, 2 Ariz. App. 358, 369, 409 P.2d 74, 86 (1965), *modified on other grounds*, 2 Ariz. App. 607, 411 P.2d 45 (1966).

⁷⁴ *Woods v. Brumlop*, 71 N.M. 221, 377 P.2d 520 (1962).

⁷⁵ *Di Fillippio v. Preston*, 53 Del. 539, 173 A.2d 333 (1961).

⁷⁶ *See, e.g.*, *Ditlow v. Kaplan*, 181 So. 2d 226 (Fla. Ct. App. 1965); *Aikin v. Clary*, 396 S.W.2d 668 (Mo. 1965); *Govin v. Hunter*, 374 P.2d 421 (Wyo. 1962).

No doubt this same principle should also be applied to the statements of the other essential elements of "informed consent"—for example, the sufficiency of the statements with respect to the method and means of procedure to be used and the inconveniences as well as the risks involved and, in particular, the amount of detail which the doctor must give to the patient. How much detail would reputable and reasonable practitioners give under similar circumstances? Would they speculate about remote possibilities or picture the most distressing possible effects? The information imparted must certainly include the more prominent features, those most likely to affect the decision of the patient to proceed or not to proceed.⁷⁷ However, the reasonable practitioner probably would not detail the one-in-10,000 possibilities or go into the more frightening aspects that, though remote, might deter the patient unnecessarily.⁷⁸ Unfortunately no iron-clad rule can be formulated; each case must be determined according to its own facts.

There are certain other elements to be considered. There is the question of capacity to consent, but that we shall discuss in the next section of this article. There is also the question of the manner of making proof. If the action is given the label of an assault and battery based upon complete absence of effective consent, lay testimony could be used to prove the deficiency, but if the action is based upon inadequacy of information furnished, *i.e.*, on negligence, then the medical standards of the community come into the case, and the plaintiff will have to offer expert testimony in proof.⁷⁹ If, as has been suggested, the standard of the reasonable physician is to be applied in all cases, then the plaintiff will always be required to introduce expert testimony to determine that standard. Because of the "conspiracy of silence" this may cause the plaintiff greater difficulty than the defendant, who will doubtless be able to get other doctors to testify in his defense. As a mitigating factor, the courts have ruled as a matter of law that the standard has been violated when the physician either is silent as to the possibility of risk,⁸⁰ or assures the patient that no danger could result, if in fact this is known by the physician to be an untrue statement.⁸¹ In these situations, the plaintiff will not be required to offer expert testimony to prove his case, and the burden may be upon the defendant physician

⁷⁷ The standard was found violated by a failure to inform a patient of the 3% risk of death, paralysis, or other injury in an arteriogram procedure, *Bowers v. Talmadge*, 159 So. 2d 888 (Fla. Ct. App. 1963), and by a failure to disclose the 1% chance of loss of hearing in a stapedectomy with a vein graft (ear operation). *Wilson v. Scott*, 412 S.W.2d 299 (Tex. 1967).

⁷⁸ The reasonable medical practitioner would not inform the parents of a child of the remote possibility that the child might revive from the anesthesia and, in the course of his ensuing struggle, cause a catheter to puncture his heart. *Williams v. Menihan*, 191 Kan. 6, 379 P.2d 292 (1963).

⁷⁹ See, *e.g.*, *Williams v. Menihan*, 191 Kan. 6, 379 P.2d 292 (1963); *Aiken v. Clary*, 396 S.W.2d 668 (Mo. 1965).

⁸⁰ *Collins v. Meeker*, 198 Kan. 390, 424 P.2d 488 (1967); *Natanson v. Kline*, 187 Kan. 186, 354 P.2d 670 (1960); *Mitchell v. Robinson*, 334 S.W.2d 11 (Mo. 1960), *distinguished in Aiken v. Clary*, 396 S.W.2d 668, 673 (Mo. 1965).

⁸¹ *Woods v. Brumlop*, 71 N.M. 221, 377 P.2d 520 (1962).

to prove that his failure to disclose did, in fact, conform to accepted professional standards.⁸²

As a final element, a mere showing of negligence will not suffice to establish liability. The plaintiff must also show proximate cause, and in this context this means that he must prove that he would not have undergone the operation or procedure if he had been fully informed of the risk.⁸³ The subjective element is large, and it may simply be a jury question as to the credibility of plaintiff's testimony to this effect.⁸⁴

We are discussing in general "the role of law in medical progress." In our consideration of the subjects of homotransplants and abortion, the law was seen as the benefactor of medicine by clearing the way. Candor compels the observation that the legally evolved doctrine of informed consent may well operate otherwise. It may add to the frustrations felt by doctors toward the law, lawyers, and the courts by seeming to create a disguised and dangerous pitfall into which a relatively innocent practitioner may inadvertently tumble. Possibly more extensive nonlitigious and objective intellectual cooperation between the professions, in institutes, conferences, joint publishing efforts, or otherwise, could hammer out the standards in terms of specifics and thus smooth the path toward better mutual understanding than that pictured by Dr. Child.⁸⁵

V

THE SUBJECT'S CONSENT TO HUMAN EXPERIMENTATION

We have already noted the importance of informed consent in the situation where the doctor elects to employ an experimental drug or treatment.⁸⁶ In these instances the physician's goal and the patient's hopes coincide, and consent only serves the purpose of alerting the patient to the unusual risks that may be involved. In this section we will be concerned with the possibility of unhappy results where the experiment in which the patient or other volunteer participates holds out little or no hope of benefit to him. Such nontherapeutic experiments may involve healthy persons who volunteer to become guinea pigs for the sake of making contributions to medical science or persons who are paid for their participation. If injury results from such experimentation, the possibility of a damage suit again rears its head.

⁸² *Collins v. Meeker*, 198 Kan. 390, 424 P.2d 488 (1967). But see Comment, *Informed Consent in Medical Malpractice*, 55 CALIF. L. REV. 1396 (1967), in which it is argued that the physician should always have the initial burden of proof when he makes less than a full disclosure of all known material risks.

⁸³ Compare *Natanson v. Kline*, 187 Kan. 186, 354 P.2d 670 (1960) and *Shetter v. Rochelle*, 2 Ariz. App. 607, 411 P.2d 45 (1966) with *Aiken v. Clary*, 396 S.W.2d 668 (Mo. 1965), where the court held that, while the plaintiff did not have to show that he would not have consented had he been fully informed, "this does not mean, however, that plaintiff is not required to establish a causal connection between the doctor's failure sufficiently to inform and the injury for which recovery is sought." *Id.* at 676.

⁸⁴ See *Russell v. Hardwick*, 166 So. 2d 904 (Fla. Ct. App. 1964).

⁸⁵ Note 3 *supra* and accompanying text.

⁸⁶ See p. 582 *supra*.

For the paid subjects, the primary benefit is the monetary reward. For the others, there is generally no benefit other than satisfaction of a possible desire to promote the general welfare. Not many persons are willing to put up with personal injury or even serious inconvenience either for the typically meager compensation provided or for the sake of the advancement of medical science. In such cases, moreover, in obtaining informed consent there can be no special considerations, such as emergency conditions or patient apprehension, warranting the investigator in withholding information or not obtaining consent. Accordingly the law should not and does not provide these excuses for failing to do so. So far as can be ascertained, there are no decided cases on the subject, but it seems practically certain that there will be such in the future. We must assume that the medical investigator will be held liable in damages if he does not make a proper disclosure and obtain an effective consent. Otherwise his action exposes him to liability, and if something goes wrong he must be held responsible. It has been said that he experiments at his peril, and this is certainly true unless consent has been obtained. We must ask, however, what is the necessary disclosure and what is an effective consent.⁸⁷

At the outset we should note again that experimentation on a human subject without first obtaining an informed consent has especially pronounced moral aspects, as well as those of a strictly legal nature.⁸⁸ This moral aspect is even more important when the experimentation involves, as it often does, children, mental incompetents, students, prisoners, nurses, employees, and others who may be handicapped or subject to pressure in consenting to the experimentation. In such cases the moral aspects will have a direct bearing upon development of legal conclusions.⁸⁹

A. Existing Codes, Standards, and Rules

We should first look at some of the ideas on the subject that have emerged in recent years in the form of specific codes and rules. Ever since the Nuremberg trials brought to light the wretched practices of the Nazis in Germany, the concern of interested persons and organizations has brought forth a variety of stated principles and rules to govern the use of human subjects in nontherapeutic medical investigation.⁹⁰ Most of these have come from the medical profession itself. In the ensuing paragraphs we review the several principal efforts briefly and chronologically. A gradual evolution of ideas and refinement of principles have taken place.

⁸⁷ Although the courts have not spoken, there is an impressive body of medical and legal literature on the subject. See, e.g., I. LADIMER & R. NEWMAN, *CLINICAL INVESTIGATION IN MEDICINE* (1963), which collects numerous materials and provides an extensive bibliography; and later references cited in Fletcher, *Human Experimentation: Ethics in the Consent Situation*, in this symposium, p. 620, n.2.

⁸⁸ See generally Fletcher, *supra* note 87.

⁸⁹ Professor Paul A. Freund, of Harvard Law School, discussing the moral aspects, has suggested, "In the end we may have to accept the fact that some limits do exist to the search for knowledge." Freund, *Is the Law Ready for Human Experimentation?*, *TRIAL*, Oct.-Nov. 1966, at 46, 49.

⁹⁰ Many of the codes and stated principles are collected in I. LADIMER & R. NEWMAN, *supra* note 87. See also Fletcher, *supra* note 87, at 628-31.

*The Nuremberg Articles (1946).*⁹¹ These Articles, drafted by a committee of the American Medical Association, comprise ten points, set up in the form of accepted and established principles to deal with nontherapeutic research. They were prepared as a guide for the Nuremberg tribunals in trying the Nazi criminals. The Articles call for voluntary consent by each subject of experimentation; they demand that human subjects be used only when fruitful results for the good of society unprocurable by other means may be promoted; experiments must be based upon prior animal experimentation and upon knowledge of the natural history of the problem; unnecessary physical and mental suffering must be avoided; there must be no experiments involving the likelihood of death or disabling injury; the risk must be set off against and must not exceed the humanitarian importance of the project; proper preparation and facilities must be provided; scientifically qualified investigators must be used; the subject of investigation must be free to withdraw at any time; and assurance must be given that the investigators will terminate the project at any time if it seems to be getting out of hand. This code was excellently framed for its purpose, to deal with the Nuremberg criminals. It did not, however, purport to settle all questions or even to be a guide for future experimental practices.

*American Medical Association, Principles of Medical Ethics (1946).*⁹² The Association adopted some but by no means all of the principles of the Nuremberg Code. A report prepared by its Judicial Council was approved by the House of Delegates in December 1946. The report sets up the following requirements for clinical investigations on human beings: "(1) the voluntary consent of the person on whom the experiment is to be performed must be obtained; (2) the danger of each experiment must have been investigated previously by means of animal experimentation; and (3) the experiment must be performed under proper medical protection and management."

*National Institutes of Health, Guiding Principles in Medical Research Involving Humans (1953).*⁹³ A clearance procedure required for projects deviating from accepted medical practice incorporated the idea of group review of the scientific and ethical propriety of each project. The desirability of group review of nontherapeutic experiments is now generally recognized and is uniformly utilized in greater or lesser degree in all reputable centers.⁹⁴

*Public Health Council of the Netherlands, Report on Human Experimentation (1955).*⁹⁵ In a published summary of a report submitted by the Council to the Nether-

⁹¹ *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10*, 2 THE MEDICAL CASE 181 (1949), reprinted in Beecher, *Experimentation in Man*, 169 J.A.M.A. 461, 472-74 (1959).

⁹² 132 J.A.M.A. 1090 (1946).

⁹³ Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. PUB. L. 467, 496 (1954).

⁹⁴ See Sessoms, *What Hospitals Should Know About Investigational Drugs: Guiding Principles in Medical Research Involving Humans*, 32 J. AM. HOSP. ASS'N 44, 62, 64 (1958).

⁹⁵ Reprinted in I. LADIMER & R. NEWMAN, *supra* note 87, at 156-58.

lands Minister on Social Affairs and Health, the following principle was included in a listing of "standards."

Experiments on children; in institutions for children, old people, etc.; on the insane; or on prisoners, which involve dangerous risks, inconvenience or pain are not approved. All experiments on the dying under any circumstances are disapproved.

*American Psychological Association, Ethical Standards of Psychologists (1959).*⁹⁶

The eighteen "principles" in this formulation brought out, among other points, the need for confidentiality of information about individual subjects of experimentation. The following was included as a limitation on research to be conducted:

Principle 16. Harmful Aftereffects. 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 aftereffects exists, research is conducted only when the subjects or their responsible agents are fully informed of this possibility and and volunteer nevertheless.

*Medical Research Council (Great Britain), Responsibility in Investigations on Human Subjects (1962-63).*⁹⁷ This statement is intended to serve as a guide for medical men engaged in research. With procedures not of direct benefit to the individual, it acknowledges the possibility of "undue influence," particularly when the investigator stands in a special relationship to the subject, such as a physician-patient relationship. It suggests that the investigator should obtain the consent while in the presence of another person to protect himself, and for the protection of the subject. The statement concludes as follows:

Owing to the special relationship of trust that exists between a patient and his doctor, most patients will consent to any proposal that is made. Further, the considerations involved in a novel procedure are nearly always so technical as to prevent their being adequately understood by one who is not himself an expert. It must therefore be frankly recognized that, for practical purposes, an inescapable moral responsibility rests with the doctor concerned for determining what investigations are, or are not, proposed to a particular patient or volunteer . . .

In the opinion of the Council, the head of a department where investigations on human subjects take place has an inescapable responsibility for ensuring that practice by those under his direction is irreproachable.

*World Medical Association, Code of Ethics (Declaration of Helsinki, 1964).*⁹⁸

This is an important document, second only to the Nuremberg Articles in worldwide influence. It constitutes a fairly complete ethical code to guide medical experi-

⁹⁶ 14 AM. PSYCHOLOGIST 279 (1959).

⁹⁷ 2 BRIT. MED. J. 178 (1964).

⁹⁸ Reprinted in 2 BRIT. MED. J. 177 (1964); Morse, *Legal Implications of Clinical Investigations*, 20 VAND. L. REV. 747, 768-69 (1967). The Declaration has been approved by the American Medical Association, the American Federation for Clinical Research, the American College of Physicians, the American College of Surgeons, the Society for Pediatric Research, and the American Academy of Pediatrics.

menters in conducting clinical research. The Declaration draws the important distinction between purely scientific experimentation, presumably on normal persons, and experimentation for therapeutic purposes carried out on patients under the doctor's care, patients whose illness does not yield to conventional treatments. More exacting standards are imposed for the former than for the latter. The provisions concerning nontherapeutic research are as follows:

(1) In the purely scientific application of clinical research carried out on a human being it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

(2) The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

(3a) Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.

(3b) The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

(3c) The consent should as a rule be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

(4a) The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

(4b) At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for the research to be continued. The investigator or the investigating team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual.

This formulation contains a number of novel expressions of the interests and duties involved in human experimentation.

*The Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (1962).*⁹⁹

These amendments, which were precipitated largely by the thalidomide tragedies, and the Food and Drug Administration regulations implementing them, established detailed "informed consent" requirements applicable to the testing of investigational drugs that are to be shipped across state lines. Although the provisions apply only to new drugs, they are nevertheless persuasive with respect to and in connection with fixing standards for experimental processes that do not involve such drugs. FDA regulations specifically require consent in all cases of scientific investigation and in all but "exceptional cases" (emergency, apprehension, etc.) in therapy situations. Consent is carefully defined as follows:

"Consent" or "informed consent" means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of all material information concerning the

⁹⁹ Pub. L. No. 87-781, 76 Stat. 780 (codified in scattered sections of 21 U.S.C.).

administration of the investigational drug, or his possible use as a control, as to enable him to make an understanding decision as to his willingness to receive said investigational drug. This latter element requires that before the acceptance of any affirmative decision by such person the investigator should make known to him the nature, duration, and purpose of the administration of said investigational drug; the method and means by which it is to be administered; all inconveniences and hazards reasonably to be expected, including the fact, where applicable, that the person may be used as a control; the existence of alternative forms of therapy, if any; and the effect upon his health or person that may possibly come from the administration of the investigational drug. Said patient's consent shall be obtained in writing by the investigator.¹⁰⁰

Notable new elements here are the requirement that consent be in writing and that the subject's possible use as a control be revealed to him.

*U.S. Public Health Service, Policy and Procedure Order No. 129 (1966).*¹⁰¹ This is a directive, a "guideline," prescribing procedures for experimentation under Public Health Service grants-in-aid of research. It requires institutional group review of all projects to assure the protection of the "rights and welfare" of individuals involved, the appropriateness of the methods used to obtain informed consent, and the objective appraisal of the risks as balanced against the potential medical benefits of the investigation. The institutions reviewing the research must also assure continuing surveillance of projects and must provide continuing advice for investigators especially with respect to the safeguarding of the rights and welfare of human subjects. The possibility of withholding grants-in-aid is a powerful sanction. The stated standards apply literally only to projects carried on under the PHS grants, but they will doubtless be applied more broadly. This directive emphasizes strongly both the legal and the ethical obligations connected with nontherapeutic experimentation on normal humans.

*American Medical Association, House of Delegates, Ethical Guidelines for Clinical Investigation (1966).*¹⁰² This document, referring to previous action endorsing the Declaration of Helsinki, enlarges upon the fundamental concepts by setting up some important "guidelines." It is a significant document with especially thoughtful differentiation between therapeutic and nontherapeutic experimentation.¹⁰³ It includes some original handling of the problem of experimentation on minors and incompetents.

¹⁰⁰ 21 C.F.R. § 130.37 (1967).

¹⁰¹ Surgeon General, Public Health Service, Dep't of Health, Education, and Welfare, Investigations Involving Human Subjects, Including Clinical Research: Requirements for Review to Insure the Rights and Welfare of Individuals, PPO 129, Revised Policy July 1, 1966.

¹⁰² American Medical Association, Declaration of Helsinki and AMA Ethical Guidelines for Clinical Investigation (undated pamphlet printed by the AMA).

¹⁰³ The provisions on these subjects are quoted in Fletcher, *supra* note 87, at 629. The experimenter's role vis-à-vis the patient was defined thus:

2. In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.

B. Comments on Existing Codes, Standards, and Rules

The foregoing are the principal existing codes and rules. They represent much professional soul-searching, and when viewed historically serve to illustrate how the medical profession has come to grips with the problems. Many of the essential rules and standards can be distilled from them; yet they still do not fully serve to meet some of the most troublesome problems encountered in the course of medical experimentation. Large gaps remain, and important questions are unanswered. Let us list some of the questions and, where possible, undertake to suggest some tentative answers.

1. *Identifying Risks and Duties With Greater Precision*

Should not some kind of line be drawn between procedures that consist only of observation of natural functions of the subject, with no attendant risks or negligible risks, and those that involve affirmative invasion of mind or body to modify the functions for the purposes of the experiment, with something more than negligible risk? Comparatively unrestricted authority might be in order as to the former, but careful laying out of the ground rules would be indicated for the latter. The former could include all manner of superficial measurements and tests, even including X-rays, electrocardiograms, electroencephalograms, simple blood tests, and so forth. The latter would include the administration of many drugs, certain biopsies, and material alterations of bodily or mental functions in some manner. The former generally involve no significant risk, the latter otherwise in varying degrees.

But can a line necessarily be drawn between the two? Is a skin biopsy "observational" and a kidney biopsy "invasional"? Is violent exercise to observe heart function just observational? And what about the varying degrees of risk? Can meaningful lines be drawn? Or is each case dependent upon its own facts? Doctors must tell us whether meaningful lines can be drawn and whether the spectrum of degree of risk can be usefully illustrated by common examples. If the existing general principles can be made more specific in this manner, this would be a valuable guide for use in the design of research projects, in selecting human subjects, in duly informing them of risks, and eventually, if need should arise, in the courts.

2. *Defining Disclosure Requirements*

The American Medical Association "Ethical Guidelines" call for a "reasonable explanation" of the "nature" of the procedure to be used and of the "risks to be expected." This raises several questions. We might ask: reasonable to whom, the investigator, the human subject, or some hypothetical "reasonable man"? Does "nature of the procedure" include duration and purpose of the project as required in the Food and Drug Administration regulations? Do "risks" include "inconveniences"? Do they include the one-in-10,000 possibility of injury? What about risks that are not reasonably to be expected to occur?

The expressed standard, "reasonable explanation," is perhaps as satisfactory as any that can be devised, but it badly needs embellishment.¹⁰⁴ Since nontherapeutic experimentation by definition does not benefit the subject affected, the standard of the reasonable medical practitioner that is applied when a doctor is caring for a sick patient will doubtless not be available, and the informed consent will be judged on recognized contract principles. This means that failure of the experimenter to disclose facts that the "reasonable man" *would want to know* before serving as the subject of experimentation will vitiate the consent. This standard may differ greatly from what a "reasonable investigator" would have revealed under the circumstances. For one thing, the jury's role would be ostensibly greater under the "reasonable man" standard and expert testimony would be largely dispensed with in establishing whether a duty had been breached.

3. *Evaluating the Voluntariness of Consent Obtained*

We find that the consent must be "voluntary"; the person involved must be "so situated as to be able to exercise free power of choice"—so say the Nuremberg Articles, the American Medical Association "Guidelines," and the FDA Regulations. But when is consent truly voluntary? When is it the result of a free power of choice? Even with a normal adult the question may be raised by opening up a great range of psychoanalytic possibilities with which the law probably ought not to concern itself. But even setting these matters aside, consider the following possibilities:

Children. What about the use of children as subjects of experimentation? If the child has reached the age of understanding so that he can appreciate the inconveniences and risks, his consent together with that of his parents should suffice, or perhaps at some age short of majority his own consent becomes sufficient, as it would be in case of needed therapy.¹⁰⁵ But what about children who are too young,

¹⁰⁴ Under the present formulation shocking action can be taken even in seemingly good causes. In *Hyman v. Jewish Chronic Disease Hosp.*, 42 Misc. 2d 427, 248 N.Y.S.2d 245 (Sup. Ct. 1964), *rev'd per curiam*, 21 App. Div. 495, 251 N.Y.S.2d 818, *rev'd*, 15 N.Y.2d 317, 258 N.Y.S.2d 397, 206 N.E.2d 338 (1965), a substance derived from cancer cells was injected into chronically ill patients, who were told only that they would receive a harmless substance which might cause some discomfort. In a separate proceeding the doctors were disciplined on the ground that this was not enough information to satisfy the informed consent requirement. See Langer, *Human Experimentation: New York Verdict Affirms Patients' Rights*, 151 Sci. 663 (1966).

¹⁰⁵ RESTATEMENT OF TORTS § 59, comment *a* at 111 (1939), dealing with therapy situations, states as follows:

"If a child or person of deficient mental condition, though under guardianship, is capable of appreciating the nature, extent and consequences of the invasion, his assent prevents the invasion from creating liability, though assent of the parent, guardian or other person is not obtained or is expressly refused. If the invasion is one the nature, extent and consequences of which the child or person of deficient mental condition is incapable of appreciating, the invasion creates a liability unless the parent, guardian or other person [standing in like relation] has consented, in which case the consent of the parent, guardian or other person, if it be within his power to give it, is effective though the child objects to the invasion."

Although this comment is addressed to therapy situations, it is possible that the same principle might apply to experimentation.

who cannot understand the material facts—the infants just born, the eight-year-olds? Obviously they cannot give “informed” consent. May the parents consent for them? In case of needed treatment for illness the parents can, of course, consent. There is less justification for validating the parental consent in the case of nontherapeutic investigation for the benefit of medical science. But because of the public’s interest in the advance of medical science, the door to the use of infants should not be completely closed so that research in diseases and conditions of infants cannot be conducted. New guidelines and possibly special safeguards are called for. Observational procedures would be unobjectionable, but procedures that involve significant dangers to the mind or body should certainly be controlled if not prohibited.¹⁰⁶

Prisoners. Can a “voluntary” consent be obtained from prisoners? Or are institutional pressures inevitable and such as to preclude freedom of choice. Federal prisoners are used in considerable numbers by federal investigators. In Iowa, prisoners may be used, but they must volunteer in writing and may withdraw consent at any time.¹⁰⁷ In Virginia, prisoners are permitted to participate in medical research under regulations prescribed by the State Board of Prisons.¹⁰⁸ Prisoners have time on their hands, and many of them might welcome medical experimentation as a means of gaining a little variety in their daily routines and some self-respect. If no pressures are exerted, if no special parole favors are held out as bait (although serving as a subject can constitute favorable evidence on the parole record), and if freedom to withdraw at any time is preserved, there would seem to be good justification for use of adult prisoners who consent after being reasonably informed.

Mental incompetents. Much the same questions arise with mental incompetents as in connection with children except that the possibilities are somewhat more favorable for using them in the process of needed therapy. They certainly should not be used without consent of a parent or guardian. Consent of the institutional authorities is, of course, necessary, but not sufficient. Again some carefully drawn guidelines would be helpful.

Students, nurses, or employees. If these subjects are adults the only question is that introduced by possible pressures. Can they really exert freedom of choice? Or will the hope of better grades or job preferment exert undue influence? If pressures cannot be eliminated these persons should not be used. Guidelines would help, but the matter defies precise definition.

Paid subjects. A financial reward prompts further concern that consent is not voluntary, that economic need may have overcome the patient’s judgment. The problem seems closely akin to the case of prisoners, students, nurses, and employees, but it has not been spelled out in any of the published principles. This would seem to be an area where guidelines could be used to point out the potential for abuse.

¹⁰⁶ See Freund, *supra* note 89, at 46-49; Morse, *supra* note 98, at 757.

¹⁰⁷ IOWA CODE ANN. § 246.47 (Supp. 1966).

¹⁰⁸ VA. CODE ANN. § 53-57.1 (Supp. 1966).

4. *The Future.*

With the vast increase in medical experimentation on human beings and the likelihood of personal damage to subjects of experimental procedures, we may be sure that some type of regulation is inevitable. One or two unfortunate occurrences will precipitate it. What form will this regulation take? Statutes adopted by state legislatures are not likely to prove satisfactory. They are not adopted in a scientific atmosphere. Moreover, they are usually too rigid, and they cannot possibly meet all of the variants of the many problems involved. Likewise, administrative regulations are likely to be rigid, bureaucratic, and not too satisfactory. Administrative "guidelines" issued by government officials are something fairly new on the scene, but they can be one-sided and can even be dangerous in an essentially scientific area. Yet in some way law is certain to take a hand.

Doubtless the optimum approach is through carefully drawn and objectively considered codes or guidelines drafted by the professions for themselves such as those above sketched. Yet these may be hard to come by, for views diverge and a consensus may be difficult to obtain. The expressions of principle to date have been characterized by progress but also by generality that is not easily applied in practice. More efforts of this kind are needed, however, until the gap between published principles and practical application is eliminated or greatly narrowed. The medical profession's good record to date is to be noted with favor, but vigilance to avoid the equivalent of the thalidomide tragedies is called for.

VI

EVALUATION OF THE ROLE OF LAW IN MEDICAL PROGRESS

The foregoing discussion should make it apparent that the law is going to play a large role in the future of at least the four medical areas explored in this article, and the same is true of other areas in which law and medicine interact. No longer will the doctor be the free agent responsible only to his conscience, his Hippocratic oath, and some rather general ethical principles. The law will be a part of his life. The sources of law are many. Legislatures fill the statute books; courts fill volumes of case reports; administrators issue reams of regulations. Neither legislators nor judges nor administrators are omniscient, especially in the scientific world of which medicine is a part. They need all the help they can get.

In the statutory field the American Law Institute's Model Penal Code has made a significant contribution to improvement in the statute law on abortion; the National Conference of Commissioners on Uniform State Laws will do the same for homo-transplantation. These important deliberative bodies are made up of objective, legally trained persons who work *pro bono publico*. Perhaps law and medicine could learn to work effectively together through a prestigious interprofessional group possessing a similar dedication to the public interest. Certain it is that in the years to come

the advance of medical science will create a host of new problems of concern to the law, and lawyers will be constantly seeking to readjust the legal order to meet changing social needs. The two professions can benefit society as well as themselves by working harmoniously side by side in seeking the solutions that best accord with the public interest.