Human Studies

Protection for the investigator and his subject is necessary.

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There is a conflict to be found in what the law says about medical research. On the one hand it says that a man experiments at his peril. In contrast it supports the almost universally held credo of Western civilization that advancement of medicine is desirable; this requires research that must be carried out in man, but it is wrong to place a man in jeopardy or to penalize him for attempting to help his brother.

The law's chilling statements concerning experimentation are really based on a considerable misunderstanding of experimentation. The phrase about peril was first used in the English law case, Slater versus Baker, 1767 (*1*), and the New York case, Carpenter versus Blake, 1871 (*2*) (and many following cases). In both of the cases mentioned the attack was based on the failure to obtain consent of the patient permitting the use of a new procedure, and this failure was construed as negligence on the part of the physician. In each of the cases the patient assumed that he would be treated in accordance with the accepted practices of the community. In each case the judgment of the court was that a physician experiments at his peril. Notwithstanding the slight connection of these cases with present-day experimentation on man, they are often referred to. Thus these factual situations, erroneously labeled experimentation (except as nearly all therapy involves trial and error experimentation), have done much to confuse legal concepts.

Position of Legal Writers

The position taken by legal writers and jurists who have summarized the issue's present position is as follows. In treating the patient "there must be no experimentation . . . we find that legal encyclopedias have unwaveringly set forth that while it is the duty of the physician or surgeon to keep up with advancements in his profession, it is also his duty not to try to forge ahead of it by trying experiments" (*3*). (Evidently nothing shall ever be done for the first time!) The doctrine is, "the physician experiments at his peril." Many similar examples could be given. In this harsh stand the law is unrealistic, for as every able physician knows, the adequate practice of medicine involves continual experimentation. No two patients respond precisely alike to any therapeutic procedure. There is no "standard" patient. Even in ordinary practice the able doctor experiments until his treatment is successful, or the patient goes elsewhere, or he dies. Nonetheless, "the trail blazing practitioner is always courting a brush with the law" (*4*).

The need for a redefinition of human experimentation becomes apparent when court rulings are encountered in which experimentation is equated with "rash action" and "ignorant and unskillful departure from approved methods" and the low esteem of the court expressed in such phrases as "rash or experimental method," "mere experiment," and "reckless experiments" (*5*). It may be added that by no means could all of the acts so castigated be labeled as foolish nor were they always the work of incompetents. The remarks quoted, which are quite typical in cases of this kind, reveal the association in the judicial mind between experimentation and professional disregard or negligence. Needless to say, "this represents either a complete misconception of scientific experimentation or the singular use of the term so that it partakes of reckless behavior or quackery. . . ." "The term 'experimentation' has been used loosely by the courts" (*3, 5*). The precedents, the cases of record, have usually "dealt not with major problems baffling to medicine and science on which basic research or applied clinical study was required, but with questions which confront the regular practitioner" (*3*).

The law does not now often deal explicitly with cases involving human experimentation; however, Jaffe (*6*) points out that the common law, the law devised and administered by the courts, has developed and continues to develop doctrines which are applicable. The physical touching of an individual without his consent may be actionable even when no physical injury has been sustained. Manipulation of an individual by deceit may be actionable as fraud. Carelessness in experimentation, if it leads to injury, may be actionable as negligence.

The Kefauver-Harris amendments to the Federal Food Drug and Cosmetic Act (1962) have legal force directly concerned, for the first time, with human experimentation. The rulings of the National Institutes of Health have the force of law. We seem to be well on our way to the formulation of a body of laws that will apply directly to human experimentation.

"Liability without Fault"

In an examination of liability, the *Duke Law Journal* (1960) [see also Wolfle (*7*)] offered, as a partial solution to the perils of the investigator, the concept of "liability without fault." If, in the course of an experiment a subject is damaged, he would be entitled to be made whole, by treatment or rehabilitation, or if not completely successful, to receive compensatory damages. Both the subject and the investigator would be protected. In this view, the investigator would not be considered at fault, for he had acted in the interests of society. Society, then, through government channels, would assume the costs of restoration or compensation of the experimental subject, similar to the arrangement whereby society, through government channels, supports most of the experimentation for which the concept of liability without fault would be fitting. Society has accepted the view that risk is reimbursable and that those who engage in hazardous pursuits deserve extra pay.

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While the first purpose is to protect the subject, the investigator must also be freed from unjust liability.

One cannot deny that difficult problems are present. For example, answers to many psychological as well as physical problems can be found only in the response to stress. What are the limits? At what point will the subject break down? Will he sustain lasting damage? Screening of astronauts requires such testing, as for example in study of G factors. One can take the view that some experiments are not ethical and never can be ethical. In the case of ethical studies one might possibly arrange a system of monetary compensation, "liability without fault," with the understanding and consent of the subject. Coordinated with such recompense every effort to make the subject whole would be carried out, through treatment and rehabilitation. The intention is that both subject and investigator should be protected. Society, through appropriate governmental channels, would bear the cost just as government now supports great areas of medical research.

There can be no question that the exposure of human experimental subjects to test situations can involve risk of injury in some necessary procedures. Even if all reasonable precautions have been taken to protect both the subject and the investigator from physical damage as well as from unethical practices, the possibility for injury may still remain. It is unreasonable to expect that the society which profits actually or potentially should not share in the responsibility for what was done. This society can do, not only in requiring a sound and ethical approach to experimentation, but also by arranging for rehabilitation and restoration of the possibly injured subject and by providing financial recompense when this is indicated, to relieve both subject and investigator of economic jeopardy.

There is uncertainty whether the physician's liability insurance will protect him, for experimental procedures, if valuable, can hardly be in accord with the usually required "accepted standards of the community." These procedures of course go beyond and are outside of such standards.

Even though the public recognizes the necessity for medical research, there is no case law or legislation that will protect the subject, the investigator, or the hospital in some areas where suit is possible.

Under the present circumstances in the case of accident, the injured subject would, if he sought recompense, have no recourse in most cases except to sue for damages. He might proceed against the investigator and his staff, against the hospital, against the laboratory, against the governmental agency or other source of funds, or against the hospital's review boards—the research committee or the committee on ethics which had approved the research plan. The general practice and principle would be based upon negligence or some other defect on the part of the investigator or sponsor. If the plaintiff won, payment might be required from any or all of the defendants.

This could cause considerable injustice. "Studies on human beings, because they involve some intervention, exposure, manipulation or deprivation, are not intentional assaults and batteries . . ." (*8*). It is not appropriate that either the subject or the investigator should have to face the consequences alone. The injured subject has the right to expect to be "made whole" insofar as medical care and money can make this possible and the careful and responsible investigator has the right to legal support of his research.

Monetary Compensation

On some occasions precedents have already been established by federal agencies wherein funds for liability insurance have been included in the grants made. For example, allowances have been made by NIH under the 1957 Price-Anderson amendments to the Atomic Energy Act. The Congress has not made similar provisions for other hazardous programs. In a 1963 report, Columbia University Law School, through its Legislative Drafting Fund for the National Security Industrial Association, has recommended extension of advance protection. The National Foundation for Infantile Paralysis purchased liability insurance for its Salk vaccine field studies. In a study of seat belts, NIH Project R.G. 6284, accident insurance was purchased with $100,000 maximum liability with $100 per week for a year of incapacity. The need for protection has been recognized (*8, 9*).

"The Report on Harm in Government Programs states that 'Compensation for members of the public injured in a catastrophic accident would depend to a large extent upon their ability to recover damages by means of a lawsuit. Such suits would be governed by the law of torts which, generally speaking, holds an actor whose conduct injured another—either through carelessness or, in exceptional situations, even in the absence of fault—liable for compensatory damages to the injured person.' The application of liability without fault, although growing, particularly where there is a 'substantial risk . . . regardless of the degree of care' is still generally restricted to cases of injury arising out of the direct operation of a defendant, as opposed to indirect cause. When and whether the doctrine may apply depends on legal action and local law" (*8*).

As Freund (*10*) put it, "The question is an instance of a pervasive confrontation between two social philosophies, the one putting primacy on responsibility, blameworthiness, rewards and penalties for behavior, the other stressing security of the victims against the impersonal dooms of modern life. The conflict marked the early days of unemployment compensation, when debate centered on employer or plant funds versus pooled funds—the former providing an incentive to a firm to regularize employment, the latter providing greater assurance of compensation of the unemployed.

"A combination of the two forms of liability with and without fault is possible, as the current Keeton–O'Connell plan for automobile accident compensation demonstrates. Under that plan, compensation would be due, without inquiry into fault, for expenses and loss of wages, up to $10,000; recovery for pain and suffering would require a lawsuit involving proof of the defendant's fault. In the field of experimentation, a similar combination might be tried, perhaps with the variation that the recovery based on fault would require proof not simply of fault but of gross fault, in order to discourage speculative claims while retaining some extrinsic deterrent against recklessness. The existence of the basic compensation plan might serve, furthermore, to improve the general attitude of judge and jury toward the experimentation itself."

Ladimer (*8, 11*) suggests the feasibility of application of the principle of the workmen's compensation concept rather than employer liability or the malpractice approach. In the approach to these matters it should "not be neces-

sary to show fault, negligence or lack of caution." To take another approach, limited health and accident insurance could be written on each subject.

Practical problems remain. Which experimenters would be protected? How would psychological or physical damage be assessed? There are already legal precedents, of course, for reimbursement for injury. It would seem probable that something like these could be applied to this new area. "But the fact that such details and the underlying legal and moral issues are being seriously considered constitutes somber evidence that scientific inquiry will prove increasingly powerful in gaining knowledge of man himself" (*7*). In this process those responsible for the growth of knowledge must be protected.

References and Notes

1. Slater v. Baker, 2 Wils. K.B. 359 95 Eng. Rep. 860, 1767. Cited in Proceedings of a Conference on Use of Human Subjects in Safety Evaluation of Food Chemicals, at the National Academy of Sciences, National Research Council, Washington, D.C. (1967).
2. Carpenter v. Blake (N.Y. 1871) 60 Barb. 488. Cited in Proceedings of a Conference on Use of Human Subjects in Safety Evaluation of Food Chemicals, at the National Academy of Sciences, National Research Council, Washington, D.C. (1967).
3. I. Ladimer, *J. Public Law* **3**, 467 (1954).
4. G. I. Swetlow and M. G. Florman, *Med. Econ.*, p. 54 (Dec. 1949).
5. E. L. Cady, *Ann. West. Med. Surg.* **6**, 164 (1952).
6. L. L. Jaffe, *Dædalus* **98**, No. 2, of the Proceedings of the American Academy of Arts and Sciences, p. 406 (spring 1969).
7. D. Wolfle, *Science* **132**, 989 (1960).
8. I. Ladimer, *J. Chronic Dis.* **16**, 1229 (1963).
9. I have been informed that it is possible for a request for funds for liability insurance to be included in routine grant applications to the National Institutes of Health. The source of this information is Mr. Nathaniel Karol, Division of Grant Administration Policy Bureau, Secretaries Office, Department of Health, Education, and Welfare.
10. P. A. Freund, *Dædalus* **98**, No. 2, of the Proceedings of the American Academy of Arts and Sciences, p. 314 (spring 1969).
11. I. Ladimer, *J. Clin. Pharmacol.* **7**, 125 (1967).

NEWS AND COMMENT

Smoking and Health: Closing the Ring on the Cigarette

Four years ago, when the first major legislative struggle on the smoking and health issue was taking place, lobbyists for the tobacco industry and their congressional allies handled the antismoking forces as deftly as a cowhand from Marlboro country might rope a calf. Now, however, the smoking and health question is again agitating Washington, and this year the tobacco industry's problems look less easily manageable.

In coping with the health issue in 1965, the industry clearly made the best of adversity. The 1964 report of the Surgeon General's Advisory Committee on Smoking and Health had said that cigarette smoking was causally related to lung cancer in men; that it was the most important cause of chronic bronchitis; and that it was associated closely enough with other ailments, including coronary heart disease, to be highly suspect as a possible causal factor. Here, for the first time, was a warning against cigarette smoking by a federally sponsored panel of experts whose membership had been approved by the tobacco industry—a warning which, moreover, was stated as plainly as a skull and crossbones.

In light of this development, voluntary health agencies such as the American Cancer Society had reason to hope that, if Congress took no effective action of its own to discourage smoking, it would at least not prevent such action by the state and federal regulatory agencies. But Congress, aided by the tobacco lobbyists and its own talent for grinding sharp edges off unpleasant facts, enacted the Cigarette Labeling Act, requiring on each cigarette package the message "Caution: Cigarette Smoking *May Be* (emphasis supplied) Hazardous to Your Health."

Worried as it was about court suits being brought by cancer victims or their survivors, the tobacco industry itself saw an advantage in having a warning label, particularly if worded as mildly as the one Congress adopted. Yet, from the industry's standpoint, the labeling act had a still greater merit: It largely preempted other action in the smoking and health field for a 4-year period. Principally, this meant that the Federal Trade Commission (FTC), which had been moving to require a strong health warning on cigarette packages and in all advertising, was powerless to act.

Despite this setback in Congress to their cause, the antismoking forces—led by the U.S. Surgeon General and private groups such as the Cancer Society, the National League for Nursing, and the National Congress of Parents and Teachers—have persevered in their crusade, using every means of publicity and persuasion at their command. Though their financial resources have been limited compared to the tobacco industry's, these forces nevertheless represent a broad, powerful coalition of health and civic organizations which are active in nearly every community. Furthermore, the propaganda resources of a major government agency such as the U.S. Public Health Service are substantial. For example, the PHS once had 53,000 U.S. mail trucks displaying a large poster reading "100,000 Doctors Have Quit Smoking (Maybe They Know Something You Don't)."

In June of 1967, the Federal Communications Commission (FCC), to everyone's surprise, applied its "fairness doctrine" to cigarette advertising, holding that broadcasters who carry cigarette commercials must also carry some antismoking messages. The result was that the PHS and the Cancer Society and other voluntary health agencies suddenly found their antismoking "spots," which most broadcasters had been leery of using, in heavy demand.

Clearly, the smoking and health issue has been kept alive, and smokers gradually are responding. Per capita consumption of cigarettes has gone down by almost 3½ percent since release of the report by the Surgeon General's committee in early 1964. Furthermore, production during the first 3 months of 1969 was about 1.5 million packs a day below that for the same period in 1968; this suggests that there are now about 1.5 million fewer smokers, inasmuch as the average smoker consumes about a pack a day.

In Congress the smoking and health issue has been an embarrassment because it touches the financial nerves of a sizable block of southern and border states (some of them potently repre-