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Toward a Theory of Control of Medical Experimentation With Human Subjects: The Role of Compensation

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Although the use of human subjects in experimentation is not new, a satisfactory mechanism for compensating victims of untoward experiments has not yet been developed. The authors outline the remedies that are now available or that could be developed under common law principles. Rejecting these remedies as insufficient, the authors suggest a system, patterned after workmen's compensation laws, that can serve both as a control over researchers and as a just and efficient means of compensating injured subjects of medical experimentation.

I. INTRODUCTION

DISCOVERY IS the basis of progress in most areas of human endeavor and discoveries are made usually only after long periods of investigation. Behind every one of these discoveries lie costs that must be borne by society and from each one come benefits that must be distributed. In many cases, the balancing of costs against benefits is a constant process. Investigation continues only after the costs have been weighed against the benefits that have resulted and the quantum of anticipated gain is found to be sufficient to justify inquiry.

What is true for the progress of man is particularly evident in the field of scientific research, including the medical sciences. In this area the costs and benefits are clear, but they may be difficult to quantify. In a laboratory experiment the scientist can estimate the cost of his time, apparatus, and reactants, and the total of this calculation can be compared to the gains that may result from the

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study. But in the final stages of any medical experiment there is another factor that greatly complicates this calculus: the cost of human life. It must be decided whether the experiment should be performed if it is potentially harmful to those who participate in it.

This article will examine the remedies available to compensate those injured when this potential for harm is realized. It will first define the unique problems presented by an effort to maximize both deterrence and compensation in medical experimentation. The article will then address the remedies designed to ensure compensation of those injured in experimentation. The ability of each remedy simultaneously to discourage harmful activity in advance and provide fair compensation to injured subjects after the fact will be considered. First, the existing common law remedial theories will be examined. Secondly, the outlines of a comprehensive compensation system will be proposed, and its capacity for handling these problems will be compared with that of the common law theories discussed. Finally, the possibility of instituting such a compensation system in tandem with the existing common law remedies will be considered.

II. DETERRENCE AND COMPENSATION

During the past decade, health professionals, government officials, philosophers, and legal scholars have come to realize that the guidelines for the use of human beings as experimental subjects expressed in the Nuremberg and Helsinki Codes¹ have not been fully implemented in the United States.² Disregard of the principles of

1. *United States v. Brandt*, 2 Trials of War Criminals Before the Nuremberg Military Tribunals (The Medical Case) 181 (Military Tribunal I, 1947) (Nuremberg Code); 271 *NEW ENG. J. MED.* 473 (1964) (Helsinki Code).

2. In 1972 exposure of the so-called Tuskegee Study focused public attention on the use and misuse of human subjects in experiments in the United States. In this 30-year study by the United States Public Health Service, 400 poor black men diagnosed as having syphilis were examined periodically to determine the nature of their disease and were reportedly induced through cash payments and other promises to remain in the study and to entrust their treatment to the physicians working on the project. During the course of the study, penicillin was discovered to be an effective agent in the treatment of syphilis, but such treatment was withheld from the study group. *N.Y. Times*, July 26, 1972, § 1, at 1, col. 1. An estimated 107 subjects died from the effects of the disease. *N.Y. Times*, Sept. 12, 1972, § 1, at 23, col. 1.

Exposure of the Tuskegee Study occasioned reports cataloging other experimental studies in which questions existed as to whether the subjects' rights had been respected, including the following excerpt from the *N.Y. Times*, July 30, 1972, § 4, at 2, col. 4:

Even with a score of proclamations, codes, declarations, state-

the Codes has led to a wide variety of practices in this country, some of them shading into the unacceptable use of human subjects.³ Nevertheless, since society cannot expect medical science to progress at a desirable rate without reliance on human subjects, it has not been seriously suggested that experimentation involving human beings should cease altogether.⁴ Rather, recent inquiry has concen-

ments and guidelines formulated since the Nuremberg Code that are now supposed to be applied to all human experimentation, many questionable studies have been done in recent years and, to loud cries of "human guinea pigs," several have become embroiled in public controversy. Almost without exception, they involve members of minority or disadvantaged groups.

Eight years ago, as part of a study of immunity to cancer, a leading New York cancer specialist injected live tumor cells into elderly chronically ill patients without ever telling them in plain English what they were being given and why. The researcher, Dr. Chester Southam, was found guilty of "unprofessional conduct" by the state Board of Regents. Fortunately, nothing went awry in the subjects, all of whom rejected the tumor cells.

Nearly 400 poor women—most of them Mexican-Americans who had already borne many children and had come to a San Antonio family planning clinic for contraception—were enrolled in a study a few years ago to determine whether oral contraceptives did in fact cause psychological changes. All of the women were given identical-looking drugs, most of them active contraceptive agents. But 76 women received a "dummy," or placebo drug. Seven pregnancies occurred before the study was ended, six of them in the placebo group.

In 1967 coercion was charged in conjunction with a study in which live hepatitis virus was injected into mentally retarded children at Willowbrook State Hospital on Staten Island. Parents, who were said to have a poor understanding of the study, were allegedly being forced into consenting to their children's participation by way of getting them into the crowded hospital.

The controversy dissipated after changes were made in the consent procedure and the medical rationale was thoroughly explained. But to this day, many scientists are still objecting to the use of mentally defective children in research, subjects who themselves cannot possibly give informed consent to what is being done to them.

In the proceedings before the Board of Regents in the case involving the injection of cancer cells into chronically ill patients, the researchers introduced in their defense testimony of "well-known cancer and other professional researchers" to the effect that the practices in question did not differ significantly from those of the profession generally. Langer, *Human Experimentation—New York Verdict Affirms Patients' Rights*, 151 *SCIENCE* 663, 666 (1966).

3. A review of the human experimentation conducted in 100 studies, selected because of their consecutive publication in 1964 in a single "excellent" medical journal, led a research scientist to conclude that 12 "seemed to be unethical." Beecher, *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 1354, 1355 (1966).

4. The recent promulgation of regulations governing the procedures to be used in research involving human subjects at institutions receiving funds from the Department of Health, Education, and Welfare is evidence of the consensus that the use of human subjects is necessary. See 39 Fed. Reg. 18914-20 (1974).

trated on defining appropriate circumstances for the use of human subjects and deciding who those subjects should be.⁵ Although there is no general agreement on the circumstances that justify the use of human subjects, it is now widely conceded that in any event subjects must give their "free and informed consent." Thinkers and commentators have turned, therefore, to the task of defining this latter concept and determining if and how it can be achieved.⁶

Throughout this period of development, the stepchild question has been how to compensate human volunteers who are injured in the course of experimentation.⁷ The courts have made no attempt to distinguish negligent injuries occurring in the purely therapeutic setting from those arising in the experimental context.⁸ Some writers, moreover, have indicated that a volunteer's free and informed consent should operate as an assumption of the risk of non-negligent injuries resulting from experimentation.⁹ Three factors

5. EXPERIMENTATION WITH HUMAN BEINGS (J. Katz ed. 1972); *Ethical Aspects of Experimentation with Human Subjects*, 98 DAEDALUS (1969) (entire issue devoted to this subject).

6. See, e.g., H. BEECHER, RESEARCH AND THE INDIVIDUAL 18-32 (1970); Blumgart, *The Medical Framework for Viewing the Problem of Human Experimentation*, 98 DAEDALUS 248, 255-62 (1969); Freund, *Legal Frameworks for Human Experimentation*, 98 DAEDALUS 314, 322-24 (1969); Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 DAEDALUS 219, 220-22 (1969); Macklin & Sherwin, *Experimenting on Human Subjects: Philosophical Perspectives*, 25 CASE W. RES. L. REV. 434 (1975).

7. Only three articles have addressed the issue directly: Calabresi, *Reflections on Medical Experimentation in Humans*, 98 DAEDALUS 387 (1969); Note, *Medical Experiment Insurance*, 70 COLUM. L. REV. 965 (1970); Silverstein, *Compensating Those Injured Through Experimentation*, 33 FED. B.J. 322 (1974). The first two articles present the poles of thought current in general discussion of no-fault compensation. Calabresi views liability based on fault as the foundation of due care in an individual's actions, whereas the latter Note is strictly concerned with compensation of the victims. "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." Freund, *supra* note 6, at 322. Silverstein does recognize the competing goals of deterrence and compensation in the federal system of compensation outlined in his article. His proposal, however, does not provide for the continued deterrent force of the growth of the common law through private litigation.

8. Cf. *Cooley v. Karp*, 349 F. Supp. 827 (S.D. Tex. 1972), discussed in note 30 *infra* and accompanying text.

9. "The legal requisites for legitimate, *liability-free* experimentation can be described in threefold form: . . . informed, voluntary consent . . ." Freund, *supra* note 6, at 321 (emphasis added). Freund does proceed, however, to discuss briefly the possibility of "compensatory liability without fault." *Id.* at 321-22.

may have contributed to such a belief: First, the momentum of the rhetoric used in the discussion of some of the other issues concerning human experimentation; secondly, confusion with the principles governing the effect of consent in a normal physician-patient relationship; and finally, the fiction that monetary compensation can make an individual whole.

In the commentary on whether consenting human subjects should be used in medical experimentation, support for the proposition that they should has been drawn from comparisons to other situations in which society has allowed volunteers to be exposed to grave risks because of the public need. Extension of these analogies in order to decide how to allocate the human costs of medical experimentation, however, leads to erroneous conclusions. Astronauts and soldiers volunteering for dangerous assignments, for example, have been cited as parallels to the subjects used in medical research, and these modern heroes are in turn likened to the sacrificed victims of older cultures.¹⁰ This latter comparison demonstrates the swiftness with which rhetoric can lead to unwarranted conclusions. By reasoning that human volunteers are like sacrificial victims of old, we are propelled toward attaching all of the characteristics of such victims to these individuals. Specifically, we require them to bear the entire cost of these pursuits. Admittedly, society might decide that the human volunteer is the most appropriate bearer of the costs of untoward but nonnegligent results of medical experimentation. A decision incorporating such a major value judgment, however, should not be based on superficial analogies to related but readily distinguishable situations. The same care that has attended the consideration of whether the use of human subjects should ever be permitted should be taken in deciding how the costs of human experimentation should be distributed when either negligent or unavoidable injury results.

Informed consent has been perhaps the most fluid concept of the past decade in the field of medical malpractice.¹¹ To a large extent, this development reflects the rapidly changing and increasingly complex procedures that are commonplace in modern medical treatment. Free and informed consent in the experimental context, however, though it bears some resemblance to informed consent in the normal therapeutic situation, has its own meaning and

10. *Id.* Cf. Burger, *Reflections on Law and Experimental Medicine*, 15 U.C.L.A.L. REV. 436, 437 (1968); Jonas, *supra* note 6, at 223-24.

11. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* 165-66 (4th ed. 1971).

implications. Indeed, these different kinds of consent may address issues that are not only distinct but opposite. For instance, in the normal physician-patient relationship, the patient acts primarily out of self-interest, and the physician has no adverse interest that might interfere with his or her judgment as to the appropriate treatment for the patient. Society in such a case has only the attenuated interest of preferring a healthy populace to an ill one. All of these factors are altered to some degree in the context of experimentation.¹² The change in these considerations, therefore, should produce a corresponding change in the quantity and quality of the information an individual receives to enable him or her to decide whether to consent to a suggested experimental procedure. This modification should also condition the consequences of that decision, including the allocation of the costs. In the ordinary physician-patient relationship, allowing the patient to bear the costs associated with nonnegligent injuries sustained as a result of consensual treatment can be supported by the logical proposition that costs should flow in the same direction as benefits. In the experimental setting, however, placing the costs on the subject is less clearly justified, since most of the benefit is directed not to the subject but to the research community and, ultimately, to society.

If consent does not shift cost-bearing to the subject, then, what does it accomplish? From the perspective of the lawyer, who is accustomed to looking through the lens of liability, it might seem that consent has no function if it does not move the risk of monetary loss. But this view results from treating as fact the fiction that money damages can truly compensate an injured human being. In reality, consent establishes who will endure the actual suffering if an experiment results in pain and injury, experiences that cannot be shifted after the fact.

That the function of consent and the compensation of injuries in the context of medical experimentation have not received adequate attention is at first surprising, since one of the primary reasons for society's hesitancy to allow the use of human volunteers is

12. In the investigator-subject relationship, the primary purpose is to gain knowledge; the direct benefit to the subject may be nil, minor, or even beneficial, but is in any case subsidiary. The investigator may or may not be a physician; the subject may or may not be a patient. In the former, the main objective is to secure knowledge; in the latter, the welfare of the patient is the overriding consideration. As stated initially, the former relationship may be characterized as a scientific alliance

Blumgart, *supra* note 6, at 255-56.

the significant probability of injury. One explanation for this lack of attention may be society's unwillingness to acknowledge too directly its role in permitting one individual's life to be jeopardized, even for the good of the many.¹³ This admission of the relative worth of human life is seen by some as an erosion of the value generally accorded human life in modern society. This reasoning, however, can result in a paradox: we value the life of the individual so highly in the abstract that we refuse to face the task of valuing it in the particular case.¹⁴ But avoiding the compensation issue is not a rational mode of coming to terms with the decision to permit the use of human volunteers in dangerous experimentation, once that decision has been made.

This reaction, though, may be explained as a reflection of a

13. Congress recently enacted legislation establishing a Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. National Research Service Award Act of 1974, Pub. L. No. 93-348, tit. II, § 201, 88 Stat. 342. As first proposed in S. 2072, 93d Cong., 1st Sess. (1973), the Commission was to have been charged with the task of developing "a mechanism for the compensation of individuals and their families for injuries or death proximately caused by participation of such individual in a biomedical or behavioral research program." S. 2072, § 1202(a)(5). The Senate version retained this responsibility. However, this specific charge was substituted in CONF. REP. No. 93-1148, 93d Cong., 2d Sess. (1974), with the direction to the Commission to "make recommendations to the Secretary [of HEW] . . . concerning any other matter [in addition to administrative procedures necessary to implement ethical guidelines in conducting research] pertaining to the protection of human subjects of biomedical and behavioral research." The Conference Committee's treatment of the tenure and authority of the Commission, which it reduced from 5 to 2 years and from regulatory to advisory, makes clear the context of the elimination of specific reference to compensation. Congress, at the urging of a majority of the House members, not only is unwilling to confront squarely the role society plays in risking experimentation subjects' lives, but also is unwilling to give up the beneficial results of such activity.

14. This type of behavior has been christened the "Pompey syndrome" by Edmond Cahn in *Drug Experiments and the Public Conscience*, excerpted in EXPERIMENTATION WITH HUMAN BEINGS 184 (J. Katz ed. 1972). The phrase is taken from Plutarch's description of Pompey on being told by a lieutenant that the lieutenant would slit the throats of Antony, Caesar, and Lepidus, guests on Pompey's ship, if Pompey granted him permission. Pompey regretfully refused permission, indicating he would have applauded the act which would have left him sole ruler of the Roman empire if he could have avoided the appearance of complicity. But, the lieutenant's action would have implicated him. Similarly, Cahn suggests society would like to have the benefits of research once completed without acknowledging the risks to which a fellow human being was subjected to obtain that knowledge.

To the extent that Calabresi's concern is avoiding the appearance of "purposive choices to kill individuals for the collective good," Calabresi, *supra* note 7, at 393, he may be said to partake of the Pompey syndrome.

valid concern that compensation of injured volunteers might encourage questionable experimentation.¹⁵ Society in general and the professionals working in human experimentation in particular may fear that making compensation available to injured volunteers might become a license to undertake procedures not otherwise acceptable. They have recognized that the problem is how to make two goals, deterrence and just compensation,¹⁶ directly rather than inversely related.

Indeed, another explanation of the scant discussion of compensation in the literature on human experimentation may be the failure to distinguish between deterrence and the obligation to compensate, although the interrelation of these concepts is the primary dynamic in the fault system with which we are most familiar. Assessing costs to the party "at fault," the most common goal of tort law, is a device well suited to sorting out costs among private parties. When each party has equal ability to influence a source of injury, charging costs to the one at fault both provides a source of funds for compensation and serves as a deterrent to similar injuries in the future. However, as the development of products liability and the spread of other forms of strict liability indicate, traditional liability based on fault does not achieve a proper distribution of responsibility when one of the private parties possesses greater control over the sources of injury.¹⁷ Clearly, the ability to influence or control sources of injury has been recognized as a reason for altering society's scheme of assessment of injury costs on the basis of fault.

Medical experimentation presents another context in which the traditional remedies that have evolved to redress wrongs between pri-

15. In dealing with a problem very similar to the one at hand—the choice between expending resources on the rescue of a present, known accident victim and devoting those resources to preventive measures to increase the statistical chances of saving future lives—Charles Fried has urged that moral intuitions be taken seriously and subjected to rational analysis to reveal their structures, instead of being dismissed with the epithet "value judgment." Fried, *The Value of Human Life*, 82 HARV. L. REV. 1415, 1416 (1969).

16. Although the terms deterrence and compensation are here borrowed from accident law, it should be noted that the question here presented is not the normal one found in that context:

In medical experiments, much of this process [the indirect choice of accident victims and the indirect controls] seems reversed. It is the lives to be saved by the experiment that seem future and conjectural, while the life to be risked or taken is both present and real. Most of the elements of fault are absent—the victim usually is sick through no choice or fault of his own.

Calabresi, *supra* note 7, at 391.

17. See Prosser, *The Assault Upon the Citadel*, 69 YALE L.J. 1099 (1960).

vate parties do not produce results that comport with our notions of justice. The feeling that costs are not being properly allocated appears on the surface to be a reaction to the same considerations that have resulted in the placing of costs on the manufacturers in the products liability area. Closer examination, however, reveals significant differences. The manufacturer has the ability not only to produce nondefective products but also to spread the costs that arise from the use of defective products. In a medical experiment, however, the researcher is frequently engaging in the very research that is necessary to refine his hypothesis. The experiment is the equivalent of developmental tests in the manufacturing process. If the hypothesis has not reached the experimental stage prematurely, the researcher arguably cannot design a safer procedure. Further, unlike the manufacturer, the researcher usually does not operate in a market situation. Therefore the imposition of liability without fault would not serve as an effective cost-spreading mechanism.

Although the rationales that support the doctrine of strict liability are inapplicable to medical experimentation, still the suspicion persists that the costs of nonnegligent injury occurring in the course of human experimentation are not justly allocated. What gives rise to this suspicion? In what other ways does the injury arising out of medical experimentation differ from a normal accident? One answer is that society has allowed the researcher to expose the subject to a risk of substantial harm, not for the subject's benefit but for its own. Since the aim is public benefit, our intuition is that the untoward costs should not fall upon the individual, whether they result from the researcher's fault or not.

Clearly, the desire to compensate the victims of experimentation should not eclipse concern for deterrence and control. The possibilities of poorly designed or unwarranted experiments cannot be discounted. Since it is obviously preferable to prevent injuries in medical experimentation entirely, considerable attention has been given to deterrent measures that operate prospectively, such as review committees.¹⁸ Unfortunately, such procedures do not constitute an integrated control mechanism and do not contain devices designed to recognize and compensate nonnegligent injuries. It is suggested

18. 45 C.F.R. §§ 46.1-22 (1974) sets forth regulations that apply to institutions conducting research funded by the Department of Health, Education, and Welfare. For a comprehensive analysis of the review committee as a control mechanism see Cowan, *Human Experimentation: The Review Procedure in Practice*, 25 CASE W. RES. L. REV. 533 (1975).

that only the addition of retrospective remedies can achieve these goals. What is needed is a system that reweaves the common law threads of control, deterrence, and compensation into a modern pattern appropriate to the particular characteristics of human experimentation.

III. COMMON LAW THEORIES

The pride and genius of the common law has been its enduring flexibility. Repeatedly, as changes in society have given rise to novel questions, the common law has resolved them through the application of existing principles.¹⁹ Nevertheless, as society has grown more complex, courts have deferred to legislative solutions more frequently. Sometimes this deference has been but a cue to the legislatures to create statutory causes of action to enable courts to act with assurance in these new areas.²⁰ In other instances, legislatures have determined that the problems are better handled in administrative forums.²¹ At other times what has emerged is a pattern of interrelated administrative and judicial action.²²

19. As the legal profession began to recognize problems in the field of medical experimentation generally and to consider possible solutions, the medical community questioned the appropriateness and competence of the law in seeking such solutions. One response to this criticism came from then-Circuit Judge Warren Burger, who pointed out that the role of the law in this area, as in any other, is to mediate between those values inherent in the pursuit of medical knowledge and the other values of society generally. "Science unrestrained would be somewhat like an absolute monarch—a great servant, but, a terrible master. Law is inherently restraint. It is a restraint on science as it is a restraint on kings, congresses and presidents, and none of them really likes it very much. Those who become impatient with the slow pace of the law's response to the needs of science must remember that the history of Western philosophy shows that we cherish many values above scientific advances; science must function within this framework." Burger, *supra* note 10, at 441.

20. Recognition of the right to maintain an action for invasion of privacy is a good example of this. A strong theoretical argument for the recognition of such a right had been developed in Warren & Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890). But the New York Court of Appeals, the first state high court to be confronted with the problem, refused to recognize the existence of the right to be left alone. *Roberson v. Rochester Folding-Box Co.*, 171 N.Y. 538, 64 N.E. 442 (1902). The state legislature reacted to public indignation over *Roberson* by creating a statutory cause of action in this area. Ch. 132, §§ 1-2, [1903] N.Y. Laws 308.

21. Workmen's compensation systems, discussed in notes 88-93 *infra* and accompanying text, are an obvious example of such a determination.

22. The relationship among private arbitrators, the National Labor Relations Board, and the courts, which has emerged in the field of labor relations within the jurisdiction of the NLRB in the past decade, is an example of such a mix.

There are, however, two aspects of the common law mechanism that recommend it as a system for compensating subjects injured in the experimental context. The common law provides a retrospective remedy, thereby committing society's limited resources to the resolution of only those problems that have actually arisen. Consequently, where the common law or the common law bolstered by statutory causes of action is sufficient to resolve new problems, such a system brings about the most efficient expenditure of public resources. In addition, the common law system of compensation does not focus attention on society's decision to accept the risk of injury inherent in the activity giving rise to liability. It has been argued that the effect of the common law in the area of accident law generally has been to mask the communal choice to prefer efficiency to human lives.²³ If it could provide a means of sufficient deterrence and adjust compensation in the experimental context, then the common law system would also camouflage the decision to accept the known risk to volunteers in exchange for some speculative good, a major factor in society's uneasiness toward human experimentation in general. Therefore, before considering the imposition of administrative structures to resolve the problems of injury to human subjects, we should examine the potential of the common law in the area.

A. *The Types of Situations in Which Injuries Occur*

There are three types of situations in which injury to subjects of experimentation may occur. First, the common negligence of the researcher-physician may cause injury to the volunteer. Secondly, injury may arise in an experiment that should not have been conducted in the first place. Experiments that fail to meet the prevail-

23. In the field of accidents, much of the control over the taking of human life is accomplished by what economists call the market. Limbs and lives are given a money value; the activities that take lives or limbs in accidents pay the victims; and people quite coldly decide whether it is cheaper to install a safety device or to pay for the accidents that occur because the safety device is missing. Despite the enormous oversimplification of the foregoing example (the effect of "fault" in determining accident payments, for instance, is ignored), it indicates how "accidents" are controlled in an indirect fashion which, nonetheless, takes into account both the values of the lives taken and the cost of saving them.

The beauty of the market device is that no one seems to be making the decisions to take lives and, therefore, no blatant infringement of the commitment to human life as sacred occurs.

Calabresi, *supra* note 7, at 389-90.

ing standards for approving the use of human volunteers²⁴ or that lack adequate consent of the subject²⁵ fall within the second category. In such situations the injury complained of may or may not relate to a defect in the execution of the experiment. Finally, injury to the volunteer may occur notwithstanding the absence of negligence, the appropriate approval of the experiment, and the sub-

24. The Nuremberg Code is generally viewed as stating the minimum requirements to justify the use of human beings in experiments. Among the principles of significance to the present considerations are:

- 2) The experiment should be such as to yield fruitful results for the good of society, *unprocurable by other methods or means of study*, and not random and unnecessary in nature.
- 3) The experiment should be so designed and *based on the results of animal experimentation* and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
- 4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
- 5) No experiment should be conducted where there is a *priori* reason to believe that death or disabling injury will occur

United States v. Brandt, 2 Trials of War Criminals Before the Nuremberg Military Tribunals (The Medical Case) 181, 182 (Military Tribunal I, 1947) (emphasis added).

25. In essence, the consent of the subject is merely one of the requisites to a justifiable experiment. It has been accorded such significance, however, as to merit separate treatment. In the present context, it can be distinguished from the other essential elements, set out in note 24 *supra*, stated by the Nuremberg Code by its extrinsic nature. The other factors inhere in the experiment, whereas obtaining each subject's consent is an individual process by which the same experiment will be viewed as justifiable with respect to one subject (a consenting one) and unjustifiable with respect to another (a nonconsenting one). The primary importance attached to this factor is evident from the extended statement of the principle in the Nuremberg Code:

- 1) The voluntary consent of the human subject is absolutely essential.

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

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

United States v. Brandt, 2 Trials of War Criminals Before the Nuremberg Military Tribunals at 181-82.

ject's valid consent. Such unavoidable injuries are the specific untoward results that have given society pause in accepting human experimentation.²⁶

Where the negligence of the researcher-physician is the cause of injury, the common law provides the universally accepted remedy—an action for malpractice.²⁷ To be sure, the experimental nature of the main enterprise may make the recognition of negligence in the traditional sense difficult. On the other hand, it is clear that a subject's consent, as in the normal therapeutic situation, does not relieve the researcher-physician of his common law duty of care.²⁸ Thus, even where consent is given, if the harm can be traced to the researcher's error, the traditional remedy for negligence should provide the injured subject compensation.

B. Consent

In many cases harm will not be traceable to a negligent act; the injured party might attempt to base a cause of action on the researcher's failure to obtain the proper consent of the volunteer. The victims of the Tuskegee study, however, are the first injured subjects to seek recovery on the explicit ground that free and informed consent was not obtained.²⁹ Prior to this case, the courts appear

26. Another dimension that should be noted in charting an abbreviated typology of situations in which a human subject may be injured in medical experimentation is that of the therapeutic versus the nontherapeutic situation. It is beyond the scope of this article to deal with the gradations from the purely therapeutic and nonexperimental situation to the experiment in which the goals are wholly experimental and of no therapeutic value to the individual volunteer. The formulation of a workable definition of experimentation has been addressed elsewhere. See, e.g., H. BEECHER, *supra* note 6, at 88-90; Moore, *Therapeutic Innovation: Ethical Boundaries in Initial Clinical Trials of New Drugs and Surgical Procedures*, 98 DAEDALUS 502 (1969). For the purpose of this article, the proposition that a procedure may be both experimental and therapeutic is assumed. See generally 45 C.F.R. § 46.3(b) (1974). While the two areas overlap, this article will also proceed on the premise that where a procedure is both therapeutic and experimental, the latter characterization controls.

27. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* 161-65 (4th ed. 1971).

28. 45 C.F.R. § 46.9 (1974) provides:

Any organization proposing to place any subject at risk is obligated to obtain and document legally effective informed consent. No such informed consent, oral or written, obtained under an assurance provided pursuant to this part shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal right, *including any release of the organization or its agents from liability for negligence* [emphasis added].

29. The Tuskegee Study case, a class action on behalf of all of the participants, both syphilitic group members and nonsyphilitic control group members

not to have had the opportunity to distinguish the informed consent required in the normal physician-patient relationship from the free and informed consent required in the experimental situation. Where the experimentation has offered some therapeutic benefit to the subject, at least one court has ignored the experimental nature of the activities in assessing the quality of information that the physician conducting research should supply in seeking a subject's consent.³⁰ In addition, the concept of consent in the normal therapeutic situation is changing. An examination of two recent cases demonstrates some of the difficulties surrounding the consent issue.

In *Karp v. Cooley*,³¹ a suit instituted by the widow of the recipient of the first mechanical heart, the court required only the type of consent obtained from the normal candidate for surgery, although the physician himself was the developer of the experimental device.³² Plainly, the medical procedure in this case, though employed in a therapeutic setting, was experimental in the extreme. Nevertheless, the court treated the experimenter-subject relationship

in the study, was recently settled out-of-court on what was to have been the first day of trial in the civil suit. The settlement provided for individual monetary awards not only for the syphilitic participants or their estates, but also for members of the control group, N.Y. Times, Dec. 18, 1974, § 2, at 56, col. 4. The settlement with the nonsyphilitic participants or their estates could be based only on the researchers' failure to obtain their *informed* consent, since generally the nonsyphilitic participants received only benefits, e.g., free medical care, as a result of their participation.

30. *Karp v. Cooley*, 349 F. Supp. 827 (S.D. Tex. 1972).

31. *Id.*

32. The mechanical heart substitute was implanted after the patient's condition deteriorated following heart surgery. The patient had signed a specially prepared consent form which stated in part:

In the event cardiac function cannot be restored by excision of destroyed heart muscle and plastic reconstruction of the ventricle and death seems imminent, I authorize Dr. Cooley and his staff to remove my diseased heart and insert a mechanical cardiac substitute. I understand that this mechanical device will not be permanent and ultimately will require replacement by a heart transplant. I realize that this device has been tested in the laboratory but has not been used to sustain a human being and that no assurance of success can be made.

349 F. Supp. at 831. The criteria that the court considered in determining the sufficiency of this consent procedure are made clear in the opinion: "Upon a review of all the evidence produced, it could not be concluded by a jury that Dr. Cooley had violated the medical standard in this community by the information he gave *or did not give* to Mr. Karp concerning his surgery." 349 F. Supp. at 834 (emphasis added). That the court did not consider appropriate inquiry into the subject-patient's actual understanding of the experimental procedures to which he supposedly gave his consent is also made clear: "Texas law would require that a jury be instructed that Mr. Karp is charged with reading the consent even if in fact he did not." 349 F. Supp. at 835.

no differently than the normal physician-patient relationship. Given the experimental nature of the situation, a determination whether the procedure's potential for successful use in human beings had been clearly indicated should have been put at issue even before the question of the validity of consent was reached. The *Cooley* court, however, did not perceive any material difference between the case at bar and the normal therapeutic situation and never considered the threshold question.³³ Not surprisingly, then, because the court failed to recognize any difference between experimental and accepted methods of therapy, it was content to leave the determination of the type and quality of information that should be given a patient in an experimental, albeit therapeutic, setting to the attending physician. Liability would be imposed only when the physician's decision failed to conform to the standard of the "reasonable medical practitioner."³⁴ This resolution of the consent issue is consistent with the test employed by the majority of jurisdictions in assessing the adequacy of information supplied in the normal physician-patient relationship.³⁵

Since the surgeon in *Cooley* was the developer of the experimental device employed, the court's limited scrutiny is especially disturbing. A physician has a duty to his patient to choose the best treatment and so must balance the probable effectiveness of and the dangers posed by the contemplated action. At the same time, the researcher has a personal interest in establishing the efficacy of the experimental device, procedure, or therapy that he has developed

33. The court's paraphrase of the issues raised by the plaintiff does not make clear whether the question of the development of the procedure to a point of readiness for human use was explicitly raised. The plaintiff generally questioned whether "under the circumstances the defendants were negligent in performing the corrective surgery, implanting the mechanical heart, and submitting the patient to the surgery for inserting the human donor heart . . ." 349 F. Supp. at 832. The court interpreted this issue as questioning the treatment chosen in view of the particular patient's condition, rather than as questioning the appropriateness of the therapeutic use of the treatment at that stage of its development.

34. In granting the defendants' motion for a directed verdict, the court stated, "Upon a review of all the evidence produced, it could not be concluded by a jury that Dr. Cooley had violated the medical standard in this community by the information he gave or did not give to Mr. Karp concerning his surgery." 349 F. Supp. at 834.

35. Annot., *Malpractice: Physician's Duty to Inform Patient of Nature and Hazards of Disease or Treatment*, 79 A.L.R.2d 1028 (1961); Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533, 1555-61 (1970).

or the hypothesis he seeks to prove. And yet, the court failed even to mention this conflict of interest.

In contrast to the approach of the *Cooley* court, the United States Court of Appeals for the District of Columbia has gone so far as to reexamine the traditional standards for judging the adequacy of information upon which informed consent is obtained in the normal therapeutic situation. In *Canterbury v. Spence*³⁶ the plaintiff consented to a recognized and accepted treatment, but he had not been told that the treatment resulted in injury in a small but statistically predictable percentage of cases.³⁷ Plaintiff's treatment resulted in one of these statistically predictable injuries. The physician, however, attempted to justify his failure to inform the plaintiff of the risk on the ground that despite the remoteness of the risk, the disclosure of such information might have caused the patient not to consent to the needed treatment.³⁸ The court noted that prior to the treatment the patient had been suffering considerable but bearable back discomfort, whereas after the treatment the patient was left partially paralyzed. In view of these facts, the court strongly affirmed the patient's right to choose between bearing his present known pain and bearing the risk of severe injury involved in seeking the relief that might result from the treatment. To make such a choice, the patient must be informed of all material risks attendant to the proposed procedure.³⁹ Except in the most unusual case, the court reasoned, the physician may not legally inform the patient of only selected risks.⁴⁰

The *Canterbury* court rejected the majority position that a physician need only inform a patient of those risks that other physicians practicing in the community customarily reveal to their patients. Since the foundation of the opinion was the patient's right to self-determination, the court measured the scope of the physician's duty

36. 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972).

37. "Dr. Spence further testified that even without trauma paralysis can be anticipated 'somewhere in the nature of one per cent' of the laminectomies performed, a risk he termed 'a very slight possibility.'" 464 F.2d at 778.

38. 464 F.2d at 778.

39. The root premise is the concept, fundamental in American jurisprudence, that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body. . . ." True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.

464 F.2d at 790 (footnotes omitted).

40. 464 F.2d at 788-89.

by the patient's need for information.⁴¹ Liability for nondisclosure would arise, however, only in situations where the knowledge of an unrevealed material risk would have caused the patient to decide against the therapy. The question whether the disclosure of the unrevealed risk would have had such an effect on the patient's choice is determined on the basis "of what a prudent person in the patient's position would have decided if suitably informed of all the perils bearing significance."⁴²

Cooley and *Canterbury* represent the poles of present judicial thought that would provide the backdrop of the common law in a suit based on the failure to obtain adequate consent from an injured subject of human experimentation. The approach taken in *Canterbury* would very likely produce a more searching inquiry in the experimental situation. If the *Cooley* court had applied the *Canterbury* standard, it might have questioned the patient's ability to consent without information on whether the experimental procedure had been developed to a point where its readiness for use on human beings was indicated. At the very least, *Canterbury's* rejection of the medical-community-standard test and the court's emphasis on the relationship of the particular physician to the particular patient would have resulted in a more satisfying inquiry into the physician's apparent conflict of interest in *Cooley*.⁴³

41. [T]he patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision. . . . [A]ll risks potentially affecting the decision must be unmasked.

464 F.2d at 786-87.

42. 464 F.2d at 791.

43. Even under the majority standard expressed in *Cooley*, recent codifications of practices for obtaining consent of human volunteers in federally funded research should be strong evidence of what a reasonable researcher-physician would have revealed to the subject in circumstances similar to the *Cooley* situation today. An example of such official requirement is 45 C.F.R. § 46.3(c) (1974), which provides:

"Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

- (1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
- (2) a description of any attendant discomforts and risks reasonably to be expected;

In the most widely known incidents that have raised the public's concern about human experimentation, consent, as a practical matter, has been totally lacking.⁴⁴ The common law requirement of consent, whether measured by the majority standard as set out in *Cooley* or by the *Canterbury* standard, would seem to provide relief in such cases where injury has resulted. More difficult problems arise when injury occurs in the context of experimentation and consent, as defined in the therapeutic setting, has been granted. The question then becomes whether there is a need to distinguish consent given in the experimental situation from that given in the course of normal therapy.

The limitations on liability in the therapeutic setting serve to illustrate the role of consent given in the ordinary physician-patient relationship. Even under the more liberal *Canterbury* test, there are two major qualifications to availability of relief. There must be an injury, and the failure to place the injured party in a position to give informed consent must be the cause of that injury.⁴⁵ If the fact-

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- (3) a description of any benefits reasonably to be expected;
 - (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
 - (5) an offer to answer any inquiries concerning the procedures; and
 - (6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

Moreover, in any research conducted in institutions subject to disclosure and consent requirements, a subject's private cause of action for injury in an experiment where consent was obtained without full disclosure of material risk should be recognized as a statutory tort. 45 C.F.R. § 46.5(a) (1974) requires that organizations that have projects funded by the Department of Health, Education, and Welfare and involving human subjects file general assurances of ongoing review and implementation procedures in accordance with 45 C.F.R. § 46.6 (1974). 45 C.F.R. § 46.6(a) (1974) speaks of the organization's "statement of principles which will govern the organization in the discharge of its responsibilities for protecting the rights and welfare of subjects." The context of this section implies strongly that the required statement of principles is not limited in its application to subjects in HEW funded research, but should extend to all subjects in the organization's research activity, regardless of source of funding. Therefore, since he or she would be a member of the class which the regulations are designed to protect, the injured subject should be permitted to recover on the basis of a statutory tort. *Cf. Griffin v. United States*, 351 F. Supp. 10 (E.D. Pa. 1972).

44. See note 2, *supra*.

45. No more than breach of any other legal duty does nonfulfillment of the physician's obligation to disclose alone establish liability to the patient. An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence. . . . And, as in malpractice actions generally, there must be a causal relationship between the physician's

finder decides that a prudent person, given the information the injured patient did not have, nonetheless would have consented to the procedure, there is no liability under *Canterbury*. Because the patient is the major beneficiary in the normal therapeutic situation, these limitations are understandable. The treating physician and the patient have the same basic objective—achieving relief and recovery. Where the limitations contained in *Canterbury* operate to deny relief, notwithstanding the failure to provide the patient with all of the material facts, plaintiff's uncompensated burden may be viewed as a justifiable trade-off for his or her anticipated benefit. Moreover, since the aim of the physician and the patient is to benefit the patient only, it is not likely that the physician's judgment will be clouded by any interests not shared by the plaintiff. Therefore, in the normal therapeutic situation the primary function of consent is to allow the patient to determine what will be done to his or her body; the deterrent effect of consent is negligible.

The possibility of researcher conflict of interest in the experimental context, however, greatly increases the role of consent as a deterrent. The researcher should not be permitted to select the risks that he or she deems it advisable to reveal to a subject; nor should the fact-finder be charged with deciding whether a "prudent person," even if provided with the undisclosed material information, would have consented to the experiment.⁴⁶ These limitations clearly diminish the measure of control that the requirement of full and informed consent is capable of providing. Such a result is inappropriate in the experimental situation where, unlike the therapeutic situation, the interests of researcher and subject may conflict and the major benefits of the endeavor flow not to the subject but to society. These distinguishing features indicate that more control is needed in the experimental context than in the therapeutic context.⁴⁷

failure to adequately divulge and damage to the patient.
464 F.2d at 790.

46. Cf. Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 *YALE L.J.* 1533, 1563 (1970).

47. So that the control feature of the consent requirement is fully utilized and so that subjects are adequately protected, failure to make full disclosure of the known risks to the subjects in human experimentation should be actionable per se when injury has resulted. Inquiry should not be made whether the subject would have consented if full information had been given. Whether there should be a private cause of action where consent was not based on full information, but injury has not occurred—perhaps largely an academic question—raises the problem of windfall to the subject. A more appropriate remedy for such a failing would be administrative review of the researcher's

In addition, because it has developed in the therapeutic setting, the present common law concept of consent does not address an important problem inherent in human experimentation. The common law requirement of consent contemplates the disclosures of known risks only.⁴⁸ The *Canterbury* case, which advocates the broadest consent requirement, would seem to impose liability for a failure to make disclosure of the general possibility of unknown risks.⁴⁹ In the experimental situation, however, the unknown risk is the greatest source of potential injury. Consequently, a subject who consents to experimentation with the specific knowledge that injury may result from an unknown risk and who suffers harm from such a cause would not be afforded a remedy under the present common law concept of consent.

The common law should begin to take into account the differences between the purpose of consent in the normal physician-patient relationship and the purpose of consent in the context of human experimentation. If such a development took place, the common law would acquire the capacity to address more of the problems that arise from experimentation. The basic issue in experimentation cases should be the validity of the injured subject's consent. The threshold question, then, would be the ability of the subject to consent. Since the concept of free and informed consent can be viewed as creating an exception to the general rule of incapacity to consent to serious battery, attention should be focused on the question whether the particular experiment met the basic criteria justifying the use of human subjects.⁵⁰ A subject's consent should be viewed as void and not within the exception in cases where the experiment did not meet such criteria.⁵¹

Furthermore, development of the common law in this area would

actions with appropriate sanctions imposed. See, e.g., Board of Regents of Univ. of St. of N.Y., *Licenses Suspended, Suspensions Stayed, Respondents Placed on Probation*, 34 J. MEETING OF BOARD OF REGENTS OF UNIV. OF ST. OF N.Y. 787 (1965). In this case there was no indication of any permanent physical harm resulting from the injection of cancerous cells into subjects who were ill with diseases other than cancer. However, despite the absence of proof of physical harm to the research subjects who rejected the cells, the two physician-researchers had their licenses to practice medicine suspended.

48. See note 39 *supra* and accompanying text.

49. Since *Canterbury* requires the disclosure of all known material risks, the statistically predictable injury rate from unknown risks must be pointed out to the subject. Notes 39-40 *supra* and accompanying text.

50. See note 54 *infra* and accompanying text.

51. This is, perhaps, only another way of viewing the warranties made when a researcher solicits human volunteers.

provide remedies for injured subjects whose consent was not based on all the information available at the time the experiment began.⁵² If the concept of consent were expanded in this manner, the imposition of personal liability on the researcher would also insure that every effort would be made to be certain that the subject fully understood the risks that he or she was assuming. Such liability would complement the systems of prospective controls that have been developing in recent years,⁵³ guaranteeing that these provisions would be substantive rather than formal.

But even if existing doctrines were expanded, the common law concept of consent would not hold promise as a means of compensating victims of unknown risks in human experimentation. The central component of the consent doctrine is the duty to disclose. Therefore, the imposition of liability on a consent theory for injuries due solely to unknown risks would have to be based on the failure prior to the experiment to provide information which, in fact, the experiment itself generated. The courts justifiably would resist stretching the concept of consent so far. Thus, it is necessary to ascertain whether some of the newer theories of liability in which negligence is not an element of the cause of action are transferable to the area of human experimentation.

C. *Warranty and Strict Liability*

The second common law concept that appears to promise relief in some situations where human volunteers have been injured is warranty. An express warranty, first of all, may arise from the review procedures currently being followed in some institutions. When an experiment using human beings is submitted for review prior to commencement, three broad requirements should have been met: (1) the proposed research must have been advanced as far as possible through the use of laboratory animals and techniques not placing human beings at risk; (2) the results of these efforts should indicate a sufficient probability of benefit to justify proceeding to the stage of human experimentation;⁵⁴ and (3) the researcher must have taken due care in the planning of the experiment to eliminate avoidable risks. The submission of the experiment to the review committee should be viewed as a personal express warranty

52. See note 46 *supra* and accompanying text.

53. See generally 45 C.F.R. §§ 46.1-.22 (1974); National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342.

54. See notes 24, 25 *supra*.

by the researcher that these conditions have been fulfilled. Similarly, the approval of the review committee should be taken to be an express warranty by the institution that the requirements have been met. Even where no review is required or obtained, the decision to conduct the experiment should be held to give rise to an implied warranty of fulfillment of the three prerequisites. When a volunteer is injured in an experiment that does not in fact meet these specifications, both the approving institution and the individual researchers should be held liable for breach of their warranties. Alternatively, liability could be based on negligence of these parties for wrongly approving and continuing such a project.

Though it is clear that the principles of warranty can be applied to medical experimentation, it is more difficult to determine to what extent the related concept of enterprise liability⁵⁵ can be employed to compensate injured volunteers and to control the experimental use of human beings. Several recent lines of cases give guidance in this area and also indicate how likely the courts are to find such liability in medical experimentation.

One series of cases addresses the problems arising from transfusions of infected blood. In the course of medical treatment a patient may get a transfusion that causes severe injury or death, when the blood serum has been donated by or purchased from an individual with hepatitis. The current state of medical knowledge has provided no completely accurate method to detect the presence of hepatitis infection in blood available for transfusion.⁵⁶ Formerly, if the blood bank, hospital, and medical personnel had used all available procedures for detecting these elements, courts did not hold them liable for injuries sustained when transfusions did result in patients contracting hepatitis. Recently, however, the leading case for nonliability of such parties, *Perlmutter v. Beth David Hospital*,⁵⁷ has been rejected by several courts.

55. As used in this article, this term indicates the principle of distributing the total costs of developing products and services evenly through the population that benefits from their availability. It is broader in significance than normal products liability theory in explicitly attempting to postulate cost-spreading mechanisms where there may not be an ultimate product or service to facilitate cost-spreading procedures.

56. Recent developments in testing for the presence of hepatitis virus in blood available for transfusions have increased to 35 percent the capacity to detect the virus. N.Y. Times, Apr. 17, 1974, at 24, col. 6. See also Franklin, *Tort Liability for Hepatitis: An Analysis and a Proposal*, 24 STAN. L. REV. 439, 444 (1972).

57. 308 N.Y. 100, 123 N.E.2d 792 (1954).

In *Perlmutter*, major reliance was placed on characterization of the blood transfusion as a service rather than a sale. This distinction allowed the court to find that there was no attendant implied warranty of any kind under the Sales Act. The service characterization of *Perlmutter* was first rejected in *Cunningham v. MacNeal Memorial Hospital*,⁵⁸ which flatly held the blood transfusion in that case to be a sale, which gave rise to strict liability in tort.⁵⁹ In reaching this conclusion, the court analyzed section 402A of the *Restatement (Second) of Torts*, which places on the seller liability for injuries caused by a defective product.⁶⁰ Moreover, the court rejected defendant's argument that the hepatitis-infected blood came within the exception that comment K of section 402A creates for unavoidably dangerous products.⁶¹ It interpreted this exception to

58. 47 Ill. 2d 443, 266 N.E.2d 897 (1970).

59. *Id.* at 452, 266 N.E.2d at 902.

60. RESTATEMENT (SECOND) OF TORTS § 402A (1965) provides:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

This section, which was adopted by the American Law Institute in 1964, has been interpreted both as a reaction to the difficulties that injured consumers faced in proving where the negligence which was the cause of injury had occurred in the chain of supply and as an effort to distribute the total of the expected cost associated with the use of a product through the consuming public.

In *Cunningham*, the emphasis of the decision was not based upon the applicability of either of the above policies to the situation of transfusion-related hepatitis, but rather upon characterization of the provision of blood by the hospital as a sale, which triggered the application of § 402A.

61. Comment *k* to § 402A provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it

apply only to pure products and held that the blood in this case was not pure when sold to the patient, because it contained the hepatitis infection.

Cunningham has been criticized for its mechanical application of strict liability under section 402A, on the ground that it allowed a major policy decision to rest on an act of judicial labelling.⁶² Two other courts that have rejected the *Perlmutter* rationale have attempted to deal more directly with the policy choices involved. The Pennsylvania Supreme Court in *Hoffman v. Misericordia Hospital of Philadelphia*⁶³ recognized that implied warranties of merchantability and fitness for a particular purpose can arise in nonsales transactions. Moreover, the decision suggested strongly that recovery would be based on contract principles of warranty rather than on tort principles. However, although the court alluded to the policy questions left unanswered by *Cunningham*, it did not discuss them fully, because the case was before the appellate court on the issue whether defendant's demurrer should be sustained.

The policy questions were addressed directly by a New Jersey court in *Brody v. Overlook Hospital*,⁶⁴ which discarded the judicial immunity created by *Perlmutter* in favor of strict liability in tort. The court reasoned that strict liability would force hospitals to choose suppliers whose collection practices were least likely to result in gathering contaminated blood and would encourage them to take more active roles themselves in screening donors.⁶⁵ Essen-

unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but, apparently reasonable risk.

62. See Franklin, *supra* note 56, at 461; Note, *Strict Liability for Disease Contracted from Blood Transfusions*, 66 Nw. U.L. Rev. 80, 87 (1971).

63. 439 Pa. 501, 267 A.2d 867 (1970).

64. 121 N.J. Super. 299, 296 A.2d 668 (Super. Ct. 1972).

65. The blood banks stand in the same position to the hospital as the manufacturer of a product does to a distributor—as a supplier to a marketer. It can be anticipated that adoption of a strict liability standard for the State of New Jersey will have the beneficial effect

tially admitting that these efforts on the part of hospitals would at best only reduce the incidence of liability, the court went on to endorse strict liability as a loss-spreading device.⁶⁶

As in the blood serum cases, an unavoidable injury in a medical experiment gives rise to a clash between the law's growing tendency to impose costs on the activities that produce them and the notion that the healing professions should be held liable only for fault.⁶⁷ Just as some courts have found hepatitis-infected blood to be defective, focusing on the result of its use and not on what physicians could know at the time of its administration, so they could hold experiments that in fact cause injury to be defective. It is possible, however, to distinguish the medical experimentation situation from the blood serum cases on the basis of foreseeability in a narrow sense. In the blood serum cases, the risk of hepatitis is specifically anticipated. To some extent, altered collection procedures can remedy the problem. The most troublesome risks of medical experimentation, however, are those that are totally unforeseeable. What significance, then, should this distinction have?

The issue of liability for unforeseeable consequences has been treated in a series of cases. The central problem is to determine the warrantor's responsibility when he sells a product that despite appropriate manufacture and use causes injury to a significant portion of its consumers. The two leading cases in this area are *Green v. American Tobacco Co.*⁶⁸ and *Pritchard v. Liggett & Myers To-*

of forcing hospitals to deal only with those blood banks which have good safety records, thus decreasing the risk of the patient's becoming infected with hepatitis as a result of a transfusion.

Even in the comparatively low number of cases in which the hospital has recourse to only a single blood bank, imposition of strict tort liability may well spur the hospital to take a more active role in influencing the bank's collection processes, *i.e.*, more careful screening of donors. Most importantly, the imposition of strict liability cannot help but force hospitals both to supervise more carefully their own use of blood, and to encourage medical research to develop either a more satisfactory test for hepatitis or an immunization vaccine to be given against the disease to a patient about to undergo a transfusion.

Id. at 307-08, 296 A.2d at 672-73.

66. "Another important policy justification for strict liability is that of 'loss spreading.' If the hospital bears the loss resulting from hepatitis-infected blood, it will tend to spread the loss among all parties, *i.e.*, donors, blood banks, perhaps its patients." *Id.* at 308, 296 A.2d at 673.

67. Franklin, *supra* note 56, at 472, 476.

68. The litigation of this case spanned 12 years, including seven stages. After the case was filed in 1957, there was a jury trial in the United States District Court for the Southern District of Florida in which a general verdict was returned for the defendant on the basis of the answers to four written in-

*bacco Co.*⁶⁹ In *Green*, the Florida Supreme Court held that the consumer was entitled to rely on implied assurances that cigarettes were wholesome and found that the manufacturer could be held absolutely liable for a consumer's death from cancer caused by smoking cigarettes.⁷⁰

Although by the time of trial the causal connection between smoking and lung cancer had been demonstrated, it was unknown at the time plaintiff purchased and smoked the cigarettes that allegedly caused his death from cancer. Therefore the case turned on

interrogatories. Briefly, the interrogatories indicated that the jury believed the plaintiff's husband had died of lung cancer, a proximate cause of which was the smoking of defendants' product, Lucky Strikes. However, the jury also found that the defendant could not by "reasonable application of skill and human foresight" have known of the carcinogenic effects of its product.

At the first hearing in appellate court, 304 F.2d 70 (5th Cir. 1962), the jury's verdict was upheld. However, on petition for rehearing, 304 F.2d 85 (5th Cir. 1962), the court agreed to certify to the Supreme Court of Florida, under its procedure allowing it to render advisory opinions to federal courts faced with novel questions of Florida law in diversity cases, the question of a manufacturer's liability absent the foreseeability of the harm which its product could cause.

The Supreme Court of Florida responded in 154 So. 2d 169 (Fla. 1963), that the United States Court of Appeals had misinterpreted Florida law on the issue of manufacturer liability absent foreseeability. The manufacturer's opportunity for knowledge of a defect causing an injury to a customer was irrelevant to his liability. On the basis of the Florida court's interpretation, the original jury verdict was overturned and a new trial ordered by the federal appellate court, 325 F.2d 673 (5th Cir.), *cert. denied*, 377 U.S. 943 (1963).

In the second jury trial in 1964, the defendant produced expert witnesses who testified, over plaintiff's objection, that the cause of lung cancer was unknown and that research had not established a fundamental link between cigarettes and cancer. In assessing the credibility of the expert witnesses for each side, the jury apparently believed the defendant's and rendered a verdict accordingly.

On appeal, a three-judge panel for the United States Court of Appeals for the Fifth Circuit reversed the jury verdict and rendered judgment for the plaintiff, notwithstanding the verdict. 391 F.2d 97 (5th Cir. 1968). The majority held that the question of causation had been foreclosed by the first jury finding and it was error to have submitted the issue of causation and evidence on the point to the jury.

Finally, the Fifth Circuit agreed to reconsider en banc the reversal of the second jury verdict, 409 F.2d 1165 (5th Cir. 1969). The majority of the court, sitting en banc, overruled the three-judge panel, holding the evidence on causation was admissible at the second trial and reinstating the jury verdict for the defendant. However, this action theoretically did not affect the Florida common law on manufacturers' liability despite lack of opportunity for knowledge of a product's defect.

69. 350 F.2d 479 (3d Cir. 1965).

70. 154 So. 2d at 170-71.

whether liability should be imposed for breach of an implied warranty when the manufacturer or warrantor could not by reasonable application of human skill and foresight have known of the danger.⁷¹ The court concluded that a manufacturer's or seller's actual knowledge or opportunity for knowledge of a defective or unwholesome condition was completely irrelevant to the issue of liability on the theory of implied warranty. The court said: "The contention that the wholesomeness of a product should be determined on any standard other than its actual safety for human consumption when supplied for that purpose, is a novel proposition in our law, and one which we are persuaded has no foundation in the decided cases."⁷²

In *Pritchard*, the second tobacco case, the plaintiff brought an action for personal injury alleging that he had contracted lung cancer as a result of smoking cigarettes. The defendant pleaded assumption of the risk and contributory negligence as affirmative defenses to plaintiff's claim of breach of implied warranty. As in *Green*, the central question was foreseeability, but in this case the specific issue was whether a consumer could be held to have assumed an unforeseen risk. The court stated that a person who voluntarily exposes himself to a danger of which he has knowledge or notice assumes the attendant risk. However, the court held that since contributory negligence is not available as a defense in an action for personal injury based on breach of warranty, assumption of the risk is likewise not available.⁷³ Thus, in the case of the unfore-

71. 154 So. 2d at 170; 391 F.2d at 100.

72. 154 So. 2d at 173, *quoted in* 391 F.2d at 105. A possible qualification of the *Green* doctrine regarding foreseeability is given in the case of *Caputzal v. Lindsay Co.*, 48 N.J. 69, 222 A.2d 513 (1966). This was an action by the purchaser of a water softener against the manufacturer for injury allegedly resulting from drawing water from the faucet. The machine malfunctioned and caused the water to take on a rusty color. The plaintiff, upon seeing the color of the water, feared that he had been poisoned and had a heart attack. The court held that even if the device was so defective as to cause the rusty color, the plaintiff's attack, caused by fright at the sight of the water, was an extraordinary occurrence not reasonably foreseen in the normal person. It was an idiosyncratic reaction and defendant therefore was not liable for its consequences. The court did intimate that if the defendant had had notice of the idiosyncrasy, it probably would have held defendant liable for the injury. Thus, *Caputzal* formulates a rule concerning individual differences in reaction and not one about the problem of foreseeability of the possible effects of a product. Because of this difference in direction it would appear that the *Green* rule is the accepted one on the general problem of foreseeability.

73. 350 F.2d at 485-86.

seen danger it is the manufacturer who must bear the risk and not the consumer.

Unlike the cigarette manufacturer, however, the medical researcher will seldom have warranted that his procedure is harmless. The very nature of his activity argues against implying any such warranty, since it is the researcher's purpose in conducting the experiment to find out whether the procedure is safe and effective. Because it is impossible for a researcher to warrant that the very treatment he is testing is harmless, application of the principles of warranty appears ineffectual as a method of shifting the costs of experimentation from its victims.

Although we react strongly to placing experimental costs on the subject, we cannot deny that the unforeseen injuries resulting from experimentation differ from those that have justified reallocation of costs in other areas of tort law. In the cases concerning hepatitis-infected blood, the imposition of liability could be justified because it created an additional incentive to solve a definable problem. The variety of injuries that could occur in medical research using human beings, however, is as great as the number of individual experiments, and there is no single identifiable source of injury that can be attacked. As a device for directing the efforts of researchers and controlling their conduct, therefore, strict liability is likely to be ineffective.

Enterprise liability may make more sense, though, when its potential as a cost-spreading mechanism is considered.⁷⁴ If presently evolving explicit control devices are working properly, any control effect of imposing strict liability would duplicate these review procedures in any event. The primary result of imposing strict liability, therefore, would be to shift the costs of injury in medical experimentation from the individual volunteer to the group or institution performing the experiment. Such loss-spreading, however, might lead to the curtailment of important research, and it seems clear that society does not want such a result, having placed a high

74. Recent developments in the concept of products liability generally indicate a shift in emphasis from deterrence to cost-spreading. The California Supreme Court and a New Jersey intermediate appellate court have rejected the RESTATEMENT (SECOND) OF TORTS § 402A (1965) criterion that the defect in a product must make it "unreasonably dangerous before liability will be imposed." *Cronin v. J.B.E. Olson Corp.*, 8 Cal. 3d 121, 501 P.2d 1154, 104 Cal. Rptr. 433 (1972); *Glass v. Ford Motor Co.*, 123 N.J. Super. 599, 304 A.2d 562 (Super. Ct. 1973); cf. *Brody v. Overlook Hosp.*, 121 N.J. Super. 299, 296 A.2d 668 (Super. Ct. 1972) (discussed at text accompanying note 64 *supra*).

priority on advancing medical knowledge. But even if some means is devised to assure that research is not drastically cut back, the imposition of liability in medical experimentation, though it will relieve the individual of the cost of society's priorities, will not necessarily reduce the number of injured volunteers.

Even if courts were ready to apply strict liability in some cases involving medical experimentation, it is unlikely that they would adopt it, at least initially, in all situations. Some courts, moving in the direction of strict liability, would probably look for some transaction from which a warranty could be implied, whether sale or provision of services, as most courts dealing with the blood serum cases have done. The case of pure experimentation would pose difficulties in this regard, precisely because there is no promise of benefit to the volunteer. As mentioned above, no representation—express or implied—is made in such a situation as to the value of the procedure to the individual. No service is rendered. In fact, it is the volunteer who is rendering the service, and the safety of the procedure is usually explicitly disclaimed. The same is often true in the experiment with a subject for whom some beneficial result is expected, but in such a case the service nature of the transaction would provide the opportunity for a court to apply strict liability under *Hoffman*,⁷⁵ if it were so inclined. This could lead to the anomalous result of making relief available to injured subjects who had expected some benefit from the experiment but not to those who incurred unnecessary risks for the benefit of society.

Although some courts have overcome their reluctance to go beyond fault as a basis for liability in cases related to medicine, it would be premature to speculate that the development of strict liability in all medical contexts will parallel that in the blood serum cases. Several courts have explicitly rejected invitations to carry products liability theory into cases relating to the medical profession generally. In *Magrine v. Krasnica*,⁷⁶ for example, the plaintiff sought recovery on the theory of products liability against a dentist for an injury incurred because of a defective hypodermic needle. In this case, the plaintiff was injured when the needle separated from the syringe and became embedded in her jaw. The defendant testified that he did not know why the needle had broken or from

75. 439 Pa. 501, 267 A.2d 867 (1970). See generally text accompanying note 63 *supra*.

76. 94 N.J. Super. 228, 227 A.2d 539 (Hudson County Ct. 1967), *aff'd sub nom. Magrine v. Spector*, 100 N.J. Super. 223, 241 A.2d 637 (Super. Ct. 1968), *aff'd per curiam*, 53 N.J. 259, 50 A.2d 129 (1969).

whom he had purchased it, but he did know the manufacturer. The trial court rested its judgment for the defendant on two grounds: First, the doctrines behind products liability did not support its extension to cover the dentist in this situation,⁷⁷ and secondly, the state's malpractice law expressed a public policy to impose liability on doctors only for their negligence.⁷⁸ The intermediate appellate court affirmed on the basis of the former reasoning only, over a strong dissent.⁷⁹ The New Jersey Supreme Court affirmed both the trial court's and the intermediate appellate court's opinions and reasoning, not seeming to recognize any difference between them.⁸⁰

Two California courts have read *Magrine* approvingly as standing for the proposition that a physician should not be viewed as standing in the same position as the retailer of the instruments he uses or the drugs he prescribes.⁸¹ Rather, these courts have suggested, a doctor's situation is analogous to that of the consumer in a normal retail transaction.⁸² However, because these cases rely on the characterization of the physician and hospital as mere users of defective products in their essentially therapeutic relationship to the patient, they are not strong authority for resisting the application of strict liability for injuries to experimental subjects. To the extent that such injuries result from the basic choices that the researcher makes in designing the experiment, it is the researcher who possesses the power to control and the superior ability to know of dangers, the attributes that are the foundation for the application of strict liability to manufacturers. It is the researcher who constructs the basic hypothesis of an experiment. Thus, unlike the doctor in the therapeutic context, he is not a mere consumer and should not be treated as one.

77. 94 N.J. Super. at 233-39, 227 A.2d at 542-46.

78. *Id.* at 240, 227 A.2d at 546.

79. 100 N.J. Super. 223, 241 A.2d 637 (Super. Ct. 1968).

80. The per curiam decision read in whole:

The judgment appealed from is affirmed substantially for the reasons expressed by Judge Lynch, 94 N.J. Super. 228, 227 A.2d 539 (City Ct. 1967), and in the majority opinion of the Appellate Division, 100 N.J. Super. 223, 241 A.2d 637 (App. Div. 1968).

53 N.J. 259, 250 A.2d 129 (1969).

81. *Silverhart v. Mount Zion Hosp.*, 20 Cal. App. 3d 1022, 98 Cal. Rptr. 187 (Ct. App. 1971); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (Ct. App. 1971).

82. *Silverhart v. Mount Zion Hosp.*, 20 Cal. App. 3d at 1026-27, 98 Cal. Rptr. at 190-91, extended the *Magrine* reasoning that only negligence should be the basis of liability for injury from faulty instruments or drugs in the medical profession to include hospitals.

Perhaps the most significant lesson to be learned from the cases concerning hepatitis-infected blood transfusions is how legislatures react to the imposition of liability on the medical profession on other than a traditional fault basis. Since *Perlmutter*, a widely criticized split decision, which raised the specter that courts not persuaded by the *Perlmutter* rationale could base liability on implied warranty, 41 states have enacted statutes for the purpose of limiting the scope of liability to negligence in similar situations.⁸³ This legislative response suggests that judicial recognition of strict liability for medical experimentation would not be the final chapter in providing compensation to injured victims. After juries returned large verdicts in a few cases, the well-organized medical lobby could be expected to prevail upon the legislature to reject strict liability in this area. In any event, even if strict liability became the rule, the basic issue of benefit would distinguish the patient injured by a transfusion of infected serum from the volunteer in a medical experiment. Without the implementation of some new system of liability, many of those injured in experiments would have to bear the losses without assistance from society.

D. *Inadequacies of the Common Law Mechanisms*

If we are willing to wait for its slow evolution, traditional common law concepts may provide, in the end, a patchwork of remedies for experimental subjects who have not consented or who have been injured under circumstances vitiating their consent. But even if the common law does work when the issue is consent, it is unlikely to develop a remedy for the injured subject who has freely and validly consented to an experiment that is properly planned, approved and executed. Assuming that the system of prospective safeguards for human volunteers is operating well, the great majority of experiments would be conducted correctly and would thus leave the largest class of injured human subjects⁸⁴ without a remedy.

83. Franklin, *supra* note 56, at 474-76. Franklin, in his article on liability for hepatitis-infected blood transfusions, notes that some state legislatures have chosen to condition the statutory elimination of strict liability for such transfusions on the observance by hospitals of practices designed to screen out donors likely to be hepatitis carriers. He proposes that in granting hospitals immunity from general tort liability legislatures require hospitals to carry first-party insurance covering the medical expenses and lost income arising from patients' transfusion-associated hepatitis. *Id.* at 477-79.

84. This assumes both the competence of the researchers to avoid negligent mistakes and the efficacy of prospective reviews in eliminating unwarranted procedures and assuring the efficacy of consent procedures.

These people are the victims of disproven hypotheses. They dramatize the very risks that raise the moral dilemma in deciding whether the use of human beings in experimentation is ever justified. And yet, because the source of their injuries will be evident after the fact, these subjects also epitomize the purpose behind experimentation. The experiment having revealed the danger, large numbers of individuals will be spared the type of injury the volunteers have received.

The only common law concept that offers any possibility of giving these victims a remedy is absolute liability. At one time any physician who injured his patient while using a nonstandard procedure was held to a standard of absolute liability,⁸⁵ but the courts rejected that reasoning long ago.⁸⁶ Readopting strict liability appears to be inconsistent with society's decision to allow the use of human volunteers because the probable result would be a severe reduction in the amount of medical research conducted. This reduction would defeat society's desire to advance medical knowledge as rapidly as is consistent with responsible research techniques. However, were this contradiction resolved, the question would remain whether absolute liability is a viable answer to the needs of the injured subject. There is no doubt that the rapid advance of theories of enterprise liability has eroded the traditionally strong association of fault with liability apparently making strict liability a good solution for the victims of faultless experiments. The difficulty for the experimental context is that the courts have adopted enterprise liability only where there was a defective marketable product or service, underscoring the fact that the motivation for moving away from fault is primarily the search for deterrence and cost-spreading mechanisms.

The application of enterprise liability to a properly conducted medical experiment that results in the unavoidable injury of a human volunteer breaks down in two respects. First, since by hypothesis neither planning nor execution was defective, there is nothing

85. See, e.g., *Carpenter v. Blake*, 60 Barb. 488 (N.Y. Sup. Ct. 1871), *rev'd on other grounds*, 50 N.Y. 696 (1872); *Slater v. Baker*, 95 Eng. Rep. 860 (K.B. 1767).

86. See, e.g., *Fortner v. Koch*, 272 Mich. 273, 282, 261 N.W. 762, 765 (1935), where the court said:

[I]f the general practice of medicine and surgery is to progress, there must be experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him, and must not vary too radically from the accepted method of procedure.

short of not conducting the experiment that could have been done to avoid the injury. Deterrence thus is not served by imposing absolute liability. Secondly, as to cost-spreading, generally there is not a currently marketable product that can serve as a device for passing costs through to the public. For research focusing on experimental procedures as opposed to experimental devices, even at the successful conclusion of the experiment, there may not be an adequate market structure capable of passing the costs to the beneficiaries of the knowledge gained. Furthermore, even though proof that either a procedure or a device is useless may represent an advance, the failure of the research project means no market structure will materialize to impose costs on those who benefit from the knowledge gained.

Beyond the theoretical difficulties with the use of absolute liability in the experimental field, the practicalities of who is to bear the costs of faultless liability are equally troubling. The individual researchers or their supporting institutions might handle the costs through insurance, but the high risk and the relatively small pool through which to spread this cost suggest that insurance may not be the most efficient cost-spreading device. If the institutions were unable to obtain insurance, they would be forced to become self-insurers. Institutions spread costs among those who happen to be patients and these would not necessarily be the beneficiaries of the experimentation. The result is a most inequitable means of cost-spreading. There is no objection to a cost-spreading scheme that imposes costs throughout society since society in the aggregate is benefitted by experimentation, originally mandated the research, and has the capacity to regulate the research if the costs grow too large. But it is manifestly unfair to burden only a segment of society that is not directly aided and that is so burdened only through the happenstance of being present at an institution where research has produced an injury.

The imposition of liability through the common law carries a stigma of condemnation that would be unacceptable from the standpoint of the researcher. It cannot be expected that the imposition of strict liability will be understood as only an attempt to help injured subjects. The idea of liability without fault that is embodied in enterprise liability is a new concept and to most people common law liability is still inextricably bound to some indication of fault. Researchers and institutions who have conducted proper experiments and met their duties to the subjects could understandably interpret their liability as a condemnation of their humanitarian ef-

forts. In the commercial setting, where enterprise liability was developed, the imposition of absolute liability is merely another expense which is crucial only if it destroys the profit-margin. In medical experimentation, the reward system is more complicated and more sensitive to the imposition of absolute liability. Having liability substituted for the praise of his or her efforts that the researcher may have expected from society when he or she decided to devote his or her talents to research could result in a decision to forgo research for other readily available and more profitable alternatives. There is a compelling argument, therefore, for legislative intervention in the field of experimental medicine, in order to create a flexible system of compensation that would ensure justice to the individual without discouraging the advancement of medical knowledge.

IV. A PROPOSAL: FEDERAL COMPENSATION FUND

A. *Coverage*

Reliance on the common law with its attendant disfunctions may work an injustice by leaving the victims of experimentation without compensation. While the volunteer has not been wronged in the traditional sense, he or she has been injured in an activity designed to benefit society. To satisfy our sense of justice, society should devise a system that places the costs on those who benefit. In many ways, the situation resembles the one addressed by workmen's compensation funds.

A comparison of the employment relation with medical experimentation reveals several significant similarities. In both cases, activities that society deems necessary give rise to a certain number of unavoidable injuries. Although statistical projections may predict the total number of incidents, prospective identification of the particular activities that will result in injury is impossible. Therefore, to avoid these injuries, society would have to forgo all hazardous activities. Developing technology is a contributing factor to injury in both industry and medical experimentation. The industrial revolution, by introducing complicated machinery, increased not only the number of dangers in any given work situation but also possibly the severity of the injury.⁸⁷ Medical experimentation finds its major

87. In the initial enthusiasm for progress that was generated by the industrial revolution, the sketchy common law principle of employer liability for injuries received by his employees in the course of their duties was eroded. Insulating doctrines, such as the fellow-servant rule, were announced. Farwell

justification for subjecting human beings to risk in the prospect of improved medical technology. In both fields, use of common law remedies to compensate the victims of the unavoidable injuries growing out of greater sophistication has serious drawbacks. Prior to the introduction of workmen's compensation, common law remedies were available to some victims of work-related accidents, but the requirement of a finding that the employer was solely responsible for the injury barred most injured workmen from common law recovery.⁸⁸ Similarly, under present common law theories applicable to experimental injuries, the requirement that some defect in the execution be found to trigger liability appears to bar the majority of injured human volunteers from obtaining relief. This analysis suggests that the workmen's compensation system may provide a model for handling the compensation of injured human volunteers.⁸⁹

Before proceeding, however, the differences between the two fields that may affect the model-building must be outlined. Workmen's compensation had to face the difficult fact that workers who were themselves at fault would be compensated for their injuries in a significant percentage of cases.⁹⁰ A balance was struck whereby

v. Boston & W.R.R., 45 Mass. (4 Met.) 49 (1849); Priestley v. Fowler, 150 Eng. Rep. 1030 (Ex. 1837). This development parallels the judicial rejection of the absolute liability of a physician who injures a patient in the course of experimentation. See note 86 *supra* and accompanying text. However, as the spread of industrialization gave rise to an ever-increasing number of industrial accidents, courts began to move again toward doctrines supporting findings of employer liability by creating exceptions to their initially broad insulating rules. See, e.g., Fitzwater v. Warren, 206 N.Y. 355, 99 N.E. 1042, 42 L.R.A. (n.s.) 1229 (1912) (employee does not assume the risk of employer's violation of safety statute); Flike v. Boston & A.R.R., 53 N.Y. 549, 13 Am. R. 545 (1873) (fellow-servant rule does not apply to employees responsible for carrying out employer's common law duty to provide for employee safety); Louisville, N. & Gr. S.R.R. v. Fleming, 82 Tenn. 128 (1884) (employee's contributory negligence is only considered as mitigating damages). See generally A. LARSON, *THE LAW OF WORKMEN'S COMPENSATION* §§ 4.10-40 (1972).

88. In a study of industrial accidents in Germany in 1907, only 17 percent of the reported injuries were attributed solely to the employer's fault. This study also reported that 42 percent of all known industrial accidents in one year in Germany were "inevitable accidents connected with employment." A. LARSON, *supra* note 87, at § 4.30.

89. This assumes that with the present prospective reviews, few, if any, unwarranted experiments will be performed. It further assumes the general competence of researchers, discounting negligence as a major cause of injury. These assumptions are difficult to test, however, because of the present lack of data on the use of human subjects in the United States.

90. The 1907 German study indicated that in 29 percent of the reported accidents, the injured employee was either negligent or at fault and in 5 per-

work-related injuries were compensated regardless of fault, but both the type of injury covered and the measure of damages were narrowly drawn. In response to the view that the interest protected was the worker's productive ability, for the most part only injuries that impaired earning capacity were covered. The measure of damages being lost wages, all vestiges of recovery for pain and suffering and for physical injuries not interfering with work functions were eliminated.⁹¹ Finally, since the worker's fault was ignored for purposes of recovery, employers argued that their fault should similarly be discounted. As a result, the legislatures have generally made workmen's compensation the exclusive remedy available to the injured employee, even in those cases where the injury was caused solely by the employer's fault.

In the field of medical experimentation, fault is not the two-sided coin that it is in industrial accidents. Injuries will rarely, if ever, result from the subject's negligence or fault. Therefore, the reasons for limiting coverage in workmen's compensation to injuries affecting the ability to work and for denying recovery for pain and suffering are not operative in the researcher-subject relationship. Furthermore, since subject fault is not an issue, the researchers have no basis for demanding that their fault also be ignored. In making reference to the workmen's compensation model, we must not lose sight of the policy and politics that caused it to preempt the control system of the common law.

In any proposal for a compensation program for injured volunteers, the major questions are how it will treat fault and whether it will stultify or even terminate the development of common law remedies. The system proposed here is one that recognizes that the injured volunteer's right to recover from a compensation fund should both compensate and deter. The proposed fund is federal and accomplishes broad but fair compensation through adoption of the positional risk test, a workmen's compensation concept.⁹² An incen-

cent of the cases, the injured employee was jointly negligent with the employer. A. LARSON, *supra* note 87, at § 4.30.

91. "A compensation system, unlike tort recovery, does not pretend to restore the claimant what he has lost; it gives him a sum which, added to his remaining earnings ability, if any, will presumably enable him to exist without being a burden to others." *Id.* § 2.50.

92. This term was first developed in the workmen's compensation field. In the context of workmen's compensation, its application limits compensable injuries to those which the employee would not have otherwise incurred had he not been in the spatial position demanded by his work. This concept goes beyond the traditional workmen's compensation standard of awarding compen-

tive to achieve adequate design control is created by not including an exclusive remedy clause.

The proposed fund is federal in recognition of the degree to which the federal government has legitimized the use of human volunteers in medical experiments through its extensive direct funding of research and indirect support of research institutions funded from other sources.⁹³ Encouraging the advancement of medical knowledge despite recognizable risks places responsibility on the federal government to make provision for the proper allocation of the full costs.

Although administered by the federal government, the fund would not be limited to federally funded research. The benefits that accrue to society when a particular hypothesis is proved or disproved do not vary according to the nature of the project's funding. The results of medical experimentation, whether publicly or privately funded, are published in journals that are widely distributed throughout the medical community. Depending on the stage of the reported research, such dissemination encourages further experimentation, building on the hypothesis as altered by the results of the reported experiment, or serves as the basis for changing modes of treatment. The nationwide activity stemming from the experiment established the jurisdictional basis for federal intervention.⁹⁴

sation only for injuries arising out of the employment by compensating for injuries inflicted by neutral risks. *Id.* §§ 10.00-33.

We use the term positional risk to make it clear that the standard for compensability in the context of medical experimentation is whether the injury would have been avoided if the victim had not participated in the experiment.

93. The continued federal activity in this area is manifested in the National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342.

94. *Cf.* 7 U.S.C. §§ 2131-55 (1966), which creates federal procedures including licensing for research facilities that use experimental animals transported in interstate commerce and for dealers and exhibitors of such animals. One of the express congressional intentions in adopting this law in 1966 was "to insure that certain animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment." *Id.* § 2131.

Although the interstate commerce connection may seem attenuated since the regulated activities may be initially limited in scope to one state, or the primary interstate commerce resulting from the experiment may be only journal articles and other correspondence, other federal regulation grounded on the interstate commerce clause has been found appropriate on arguably minimal jurisdictional acts. *United States v. Sullivan*, 332 U.S. 689 (1948), upheld the constitutionality of the Federal Food and Drug Act of 1938 in regulating the treatment of drugs even after their interstate transport was complete. *Mandeville Island Farms v. American Crystal Sugar Co.*, 334 U.S. 219 (1948), recognized that if a product is ultimately to pass into interstate commerce, there

We have seen that the federal government's encouragement of research has made it the most appropriate administrator of the fund. Its taxing structure is also the most efficient means of distributing costs to society, which is the real beneficiary because the current market structure is incapable of passing the costs of proving or disproving an hypothesis on to society.

As an initial proposition, the possibility that the availability of such compensation to injured volunteers would be interpreted as license to embark on high-risk experiments cannot be discounted.⁹⁵ To guard against such reactions, it is suggested that each research project that puts human subjects at risk should be roughly categorized according to the probability of the risk materializing and the severity of the possible injury.⁹⁶ If the combination of severity and probability of risk is high by relative standards but within acceptable limits because of the importance of the expected findings, the researcher and/or the sponsoring institution should be asked to indemnify the fund for a percentage of any damages that might oc-

is constitutional power for the Congress to create a private cause of action for antitrust conduct that took place entirely intrastate, prior to the entry of the product into interstate commerce. More recently, the Supreme Court upheld the constitutionality of Title II of the 1964 Civil Rights Act and its application to a small family-owned restaurant in Birmingham, Alabama, Ollie's Barbecue, as valid exercises of federal power under the interstate commerce clause in *Katzenbach v. McClung*, 379 U.S. 294 (1964). See *Heart of Atlanta Motel v. United States*, 379 U.S. 241 (1964). In that Act, Congress exerted its power over interstate commerce as a jurisdictional basis to control a social problem, a use of that power similar to the proposal made here. Finally, while the commerce clause powers are generally used in relation to tangible items, the intangible commodity of insurance coverage has been held to be subject to federal regulation under the commerce clause. *United States v. South Eastern Underwriters Ass'n*, 322 U.S. 533 (1944).

95. Having removed the employer's liability in tort, many workmen's compensation systems have included various devices to create incentives for the employer to exercise care. Where employers obtain private insurance, the prospect of increased premiums is such an incentive. In states with public funds, linking the employer's rate of contribution to the fund to his individual experience rating is a similar incentive. In many instances, such devices alone have not resulted in lowering accident rates to an acceptable level, as evidenced by separate statutes that require specific safety measures. Whether continued employer liability in tort for injuries to workers arising out of employer fault would have made such statutes unnecessary must be left largely to the realm of speculation.

96. The existing prospective review of research proposals should prevent most excessively risky experiments, but the compensation fund by reviewing the risks to allocate relative liability provides another layer of deterrence, thereby helping to protect the individual from unjustified human experimentation.

cur. The extent of the indemnification would be commensurate with the risk. Other considerations such as the identity of the subjects—adults, children, institutionalized persons—or the likelihood of benefit to the subjects would also be significant in working out an indemnification agreement. For example, an experiment with a relatively low possibility of risk, involving a minor potential injury, among a group of adults for whom there is a high probability of benefit would usually call for no indemnification by the researcher or the sponsoring institution. On the other hand, an experiment with a high risk of serious injury among the same group of subjects might call for 30 percent indemnification. This high-risk experiment conducted on a group of subjects with no expectation of any direct benefit might involve 40 percent indemnification.

Whether the injury would have been avoided had the subject not participated in the experiment should be the sole criterion for determining which injuries would be compensable. Such positional risk analysis would not necessarily result in compensation for all the injuries a subject might sustain during the course of an experiment. Many subjects participate in experiments in the hope that the experiment will produce a cure for the disease from which they suffer. The criteria set out would limit coverage to the injuries that would not have occurred or been likely to have occurred had a normal therapeutic course been pursued.⁹⁷ The significant fact to be emphasized is that under this plan the possibility of therapeutic benefit from the experiment would not preclude the subject from recovery altogether. At the other end of the spectrum, if the subject does not stand to benefit directly, all injuries he or she experiences would be covered. Clearly the gradations between these two situations are many and difficult to draw, but the application of the single standard is most reflective of the true costs, providing windfalls neither to the subject at the expense of society nor to society at the expense of the subject.

Questions of fault would not be entertained in relation to the issue of what is a compensable injury. However, unlike the typical workmen's compensation program, fault could retain significance in the medical experiment compensation fund. Once a claim was found to be substantial, the possibility that fault was a causative factor in the injury would be investigated. When the inquiry moved from the question of compensability of the injury to the question of fault, the burden of proof would shift to the researcher. The fea-

97. See note 92 *supra* and accompanying text.

ture of placing the researcher in the position of affirmatively showing absence of fault would enhance the control aspects of the system. When the investigation suggested that there was a basis for common law fault liability, the victim would be free to pursue the available common law remedies. If he or she were successful in winning a judgment, he or she would reimburse the compensation fund in the amount of the award. If the victim were not prepared to pursue the potential common law remedies, even though the investigation suggests that fault was a factor, the compensation fund would be empowered to seek common law relief to the extent of the award actually made to the victim plus administrative and litigation costs. In other words, the compensation fund would only arrest development of the common law remedies not founded on fault.

Creating a two-step system of an administrative proceeding followed, when fault appears to be an issue, by a judicial proceeding may seem cumbersome, but it appears to be the most appropriate mechanism for maximizing the conflicting goals of victim compensation and continued common law development. First, compensation is certain and prompt. Basic compensation to the victim is not left to the vagaries of the common law of the jurisdiction or to the happenstance of the particular events of the injury. The procedure will serve the important goal of providing more expeditious payment of compensation than is available from a civil suit. Secondly, because recourse to the common law is retained, researchers and their supporting institutions are not insulated from the results of their wrongful acts. All those involved in medical experimentation using human volunteers will have a strong incentive to plan and execute their projects with the greatest care.

The complex compensation fund system finds further justification in its ability to explore the currently undefined dimensions of researcher fault. A compensation system having no stake in determining the fault issue would shed little light on this important question.⁹⁸ Experience with the system may well reveal that re-

98. The compensation system proposed in Note, *Medical Experiment Insurance*, 70 COLUM. L. REV. 965 (1970), leaves two major tasks unaccomplished. In failing to address the question of fault, it creates no deterrent mechanisms. In focusing on compensation of experimentation victims to the exclusion of other goals, it would provide only half of the information needed to determine the degree to which deterrence should be a concern. In addition, that proposal would give us a numerator but no denominator for computing the ratio of injured subjects to the total number of human subjects used

searcher fault has been reduced to an insignificant problem through successful prospective controls and the minimization of error by researchers sensitive to their responsibilities in using human subjects.

If it becomes apparent that researcher fault is a minimal problem, presently available sanctions, other than recourse to judicial common law remedies, would be sufficient. It is already contemplated by the present regulations issued by the Department of Health, Education, and Welfare that a finding of failure to discharge either personal or institutional responsibilities for the protection of the rights and welfare of human subjects should be a major factor in considering applicants for future funding.⁹⁹ A finding of fault would also be possible grounds for termination or suspension of present funding.¹⁰⁰

Just as the federally administered fund would not interfere with development of most common law remedies in the forum of the state courts, neither would the federally imposed standards displace the authority of the individual states to discipline their practitioners. In fact, cooperation between the federal system and the state medical boards should be maximized. It is to be anticipated that the multifaceted controls would draw the criticism that new and unusual burdens were being placed on the practitioner. In response, it should be emphasized that the system would apply only to human experimentation, an unusual and hazardous activity that the federal government supports directly and indirectly. Under these circumstances, the federal government is justified in playing an extensive reinforcing role in administering controls.

Gathering information on the general scope of medical experimentation is essential in pinpointing the specific problem areas. Prior to starting the experiment, an informational statement would be required of all human experimentation projects. In cases where

in experimentation in the United States. It would also fail to provide data for a qualitative analysis of these figures.

99. See 45 C.F.R. § 46.21 (1974), which provides for early termination of awards and prejudice in being considered for subsequent grants where a researcher or institution has failed to comply with the federal regulations governing the use of human volunteers.

100. The major shortcoming of the present provision for considering prior failure to observe the federal standards for using human volunteers is that it is limited to scrutiny only of prior experiments that were themselves subject to federal regulation. See 45 C.F.R. § 46.21 (1974). The system here proposed would for the first time allow the gathering of data on all research that places human subjects at risk and place in perspective the resulting injuries.

the experimental proposal is reviewed by the supporting institution, copies of documents prepared for that purpose likely will be sufficient. For research conducted in settings where such review is not required, this report will impose an added requirement on the researcher, but a minimal one. The report would consist of notification of the intent to use human subjects, an outline of the intended conduct of the experiment, an estimate of how many subjects were to be used, and a statement of the review procedures to which the proposal had been submitted. On the basis of this report, the level of indemnification, if any, from the researcher and/or the supporting institution would be determined. At the close of the experiment, a similarly brief notification would be filed with the fund indicating the actual number of human subjects and the occurrence of any injuries. The filing of this final report should not be confused with a statute of limitations against subjects whose injury from the experiment becomes apparent only after a long passage of time. Any injury which can be shown to result from medical experimentation should be compensated, regardless of when it becomes manifest. Any statute of limitations should run only from that time. It must be stressed that these reports are information-gathering devices. They would not be designed to be the basis for a wholesale review of the proposed project but would encourage the growth of review procedures at the research institution, where they would be most effective.¹⁰¹ They would serve as the basis of the indemnification determination and give the first overall picture of the state of human experimentation in the United States. The information assembled from these reports should place society in a position to evaluate the true costs of its commitment to the rapid advance of medical knowledge more closely. Informed decisions as to the viability of continuing that commitment will then become possible.

One of the most difficult problems in creating the compensation fund is measuring the "cost" of the injury to the human subjects. The compensation fund would naturally cover the direct and readily ascertainable cost of medical expenses and loss of earnings, but should the coverage extend to the cost of pain and suffering? Unless both the compensation and control features of the program are to become illusory for that significant portion of human subjects who are already ill, aggravated pain and suffering must be a basis for compensation. The healthy subject and the unhealthy one

101. See generally note 13 *supra*; Cowan, *Human Experimentation: The Review Procedure in Practice*, 25 CASE W. RES. L. REV. 533 (1975).

would be entitled to compensation for the pain and suffering resulting from the untoward consequences of their participation in the study. The measure of this kind of award could be calculated as it is in traditional tort law. However, the award would not cover the pain and suffering that is an anticipated result of the experiment and of which the subject was apprised. In that case the subject would have consented to the pain and suffering and may have been compensated for it as a condition to agreeing to participate.

B. *Mechanics*

The mechanics of the system proposed here would be simple. When a researcher determined that an experiment would place human beings at risk,¹⁰² he or she would file a form with the compensation fund stating the nature of the experiment, the probability of injury, the severity of the injury if it should occur, and the number of subjects.¹⁰³ In most cases the report to the fund would be reviewed at the same time by the researcher's sponsoring institution in considering whether the use of human subjects in the proposed study is justified and if so whether procedures for obtaining consent are adequate. The sponsoring institution would also have an obligation to review the initial report made to the fund to ensure that it was as accurate a reflection of the characteristics of the experiment as could be prepared prospectively. The initial report would provide the fund with the needed information on risk to decide if partial indemnification were required and if so at what level. If the fund decided a percentage indemnification were necessary, assuming the researcher and the sponsoring institution were willing to accept the liability, an agreement would be signed.¹⁰⁴

In the event that the experiment were performed without injury, which can reasonably be expected in the vast majority of cases, the only other form that would need to be filed with the compensa-

102. Cf. 45 C.F.R. § 46.11 (1974).

103. Such a report would resemble an abbreviated environmental impact statement in its intended use.

104. If the researcher and/or his sponsoring institution were to dispute a compensation board's initial assessment of risk, provision could be made for a *de novo* hearing on the appropriate percentage of indemnification, should an injury actually occur. To avoid this becoming an issue with every injury, however, the parties responsible for indemnification should be required to reserve specifically their right to challenge the initial determination of risk in the event injury occurs. The time of the researchers and the resources of the compensation system should not be expended in disputes over this issue unless indemnification is actually required, when a compensable injury has occurred.

tion fund would be a closing statement verifying the actual number of subjects used in the course of the study and that no immediate injury had occurred to any of them as a result of their participation. These reports would provide needed data for a perspective on how human subjects are being used in the United States and at what risk.

If an injury did occur during the experiment, a claim would immediately be filed with the fund. Accompanying the claim would be a full explanation of the circumstances of the injury, indicating whether it fell within the range of risk initially reported to the fund. If the injury were not the result of negligence and if there were no other irregularity in the experiment (*e.g.*, failure to obtain adequate consent), the fund would pay the claim and seek any indemnification agreed upon under the initial agreement with the researcher and his sponsoring institution. This would constitute a final settlement of the claim.

If the evidence suggested researcher negligence or other irregularity, the fund would still pay the claim, but this would be only the first step. The payment of the claim would leave the subject free to pursue the common law remedies available in the jurisdiction where the experiment took place. If a person received compensation from the fund and subsequently recovered under common law, the fund would be reimbursed from the judgment. Alternatively, the failure of the subject or his representative to seek common law redress would give the fund the right to sue the party at fault in court for the amount paid to the claimant plus the fund's costs of administration and litigation. Any judgment the fund received in excess of the award originally made would be given to the claimant.

V. CONCLUSION

The common law, by acting after the fact to assess the relative rights and liabilities of parties involved in an experiment that has produced an injury, accords two advantages. First, retrospective examination of the cases avoids delay of experimentation. Secondly, consideration of only those cases where there is reason to think an injury or other wrong has occurred results in the most efficient expenditure of time and attention. Given the lifesaving intent of the activities to be regulated by the system proposed here, objections of delay and inefficiency cannot be lightly dismissed. However, the concern over delay is illusory, because this system will not be operating in a vacuum. Its prospective devices provide neither the

first nor the only scrutiny to which most experiments will be subjected. The present regulations governing review of projects directly funded by the government and those conducted in institutions receiving substantial government support are an existing check against the premature launching of experimental programs. The goal of the compensation fund proposal would be to execute its prospective procedures during the same period as the presently required review. Achieving coordination of the new procedures with the existing ones would make objections of delay unwarranted, since the choice to impose preexperiment review has already been made.

Furthermore, to the extent that the proposed system will operate with information already required by present review procedures, it cannot be seen as a seriously inefficient expenditure of resources. Rather, the contemplated procedures improve efficiency by making double use of the information generated prior to the experiment.

More significantly, essential notions of fairness and equity argue against giving credence to criticism based on minimal delays or inefficiencies. The inability of the common law to provide redress in the majority of injury cases—where the injuries were not the result of researcher fault—underscores the need to create a sure remedy for these victims. A compensation fund supported out of the federal tax structure would achieve the proper nexus between cost and benefit. At the same time, the indemnification agreements would inject the requisite measure of deterrence into the scheme. Finally, the proposed system would ensure just compensation of victims without placing the largely unjustified stigma of fault on the researcher.

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