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By Alan Meisel*

The Expansion of Liability For Medical Accidents: From Negligence to Strict Liability By Way of Informed Consent

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I. INTRODUCTION

Victims of medical accidents traditionally have resorted to a cause of action in negligence to obtain damages for their injuries. There is an ongoing expansion of liability caused by a subtle erosion of negligence as the basis for recovery, first through the broad application of *res ipsa loquitur* and later through the growth of the doctrine of informed consent, causing movement toward a system of strict liability for medical accidents. Recently there even have been some head-on assaults on the citidel of negligence to replace it with strict liability as the basis for recovery in medical accident cases. The informed-consent doctrine has been responsible for the greatest portion of the erosion of negligence, because informed consent is closely akin to strict liability in tort. While this development presages greater equity for medical-accident victims, it threatens to undermine some of the important functions of the informed-consent doctrine.

Medical patients whose treatment¹ has not brought them their hoped-for succor, and who have in fact been harmed rather than healed by the medical² intervention, have had a legal remedy available to them in negligence.³ However, not all individuals who have experienced "bad results"⁴ from the medical intervention have been

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1. The term "treatment" will be used broadly to include not only those medical procedures that are intended to ameliorate illness and injury, but also diagnostic procedures designed to determine the nature of the disorder and the appropriate course of treatment.
 2. The terms "medical" and "medicine" are used herein to include treatment that might more properly be characterized as surgical, dental, or podiatric. The same general principles of liability apply, however, regardless of the characterization of the treatment. W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 32, at 161-62 (4th ed. 1971) [hereinafter cited as PROSSER]; see, e.g., *Simpson v. Davis*, — Kan. —, 549 P.2d 950 (1976).
 3. Other civil causes of action, in addition to negligence, may be brought against physicians for misfeasance or nonfeasance. Abandonment, assault and battery, breach of contract, deceit, and miscellaneous other charges form the basis for action against physicians. See generally 1 D. LOUISELL & H. WILLIAMS, *MEDICAL MALPRACTICE* ¶¶ 8.08-.13 (1973) [hereinafter cited as LOUISELL & WILLIAMS]; Smith, *Antecedent Grounds of Liability in the Practice of Surgery*, 14 *ROCKY MT. L. REV.* 233 (1942). The great bulk of cases against physicians, however, involve allegations of negligent medical treatment, or what is usually referred to as "malpractice."
 4. The problem of defining "bad results" is exceedingly complex. The term may be defined from the patient's perspective, from the physician's, or from the perspective of the larger medical profession (i.e., the so-called "experts" in a particular area of medicine). It may be viewed in terms of a deviation from an expected outcome if the best

able to avail themselves of this remedy. When an individual cannot demonstrate medical negligence,⁵ no remedy has been available. Thus, a situation existed in which two individuals with identical, bad results from their medical treatment might be treated differently in terms of a legal remedy. The one who could demonstrate

available treatment had been accorded, if the generally accepted treatment had been accorded, or by comparison with the outcome in similar cases. Further complicating the problem is the consideration that the patient is ordinarily ill or injured before he seeks medical treatment; thus the bad results that would have resulted had no medical intervention occurred must be distinguished from those arising from the medical intervention (what is referred to as "iatrogenic" disease). See generally 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 8.07. Some medical procedures are, however, performed on healthy persons, notably in the case of "normal" volunteers for medical experimentation. See Silverstein, *Compensating Those Injured Through Experimentation*, 33 FED. B.J. 322 (1974). In addition, some medical procedures are performed preventively on persons who are not ill or injured.

- The present discussion is concerned only with the bad results that are the consequence of medical acts or omissions (whether negligent or not), and not with the bad results from illnesses or injuries for which the patient originally sought medical attention. Although this is a viable conceptual distinction, it is often quite difficult in practice to separate the bad results of medical care from those that would have materialized had no medical care been obtained at all. See authorities cited note 244 *infra*. Bad results not caused by medical negligence are not presently compensable, although they might be under a program of national health insurance or social insurance generally. See Bernstein, "No-Fault" Compensation for Personal Injury in New Zealand, in U.S. DEPT OF HEALTH, EDUCATION, AND WELFARE, REPORT OF THE SECRETARY'S COMMISSION ON MEDICAL MALPRACTICE 836 (App. 1973) [hereinafter cited as HEW, MEDICAL MALPRACTICE]. Such injuries may be compensable, however, even in theory, where there is proof that medical negligence on the part of the physician is the "intervening" cause of the bad results. See generally 2 F. HARPER & F. JAMES, THE LAW OF TORTS § 20.5(5) (1956) [hereinafter cited as HARPER & JAMES]; 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 8.07; PROSSER, *supra* note 2, § 44.
5. Throughout this paper, the shorthand phrase "medical negligence" is used to apply to those acts or omissions of physicians that traditionally are grounds for liability in negligence. Such negligence may take several specific forms. The classic malpractice case of *Pike v. Honsinger*, 155 N.Y. 201, 209-10, 49 N.E. 760, 762 (1898), lists several specific species of negligent medical practice: (1) failure to possess a reasonable degree of learning and skill; (2) failure to exercise reasonable care and diligence in the exercise of skill; (3) failure to use best judgment in the exercise of skill and application of knowledge; (4) failure to keep abreast of development in medicine; and (5) departure from generally used approved methods. See also 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 8.04.

This definition of medical negligence excludes the more recently recognized duty of a doctor to make disclosure of "material" information to the patient before treating, known as "informed consent." The

negligence might obtain substantial monetary compensation not only for his out-of-pocket expenses, but also for his pain and suffering, while the other would walk away empty-handed. In fact, a more seriously injured patient might obtain no compensation while a less seriously injured one who could convince a jury that the medical procedure had been performed negligently, would be entitled to compensation.

There are two ways in which a medical accident may be caused. Some accidents result from the physician's negligence—that is, from his failure to adhere to accepted standards of practice, or his failure to possess or exercise the requisite degree of skill or care in carrying out the medical procedure. Other medical accidents may result from what may be referred to as "statistical risks."⁸ That is, there

reason for this exclusion is that courts are increasingly coming to the realization that the determination of whether or not information is material does not require the special expertise of a physician. See pp. 97-98 *infra*. Thus, breach of this duty is not "medical" negligence. There is also some question as to whether the cause of action for informed consent is properly brought in negligence or in trespass. See note 111 *infra*.

6. What is referred to herein as a "statistical risk" is the same as the "unavoidable accident" of classic tort law—that is, even in the exercise of due care, the accident could not have been avoided. See PROSSER, *supra* note 2, § 29. This is similar to what Louisell and Williams refer to as one of the meanings in medicine of "calculated risk":

In the first sense, "calculated risk" usually defines a procedure which is considered to carry an inherent probability that a bad result will occur in a more or less fixed percentage of cases . . . whether or not there is negligence; hence whenever a bad result occurs it is likely to be designated as one of an "irreducible minimum" number. Calculated risks sometimes are actually figured out on a statistical basis, with substantial numbers of cases reviewed as the basis of the calculation. On the other hand, the expression simply may cloak merely subjective impressions that some poor results inevitably occur in certain procedures, and thus be without statistical foundation for which analysis of cases, negligent or otherwise, is essential.

2 LOUISELL & WILLIAMS, *supra* note 3, ¶ 19.02, at 568 (footnotes omitted).

A physician is not required to exercise the highest degree of care, but merely the reasonable care and skill usually possessed by physicians of the same school and locality. *Trogon v. Fruchtman*, 58 Wis. 2d 569, 584, 207 N.W.2d 297, 305 (1973). See generally 1 LOUISELL & WILLIAMS, *supra* note 3, ¶¶ 8.04-.06. Thus, the term "statistical risk" as used herein includes both those bad results that would have occurred not merely if the defendant-physician had failed to possess and exercise the highest degree of skill, but also those resulting from a failure to possess and exercise a *reasonable* degree of skill and care.

An example of a "truly unpreventable complication" is the risk of hepatitis from a blood transfusion. See Comment, *Blood Transfusions*

is some risk that any procedure, even when performed in compliance with the generally accepted manner of performing the activity, may fail to yield the intended result or also may yield a bad result.⁷ As long as the physician's conduct conforms to what is generally accepted among individuals of like training and experience, the courts have been unwilling to say that he should have behaved differently.⁸ The fact remains that in medicine, as in all human pursuits, things often do not turn out the way they are supposed to even when all procedures are performed in a commonly accepted way.⁹

and the Transmission of Serum Hepatitis: The Need for Statutory Reform, 24 AM. U.L. REV. 367, 368 (1975).

7. People are normally hurt by a simple, traumatic blow of one kind or another, but when a doctor begins prescribing drugs or rummaging around a patient's insides, infinitely greater possibilities of adverse effects arise. The origins of much ill health are so obscure that strictly non-negligent medical treatment may provoke untoward physiological responses.
J. O'CONNELL, ENDING INSULT TO INJURY 72 (1975). See also HEW, MEDICAL MALPRACTICE, *supra* note 4, at 22, 24.
8. See *Lane v. Calvert*, 215 Md. 457, 462-63, 138 A.2d 902, 905 (1958); *Williams v. Chamberlain*, 316 S.W.2d 505, 510-11 (Mo. 1958); *Gore v. Brockman*, 119 S.W. 1082 (Mo. 1909); *Teig v. St. John's Hosp.*, 63 Wash. 2d 369, 375, 387 P.2d 527, 531 (1963).

Permitting the medical profession in effect to establish the legal standard by which the adequacy of its performance is measured may have the effect of encouraging (or at least failing to discourage) the "inadvertence, carelessness, indifference, cost-paring and corner-cutting that normally is associated with negligence." PROSSER, *supra* note 2, § 33, at 167. See also pp. 135 *et seq. infra*.

Of course, the victims of "statistical risk" medical accidents may bring suit under a negligence theory alleging that their injury resulted from medical negligence. The determination that the injury actually resulted from a "statistical risk" is never explicitly made. The conclusion is an inferential determination based upon the plaintiff-patient's inability to convince the trier of fact that the physician has performed in a negligent manner. See HEW, MEDICAL MALPRACTICE, *supra* note 4, at 22-24.

9. See, e.g., *Di Filippo v. Preston*, 53 Del. 539, 173 A.2d 333 (1961) (in approximately 2% of thyroidectomies, there is damage to the recurrent laryngeal nerves resulting in loss of voice, even in the absence of negligence).

The fact that there is a statistical risk of something going wrong even in the absence of negligence may merely be another way of stating that we are unable to explain why the bad results occurred. As the understanding of a particular procedure and of human physiology increases, a new, accepted way of performing the procedure may evolve, and either eliminate or reduce the statistical risk of bad results. In any event, there are times when things "go wrong" and we are unwilling to ascribe the cause to the failing of a particular individual.

The true medical accident—bad results caused by the medical intervention—must be distinguished from the pain, suffering, and poor results that are traceable directly to the patient's underlying illness or injury. Because medical procedures generally are not performed on individuals who are not already ill or injured, the problem of separating the bad results caused by the medical treatment from the bad results that would have occurred without medical intervention can be quite difficult in practice.¹⁰

The compensation of only those medical-accident victims whose injuries are attributable to negligent medical care may be seriously at odds with common contemporary notions of fairness.¹¹ The in-

Medical accidents resulting from negligence or from statistical risks might both be said to occur because the procedure was performed in the "wrong" way. The difference between the two cases is that in negligence, it is generally known what the "right" way is; with statistical risks, a means of preventing the accident has not yet been developed. An alternative view would hold that in some activities, there is an irreducible minimum number of accidents, which may vary with the state of the art, but will never disappear entirely.

The explanation for a medical accident arising from a statistical risk may be a peculiarity of a particular patient's physiology or anatomy, about which the physician could not have known. Alternatively, the explanation may be that medical knowledge has not yet advanced to the point of understanding why the outcome in this particular case differs from the result that is to be expected. There is an unwillingness to denominate an action as negligent when a respectable body of medical opinion does not prescribe a different course of action.

10. See note 4 *supra*.

11. In an age when fairness was seen exclusively as a matter of the relative degrees of wrongdoing of the victim and the injurer, 2 HARPER & JAMES, *supra* note 4, § 13.2, at 761-62, like cases were treated similarly by shifting the loss from the victim to the injurer only when the injurer was guilty of wrongdoing. In other words, fairness would be achieved by treating differently cases involving similar injuries, so long as cases involving a "wrongful" cause of the harm were treated similarly.

To the extent that fairness has increasingly been viewed as including not just the parties to the lawsuit, but the larger society as well, the precept of treating like cases similarly acquires a new meaning. *Id.* at 761-63. The question of whether or not there has been "personal moral shortcoming," *id.* at 762, on the part of the injurer is increasingly being viewed as irrelevant in determining whether cases are "like." We are more inclined to look at the outcome of the interaction between the victim and the injurer before determining whether the cases are alike. See J. O'CONNELL, *supra* note 7, at 65. Equally important, the societal interests in the cases must be taken into account before determining whether they are "like."

[W]hile no social good may come from the mere shifting of a loss, society does benefit from the wide and regular distribution of losses, taken alone. The administration of losses in this way may entirely change evaluations of what is fair. If

equity arising from one individual being denied compensation while another with identical injuries obtains recompense has created an impetus for the courts to find ways of compensating victims of medical accidents without regard to whether negligent conduct or a "statistical risk" was responsible for the accident. While complete compensation has not and may never be achieved,¹² the courts gradually have modified the rules under which compensation is awarded to medical-accident victims so as to reduce the likelihood of individuals with substantial injuries going uncompensated while others with less serious injuries receive compensation.

The result of the courts' efforts has been to increase the availability of compensation to victims of medical accidents.¹³ Less noticeable, but of far greater fundamental significance, is that the trend of the decisions slowly has and almost imperceptibly been toward the creation of a judicially fashioned system of strict liability for medical accidents. This trend is composed of three distinct movements. First, there has been a movement toward strict liability engendered by the application of *res ipsa loquitur* in medical-accident cases. This has produced a subtle erosion of the negligence

a certain type of loss is the more or less inevitable by-product of a desirable but dangerous form of activity it may be just to distribute such losses among all the beneficiaries of the activity though it would be unjust to visit them severally upon those individuals who had happened to be the faultless instruments causing them.

2 HARPER & JAMES, *supra* note 4, § 13.2, at 763 (footnotes omitted).

The societal interest in accident cases includes, however, more than merely an equitable *distribution* of the losses occasioned by accidents. There is also legitimate concern with the efficient use of resources, or more specifically with the minimization of the costs of accidents—that is, the costs of avoiding accidents in the first instance, the costs of paying compensation to the victims of accidents that cannot or have not been prevented, and the costs of administering a system that attempts both to avoid accidents and to compensate accident victims. See G. CALABRESI, *THE COSTS OF ACCIDENTS* 26-31 (1970); Calabresi & Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055 (1972). But see Fletcher, *Fairness and Utility in Tort Theory*, 85 HARV. L. REV. 537 (1972); authorities cited note 255 *infra*. In this context, it no longer always suffices to say that the accident victim should bear the loss unless it can be demonstrated that the injurer's *wrongful* conduct caused the loss.

12. Theoretically, complete compensation of accident victims could be obtained. See note 26 *infra*. But total loss-spreading faces several practical obstacles. The cost of operating a compensation system that spreads all losses would probably be prohibitive, and the problem of defining what an "accident" is will pose other practical barriers. Cf. note 244 *infra*.
13. Oelsner, *Jury Awards Going Up in Personal Injury Suits*, N.Y. Times, July 6, 1975, at 1, col. 5 (city ed.).

requirement. Starting later, there has been a more direct circumvention of the requirement of medical negligence to impose liability through the use of the informed-consent doctrine. Finally, there have been a few direct assaults in recent years on the negligence requirement in medical-accident litigation.

The battle over strict liability for medical accidents, as well as for other types of accidents,¹⁴ is but one of the fronts¹⁵ in the war being waged against a system of compensating accident victims which is rooted in a philosophy of classical liberalism, nurtured by a laissez-faire economic system,¹⁶ and legitimized by the moral posture that the losses from injuries must be borne by the individual upon whom they have fallen unless they have been occasioned by another's blameworthiness.¹⁷ While the black-letter rules remain basically the same—that is, the plaintiff patient must demonstrate that medical negligence caused the injury—the interpretation and application of the rules is such that today the medical-accident victim stands a far greater chance of fitting his case within them, and thus obtaining compensation, than in the past.

This article will examine the various ways in which the courts have been fashioning rules of liability for medical accidents that add up to an incipient system of strict liability. This examination will concentrate on the broader strategic advances. The road toward strict liability has not been without its detours.¹⁸ It is the obvious judicial circumlocutions, which appear necessitated by the inability of the courts under existing rules of law to award com-

14. See Section II *infra*.

15. See generally PROSSER, *supra* note 2, § 81. (discussion of other judicial and legislative applications of the principles of strict liability).

16. See generally 1 HARPER & JAMES, *supra* note 4, at xxvii *et seq.*; 2 *id.* § 12.3, at 752.

17. The general principle of our law is that loss from accident must lie where it falls "All the cases concede that an injury arising from . . . an act that ordinary human care and foresight are unable to guard against, is but the misfortune of the sufferer, and lays no foundation for legal responsibility." If this were not so, any act would be sufficient, however remote, which set in motion or opened the door for a series of physical consequences ending in damage The requirement of an act is the requirement that the defendant should have made a choice. But the only possible purpose of introducing this moral element is to make the power of avoiding the evil complained of a condition of liability.

O.W. HOLMES, *THE COMMON LAW* 76-77 (M. Howe ed. 1963) (footnotes omitted).

18. The law did not begin with a theory. It has never worked one out. The point from which it started and that at which I shall try to show that it has arrived, are on different planes. In the progress from one to the other, it is to be expected that its course should not be straight and its direction not always visi-

pensation to severely injured medical-accident victims, that are our main area of concern, and not the routine application of well-established general principles to novel situations of fact.

II. THE WAR ON NEGLIGENCE

The judicial movement toward strict liability for medical accidents is not an isolated occurrence. Aided by both legislative and judicial armaments, similar activity has been taking place in other areas of accident law since at least the beginning of the present century.¹⁹ Although liability without fault, or strict liability,²⁰ has been known to the common law for certain civil wrongs for many centuries,²¹ a landmark development was the enactment of no-fault insurance for employment-related injuries in the early 1900's.²² More recently, strict liability has come of age in the law of products liability, culminating in the adoption in the American Law Institute's Restatement Second of Torts of a strict products liability provision,²³ and its rapid adoption in numerous jurisdictions.²⁴

ble. All that can be done is to point out a tendency, and to justify it.

Id. at 63.

19. See J. FLEMING, AN INTRODUCTION TO THE LAW OF TORTS 13-20 (1967); 1 HARPER & JAMES, *supra* note 4, at xxix-xliv; 2 *id.* at 785-870 (1956 & Supp. 1968); PROSSER, *supra* note 2, §§ 76, 96-99. See also O'Connell, *It's Time for No Fault for All Kinds of Injuries*, 60 A.B.A.J. 1070 (1974).
20. Prosser distinguishes two different senses of the word *fault*—moral wrongdoing, and departure from what is required by law. He therefore prefers to speak of "strict liability," rather than "liability without fault," the former involving the imposition of liability as a means of "allocating a more or less inevitable loss . . . upon the party best able to shoulder it." PROSSER, *supra* note 2, § 75, at 495.
21. *Id.* § 75, at 492-93.
22. See generally S. HOROVITZ, INJURY AND DEATH UNDER WORKMEN'S COMPENSATION LAWS (1944); A. LARSON, THE LAW OF WORKMEN'S COMPENSATION (1966); W. SCHNEIDER, SCHNEIDER'S WORKMEN'S COMPENSATION (3d or perm. ed. 1941).
23. RESTATEMENT (SECOND) OF TORTS § 402A (1965).
24. Section 402A seems merely to have stated baldly what had been more or less the case for quite a while.

[A]ll of the trouble lay with the one word "warranty," which had been from the outset only a rather transparent device to accomplish the desired result of strict liability. . . . Why not, then, talk of the strict liability in tort, a thing familiar enough in the law . . . and discard the word "warranty" with all its contract implications?

Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 802 (1966). See also 2 L. FRUMER & M. FRIEDMAN, PRODUCTS LIABILITY § 16A[3], at 3-248 n.2 (1975) [hereinafter cited as FRUMER & FRIEDMAN]; PROSSER, *supra* note 2, § 98, at 657 n.54 (collecting cases in other jurisdictions following § 402A).

There also has been substantial interest in strict liability for automobile accidents, though the activity here as in workmen's compensation at the beginning of this century has been legislative rather than judicial. Some optimistic proponents of strict liability view it as a possible panacea for a variety of social ills,²⁵ and one common-law jurisdiction has taken a substantial step toward the adoption of a comprehensive social insurance system for accidents.²⁶

Prosser appropriately characterized the judicial efforts to adopt strict liability in a military metaphor. In 1960, reporting on the progress then occurring on the products-liability front, he sent a dispatch proclaiming that:

One major bastion, that of negligence liability, has been carried long since, and its guns turned inward upon the defenders. Another, that of the strict liability of the seller of food and drink, is hard pressed and sore beset, and may even now be tottering to its fall. Elsewhere along the battlements there have been minor breaches made, but the defense is yet stout. War correspondents with the beleaguering army are issuing daily bulletins, proclaiming that the seige is all but over. From within the walls comes the cry, not so; we have but begun to fight. Watchman, what of the night?²⁷

Six years later, Prosser reported on the fall of the citadel:

The fall of a citadel is a dramatic moment. . . .

In the field of products liability, the date of the fall of the citadel of privity can be fixed with some certainty. It was May 9,

25. See J. O'CONNELL, *supra* note 7; O'Connell, *supra* note 19.

26. See Accident Compensation Act, 1972, no. 43, 1 N.Z. STAT. 521. For a discussion of this act see Franklin, *Personal Injury Accidents in New Zealand and the United States: Some Striking Similarities*, 27 STAN. L. REV. 653 (1975); Palmer, *Abolishing the Personal Injury Tort System: The New Zealand Experience*, 9 ALTA. L. REV. 169 (1971); Palmer, *Compensation for Personal Injury: A Requiem for the Common Law in New Zealand*, 21 AM. J. COMP. L. 1 (1973); Palmer & Lemons, *Toward the Disappearance of Tort Law: New Zealand's Compensation Plan*, 1972 U. ILL. L.F. 693; BRIT. MED. J., Nov. 29, 1975, at 529.

A less ambitious form of social insurance seeks to provide compensation for the victims of crimes. Here, of course, the effort has been not to substitute strict liability for negligence as a basis for obtaining compensation, but to provide compensation where often, as a practical matter, none was obtainable. In 1963, New Zealand passed the first contemporary system for compensating victims of crime, and Great Britain followed in 1964. H. EDELHERTZ & G. GEIS, *PUBLIC COMPENSATION TO VICTIMS OF CRIME* 11 (1974). In the United States, 7 states (Alaska, California, Hawaii, Massachusetts, Maryland, New Jersey, and New York) had, by 1974, enacted programs of social insurance for victims of crimes. The experience under these state programs is discussed in detail in H. EDELHERTZ & G. GEIS, *supra* at 21-187.

27. Prosser, *The Assault upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1099 (1960) (footnotes omitted).

1960, when the Supreme Court of New Jersey announced the decision in *Henningsen v. Bloomfield Motors, Inc.* The leaguer had been an epic one of more than fifty years. The sister fortress of negligence liability had fallen, after an equally prolonged defense, in 1916. Much sapping and mining had finally carried a whole south wing of the strict liability citadel, involving food and drink; and further inroads had been made into an adjoining area of products for what might be called intimate bodily use, such as hair dye and cosmetics. Heavy artillery had made no less than eight major breaches in the main wall, all of them still stoutly defended.

Then came the *Henningsen* case. . . .
The citadel fell.²⁸

O'Connell, in writing about strict liability for automobile accidents, adopted Prosser's military metaphor:

No-fault auto insurance seems to have come of age. If so, no army of trial attorneys or timid insurance executives will be able to halt its progress. Recognition grows daily that the theory of negligence as applied to all automobile accidents is intellectually inert.²⁹

The battles over products liability and automobile accidents have progressed to a substantial degree, and though they are not clearly won, victories seem assured primarily by judicial incursions in the case of products liability, while the inroads on the fault requirement in automobile accidents have been secured through legislative advances.³⁰ While both of these assaults have been progressing, an-

28. Prosser, *supra* note 24, at 791-93.

29. O'Connell, *Expanding No-Fault Beyond Auto Insurance: Some Proposals*, 59 VA. L. REV. 749 (1973). Although adopting Prosser's military metaphor, O'Connell has characterized Prosser's style as "pretentious." See *id.* at 760.

30. By May 1975, 23 states (Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New York, Oregon, Pennsylvania, South Carolina, South Dakota, Texas, Utah, and Virginia) had enacted no-fault automobile insurance in some form. NATIONAL UNDERWRITER CO., FIRE CASUALTY & SURETY BULLETINS—AUTO (CASUALTY), at Nc-1 to Ny-6. In addition, several no-fault bills were introduced in the 93d and 94th Congresses. See S. 354, 93d Cong., 1st Sess. (1973); S. 1606, 93d Cong., 1st Sess. (1973); S. 354, 94th Cong., 1st Sess. (1975); H.R. 10, 358, 1400, 1680, 4023, 93d Cong., 1st Sess. (1973); H.R. Con. Res. 116, 93d Cong., 1st Sess. (1973); H.R. 285, 1272, 1900, 94th Cong., 1st Sess. (1975).

Commentators have disagreed on the consequences of no-fault automobile insurance. Compare Lubasch, *The Early Returns on No-Fault Insurance Show It's Working*, N.Y. Times, Oct. 5, 1975, § 4, at 6, col. 4 (city ed.), with Lindsey, *No-Fault Insurance Failing to Cut Rates*, N.Y. Times, Jan. 24, 1976, at 1, col. 1 (city ed.). See also Widiss, *Accident Victims Under No-Fault Insurance: A Massachusetts Survey*, 61 IOWA L. REV. 1 (1975).

other has also progressed almost unnoticed. Though much has been written about this battle, few if any have viewed it as a part of the same war.³¹

31. The last few years, especially 1975, have seen much comment in the lay, professional, and scholarly presses, about a malpractice "crisis." A crisis, however, has been warned of for more than a quarter of a century. See L. REGAN, *DOCTOR AND PATIENT AND THE LAW* 7 (2d ed. 1949). The response of the medical profession, judging at least by the titles of some recent articles in medical journals, has often been histrionic. See, e.g., Downey, *Medical Malpractice Bares Its Fangs at Hospitals, and Its Venom May Prove Deadly*, 3 *MOD. HEALTH CARE* 21 (June, 1975); Perry, *Are We at Armageddon?*, 62 *J. FLA. MED. ASS'N* 34 (1975); Hunter & Conroy, *Malpractice Fever—A Social Disease*, 61 *J. FLA. MED. ASS'N* 866 (1974). Professor Curran claims that "there may have been some basis for a charge of 'crying wolf' too often in the past about malpractice litigation, but it is now clear that the most chronic problem of all, rising insurance premiums and inadequate insurance coverage, has become, in 1975, a genuine national economic crisis." Curran, *Malpractice Insurance: A Genuine National Crisis*, 292 *NEW ENG. J. MED.* 1223 (1975).

Although the cost and availability of malpractice insurance have become serious problems in many parts of the country—so serious in fact that physicians have engaged in strikes over the issue, see *Am. Med. News*, June 9, 1975, at 1, col. 1—medical practice seems to be continuing in much the same way as it did before the "crisis," though some physicians have chosen to practice without insurance, Altman, *Alaska Doctors Work Uninsured*, *N.Y. Times*, July 26, 1975, at 49, col. 1, a practice referred to by doctors as "going bare." See *Am. Med. News*, Sept. 27, 1976, *Impact Section*, at 5, col. 1.

In response to this "crisis," many states have attempted piecemeal procedural or substantive reforms of medical malpractice laws. This legislation is summarized in *NATIONAL CENTER FOR HEALTH SERVICES RESEARCH, HEALTH POLICY CENTER, GEORGETOWN UNIVERSITY, LEGISLATIVE BRIEFS—HIGHLIGHTS OF ENACTED STATE LEGISLATION (1975)* (updates available from National Center for Health Services Research, 5600 Fishers Lane, Rockville, Md. 20852), and in *LEGISLATIVE DEPARTMENT, PUBLIC AFFAIRS DIVISION, AMERICAN MEDICAL ASSOCIATION, 3 STATE HEALTH LEGISLATION REPORT*, October, 1975. See also Comment, *An Analysis of State Legislative Responses to the Medical Malpractice Crisis*, 1975 *DUKE L.J.* 1417. There have been numerous proposals for reform, many of which include some form of "no-fault" liability. Keeton, *Compensation for Medical Accidents*, 121 *U. PA. L. REV.* 590, 598 n.25 (1973), and Defense Research Institute, *Medical Malpractice Position Paper*, 42 *INS. COUNSEL J.* 59 (1975), contain bibliographies of such proposals.

A few commentators, however, have realized that a system of strict liability has been developing for some time. See, e.g., 2 *HARPER & JAMES, supra* note 4, § 17.1, at 58-59 n.15 (Supp. 1968):

The pressure of hardship from [the conspiracy of silence] and other sources has induced counsel, courts, and occasionally legislatures to use their ingenuity in alleviating it by inventing or expanding rules which will either circumvent, or help

The battle over liability for medical accidents has been waged almost exclusively on the judicial battleground.³² Despite this similarity with the battle on the products-liability front, the tactics employed have been quite different. The products-liability battle has been fought in the traditional style with opposing armies using conventional warfare: sharply drawn lines of attack, battles fought in the open, and war correspondents reporting regularly. The battle over medical accidents has not even been discussed as such. Rather, it has been a battle waged with guerilla tactics. Camouflage has been employed heavily by all the contending forces so that the battle has been waged at first in terms of "malpractice" and "*res ipsa loquitur*" but more recently with the weapon of "informed consent," which probably explains why the war correspondents have failed to notice that this battle is part of a larger war.

It is time to look closely and forthrightly at what has been happening, and by pulling back the shroud of secrecy imposed by the censors in the war department, to show the battle for what it is: another front in the assault on the fault requirement.³³

III. THE FAULT SYSTEM AND MEDICAL ACCIDENTS: THE GATHERING STORM

The earliest efforts to facilitate the compensation of medical accident victims without regard to medical negligence took place within the negligence framework. The efforts were aimed, at least

the plaintiff to meet, the requirement. These are of various kinds and include . . .

(4) [i]nvoking a substantive law theory which may not be dependent on medical testimony, notably the doctrine of informed consent.

See also Comment, *Medical Malpractice: A Move Toward Strict Liability*, 21 LOY. L. REV. 194 (1975).

32. Recently, several state legislatures have enacted statutes codifying—and attempting to restrict—the judicially created doctrine of informed consent. See note 97 *infra*.
33. It is not only in the context of medical accidents that there has been a notable lack of forthrightness:

Frequently, when the courts have been unwilling to say outright that the defendant is liable without negligence, something approaching this result has been accomplished by the creation of presumptions. . . . In some cases, at whose number one may only guess, where there has in fact been no negligence but the defendant is unable to prove it, this will arrive at the same result as strict liability.

PROSSER, *supra* note 2, § 81, at 539-40 (footnotes omitted). See also J. FRANK, *LAW AND THE MODERN MIND* 338-50 & *passim* (Anchor Books ed. 1963) (discussing legal fictions).

ostensibly, at lowering a practical barrier to proving that medical negligence had caused the plaintiff's injuries.

In order to secure a favorable verdict, the medical-accident victim must, of course, demonstrate that the defendant strayed from the recognized standard of care in the profession.³⁴ This imposes upon the plaintiff the burden of establishing first what the professional standard of care is in any given case, and then the fact of the defendant's departure therefrom. Because, generally, the only acceptable manner of proof of the standard of care is the testimony of another physician,³⁵ it is incumbent upon the plaintiff to secure this testimony in order to survive a dismissal of the action.

This requirement has often posed an insurmountable obstacle to the medical-accident victim, who routinely has been met with the unwillingness of one physician to provide evidence which might impose liability upon a colleague. What aptly has been dubbed "the conspiracy of silence"³⁶ has effectively prevented numerous medical-accident victims from prevailing at trial, and probably has deterred numerous others from instituting litigation.³⁷ This unwillingness

34. 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 8.04; PROSSER, *supra* note 2, § 32, at 161-63.

35. PROSSER, *supra* note 2, § 32, at 164. Only "[w]here the matter is regarded as within the common knowledge of laymen . . . [may] the jury . . . infer negligence without the aid of any expert." *Id.* at 164-65. See also pp. 98-99, 135-38 *infra*.

36. See generally Belli, *An Ancient Therapy Still Applied: The Silent Medical Treatment*, 1 VILL. L. REV. 250, 254-57 (1956); Kayajanian, *Confronting the Conspiracy of Silence: We Have a Tiger by the Tail*, 6 U.W.L.A.L. REV. 40 (1974); Kelner, *The Silent Doctors—The Conspiracy of Silence*, 5 U. RICH. L. REV. 119 (1970); Seidelson, *Medical Malpractice Cases and the Reluctant Expert*, 16 CATH. U. OF AM. L. REV. 158 (1966); Note, *Overcoming the "Conspiracy of Silence": Statutory and Common-Law Innovations*, 45 MINN. L. REV. 1019 (1961); Comment, *Medical Malpractice—The "Locality Rule" and the "Conspiracy of Silence"*, 22 S.C.L. REV. 810 (1970). For a Canadian view of the problem see Grange, *The Silent Doctor v. The Duty to Speak*, 11 OSOODE HALL L.J. 81 (1973).

37. Because medical-accident litigation is often lengthy, expensive, and uncertain, Note, *Comparative Approaches to Liability for Medical Maloccurrences*, 84 YALE L.J. 1141 (1975); J. O'CONNELL, *supra* note 7, at 29-47, the fault system probably deters many persons or their attorneys from bringing lawsuits. CENTER FOR THE STUDY OF DEMOCRATIC INSTITUTIONS, *MEDICAL MALPRACTICE: A DISCUSSION OF ALTERNATIVE COMPENSATION AND QUALITY CONTROL SYSTEMS* 4 (1971). In addition, countless other medical-accident victims, who are not even aware that their condition has been occasioned or worsened by the medical intervention, never seek compensation. *Id.*; Havighurst & Tancredi, "Medical Adversity Insurance"—A No-Fault Approach to Medical Malpractice and Quality Assurance, 1974 INS. L.J. 69, 73.

stems in part from the desire of organized medicine to protect its good name, not by aiding in weeding out incompetent practitioners as might be hoped,³⁸ but by pressuring physicians to "protect" other physicians by their silence. Still other pressure is applied by insurance companies whose motivation in silencing physicians is their own financial well-being, and whose power stems from their ability to cancel or refuse to renew the professional liability insurance of a physician who breaks the rule and offers testimony.³⁹

However, plaintiffs' ingenuity and judicial receptivity have combined to circumvent this barrier to compensation, especially where the manifest unfairness to the plaintiff of denying compensation for egregious injuries could not be overlooked, primarily⁴⁰ through

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38. See, e.g., Brody, *Incompetent Surgery is Found Not Isolated*, N.Y. Times, Jan. 27, 1976, at 1, col. 6 (city ed.); Rensberger, *Few Doctors Ever Report Colleagues' Incompetence*, N.Y. Times, Jan. 29, 1976, at 1, col. 1 (city ed.); Wilford, *A.M.A. Disputes, but Others Praise, Series About Incompetent Physicians*, N.Y. Times, Feb. 6, 1976, at 1, col. 1 (city ed.). See also Rensberger, *Death of 2 Doctors Poses a Fitness Issue*, N.Y. Times, Aug. 15, 1975, at 1, col. 5 (city ed.); Rensberger, *Unfit Doctors Create Worry in Profession*, N.Y. Times, Jan. 26, 1976, at 1, col. 1 (city ed.). Nor is it clear that the governmental agencies charged with policing the medical profession are able to perform the task properly. See N.Y. Times, Apr. 28, 1976, at 23, col. 1 (city ed.); HEW, *MEDICAL MALPRACTICE*, *supra* note 4, at 52.
39. *L'Orange v. Medical Protective Co.*, 394 F.2d 57 (6th Cir. 1968), noted in 11 B.C. IND. & COM. L. REV. 545 (1970), 54 IOWA L. REV. 649 (1969), 63 NW. U.L. REV. 873 (1969), 47 TEXAS L. REV. 152 (1968), 17 U. KAN. L. REV. 540 (1969), and 37 U. MO. K.C.L. REV. 154 (1969). See also Carlson, *Suing the Doctor*, Wall St. J., Feb. 28, 1969, at 1, col. 1.
40. Two other barriers to obtaining compensation within the negligence framework—the statute of limitations and the "locality rule," see note 41 *infra*—have also been the subjects of substantial attack in the last few decades.

In medical-accident litigation, where the harm that the plaintiff experiences from a medical accident often does not manifest itself for a considerable time after the medical procedure has been performed, the statute of limitations is likely to present a significant barrier to bringing any action at all. If the statute begins to run at the time the medical procedure is performed, the statute may have expired before the patient is aware that he had been harmed by the procedure, or before he begins to suspect that the cause of his difficulties may lie in the physician's negligence. See generally 1 LOISELL & WILLIAMS, *supra* note 3, § 13; PROSSER, *supra* note 2, § 30, at 144 n.54; Harper, *Texas Adopts the Discovery Rule for Limitations in Medical Malpractice Actions*, 1 ST. MARY'S L.J. 77 (1969); Sacks, *Statutes of Limitations and Undiscovered Malpractice*, 16 CLEV.-MAR. L. REV. 65 (1967). Plaintiffs' attempts to escape its application have had mixed results. There has been a modicum of success in invoking the argument that when a physician commits a negligent act and continues to treat the patient, the physician is also negligent in failing to take efforts to remedy the

the doctrine of *res ipsa loquitur*. The almost uniform unwillingness of the local medical colleagues of the defendant to offer evidence on behalf of medical-accident victims could not be entirely vitiated by modification or outright abolition of the locality rule.⁴¹ Where

original negligence, and the "continuing negligence" tolls the statute. See, e.g., *Johnson v. Caldwell*, 371 Mich. 368, 123 N.W.2d 785 (1963); *Sly v. Van Lengen*, 120 Misc. 420, 198 N.Y.S. 608 (Sup. Ct. 1923); *Gillette v. Tucker*, 67 Ohio St. 106, 65 N.E. 865 (1902); *Frazor v. Osborne*, 57 Tenn. App. 10, 414 S.W.2d 118 (1966) (collecting cases). Some courts have softened the impact of the statute considerably by interpreting it to commence running when the patient "discovers" that he has suffered an injury. Under this so-called "discovery rule," the plaintiff does, however, have the duty to use reasonable care to discover the existence of an injury. *Lopez v. Swyer*, 62 N.J. 267, 300 A.2d 563 (1973); *Ayers v. Morgan*, 397 Pa. 282, 154 A.2d 788 (1959); *Hays v. Hall*, 477 S.W.2d 402 (Tex. Civ. App. 1972); *Olsen v. St. Croix Valley Memorial Hosp.*, 55 Wis. 2d 628, 201 N.W.2d 63 (1972). See generally A. HOLDER, *MEDICAL MALPRACTICE LAW* 322-23 (1975); 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 13.11, at 382.

41. Originally, the standard of care required of a physician did not allow for the geographical locale in which he practiced medicine. See *McCandless v. McWha*, 22 Pa. 261 (1853). But an early modification of the rule established as the standard of care "that skill only which physicians and surgeons of ordinary ability and skill practicing in similar localities with opportunities for no larger experience, ordinarily possess." *Small v. Howard*, 128 Mass. 131, 136 (1880), *overruled*, *Brune v. Belinkoff*, 354 Mass. 102, 235 N.E.2d 793 (1968).

Adopted largely out of concern for rural physicians, whose access to and knowledge of new developments in medical care was thought to be limited, *Small v. Howard*, *supra* at 136, the locality rule had the consequence of requiring medical-accident victims seeking judicial redress to establish the standard of care using, as an expert witness, an individual living in the same locality as the defendant. In rural communities, where there may have been no physician other than the defendant, this was often an impossible task. Even if there were other physicians, their friendship with the defendant, or fear of retaliation in kind from him if they testified, often made them virtually unavailable.

The harsh effect of the locality rule encouraged the courts to devise means of circumventing it without formally eliminating it. *Waltz, The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DE PAUL L. REV. 408, 411-15 (1969); Comment, *Locality and Standard of Care of Medical Practitioners*, 25 ARK. L. REV. 169, 172-75 (1971). Some courts extended the geographic borders of the "same locality." See, e.g., *Warnock v. Kraft*, 30 Cal. App. 2d 1, 3-4, 85 P.2d 505, 506 (2d Dist. 1938); *Pelky v. Palmer*, 109 Mich. 561, 563, 67 N.W. 561 (1896); *McCracken v. Smathers*, 122 N.C. 602, 606, 29 S.E. 354, 355-56 (1898). Others have redefined the "same locality" to mean the "same medical locality." See, e.g., *Blair v. Eblen*, 461 S.W.2d 370, 372-73 (Ky. 1970); *Cavallaro v. Sharp*, 84 R.I. 67, 72, 121 A.2d 669, 672-73 (1956); *Teig v. St. John's Hosp.*, 63 Wash. 2d 369, 375-77, 387 P.2d 527, 531-32 (1963). Courts have also permitted the plaintiff to establish

the rule could be breached, there still remained the problems of locating a medical expert witness from some other area who would be willing to testify, as well as the expense of litigation when dealing with a nonlocal expert witness. Even when an expert witness could be obtained to testify, there still was no guarantee that the witness would be able to provide convincing evidence that the defendant's negligence had been the proximate cause of the plaintiff's injuries.

Under specified circumstances, the plaintiff, through reliance upon *res ipsa loquitur*, may have an opportunity to get his case to the jury without introducing expert evidence of the defendant's negligence. The strict statement of the appropriate circumstances for the operation of the doctrine is stated by one court as follows:

The test almost uniformly applied to determine whether the doctrine applies in malpractice suits is whether all the ultimate facts alleging negligence, or some of them, are required to be established by expert testimony; or whether " * * * a layman is able to say as a matter of common knowledge and observation that the consequences of professional treatment were not such as ordinarily would have followed if due care had been exercised."⁴²

the standard of care through interrogation of the defendant-doctor, see *Evans v. Bernhard*, 23 Ariz. App. 413, 533 P.2d 721 (1975); *Wilkinson v. Vesey*, 110 R.I. 606, 295 A.2d 676 (1972); *Ethicon, Inc. v. Parten*, 520 S.W.2d 527 (Tex. Civ. App. 1975), or through the use of medical treatises. *Iverson v. Lancaster*, 158 N.W.2d 507 (N.D. 1968); *Lewandoski v. Preferred Risk Mut. Ins. Co.*, 33 Wis. 2d 69, 76, 146 N.W.2d 505, 509 (1966). *But cf. Hickok v. G.D. Searle & Co.*, 496 F.2d 444 (10th Cir. 1974).

Today when the defendant is a medical specialist, a national standard is generally applied. A. HOLDER, *supra* note 40, at 56-57. In 1916, the Minnesota supreme court recognized that the original rationale for the locality rule, if ever valid, had ceased to be compelling, see *Viita v. Fleming*, 132 Minn. 128, 137, 155 N.W. 1077, 1081 (1916). The locality rule, though not dead, is certainly on the wane. See Nortell, *Medicolegal Rounds—Leading Cases*, 235 J.A.M.A. 1614 (1976); Waltz, *supra*. *But see* LA. REV. STAT. ANN. § 9:2794(A) (1) (Supp. 1976) (legislative enactment of common-law locality rule).

42. *Sung Wha Kim Lyu v. Shinn*, 40 Hawaii 198, 201 (1953) (quoting *Cavero v. Franklin Etc. Benev. Soc'y*, 36 Cal. 2d 301, 309, 223 P.2d 471, 476 (1950)). See generally Annot., 82 A.L.R.2d 1262, 1274 (1962).

Later cases have imposed three general conditions on the application of the doctrine: (1) the injury must be of a kind that ordinarily does not occur in the absence of someone's negligence; (2) the injury must be caused by an instrumentality or agency within the exclusive control of the defendant-physician; and (3) the injury must not have been due to any voluntary action or contribution on the part of the plaintiff-patient. See generally 2 HARPER & JAMES, *supra* note 4, §§ 19.5-8; 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 14.04, at 425; PROSSER, *supra* note 2, § 39. It is sometimes said that there is a fourth condition

In some jurisdictions, and at some times, the rule has been narrowly applied merely to permit an inference of negligence to be drawn, while at other times and places the rule has been given more powerful effect by not only permitting the plaintiff to meet his production burden, but also by shifting the burden of persuasion from the plaintiff to the defendant.⁴³

—that the evidence of negligence must be more accessible to the defendant than to the plaintiff—but it seems rarely to be enforced. 2 HARPER & JAMES, *supra* note 4, § 19.9; PROSSER, *supra* note 2, § 39, at 225-28. See also note 53 *infra*.

The Restatement defines *res ipsa loquitur* as follows:

(1) It may be inferred that harm suffered by the plaintiff is caused by negligence of the defendant when

(a) the event is of a kind which ordinarily does not occur in the absence of negligence;

(b) other responsible causes, including the conduct of the plaintiff and third persons, are sufficiently eliminated by the evidence; and

(c) the indicated negligence is within the scope of the defendant's duty to the plaintiff.

RESTATEMENT (SECOND) OF TORTS § 328D (1965).

Several states have recently enacted legislation restricting the applicability of *res ipsa loquitur* in medical malpractice cases. See NEV. REV. STAT. § 41A.100 (1975); TENN. CODE ANN. § 23-3414(3)(c) (Supp. 1975); WASH. REV. CODE ANN. § 4.24.290 (Supp. 1975) (by implication).

The case in which a foreign object is left in the patient's body during surgery is the prototype for the application of *res ipsa loquitur*. See, e.g., Dietze v. King, 184 F. Supp. 944 (E.D. Va. 1960) (surgical sponge); Swanson v. Hill, 166 F. Supp. 296 (D.N.D. 1958) (6½-inch forceps); Tiller v. Von Pohle, 72 Ariz. 11, 230 P.2d 213 (1951) (10-inch by 18-inch cloth sack); Bowers v. Olch, 120 Cal. App. 2d 108, 260 P.2d 997 (2d Dist. 1953) (surgical needle). The doctrine is also applied in situations in which an injury has occurred to a healthy part of the patient's body remote from the place of the performance of the medical procedure. See, e.g., Dodson v. Pohle, 73 Ariz. 186, 239 P.2d 591 (1952) (cheek burned by steam from vaporizer used to treat inflammation of larynx, trachea, and bronchial tubes); Ybarra v. Spangard, 25 Cal. 2d 486, 154 P.2d 687 (1944) (paralysis of right shoulder following appendectomy); Brown v. Shortlidge, 98 Cal. App. 352, 277 P. 134 (1st Dist. 1929) (tooth knocked out during adenoidectomy and tonsillectomy).

43. The procedural effects of *res ipsa loquitur* vary among the jurisdictions. At the very least, however, the plaintiff who satisfies the conditions for the application of the doctrine will avoid a nonsuit or a directed verdict for the defendant. 2 HARPER & JAMES, *supra* note 4, § 19.11, at 1099. Thus, though the plaintiff may overcome an important obstacle to compensation, the battle is not yet necessarily won.

The majority of jurisdictions adhere to the position that *res ipsa loquitur* creates only an inference of negligence, in turn permitting the plaintiff to satisfy his production burden and escape a nonsuit. *Id.* at 1100. The production of evidence of breach of duty does not of itself, however, entitle the plaintiff to a judgment in his favor. He must still

The rationale for the application of the doctrine of *res ipsa loquitur* to the medical-accident cases has been well stated by Mr. Justice Rutledge:

Malpractice is hard to prove. The physician has all of the advantage of position. He is, presumably, an expert. The patient is a layman. The physician knows what is done and what is its significance. The patient may or may not know what is done. He seldom knows its significance. He judges chiefly by results. The physician has the patient in his confidence, disarmed against suspicion. Physicians, like lawyers, are loath to testify a fellow craftsman has been negligent, especially when he is highly reputable in professional character In short, the physician has the advantage of knowledge and of proof What therefore might be slight evidence when there is no such advantage, as in ordinary negligence cases, takes on greater weight in malpractice suits.⁴⁴

The doctrine of *res ipsa loquitur* is intended merely to be an evidentiary device, a method of proof which relieves the plaintiff of establishing by direct evidence specific acts of the defendant's negligence.⁴⁵

prove the other elements of a cause of action in negligence—namely, proximate cause and damages. Even if the plaintiff is able to establish the remaining elements of the cause of action, and the defendant fails to produce any controverting evidence, the inference of negligence rarely entitles plaintiff to a directed verdict. Rather, the case will usually go to the jury, which will consider the credibility of the witnesses before returning a verdict for either party. F. JAMES, CIVIL PROCEDURE § 7.7 (1965).

The remaining jurisdictions are divided as to the procedural effect of *res ipsa loquitur*. In some, the doctrine creates a presumption of negligence requiring a directed verdict for the plaintiff unless the defendant offers sufficient evidence to rebut the presumption. 2 HARPER & JAMES, *supra* note 4, at 1101-03; PROSSER, *supra* note 2, § 40, at 230. In a few other jurisdictions, the courts go even further in permitting *res ipsa loquitur* to shift the burden of proof (*i.e.*, the risk of nonpersuasion, F. JAMES, *supra* § 7.6) from the plaintiff to the defendant, who must then introduce evidence of a greater weight if he is to avoid a directed verdict. *See, e.g.*, *Anderson v. Somberg*, 67 N.J. 291, 338 A.2d 1, *cert. denied*, 423 U.S. 929 (1975), in which the court held that since all the defendants (the physician, the hospital, and the manufacturer and supplier of an instrument) had engaged in conduct creating a legal duty to the plaintiff, the failure of any of the defendants to prove lack of culpability must result in the imposition of liability upon all. *See also* *Ybarra v. Spangard*, 25 Cal. 2d 486, 154 P.2d 687 (1944); 2 HARPER & JAMES, *supra* note 4, at 1103; PROSSER, *supra* note 2, § 40, at 230. The trend, however, is toward the majority position of giving *res ipsa loquitur* no greater effect than that of raising a permissible inference of negligence, based on a policy of giving circumstantial evidence no greater effect than direct evidence would have. PROSSER, *supra* note 2, § 40, at 231.

44. *Christie v. Callahan*, 124 F.2d 825, 827-28 (D.C. Cir. 1941).

45. 2 HARPER & JAMES, *supra* note 4, § 19.11.

While no doubt the ostensible reason for the application of *res ipsa loquitur* has weighed heavily upon the judiciary, a more compelling practical reason, while always lurking in the shadows, has only occasionally surfaced and been acknowledged forthrightly by the courts. The Supreme Court of California, long an innovator not only in medical-accident cases but in accident cases of other kinds as well, has admitted that another consideration is at work in the judicial willingness to permit the use of the doctrine:

[G]radually the courts awoke to the so-called "conspiracy of silence." No matter how lacking in skill or how negligent the medical man might be, it was almost impossible to get other medical men to testify adversely to him in litigation based on his alleged negligence. Not only would the guilty person thereby escape from civil liability for the wrong he had done, but his professional colleagues would take no steps to insure that the same results would not again occur at his hands.⁴⁶

The application of *res ipsa loquitur* represents a judicial effort to circumvent the unwillingness of the vast proportion of the medical profession to testify on behalf of patients injured at the hands of negligent colleagues, and to compensate medical-accident victims on the basis of the equities of the case rather than in accordance with strict legal rules of procedure or substance.⁴⁷

Because expert medical testimony is generally a prerequisite to the establishment of the defendant's negligence,⁴⁸ a number of jurisdictions have refused to apply *res ipsa loquitur*.⁴⁹ However, the overall trend has been toward liberalization of the conditions under which it may be invoked by a medical-accident victim.⁵⁰ The reason suggested by Mr. Justice Rutledge—the plaintiff's lack

46. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 568, 317 P.2d 170, 175 (1st Dist. 1957).

47. See W. PROSSER, *SELECTED TOPICS ON THE LAW OF TORTS* 346 (1953).

48. See note 35 *supra*.

49. See, e.g., *McDermott v. St. Mary's Hosp. Corp.*, 144 Conn. 417, 423, 133 A.2d 608, 611 (1957) ("Members of a jury are laymen as to medical and surgical methods, . . . and they cannot be expected to know what constitutes proper treatment"); *Adams v. Heffington*, 216 Ark. 534, 226 S.W.2d 352 (1950); *Bettigole v. Diener*, 210 Md. 537, 124 A.2d 265 (1956); *Williams v. Chamberlain*, 316 S.W.2d 505, 511 (Mo. 1958); *Shockley v. Payne*, 348 S.W.2d 775, 779 (Tex. Civ. App. 1961).

According to Prosser, *res ipsa loquitur* "is accepted and applied by all of our courts, including those of South Carolina, which purport to reject it by name, Michigan, which formerly did so, and Pennsylvania, which purports to limit its application to cases in which the defendant has voluntarily undertaken some responsibility." PROSSER, *supra* note 2, § 39, at 213 (footnotes omitted).

50. This liberalization has come despite substantial criticism of the doctrine. 2 HARPER & JAMES, *supra* note 4, § 19.5, at 1079-81.

of understanding of medical matters and the consequent difficulty of proof of the physician's departure from the accepted standard of care⁵¹—has played a role in causing many courts to overcome some of the opposition they may have had to softening the requirement of expert medical testimony to establish negligence. However, another factor responsible for the increased acceptance of *res ipsa loquitur* in medical-accident litigation has been the supposition that lay comprehension of illness and medical practice has *increased*.⁵²

It is ironic that two contradictory reasons are given for the increased judicial receptivity toward *res ipsa loquitur*. On the one hand it is said that because laymen are not knowledgeable about medical problems, it is unfair to impose upon the plaintiff the responsibility of explaining whether and how something went wrong in the performance of the medical procedure. Thus the burden may be shifted fairly to the defendant through the use of *res ipsa loquitur*. But on the other hand, it is said that because of the increased lay comprehension of medical matters, the jury will be able to determine whether the defendant has been negligent without the aid of expert testimony. It is clear that the only possible reconciliation of these two contradictory beliefs is that some courts are bending over backwards to permit medical-accident victims to obtain compensation for their injuries, regardless of the logic employed.

The courts have also been impressed by the contention that knowledge of what actually happened to the patient is often far more accessible to and easily explained by the physician who performed or was present at the procedure than by the patient or a third-party physician.⁵³ If the patient is unconscious when the

51. See p. 69 *supra*.

52. *Agnew v. City of Los Angeles*, 82 Cal. App. 2d 616, 619, 186 P.2d 450, 451 (2d Dist. 1947); *Reynolds v. Struble*, 128 Cal. App. 716, 725, 18 P.2d 690, 694 (1st Dist. 1933); *Corn v. French*, 71 Nev. 280, 291, 289 P.2d 173, 179 (1955), *aff'd*, 74 Nev. 729, 331 P.2d 850 (1958); *Kennedy v. Parrott*, 243 N.C. 355, 358, 90 S.E.2d 754, 756 (1956).

53. See *Dierman v. Providence Hosp.*, 31 Cal. 2d 290, 295, 188 P.2d 12, 14 (1947); *Seneris v. Haas*, 45 Cal. 2d 811, 825, 291 P.2d 915, 923 (1955); *Ybarra v. Spangard*, 25 Cal. 2d 486, 490, 154 P.2d 687, 689 (1944); *Maki v. Murray Hosp.*, 91 Mont. 251, 262-63, 7 P.2d 228, 231 (1932); *Anderson v. Somberg*, 67 N.J. 291, 338 A.2d 1, *cert. denied*, 423 U.S. 929 (1975); *St. John's Hosp. & School of Nursing, Inc. v. Chapman*, 434 P.2d 160 (Okla. 1967); *Beaudoin v. Watertown Memorial Hosp.*, 32 Wis. 2d 132, 145 N.W.2d 166 (1966). See also 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 14.04, at 425.

It is sometimes said that a condition for the appropriate operation of *res ipsa loquitur* is that evidence explaining the mishap be more accessible to the defendant than to the plaintiff. See, e.g., *Appalachian*

medical procedure is performed, whether as a result of pre-existing accident or injury, or anesthesia, the defendant doctor who was in control of the potential cause of the medical accident possesses either a superior knowledge of what happened, or the best opportunity to obtain evidence concerning the injury.⁵⁴ Courts also have placed reliance upon the fiduciary character of the doctor-patient relationship in permitting the invocation of *res ipsa loquitur*, reasoning that the confidence and trust placed in the physician by the patient demands that the doctor come forward with an explanation of what went wrong.⁵⁵ These justifications of the application of *res ipsa loquitur* add up to nothing more than a feeling on the part of their judicial progenitors that it would be grossly unjust to require the plaintiff affirmatively to prove negligence, in light of the difficulties of obtaining expert testimony and the serious injuries that have been sustained.

Although the primary effect of *res ipsa loquitur* has been procedural—that is, to permit the plaintiff to escape a nonsuit because of an inability to obtain the cooperation of a physician to provide expert testimony needed to establish medical negligence—the doctrine easily lends itself to abuse. The very issue to be established is whether or not the event the plaintiff complains of arose from “negligence” or from a “statistical risk.”⁵⁶ Therefore, to the extent that the mere happening of the event is permitted to give rise to an inference of negligence, we come very close to permitting the characterization of the event as negligence from its mere happening alone. A liberal application of the doctrine is therefore but a short step from the complete abolition of a negligence requirement.⁵⁷ As

Ins. Co. v. Knutson, 358 F.2d 679 (8th Cir. 1966); Wilson v. East St. Louis & Interurban Water Co., 295 Ill. App. 603, 15 N.E.2d 599 (1938); Levendusky v. Empire Rubber Mfg. Co., 84 N.J.L. 698, 87 A. 338 (Ct. Err. & App. 1913); Hughes v. Jolliffe, 50 Wash. 2d 554, 313 P.2d 678 (1957); Ellis v. Henderson, 95 S.E.2d 801 (W. Va. 1956), *opinion withdrawn on rehearing*, 142 W. Va. 824, 98 S.E.2d 719 (1957). An extensive discussion of this point may be found in 2 HARPER & JAMES, *supra* note 4, § 19.9, at 1094 n.1.

54. Seneris v. Haas, 45 Cal. 2d 811, 825, 291 P.2d 915, 923 (1955); Ybarra v. Spangard, 25 Cal. 2d 486, 490, 154 P.2d 687, 689 (1944); Frost v. Des Moines Still College of Osteopathy, 248 Iowa 294, 302, 79 N.W.2d 306, 311 (1956); Voss v. Bridwell, 188 Kan. 643, 660, 364 P.2d 955, 971 (1961). See also Prosser, *The Procedural Effect of Res Ipsa Loquitur*, 20 MINN. L. REV. 241, 260 (1936).

55. See Cho v. Kempler, 177 Cal. App. 2d 342, 349, 2 Cal. Rptr. 167, 171 (1st Dist. 1960).

56. See p. 54 & note 6 *supra*.

57. Some commentators have sensed the fine line between *res ipsa loquitur* and strict liability. See Rubsamen, *Res Ipsa Loquitur in California Medical Malpractice Law—Expansion of a Doctrine to the Bursting Point*, 14 STAN. L. REV. 251, 256 (1962). “[T]he expansion of the ‘doc-

such, *res ipsa loquitur* constitutes a bridge between the procedural efforts to skirt the negligence requirement and the strategies based upon entirely different substantive grounds employed to establish liability without regard to medical negligence.

Faced with both practical and doctrinal barriers to the awarding of compensation to persons seriously injured in connection with the performance of a medical procedure, the courts have struggled to fashion new rules to overcome these hurdles to compensation. The Supreme Court of California has expressed its guiding assumption this way: "[T]he maxim that for every wrong there is a remedy would be rendered nugatory, 'by denying one, patently entitled to damages, satisfaction merely because he is ignorant of facts peculiarly within the knowledge of the party who should, in all justice, pay them.'"⁵⁸

In summary, under a negligence theory, plaintiffs have had to establish that the physician who allegedly caused the injuries had departed from accepted standards of medical practice. Because another physician was needed to establish what the accepted standard of medical practice was, the medical profession as a whole, by refusing to testify, was able to thwart the awarding of compensation to individuals injured at the hands of one of its members. In response to this conspiracy of silence, the doctrine of *res ipsa loquitur* was invoked with increasing frequency by plaintiffs, and received with increased acceptance by the judiciary. The result was that more plaintiffs could obtain compensation. But compensation was still limited to those plaintiffs who, even with the assistance of judicial ingenuity and receptivity, were able to demonstrate that the physician had failed to conform to the accepted standard of medical practice, and that this deviation had been the proximate cause of their bad results. This left numerous plaintiffs without compensation, and possibly deterred many more injured patients from seeking recourse to the courts at all.⁵⁹ Clearly, so long as compensation was sought within the bounds of the negligence system, there would always be a large number of injured patients who could not obtain compensation for their injuries, no matter how egregious.

trine'—in spite of trenchant and penetrating logical criticism—may well be attributable to the strong general trend towards strict liability and social insurance—a trend which is corroding a system of liability nominally based on fault." 2 HARPER & JAMES, *supra* note 4, § 19.5, at 1080-81. See also Morris, "Res Ipsa Loquitur"—Liability Without Fault, 25 INS. COUNSEL J. 97 (1958).

58. *Ybarra v. Spangard*, 25 Cal. 2d 486, 490, 154 P.2d 687, 689 (1944) (quoting *Maki v. Murray Hosp.*, 91 Mont. 251, 262, 7 P.2d 228, 231 (1932)).

59. See note 37 *supra*.

Warfare employing procedural tactics had achieved about all that could be expected in the battle over medical accidents. What was needed was an entirely new substantive strategy that would not run headlong into the ubiquitous bastion of negligence. Loosed from the requirement of having to establish that the bad medical results were caused by the physician's failure to conform to accepted standards of medical practice, the medical-accident victim might at last find a pot of gold at the end of the litigation rainbow.

IV. INFORMED CONSENT

Medical-accident victims who found themselves stymied by their inability to demonstrate medical negligence⁶⁰ sought and found refuge in a completely different basis for liability. Since at least the beginning of the present century—and probably much longer⁶¹—it has been recognized that the physician is, as a general rule, not entitled to treat a patient unless the patient has consented to treatment.⁶² Any patient who has been treated without consenting

60. See note 3 *supra*.

61. See *Slater v. Baker*, 95 Eng. Rep. 860 (K.B. 1767).

62. Among the earliest American cases so holding are *Pratt v. Davis*, 224 Ill. 300, 79 N.E. 562 (1906); *State v. Housekeeper*, 70 Md. 162, 16 A. 382 (1889); *Sullivan v. McGraw*, 118 Mich. 39, 76 N.W. 149 (1898); *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905), *overruled on other grounds*, *Genzel v. Halvorson*, 248 Minn. 527, 80 N.W.2d 854 (1957); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 105 N.E. 92 (1914), *overruled on other grounds*, *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 1 (1957); *Rolater v. Strain*, 39 Okla. 572, 137 P. 96 (1913). By the second decade of the present century, the cases involving unauthorized treatment had become fairly numerous. See generally Note, *Consent As a Prerequisite to a Surgical Operation*, 14 CIV. L. REV. 161 (1940).

Many of the early cases, though acknowledging the general rule requiring consent, found "implied" or "tacit" consent in the plaintiff's submission to treatment. See, e.g., *McGuire v. Rix*, 118 Neb. 434, 225 N.W. 120 (1929); *Bennan v. Parsonnet*, 83 N.J.L. 20, 83 A. 948 (Sup. Ct. 1912); *Boydston v. Giltner*, 3 Ore. 118 (1869); *Beatty v. Cullingworth*, Q.B. unreported, 44 CENT. L.J. 153 (1897). Consent need not be obtained in cases of emergency, 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 9.05, at 255, but assessments of what constitutes an emergency vary widely. Compare *Jackovach v. Yocum*, 212 Iowa 914, 237 N.W. 444 (1931) (amputation of mangled arm; emergency, consent not needed), with *Wells v. McGehee*, 39 So. 2d 196 (La. App. 1949) (treatment of fractured wrist held to constitute emergency).

Extensive discussions of the basic rules governing consent to medical treatment, prior to the development of the informed-consent doctrine, may be found in 1 HARPER & JAMES, *supra* note 4, § 3.10; PROSSER, *supra* note 2, § 18; McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381 (1957); Smith, *supra* note 3, at 233-58.

may maintain an action against the physician for damages.⁶³

Through the numerous cases in which the charge of unauthorized treatment has been litigated, the courts have developed an extensive body of law specifying what sorts of behavior on the part of the patient amount to a consent. More recently—most notably in the last two decades—the courts also have begun to focus on the conduct of the physician in obtaining the patient's consent, and not merely on the conduct of the patient in giving or withholding consent. In order for the patient's consent to treatment to be valid, not only must the patient consent, but the consent must be preceded by a certain degree of explanation by the physician about the anticipated treatment. This development is referred to as the doctrine of "informed consent."⁶⁴ Thus the patient who is injured but is unable to prove medical negligence might also attempt to prove that the physician did not obtain the patient's valid consent to treatment.

63. An action for unauthorized treatment may be maintained against a doctor even if the treatment does not yield "bad results." See, e.g., *Lloyd v. Kull*, 329 F.2d 168 (7th Cir. 1964) (\$500 awarded for unauthorized removal of mole); *Bailey v. Belinfante*, 135 Ga. App. 574, 574-75, 218 S.E.2d 289, 291 (1975) ("Plaintiff testified that Dr. Belinfante had done a good job in removing his teeth, and that there was no quarrel with the work itself; the only question was whether the doctor should have taken out all of the teeth or only some of them."); *Rolater v. Strain*, 39 Okla. 572, 137 P. 96 (1913) (\$1000 awarded for unauthorized removal of a bone from foot). See also 232 J.A.M.A. 1059 (1975).

In the absence of bad results, a plaintiff may only be awarded nominal damages for injury to his dignity. See, e.g., *McCandless v. State*, 3 App. Div. 2d 600, 606-07 162 N.Y.S.2d 570, 575-76 *aff'd*, 4 N.Y.2d 785, 149 N.E.2d 530, 173 N.Y.S.2d 30 (1957) (damages for unauthorized abortion performed upon a patient in a state mental hospital held excessive, and reduced in light of testimony that patient's condition was improved by the termination of the pregnancy). See generally C. MORRIS, *TORTS* 26 (1953); PROSSER, *supra* note 2, § 9, at 35. Punitive damages may also be available where the defendant acted in bad faith. PROSSER, *supra* § 2, at 9-14; RESTATEMENT OF TORTS § 908 (1939).

64. There is an extensive body of commentary on the law of informed consent. The references prior to 1970 are collected in Waltz & Scheune-man, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628, 628 n.1 (1970). See also Alsobrook, *Informed Consent: A Right to Know*, 40 INS. COUNSEL J. 580 (1973); Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340 (1974); Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 693 (1975); Gough, *Recent Uses and Misuses of the Informed Consent Doctrine*, 10 FORUM 383 (1974); Riskin, *Informed Consent: Looking for the Action*, 1975 U. ILL. L.F. 580; Shartsis, *Informed Consent: Some Problems Revisited*, 51 NEB. L. REV. 527 (1972); Comment, *Informed*

The rendition of medical care without the patient's valid consent is at the heart of the new strategy that has been embraced by a growing number of medical-accident victims. The litigation has focused upon what constitutes a valid consent, rather than upon whether or not the physician negligently performed the medical procedure. The plaintiff may seek compensation for the injuries he received because the physician performed the procedure responsible for the injuries without adequate disclosure, which, if made, would have caused the patient to refuse treatment.⁶⁵ Both the requirement of consent to medical treatment and the contemporary doctrine of informed consent that has evolved from it are intended to protect the individual's interest in freedom from unwanted bodily intrusions,⁶⁶ whether beneficial or not.⁶⁷ Additionally, the informed-consent requirement is intended to encourage the individual to make rational decisions about medical treatment.⁶⁸

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- Consent: The Illusion of Patient Choice*, 23 EMORY L.J. 503 (1974); Note, *Advise and Consent in Medicine: A Look at the Doctrine of Informed Consent*, 16 N.Y.L.F. 863 (1970); Note, *Informed Consent—A Proposed Standard for Medical Disclosure*, 48 N.Y.U.L. REV. 548 (1973); Comment, *Informed Consent As a Theory of Medical Liability*, 1970 WIS. L. REV. 879; Note, *Informed Consent and the Dying Patient*, 83 YALE L.J. 1632 (1974); Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533 (1970) [hereinafter cited as Note, *Restructuring Informed Consent*].
65. There is some question as to whether the test of causation is an objective or a subjective one. See pp. 107-13 *infra*.
 66. The law of battery is intended to protect the individual from harmful or offensive contact with his person, 1 HARPER & JAMES, *supra* note 4, § 3.2; PROSSER, *supra* note 2, § 9, and the requirement of consent assures that the individual will be subjected only to those bodily touchings which he finds neither harmful nor offensive. See Pratt v. Davis, 118 Ill. App. 161, 166 (1905).
 67. The right to be free from unwanted "beneficial" treatment is based on both a rejection of paternalism in medical care, and on the practical ground that what is beneficial in one person's view may not be in another's. See Note, *Informed Consent and the Dying Patient*, *supra* note 64, at 1646. This view rejects the necessary primacy of "health" values, and suggests that the individual patient should alone determine whether or not he is to be treated. See generally Smith, *supra* note 3, at 237; Comment, *Informed Consent in Medical Malpractice*, 55 CALIF. L. REV. 1396, 1409 (1967) Doe v. Bolton, 410 U.S. 179, 213-18 (1973) (Douglas, J., concurring).
 68. The most extensive treatment of the interests served by the doctrine of informed consent may be found in J. KATZ & A. CAPRON, CATASTROPHIC DISEASES: WHO DECIDES WHAT? 82-90 (1975), in which the authors state that the functions of informed consent are to (1) promote individual autonomy, (2) protect the patient's status as a human being, (3) avoid fraud and duress, (4) encourage self-scrutiny by the physician, (5) encourage rational decisionmaking, and (6) educate the public. See also J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS 521-608 (1972); P. RAMSEY, THE PATIENT AS PERSON 1-58 & *passim* (1970);

While the values which the informed-consent doctrine ostensibly seeks to implement may, in their origins, have been the primary interest and purpose of the doctrine's judicial progenitors, the contemporary application of the doctrine serves a quite different purpose. The requirement of informed consent to medical treatment has, for at least the past two decades, been used as the cloth from which courts slowly have begun to fashion a no-fault system for compensating persons who have suffered bad results from medical treatment. Consequently, the development of the law of informed consent has been influenced at least as much by the desire to compensate accident victims for their injuries as to promote the lofty interests which the requirement of consent was originally intended to protect.

A. The Law of Consent to Medical Treatment

In the early part of this century, only in the clearest cases were the courts willing to find that the patient had not provided a valid

Capron, *supra* note 64; Note, *Informed Consent and the Dying Patient*, *supra* note 64, at 1643-47.

The objectives of the informed-consent doctrine are more extensive than the interests served by the earlier requirement of consent, which developed out of the law of battery. The requirement of informed consent—that is, that before a consent may be considered valid, it must be preceded by the disclosure to the patient of certain information, see pp. 80-90 *infra*—is intended not merely to protect the patient's bodily integrity, autonomy, and privacy, see note 66 *supra*, but also to encourage the patient to make a rational decision about treatment. It should be noted that at least conceptually there is no *requirement* that the patient's decision in fact be "rational." The courts, however, when confronted with the issue, have often seemed reluctant to honor what they consider to be "irrational" decisions. The cases involving patients who refuse life-saving blood transfusions are paradigmatic. See note 189 *infra*.

In addition to promoting self-determination, the duty to disclose may also play a role in keeping the costs of medical care from skyrocketing. Hicks, *Doctors Strong, Patients Weak, Costs Up*, N.Y. Times, Apr. 26, 1976, at 1, col. 1 (city ed.):

What is peculiar to the health sector and is in part related to the ongoing cost of care the [report of the President' Council on Wage and Price Stability] went on, is the "passive" role of the consumer in health services. When the patient goes to see a doctor, it is the physician who determines how and when he comes back, what other medical services or specialists he requires, what drugs he needs, and whether he needs to go to the hospital and for how long.

Id. at 11, col. 1 (citing EXECUTIVE OFFICE OF THE PRESIDENT, COUNCIL ON WAGE & PRICE STABILITY, *THE PROBLEM OF RISING HEALTH CARE COSTS* 19 (1976)). This also indicates that actual patient-participation in decisionmaking is far less prevalent than a routine application of the doctrine of informed consent would suggest.

consent to treatment. From this initial unwillingness to hold a physician liable for unauthorized treatment, a gradual shift has occurred, most notably in the last two decades, toward far more stringent standards. What would often pass for a valid consent in older cases would barely permit a physician to escape a directed verdict in contemporary cases.⁶⁹ The consequence of the more stringent standards has been greater opportunities for compensation of patients. Because of the rather complex and vague set of rules that has developed, by which the validity of the consent is measured, the mere occurrence of bad results is more likely than ever before to be compensable without regard to medical negligence.

The basic rule from which plaintiffs' counsel and compensation-minded courts have fashioned subrules, counterrules, and exceptions is that a physician must obtain the patient's consent before he is legally entitled to commence treatment. This rule traces its origins in law at least to the late 18th-century case of *Slater v. Baker & Stapleton*,⁷⁰ which held liable two medical practitioners for disuniting, without the patient's consent, a partially healed fracture. It is clear, however, from various portions of the case that even before the decision therein it was customary among surgeons not to treat patients without first having obtained their consent to treatment:

[I]t appears from the evidence of the surgeons that it was improper to disunite the callous without consent; this is the usage and law of surgeons: then it was ignorance and unskillfulness in that very particular, to do contrary to the rule of the profession, what no surgeon ought to have done⁷¹

69. In *McGuire v. Rix*, 118 Neb. 434, 225 N.W. 120 (1929), the plaintiff authorized the defendant-doctor to reduce a foot fracture by manipulation. While the patient was anesthetized, and despite the absence of an emergency, the doctor performed a surgical operation. The court refused to hold the defendant liable for unauthorized treatment, finding that "[c]onsent may be implied from the circumstances . . ." *Id.* at 440, 225 N.W. at 123. The court added that "[t]he use of anesthesia in modern surgery has modified to some extent the ancient rule of the common law requiring consent." *Id.* But see *Demers v. Gerety*, 85 N.M. 641, 515 P.2d 645 (Ct. App. 1973), *rev'd and remanded on other grounds*, 86 N.M. 141, 520 P.2d 869 (1974), in which defendant was held liable for treating a patient without consent, in part because the patient had signed a consent form while anesthetized.

70. 95 Eng. Rep. 860 (K.B. 1767).

71. *Id.* at 862. Counsel for the defendants raised the objection that the case should have been dismissed because the proof—that the treatment was rendered without the plaintiff's consent—did not conform to the pleading that the procedure was performed unskillfully. The court rejected this defense on the ground that it was more important that justice be done than that the proof conform to the pleading. Evidently,

What long passed for a valid consent to treatment was a simple interchange between patient and physician. In substance the physician said to the patient, "You need thus-and-so to get better," and the patient responded with some phrase or action indicating whether or not he intended to go along with the doctor's recommendations. The response may have been very broad: "O.K. Doc, whatever you say"; slightly less inclusive: "Go ahead and do thus-and-so"; somewhat more limiting: "Go ahead and do 'thus,' but I don't want you to do any 'so'";⁷² or even totally restrictive: "If *that's* what I need, then I'd rather be sick, and don't do anything at all."⁷³ Each of these responses (even the express prohibition)⁷⁴ has been relied upon by physicians as authorization to treat, and the courts have generally agreed that the patient has, by speaking some such phrase, authorized the physician to proceed and thereby provided the physician with a defense to an action for battery.

Slowly, the realization grew that authorization for the physician to proceed need not be the cut-and-dried matter that it had first appeared to be.⁷⁵ For example, the doctor might not have said merely that "you need thus-and-so to get better" but, trying to put the anxious patient at ease, might have said to the patient about

the problem of compensating medical-accident victims without strict adherence to procedural niceties is not of recent origin.

72. See, e.g., *Perry v. Hodgson*, 37 Ga. App. 314, 316, 140 S.E. 396, 397 (1927) (plaintiff's father agreed to operation only after repeated assurances from defendant that he would not invade the tract that drained the infection); *Demers v. Gerety*, 85 N.M. 641, 647, 515 P.2d 645, 648 (Ct. App. 1973) ("[P]laintiff emphatically told the defendant not to touch the ileostomy. If anything had to be done to the ileostomy, he would return to Boston for medical services."); *Rolater v. Strain*, 39 Okla. 572, 574, 137 P. 96, 97 (1913) (plaintiff expressly prohibited defendant from removing a bone in her foot); *Dicenzo v. Berg*, 340 Pa. 305, 309, 16 A.2d 15, 17 (1940) (plaintiff instructed defendant not to "go too much up in the neck").
73. See, e.g., *Markart v. Zeimer*, 67 Cal. App. 363, 227 P. 683 (3d Dist. 1924); *Meek v. City of Loveland*, 85 Colo. 346, 276 P. 30 (1929); *Corn v. French*, 71 Nev. 280, 282, 289 P.2d 173, 175 (1955) (plaintiff expressly prohibited defendant from removing her breast); *Throne v. Wandell*, 176 Wis. 97, 186 N.W. 146 (1922); *Beatty v. Cullingworth*, Q.B. unreported, 44 CENT. L. J. 153 (1897) (plaintiff forbade performance of a double ovariectomy).
74. See cases cited note 73 *supra*.
75. It was not until the beginning of the twentieth century that litigation over the requirement of consent to medical treatment began in earnest. See note 62 *supra*. "The question of the necessity of consent on the part of one submitting to an operation has not received much consideration at the hands of the courts of this country or in England." 1 E. KINKEAD, TORTS § 375, at 735 (1903). There was a "scarcity of legal discussion upon this point . . ." *Id.* at 738 n.39.

the procedure, "Oh, that's nothing; it is not a serious operation at all."⁷⁶ The patient would then agree to undergo it, much assured that it was a simple operation, but would later be distraught when, at the conclusion of the operation, he discovered undesirable results.

In response to this realization, there began to develop subrules, counterrules, and exceptions, beyond the original simple proposition that a physician might not treat a patient without the patient's authorization. To meet the changing circumstances, a court might say that the physician's failure to obtain the patient's informed consent raised an issue for the jury as to whether this failure constituted an unreasonable departure from the degree of skill and care required of a doctor. Not only was the physician required to obtain the patient's consent to treatment, but if he affirmatively misrepresented the nature of the procedure and of the probable consequences, the misrepresentation might be held to invalidate the patient's consent, leaving the physician open to a claim for unauthorized treatment.⁷⁷ As litigation over the contours of a legally valid consent proceeded, the concept of consent, like that of negligence, began to be viewed as being quite malleable, if not quite infinitely expandable.

B. The Affirmative Duty of Disclosure

1. *The Origins of the Physician's Obligation to Disclose Information*

The most substantial and significant development in the law of consent to medical treatment concerns the physician's disclosure of information to the patient prior to obtaining his authorization for treatment. While there are several suggestions to the contrary in the case law prior to the last two decades,⁷⁸ there never existed

76. See *Wall v. Brim*, 138 F.2d 478, 479 n.7 (5th Cir. 1943); *accord*, *Hunt v. Bradshaw*, 242 N.C. 517, 88 S.E.2d 762 (1955); *Waynick v. Reardon*, 236 N.C. 116, 72 S.E.2d 4 (1952); *Paulsen v. Gundersen*, 218 Wis. 578, 260 N.W. 448 (1935).

77. See *Wall v. Brim*, 138 F.2d 478 (5th Cir. 1943); *State v. Housekeeper*, 70 Md. 162, 16 A. 382 (1889); *Corn v. French*, 71 Nev. 280, 289 P.2d 173 (1955); *Waynick v. Reardon*, 236 N.C. 116, 72 S.E.2d 4 (1952); *Nolan v. Kechijian*, 75 R.I. 165, 64 A.2d 866 (1949); *Paulsen v. Gundersen*, 218 Wis. 578, 260 N.W. 448 (1935). But this does not mean that a doctor is under an obligation to describe in great detail all of the possible consequences of treatment. *McCoid, The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549, 590 (1959).

78. See, e.g., *Hunter v. Burroughs*, 123 Va. 113, 96 S.E. 360 (1918), in which the patient suffered burns from radiation therapy. One count of the complaint alleged that the physician knew, or in the exercise of due care should have known, of the possibility of burns to the patient's skin, and that as a result he was under an obligation to make known

any general rule that the physician's failure to provide a patient with information about the contemplated medical procedure prior to embarking upon its ministrations would invalidate the consent that the patient gave.⁷⁹ Rather, the early cases, when concerned at all with the information given the patient, directed their attention to the problem of the veracity of information that the physician may have undertaken to disclose either on his own initiative or in response to a patient's queries, though there was no legal compulsion to make any disclosure. Where the physician provided the patient with information about his medical condition or the proposed procedure, the courts have uniformly held that fraudulent, deceptive, or misleading disclosure vitiates the consent that the patient subsequently gave.⁸⁰

these dangers to the patient. The court, in affirming the overruling of the demurrer to this count, stated that "it is the duty of a physician in the exercise of ordinary care to warn a patient of the danger of possible bad consequences of using a remedy . . ." *Id.* at 133, 96 S.E. at 366. Though the failure to warn is not "per se an act of negligence"—because the duty does not exist in all cases—when the doctor knows or should have known of the dangers of the treatment, failure so to inform the patient constitutes negligence. See also *Wall v. Brim*, 138 F.2d 478 (5th Cir. 1943); *Pratt v. Davis*, 224 Ill. 300, 79 N.E. 562 (1906), *aff'g* 118 Ill. App. 161 (1905); *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905); *Kenny v. Lockwood*, [1932] 1 D.L.R. 507 (Ont. App. 1931); *Slater v. Baker*, 95 Eng. Rep. 860 (K.B. 1767).

79. *But see Smith, Therapeutic Privilege to Withhold Specific Diagnosis from Patient Sick with Serious or Fatal Illness*, 19 TENN. L. REV. 349, 350 (1946). The existence of a therapeutic privilege to withhold information from a patient, see pp. 99-107 *supra*, recognized by Smith and other writers, certainly presumes an affirmative obligation of disclosure.
80. See cases cited note 76 *supra*. The rule pertaining to the accurate disclosure of information has analogues elsewhere in the law. For example, in the law of torts, when a person who has no duty to act undertakes to act, he will be held liable for the failure to exercise reasonable care in his conduct. See generally 2 HARPER & JAMES, *supra* note 4, § 18.6; PROSSER, *supra* note 2, § 56, at 343-48. For a recent application of this rule to another area of medical practice see *Tarasoff v. Regents of Univ. of Cal.*, 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (1976) (psychotherapist who acts to treat a dangerous patient must exercise reasonable care, which may include warning third parties threatened by patient's conduct).

Similarly, the seller of real property traditionally had no affirmative obligation to disclose conditions that, were the buyer aware of them, would make the property less attractive. If, however, the seller volunteered information or responded to inquiries from the buyer, he was obligated to provide truthful information. See, e.g., *Kraft v. Lowe*, 77 A.2d 554, 557 (D.C. Mun. Ct. App. 1950). See also RESTATEMENT OF TORTS § 529 (1939); PROSSER, *supra* note 2, § 106, at 696. Like the disclosure of information concerning medical treatment, this requirement has undergone substantial change in recent years. See, e.g., Schipper

This early rule—that ordinarily no information need be provided, but if the physician does provide information, it must be truthful—contained the seeds of the requirement which began to develop in the 1950's that the physician has an affirmative duty to disclose certain information to the patient. From here it was only a short judicial step to imposing an affirmative requirement of disclosure upon the physician.⁸¹

Because of the organic growth of the law of consent to medical treatment, it is not possible to point to any particular case as marking the transition from a simple consent requirement to an "informed" consent requirement—that is, a rule requiring affirmative disclosure by the physician to the patient before the latter's consent to treatment is valid.⁸² While several cases intimated that an affirmative duty of disclosure existed, they were greatly scattered and did not constitute any coherent pattern. However, a number of cases in the 1950's together mark a clear transition from the older "simple" consent rule to the first contemporary "informed" consent cases.

In a 1955 case, the Supreme Court of North Carolina, while refusing to require that a physician disclose the risk involved in sur-

v. Levitt & Sons, 44 N.J. 70, 207 A.2d 314 (1965) (seller of residence required to disclose known danger to buyer who could not reasonably be expected to know of it before harm was done). See also RESTATEMENT (SECOND) OF TORTS § 353 (1965).

81. After reviewing the cases of *Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 88 N.W.2d 186 (1958), *Lester v. Aetna Cas. & Sur. Co.*, 240 F.2d 676 (5th Cir.), cert. denied, 354 U.S. 923 (1957), and *Kenny v. Lockwood*, [1932] 1 D.L.R. 507 (Ont. App. 1931), the Supreme Court of Kansas concluded:

[W]here the physician or surgeon has affirmatively misrepresented the nature of the operation or has failed to point out the probable consequences of the course of treatment, he may be subject to a claim of unauthorized treatment. But this does not mean that a doctor is under an obligation to describe in detail all of the possible consequences of treatment.

Natanson v. Kline, 186 Kan. 393, 406, 350 P.2d 1093, 1103 (1960).

82. One student commentator has made the rather bold claim that the doctrine of informed consent originated in dictum in *Hunter v. Burroughs*, 123 Va. 113, 96 S.E. 360 (1918). See Comment, *Informed Consent as a Theory of Medical Liability*, *supra* note 64, at 880. There are, however, suggestions in several other cases decided before *Hunter v. Burroughs*, see note 78 *supra*, that the physician has an affirmative obligation to disclose information to the patient if the subsequent consent is to be valid, and it seems that the development of the informed-consent doctrine is better characterized as an organic process than as a single event. Several cases decided after *Hunter v. Burroughs* represent various points of development in this process. See, e.g., *Wall v. Brim*, 138 F.2d 478 (5th Cir. 1943); *Kenny v. Lockwood*, [1932] 1 D.L.R. 507 (Ont. App. 1931).

gery, stated that the failure to explain the risks involved "may be considered a mistake on the part of the surgeon . . ." ⁸³ Two years later, a California appellate court, relying in part upon the North Carolina precedent, specifically held that there was an affirmative duty of disclosure upon the physician so that the patient could make an "informed" consent, though this duty could be tailored by the physician to the particular patient's emotional condition.⁸⁴ The court, however, failed to provide a detailed and explicit statement of what kinds of information the affirmative duty of disclosure envisioned. It merely stated that on remand the jury should be instructed that "the physician has . . . discretion [to withhold alarming information from the patient] consistent, of course, with the full disclosure of facts necessary to an informed consent."⁸⁵ The court actually reversed a jury verdict for plaintiff on the ground that the trial court's instruction on the duty to inform went further than required. The trial court had instructed that it was "the duty of a physician to disclose to the patient 'all the facts which mutually affect his rights and interests and of the surgical risk, hazard and danger, if any * * *.'" ⁸⁶ On appeal, it was held that the physician had discretion to take into account the condition of the particular patient when determining the amount of information to be disclosed.

Soon thereafter, the Supreme Court of Minnesota reinforced the affirmative duty of disclosure when it held liable a physician for failing to inform the patient, in advance of the operation, of the alternative forms of treatment which would not have entailed the undesirable consequence of the procedure that was actually performed.⁸⁷ Additional support for the duty was lent by an opinion

83. *Hunt v. Bradshaw*, 242 N.C. 517, 523, 88 S.E.2d 762, 766 (1955) (citing no authority for this dictum). *But see Kennedy v. Parrott*, 243 N.C. 355, 90 S.E.2d 754 (1956) (holding that patient impliedly consented to a procedure the performance of which she had not been forewarned, and characterizing the requirement of consent to medical procedures as a "fetish").

84. *See Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1st Dist. 1957). In addition to relying upon *Hunt v. Bradshaw*, 242 N.C. 517, 88 S.E.2d 762 (1955), the court placed some reliance upon *Simone v. Sabo*, 37 Cal. 2d 253, 231 P.2d 19 (1951), in which the defendant-dentist did not warn the plaintiff of a risk that later materialized. There was expert testimony that it was customary practice for a general practitioner of dentistry in the defendant's locale to inform a patient of this particular risk prior to the procedure. *Id.* at 255-56, 231 P.2d at 21. The holding of the case, however, did not turn on this point.

85. 154 Cal. App. 2d at 578, 317 P.2d at 181.

86. *Id.*

87. *See Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 434, 88 N.W.2d 186, 190 (1958). The plaintiff alleged that although he had consented to

of the Fifth Circuit stating that the physician is obligated to acquaint the patient with the medical diagnosis and the treatment that is proposed.⁸⁸

However, at the same time that some courts were imposing an affirmative duty of disclosure upon the physician, still others reiterated the older view that the physician had no affirmative duty of disclosure.⁸⁹ One court even imposed liability upon a physician for mental anguish to the patient caused by the information that he disclosed to her about her condition and its proper treatment.⁹⁰

Two cases, decided in different jurisdictions within two days of each other in 1960, clearly indicated that there was to be no turning back on the road to the imposition on the medical practitioner of an affirmative duty of disclosure. While judicial abandonment of the simple consent requirement had been in the air during the prior decade, it was never as clear as after the decisions in *Natanson v.*

the performance of a prostate operation, he did not know that it would necessarily involve the severance of his spermatic cords. He therefore sought damages on the ground that his consent to the operation was ineffective. The court reversed the trial court's dismissal of the action, holding that it was a question for the jury as to whether plaintiff's consent was effective, and stating that when no emergency exists, "a patient should be informed of the alternative possibilities and given a chance to decide before the doctor proceeds with the operation." *Id.*

88. See *Lester v. Aetna Cas. & Sur. Co.*, 240 F.2d 676, 679 (5th Cir. 1957) (dictum). Similarly, the Missouri supreme court, in 1959, suggested that the physician has an affirmative duty to disclose relevant information about treatment, at least to the extent of advising the patient what treatment is necessary. See *Steele v. Woods*, 327 S.W.2d 187, 198 (Mo. 1959).
89. See, e.g., *Hall v. United States*, 136 F. Supp. 187, 193 (W.D. La. 1955), *aff'd*, 234 F.2d 811 (5th Cir. 1956); *Woods v. Pommerening*, 44 Wash. 2d 867, 271 P.2d 705 (1954). See generally *Symposium, Morals, Medicine and the Law*, 31 N.Y.U.L. REV. 1157 (1956) (authorities in medicine, law, and ethics agreeing that the physician has a moral, but not a legal, obligation to tell the truth to patients).
90. In *Ferrara v. Galluchio*, 5 N.Y.2d 16, 152 N.E.2d 249, 176 N.Y.S.2d 996 (1958), the court upheld that portion of an award for mental anguish flowing from the "cancerphobia" plaintiff had developed upon learning from a nondefendant physician that the radiation therapy a defendant-physician had administered to her might cause cancer. Although the disclosure was not made by a defendant, the plaintiff's employment of the dermatologist who made the harmful disclosure was the result of the defendants' negligence. *Id.* at 20, 152 N.E.2d at 252, 176 N.Y.S.2d at 999; cf. *Williams v. Menahan*, 191 Kan. 6, 8, 379 P.2d 292, 294 (1963) (complete disclosure of all risks might so alarm patient as to constitute bad medical practice); *Furniss v. Fitchett*, [1958] N.Z.L. Rep. 396, noted in 4 N.Z.L.J. 65 (1958), and 34 *id.* 235 (1958); *Karchmer, Informed Consent: A Plaintiff's Medical Malpractice "Wonder Drug"*, 31 Mo. L. Rev. 29 (1966).

*Kline*⁹¹ and *Mitchell v. Robinson*⁹² that the simple ways of the past would no longer suffice.

In *Natanson*, a woman received radiation therapy after a mastectomy, and suffered injuries from the radiation. In *Mitchell* the plaintiff received insulin shock and electroshock therapy for the treatment of schizophrenia, causing the fracture of several vertebrae. In both cases, the patients' consent to treatment had been obtained.⁹³

The gravamina of the complaints were that the physicians had an affirmative duty to the patients to disclose information about the risks of the treatment, and that this duty had been breached. Both courts agreed. The *Mitchell* court phrased the duty as requiring the physician "to inform [the patient] generally of the possible serious collateral hazards . . ."⁹⁴ while the *Natanson* court went further by describing the doctor's duty as requiring

a reasonable disclosure . . . of the nature and probable consequences of the suggested or recommended . . . treatment, and . . . a reasonable disclosure of the dangers within his knowledge which were incident to, or possible in, the treatment he proposed to administer.⁹⁵

Insofar as *Natanson* and *Mitchell*, along with their immediate predecessors and progeny, firmly established the doctrine of "informed consent," they held out great promise to the injured patient who could not establish medical negligence. By requiring that the physician provide certain information to the patient before there could be valid consent, they opened the door to a host of new considerations in the determination of the validity of any particular consent to medical treatment. Courts now would have to inquire into the kind of information that the physician gave the patient. Because this inquiry would be made and judged retrospectively—that is, in the context of a suit for damages—the vulnerability of the doctor to a finding that the consent had not been valid, and hence

91. 186 Kan. 393, 350 P.2d 1093 (1960).

92. 334 S.W.2d 11 (Mo. 1960), *aff'd after retrial*, 360 S.W.2d 673 (Mo. 1962).

93. In *Mitchell*, although plaintiff's wife signed the written consent form, the plaintiff admitted that he also consented to the treatment. *Id.* at 17. In both *Mitchell* and *Natanson*, the plaintiffs apparently assumed that the consent barred an action for assault and battery, since both actions were brought in negligence. In *Natanson*, the plaintiffs pointed out that the case was not "an action for assault and battery, where a patient has given no consent to the treatment." 186 Kan. at 401, 350 P.2d at 1100.

94. 334 S.W.2d at 19.

95. 186 Kan. at 410, 350 P.2d at 1106.

to an adverse judgment, was increased. In the practical terms of obtaining compensation, this meant that litigation over medical accidents would have not just one substantial field of inquiry—the manner of performance of the medical procedure—but a second as well, the manner of disclosure to the patient of information about that procedure.

2. *The "Classical" Elements of the Duty to Disclose*

Although *Natanson*, *Mitchell* and numerous subsequent cases announced that there is a duty of affirmative disclosure, another issue remains. Under what circumstances must information be disclosed, and what kind of information must be provided? The common-law process, in which suggested answers are always to be understood as tentative and strictly applicable only to the facts of a particular case⁹⁶ has provided almost unlimited freedom for medical-accident victims to suggest and courts to accept (or reject) extensions and modifications of the rules for awarding compensation. In spite of this freedom to apply and interpret rules, the courts generally have agreed upon several "classical" elements of informed consent.⁹⁷

Mitchell and *Natanson* both recognized that the central informational component is the possible bad results that may occur from undergoing a particular procedure. While this concept has been expressed in several ways, it is generally referred to as the "risks" of the procedure.⁹⁸ It is self-evident that if an individual is to make

96. See J. FRANK, *supra* note 33, at 6-7. See also B. CARDOZO, *THE NATURE OF THE JUDICIAL PROCESS* 23 (1921).

97. A few states have also enacted statutes codifying the common-law requirements. See, e.g., FLA. STAT. ANN. § 395.11 (Supp. 1975); IDAHO CODE § 39-4304 (Supp. 1976); LA. STAT. ANN. § 40:1299.40 (Supp. 1976); NEV. REV. STAT. §§ 41A.110-.120 (Supp. 1975); N.Y. PUB. HEALTH LAW § 2805-d (McKinney Supp. 1976); OHIO REV. CODE ANN. § 2317.54 (1975); PA. STAT. ANN. tit. 40 § 1301.303 (Supp. 1975); TENN. CODE ANN. § 23-3417(a) (Supp. 1975). But see GA. CODE ANN. § 88-2906 (1971), construed in *Young v. Yarn*, 136 Ga. App. 737, 222 S.E.2d 113 (1975) (section 88-2906 a legislative repudiation of informed consent). For Canadian legislation and regulations on informed consent see the references cited in L. ROZOVSKY, *CANADIAN HOSPITAL LAW: A PRACTICAL GUIDE* 29 (1974). The U.S. Department of Health, Education, and Welfare has adopted regulations defining informed consent in the context of biomedical and behavioral research. See 45 C.F.R. § 46.3(c) (1974).

98. *Mitchell* speaks of "collateral hazards" and "dangers." 334 S.W.2d at 19. The Supreme Court of Kansas spoke, in *Natanson*, of "dangers" and "probable consequences." 186 Kan. at 410, 350 P.2d at 1106. The cases generally use words such as "peril," "risk," and "hazards." One case speaks of the "dangers lurking in the proposed treatment." *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir.), cert. denied, 409 U.S.

an informed or intelligent choice as to whether to consent to a medical procedure, he must have available to him not only the knowledge that the procedure is intended to diagnose or treat the condition from which he suffers, but also the knowledge of any risks that it may fail to do so, or that it may leave him worse off after the procedure. Disclosure of the risks of the procedure will neither guarantee that the patient will utilize the information in making a decision, nor assure that the decision will be a "reasonable" one.⁹⁹ Yet without this information most patients are obviously unable to make an informed decision.

While *Mitchell* mandated only the disclosure of risk information, *Natanson* went further by requiring disclosure of the nature of the ailment, the nature of the proposed treatment, the probability of success, and possible alternative treatments. These requirements, with slight modifications of terminology,¹⁰⁰ are the classical elements of informed consent, and constitute the basis from which the corpus of informed-consent rules, subrules, and exceptions have developed.

If the practice of medicine were akin to putting together a jigsaw puzzle, there would be little question as to what each of the classical elements of informed consent requires the physician to disclose in a particular case. That the practice of medicine is not a precise science explains both why medical accidents do occur even in the absence of medical negligence, and why a mere enumeration of the elements of informed consent does not and cannot tell the doctor precisely what information must be disclosed. To complicate matters further, the requirements for disclosure are necessarily hedged with qualifying words, which, though intended to make clear that the required degree of disclosure is something less than total, compel the doctor to attempt to second-guess the judicial process. To put the matter another way, the use of qualifying ex-

1064 (1972). The courts have not distinguished between unpleasant consequences inherent in the performance of a procedure and the risks of unpleasant (or dangerous) side effects of a procedure. Compare *Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 88 N.W.2d 186 (1958) (severance of spermatic cords a necessary consequence of a transurethral prostatic resection), with *Berkey v. Anderson*, 1 Cal. App. 3d 790, 82 Cal. Rptr. 67 (2d Dist. 1969) ("foot drop" a potential side effect or risk of myelogram). The distinction is discussed in *Plante, An Analysis of "Informed Consent,"* 36 *FORDHAM L. REV.* 639, 648-50 (1968).

99. See Section IV-D *infra*.

100. For example, "probability of success" seems to have developed into a requirement that the doctor describe "any benefits reasonably to be expected." 45 C.F.R. § 46.3(c) (3) (1974) (U.S. Department of Health, Education, and Welfare regulations for the protection of human subjects of biomedical and behavioral research).

pressions permits more freedom to the medical-accident victim to make his case for compensation.¹⁰¹

Natanson, as well as its antecedents and progeny, clearly does not require the doctor to tell the patient *all* information about risks, benefits, alternatives, diagnosis, and the nature of the treatment. To do so would require the patient to first undergo complete medical training himself.¹⁰² Even then there would be no assurance that the patient had been apprised of "all" of the information which could conceivably fall under the required elements of informed consent.¹⁰³ Instead the courts have trotted out the tired and weary old creature of tort law, the reasonable man, and asked him to stand guard around the citadel of negligence, lest the walls come crumbling down completely.

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101. To illustrate: the Supreme Court of California has held that the patient must be informed by the doctor of the material risks of the proposed treatment. See *Cobbs v. Grant*, 8 Cal. 3d 229, 244-45, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972). In a case purporting to follow this rule, the court held that where a physician failed to disclose the possibility of a stroke from the procedure, but did disclose the possibility of death, there had been adequate disclosure. See *Morgenroth v. Pacific Medical Center, Inc.*, 54 Cal. App. 3d 521, 126 Cal. Rptr. 681, 689 (1st Dist. 1976). The court said: "We think the information that a procedure carries the risk of death or serious disease in lay language sufficiently explains the range of complications that might occur, including a stroke." *Id.* But does it? It is neither impossible nor unreasonable that a person faced with risking a crippling stroke would choose to forego treatment, though the same person faced with the risk of death (assuming an equal probability of occurrence) might choose the treatment. Some persons may, in effect, prefer death to an impaired life. See generally Note, *Informed Consent and the Dying Patient*, *supra* note 64.
102. "[T]he patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required . . ." *Cobbs v. Grant*, 8 Cal. 3d 229, 244, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972); *accord*, *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 25, 499 P.2d 1, 9 (1972). In addition, the physician need not disclose risks that could materialize if the procedure were performed improperly, *Mallett v. Pirkey*, 171 Colo. 271, 466 P.2d 466 (1970); *Mull v. Emory Univ. Inc.*, 114 Ga. App. 63, 150 S.E.2d 276 (1966), though there may be liability for medical negligence. Similarly, there is no obligation to disclose the risks of properly performed procedures, if the necessity for such procedures is not reasonably foreseeable at the time that consent is obtained, *Block v. McVay*, 80 S.D. 469, 126 N.W.2d 808 (1964), although there may be liability for negligent diagnosis.
103. See *Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *cf.* *TSC Indus., Inc. v. Northway, Inc.*, 96 S. Ct. 2126, 2132 (1976) ("Some information is of such dubious significance that insistence on its disclosure may accomplish more harm than good.").

What is required then is not total disclosure, but reasonable disclosure. According to *Natanson*, reasonable disclosure requires the doctor to use simple language in explaining the necessary information to the patient.¹⁰⁴ Reasonable disclosure does not mean that the patient must be informed of all risks of the procedure, but only of those within the knowledge of the physician.¹⁰⁵ Reasonable disclosure does not even require the physician to tell the patient all that he knows, but only that which a reasonable medical practitioner would make under similar circumstances.¹⁰⁶ Nor is the doc-

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104. See *Natanson v. Kline*, 186 Kan. 393, 410, 350 P.2d 1093, 1106 (1960); *accord*, *Canterbury v. Spence*, 464 F.2d 772, 782 n.27 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 224, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972); *Corn v. French*, 71 Nev. 280, 284, 289 P.2d 173, 175-76 (1955) (by implication); *Demers v. Gerety*, 85 N.M. 641, 653, 515 P.2d 645, 654 (Ct. App. 1973), *rev'd on procedural grounds*, 86 N.M. 141, 520 P.2d 869 (1974) (concurring opinion); *Scaria v. St. Paul Fire & Marine Ins. Co.*, 68 Wis. 2d 1, 12-13, 227 N.W.2d 647, 653 (1975).
105. *Natanson v. Kline*, 186 Kan. 393, 410, 350 P.2d 1093, 1106 (1960); *accord*, *Grosjean v. Spencer*, 258 Iowa 685, 693-94, 140 N.W.2d 139, 144-45 (1966); *Petterson v. Lynch*, 59 Misc. 2d 469, 470, 299 N.Y.S.2d 244, 245 (Sup. Ct. 1969); *DiRosse v. Wein*, 24 App. Div. 2d 510, 511, 261 N.Y.S. 2d 623, 624 (1965); *Watson v. Clutts*, 262 N.C. 153, 159, 136 S.E.2d 617, 621 (1964); *Block v. McVay*, 80 S.D. 469, 477, 126 N.W.2d 808, 812 (1964) (dictum). The requirement seems to mandate disclosure not only of those risks of which the physician knew, but in addition those of which he should have known. See *Martin v. Bralliar*, — Colo. App. —, 504 P.2d 1118, 1121 (1975); *Haggerty v. McCarthy*, 344 Mass. 136, 141, 181 N.E.2d 562, 566 (1962); *Wilkinson v. Vesey*, 110 R.I. 606, 627, 295 A.2d 676, 688 (1972).
106. *Natanson v. Kline*, 186 Kan. 393, 410, 350 P.2d 1093, 1106 (1960). The physician obviously cannot divulge risks of which he is unaware, although there may be liability for failure to exercise due care to discover the risk. See *Canterbury v. Spence*, 464 F.2d 772, 787 n.84 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *Dietze v. King*, 184 F. Supp. 944, 949 (E.D. Va. 1960); *Shetter v. Rochelle*, 2 Ariz. App. 358, 370, 409 P.2d 74, 86 (1965), *modified*, 2 Ariz. App. 607, 411 P.2d 45 (1966); *Stauffer v. Karabin*, 30 Colo. App. 357, 363-64, 492 P.2d 862, 865 (1971); *Di Filippo v. Preston*, 53 Del. 539, 549-50, 173 A.2d 333, 339 (1961); *Ditlow v. Kaplan*, 181 So. 2d 226, 228 (Fla. App. 1965); *Nishi v. Hartwell*, 52 Hawaii 188, 195-96, 473 P.2d 116, 121 (1970); *Green v. Hussey*, 127 Ill. App. 2d 174, 184, 262 N.E.2d 156, 161 (1970); *Haggerty v. McCarthy*, 344 Mass. 136, 141, 181 N.E.2d 562, 566 (1962); *Roberts v. Young*, 369 Mich. 133, 140, 119 N.W.2d 627, 630 (1963); *Ross v. Hodges*, 234 So. 2d 905, 909 (Miss. 1970); *Aiken v. Clary*, 396 S.W.2d 668, 674 (Mo. 1965); *Negaard v. Estate of Fedra*, 152 Mont. 47, 55-56, 446 P.2d 436, 441 (1968); *Kaplan v. Haines*, 96 N.J. Super. 242, 257, 232 A.2d 840, 848 (1967), *aff'd*, 51 N.J. 404, 241 A.2d 235 (1968); *Wilson v. Scott*, 412 S.W.2d 299, 302 (Tex. 1967); *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 25, 499 P.2d 1, 9 (1972); *Govin v. Hunter*, 374 P.2d 421, 424 (Wyo. 1962). This rule is undergoing substantial change. See pp. 93-99 *infra*.

tor obligated to disclose commonly known risks.¹⁰⁷ Finally, reasonable disclosure requires that sufficient information be imparted to assure an "informed" consent.¹⁰⁸

The aim here is not to explore all of the possible combinations and permutations that the courts have developed in applying the informed-consent doctrine, but rather to indicate the vast opportunities lurking in the use of these judicial weasel words¹⁰⁹ for awarding compensation to medical-accident victims without regard to the presence or absence of proof of medical negligence. The courts have found in each of the elements of informed consent (and in each of the qualifying phrases used to describe them) the source of new rules of liability and means for modifying existing rules, finding them convenient weapons in the assault on the citadel of negligence.¹¹⁰

3. *Informed Consent in the 1960's—A Paper Tiger*

Despite the increasingly stringent standards that courts, in the wake of *Mitchell* and *Natanson*, began to apply in determining the validity of a consent to medical treatment, the informed-consent requirement remained something of a paper tiger. The two distinct and independent theories of medical liability—negligence in the performance of the medical procedure, and the adequacy of information disclosed and the validity of the consent obtained—were almost entirely merged from a procedural perspective. Unquestion-

107. *Canterbury v. Spence*, 464 F.2d 772, 788 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 244, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972); *Wilkinson v. Vesey*, 110 R.I. 606, 628, 295 A.2d 676, 689 (1972). This rule has analogues elsewhere in the law of torts. See, e.g., *Harvey v. Seale*, 362 S.W.2d 310, 312-13 (Tex. 1962) (occupier of real estate has no duty to warn invitees of obvious dangers).

108. *Natanson v. Kline*, 186 Kan. 393, 410, 350 P.2d 1093, 1106 (1960); *Mitchell v. Robinson*, 334 S.W.2d 11, 19 (Mo. 1960). Although it may seem tautological that the physician's duty of disclosure requires him to divulge information sufficient to obtain the patient's "informed" consent, the matter is actually far more complicated. See pp. 113-23 *infra*.

109. See J. FRANK, *supra* note 33, at 30 & *passim*.

110. Even in [a static] social order no one can foresee all the future permutations and combinations of events; situations are bound to occur which were never contemplated when the original rules were made. . . . Our society would be strait-jacketed were not the courts, with the able assistance of the lawyers, constantly overhauling the law and adapting it to the realities of ever-changing social, industrial and political conditions. . . . *Much of the uncertainty of law is not an unfortunate accident: it is of immense social value.*

Id. at 6-7.

ably there were two distinct substantive theories upon which medical liability might be premised. But because a negligence, rather than a trespass, form of action was increasingly imposed upon actions for failure to obtain informed consent,¹¹¹ some of the old bar-

111. There has been a long debate as to whether an action for unauthorized treatment sounds in trespass, or in negligence, or even in contract. For a thorough discussion of the state of confusion of the law of unauthorized medical treatment see Capron, *supra* note 64, at 364-76; Plante, *supra* note 98, at 640-48; Comment, *Informed Consent in Medical Malpractice*, *supra* note 67, at 1399-1401; Comment, *Informed Consent As a Theory of Medical Liability*, *supra* note 64, at 882-88; Note, *Duty of Doctor to Inform Patient of Risks of Treatment: Battery or Negligence?*, 34 S. CAL. L. REV. 217 (1961). See also Goldstein, *supra* note 64, at 690-98; McCoid, *supra* note 62.

Most of the early cases were brought in trespass, but a few were brought in negligence. Those brought in negligence resemble the contemporary informed-consent cases in that although consent to treatment was obtained, there was some question about the physician's failure to disclose information to the patient. See, e.g., *Hunter v. Burroughs*, 123 Va. 113, 96 S.E. 360 (1918); *Slater v. Baker*, 95 Eng. Rep. 860 (K.B. 1767). Contract has occasionally been applied to a cause of action for unauthorized medical treatment. See, e.g., *Gray v. Grunagle*, 423 Pa. 144, 223 A.2d 663 (1966); *McClees v. Cohen*, 158 Md. 60, 148 A. 124 (1930).

It is increasingly being accepted, however, that the action is properly framed in trespass only where there has been a total failure of the physician to obtain consent, because in such a case the mere performance of the procedure is the legal wrong.

However, when the patient consents to certain treatment and the doctor performs that treatment but an undisclosed inherent complication . . . occurs, no intentional deviation from the consent given appears; rather, the doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence.

Cobbs v. Grant, 8 Cal. 3d 229, 240, 502 P.2d 1, 8, 104 Cal. Rptr. 505, 512 (1972).

Before the present controversy arose, Professor McCoid suggested that the traditional dichotomy between trespass and negligence for unauthorized medical treatment was inadequate, and that judicial analysis should strive toward "a single basis for liability in all malpractice cases." McCoid, *supra* note 62, at 434. More recently, Professor Joseph Goldstein has criticized the assimilation of the cause of action for lack of informed consent to negligence, on the ground that the recovery of damages in negligence requires actual physical harm to the plaintiff and "does not recognize that a citizen can be wronged without being 'harmed.'" Goldstein, *supra* note 64, at 691. A cause of action in trespass, however, permits recovery of damages for the injury to one's dignity suffered when an unconsented touching occurs. See note 63, *supra*. Professor Capron suggests that a new "hybrid" cause of action for informed consent, at least for medical procedures used in the treatment of "catastrophic illnesses," should be formulated. See Capron, *supra* note 64, at 403-23.

riers to compensating medical-accident victims remained while new ones developed.

Under a negligence form of action, informed consent is viewed as imposing upon the physician a duty to disclose certain information to the patient and to obtain the patient's consent to treatment before proceeding. Breach of this duty, which is the proximate cause of harm to the patient, imposes liability upon the physician. As in all negligence actions, the plaintiff must carry the burden of proof on four issues: duty, breach, causation, and damages.¹¹²

The effect of the assimilation of informed consent to the negligence form of action was to transfer some of the old barriers to compensation to the informed-consent doctrine. Under the rules that developed, there still existed several ways in which physicians could avoid liability for medical accidents. While there was room for argument about all four of the elements of the cause of action in negligence for inadequate disclosure, the problems of breach of duty¹¹³ and damages never became substantial issues. Rather, the problem of establishing what the duty was—that is, what kind and degree of disclosure was required—and the problem of causation, have presented the most serious stumbling blocks to compensation of the medical-accident victim under the informed-consent doctrine.

Most significant, the medical profession managed to retain substantial control over the standard by which the duty of disclosure is tested. Thus whether or not a patient has been "fully" informed

The longer statutes of limitations in negligence may be an incentive to compensation-minded courts to view the failure to obtain an informed consent as a species of negligence rather than as assault and battery. 1 LOISELL & WILLIAMS, *supra* note 3, ¶ 13.04, at 368.

112. PROSSER, *supra* note 2, § 30, at 143.

113. The problem of determining whether the duty to disclose has been fulfilled is conceptually difficult, and is often further complicated in practice by conflicting testimony of the patient and the doctor. See, e.g., *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 578, 317 P.2d 170, 181 (1st Dist. 1957). See also *Mitchell v. Robinson*, 360 S.W.2d 673, 674 (Mo. 1962); *Wilson v. Scott*, 412 S.W.2d 299, 303 (Tex. 1967); Comment, *Informed Consent in Medical Malpractice*, *supra* note 67, at 1411 n.92 (1967).

There is empirical evidence suggesting that patients often do not recall what they have been told. In one study, of 20 patients interviewed four to six months after cardiac surgery, only 10% recalled discussion prior to surgery of potential complications; and even with some suggestion from the interviewer, only 23% recalled this discussion. See *Medical World News*, Feb. 23, 1976, at 26; 235 J.A.M.A. 993 (1976). See also Epstein & Lasagna, *Obtaining Informed Consent—Form or Substance*, 123 ARCH. INTERN. MED. 682 (1969). There is also evidence that patients often do not understand the information that is disclosed to them. See note 176 *infra*.

has been determined by reference to the prevailing standard of disclosure in the profession.¹¹⁴ Second, the invocation of the so-called "therapeutic privilege" to withhold information the disclosure of which might be emotionally upsetting to the patient, has provided a substantial loophole for evasion of the requirements of informed consent. Finally, as the cases began to signal a clear adoption of the negligence form of action for failure to obtain informed consent, the issue of causation began rather slowly to emerge as a new impediment to the compensation of medical-accident victims.

C. Expanding Liability in the Wake of *Canterbury v. Spence*

1. *The Standard of Disclosure*

Natanson recognized that the degree of disclosure made to a patient is "primarily a question of medical judgment,"¹¹⁵ and consequently that "[t]he duty of the physician to disclose . . . is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."¹¹⁶ This rule of liability closely paralleled the rules of liability in medical negligence cases generally, in that the standard to which the physician would be held not only in the exercise of skill, but also in the disclosure of information to the patient, is that of "what is customary and usual in the profession."¹¹⁷ The courts of numerous other ju-

114. *Natanson* acknowledged that the scope of the duty of disclosure is to be judged by reference to the professional custom. See *Natanson v. Kline*, 186 Kan. 393, 411, 350 P.2d 1093, 1107 (1960). *Mitchell v. Robinson* did not specifically address the question of whether expert testimony is necessary to establish what information is to be disclosed. The Missouri supreme court later clarified this point, however, when it said in *Aiken v. Clary*, 396 S.W.2d 668 (Mo. 1965), that "the question of what disclosure of risks incident to proposed treatment should be made in a particular situation involves medical judgment and . . . expert testimony thereon should be required in malpractice cases involving that issue." *Id.* at 674.

115. 186 Kan. at 409, 350 P.2d at 1106.

116. *Id.* In *Mitchell*, the court did not address the issue of the standard by which the adequacy of disclosure was to be measured. See note 122 *infra*.

117. PROSSER, *supra* note 2, § 32, at 165; 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 8.04, at 200. But

[w]here the matter is regarded as within the common knowledge of laymen, as where the surgeon saws off the wrong leg, or there is injury to a part of the body not within the operative field, it has been held that the jury may infer negligence without the aid of any expert.

PROSSER, *supra* note 2, § 32, at 164-65. See also authorities cited note 250 *infra*.

risdictions explicitly adopted this rule,¹¹⁸ and few seriously questioned it for more than a decade.¹¹⁹ Some courts even went so far as to apply the locality rule,¹²⁰ leaving it to the *local* medical community to determine what information should be disclosed to a patient.¹²¹ A corollary of this so-called "professional" standard of dis-

118. See *Dietze v. King*, 184 F. Supp. 944, 949 (E.D. Va. 1960); *Shetter v. Rochelle*, 2 Ariz. App. 358, 370, 409 P.2d 74, 86 (1965), *modified*, 2 Ariz. App. 607, 411 P.2d 45 (1966); *Stauffer v. Karabin*, 30 Colo. App. 357, 363-64, 492 P.2d 862, 865 (1971); *Di Filippo v. Preston*, 53 Del. 539, 549-50, 173 A.2d 333, 339 (1961); *Ditlow v. Kaplan*, 181 So. 2d 226, 228 (Fla. App. 1966); *Nishi v. Hartwell*, 52 Hawaii 188, 195-97, 473 P.2d 116, 121 (1970); *Green v. Hussey*, 127 Ill. App. 2d 174, 184, 262 N.E.2d 156, 161 (1970); *Williams v. Menahan*, 191 Kan. 6, 8, 379 P.2d 292, 294 (1963); *Haggerty v. McCarthy*, 344 Mass. 136, 141, 181 N.E.2d 562, 566 (1962); *Roberts v. Young*, 369 Mich. 133, 138-39, 119 N.W.2d 627, 629-30 (1963); *Aiken v. Clary*, 396 S.W.2d 668, 674 (Mo. 1965); *Ross v. Hodges*, 234 So. 2d 905, 909 (Miss. 1970); *Negaard v. Estate of Feda*, 152 Mont. 47, 55, 446 P.2d 436, 441 (1968); *Kaplan v. Haines*, 96 N.J. Super. 242, 257, 232 A.2d 840, 848 (1967); *Petterson v. Lynch*, 59 Misc. 2d 469, 471, 299 N.Y.S.2d 244, 246 (Sup. Ct. 1969); *Wilson v. Scott*, 412 S.W.2d 299, 302 (Tex. 1967); *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 24, 499 P.2d 1, 9 (1972); *Govin v. Hunter*, 374 P.2d 421, 424 (Wyo. 1962). See also Note, *Informed Consent—A Proposed Standard for Medical Disclosure*, *supra* note 64, at 551; Note, *Failure to Inform as Medical Malpractice*, 23 VAND. L. REV. 754, 768 (1970).

Some of the jurisdictions that once adhered to this rule have since abandoned it. See note 128 *infra*.

119. A few intermediate appellate courts questioned the standard, see *Berkey v. Anderson*, 1 Cal. App. 3d 790, 805, 82 Cal. Rptr. 67, 78 (2d Dist. 1969); *Cooper v. Roberts*, 220 Pa. Super 260, 267, 286 A.2d 647, 650 (1971); *Hunter v. Brown*, 4 Wash. App. 899, 907, 484 P.2d 1162, 1167 (1971), *aff'd*, 81 Wash. 2d 465, 502 P.2d 1194 (1972); *Mason v. Ellsworth*, 3 Wash. App. 298, 312, 474 P.2d 909, 918-19 (1970), and the Supreme Court of New Mexico seems never to have adopted it. See *Woods v. Brumlop*, 71 N.M. 221, 227, 377 P.2d 520, 524 (1962).

Commentators were also critical of the standard. See 2 HARPER & JAMES, *supra* note 4, § 17.1, at 60-61 n.15 (Supp. 1968); Waltz & Scheuneman, *supra* note 64, at 30-43; Comment, *Informed Consent in Medical Malpractice*, *supra* note 67, at 1404-06 (1967); Note, *Restructuring Informed Consent*, *supra* note 64.

120. See note 41 *supra*.

121. See *George v. Travelers Ins. Co.*, 215 F. Supp. 340, 344 (E.D. La. 1963), *aff'd*, 328 F.2d 430 (5th Cir. 1964); *Dunlap v. Marine*, 242 Cal. App. 2d 162, 177, 51 Cal. Rptr. 158, 167 (2d Dist. 1966); *Tangora v. Matansky*, 231 Cal. App. 2d 468, 479, 42 Cal. Rptr. 348, 356 (2d Dist. 1964); *Di Filippo v. Preston*, 53 Del. 539, 549-50, 173 A.2d 333, 339 (1961); *Visingardi v. Tirone*, 178 So. 2d 135, 137 (Fla. App. 1965), *rev'd*, 193 So. 2d 601, 605 (Fla. 1967) (specifically leaving question open); *Roberts v. Young*, 369 Mich. 133, 140, 119 N.W.2d 627, 630 (1963); *Ross v. Hodges*, 234 So. 2d 905, 909 (Miss. 1970); *Negaard v. Estate of Feda*, 152 Mont. 47, 56, 446 P.2d 436, 441 (1968); *Kaplan v. Haines*, 96 N.J. Super. 242, 257, 232 A.2d 840, 848 (1967), *aff'd*, 51 N.J. 404, 241 A.2d

closure was the requirement suggested in *Natanson*¹²² (and further developed in subsequent cases)¹²³ that expert medical testimony was required to establish the standard of care—i.e., the standard of disclosure—to which the physician was to be held, with all of the problems attendant upon this requirement.¹²⁴

A serious obstacle to the medical-accident victim's obtaining compensation was removed by a decision of the District of Columbia Court of Appeals in the 1972 case of *Canterbury v. Spence*,¹²⁵

275 (1968); *Wilson v. Scott*, 412 S.W.2d 299, 302 (Tex. 1967); *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 22-23, 499 P.2d 1, 8 (1972); *Govin v. Hunter*, 374 P.2d 421, 424 (Wyo. 1962).

122. The first opinion in *Natanson* implied, but did not hold, that expert medical testimony is needed to establish the standard of care: "How the physician may best discharge his obligation to the patient in this difficult situation involves primarily a question of medical judgment." 186 Kan. at 409, 350 P.2d at 1106. The opinion denying the motion for rehearing, however, expressly states that expert testimony is required to establish whether the disclosures actually made "are in accordance with those which a reasonable medical practitioner would make under the same or similar circumstances." 187 Kan. at 190, 354 P.2d at 673. In *Mitchell*, the defendants claimed that they informed the plaintiff of the risks of treatment "in great detail," 334 S.W.2d at 16, and the plaintiff claimed that he had been told none of the risks of treatment. *Id.* Since there was no dispute between the parties as to what risks should have been disclosed, there was no need for the court to address the issue of whether the standard of disclosure is dictated by professional custom. But in a later case, Missouri adopted a rule measuring the adequacy of disclosure by reference to the professional custom. See *Aiken v. Clary*, 396 S.W.2d 668, 673 (Mo. 1965).

123. See *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 977, 95 Cal. Rptr. 381, 392 (2d Dist. 1971); *Stauffer v. Karabin*, 30 Colo. App. 357, 364, 492 P.2d 862, 865 (1971); *Di Filippo v. Preston*, 53 Del. 539, 549-50, 173 A.2d 333, 339 (1961); *Ditlow v. Kaplan*, 181 So. 2d 226, 228 (Fla. App. 1965); *Green v. Hussey*, 127 Ill. App. 2d 174, 184, 262 N.E.2d 156, 161 (1970); *Grosjean v. Spencer*, 258 Iowa 685, 694, 140 N.W.2d 139, 145 (1966); *Collins v. Meeker*, 198 Kan. 390, 396-97, 424 P.2d 488, 494-95 (1967); *Haggerty v. McCarthy*, 344 Mass. 136, 141, 181 N.E.2d 562, 566 (1962); *Miles v. Van Gelder*, 1 Mich. App. 522, 531-32, 137 N.W.2d 292, 296-97 (1965); *Aiken v. Clary*, 396 S.W.2d 668, 674 (Mo. 1965); *Petterson v. Lynch*, 59 Misc. 2d 469, 471, 299 N.Y.S.2d 244, 246 (Sup. Ct. 1969); *Getchell v. Mansfield*, 260 Ore. 174, 180, 489 P.2d 953, 956 (1971); *Anderson v. Hooker*, 420 S.W.2d 235, 238 (Tex. Civ. App. 1967); *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 24, 499 P.2d 1, 8-9 (1972); *Stundon v. Stadnik*, 469 P.2d 16, 21 (Wyo. 1970); *Govin v. Hunter*, 374 P.2d 421, 424 (Wyo. 1962).

In jurisdictions that have abandoned the professional standard of disclosure, expert testimony may still be needed to establish both the existence of particular risks and alternative forms of treatment. See note 139 *infra*.

124. See note 41 *supra*.

125. 464 F.2d 772, 792 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).

which was soon followed in opinions of the Supreme Courts of California and Rhode Island—*Cobbs v. Grant*¹²⁶ and *Wilkinson v. Vesey*¹²⁷ respectively. *Canterbury* and its progeny discarded the professional standard of disclosure, replacing it with a “lay” standard which effectively withdrew from the medical profession the right to determine what information must be disclosed to patients.¹²⁸

Three reasons¹²⁹ were given for abandoning as a standard of disclosure “the custom of physicians practicing in the community

126. 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

127. 110 R.I. 606, 295 A.2d 676 (1972).

128. In addition to California and Rhode Island, the lay standard of disclosure has been adopted in the following cases by other jurisdictions: *Sawyer v. Methodist Hosp.*, 522 F.2d 1102, 1106-07 (6th Cir. 1975) (applying Tennessee law); *Delaune v. Davis*, 316 So. 2d 7, 12 (La. App. 1975); *Goodwin v. Aetna Cas. & Sur. Co.*, 294 So. 2d 618, 620 (La. App. 1974); *Woods v. Brumlop*, 71 N.M. 221, 227, 377 P.2d 520, 524 (1962) (implied requirement of full disclosure); *Zelesnik v. Jewish Chronic Disease Hosp.*, 47 App. Div. 2d 199, 205, 366 N.Y.S.2d 163, 170 (1975); *Fogal v. Genesee Hosp.*, 41 App. Div. 2d 468, 473, 344 N.Y.S.2d 552, 559 (1973); *Congrove v. Holmes*, 37 Ohio Misc. 95, 104, 308 N.E.2d 765, 771 (1973); *Holland v. Sisters of St. Joseph of Peace*, 270 Ore. 129, 132, 522 P.2d 208, 209, *opinion withdrawn on other grounds*, 270 Ore. 144, 526 P.2d 577 (1974); *Cooper v. Roberts*, 220 Pa. Super. 260, 266, 286 A.2d 647, 650 (1971); *Longmire v. Hoey*, 512 S.W.2d 307, 309-10 (Tenn. App. 1974); *Small v. Gifford Memorial Hosp.*, 133 Vt. 552, 557, 349 A.2d 703, 706 (1975); *Miller v. Kennedy*, 11 Wash. App. 272, 284-85, 522 P.2d 852, 860-61 (1974), *aff'd*, 85 Wash. 2d 151, 530 P.2d 334 (1975); *Scaria v. St. Paul Fire & Marine Ins. Co.*, 68 Wis. 2d 1, 12, 227 N.W.2d 647, 653 (1975); *Trogun v. Fruchtmann*, 58 Wis. 2d 569, 604, 207 N.W.2d 297, 315 (1973); cf. *Riedinger v. Colburn*, 361 F. Supp. 1073, 1077 (D. Idaho 1973); *Martin v. Bralliar*, — Colo. App. —, 540 P.2d 1118, 1121 (1975) (burden is on defendant to adduce evidence of community or national standards relieving him of the duty to disclose).

Some courts have declined to adopt the lay standard of disclosure. See *Karp v. Cooley*, 493 F.2d 408, 419-20 (5th Cir. 1974) (applying Texas law), *cert. denied*, 419 U.S. 845 (1974); *Riedisser v. Nelson*, 111 Ariz. 542, 544, 534 P.2d 1052, 1054 (1975); *Coleman v. Garrison*, 327 A.2d 757, 762-63 (Del. Super. 1974), *aff'd*, 349 A.2d 8, 9 (Del. 1975); *Charley v. Cameron*, 215 Kan. 750, 756, 528 P.2d 1205, 1210 (1974); *Marchlewicz v. Stanton*, 50 Mich. App. 344, 349, 213 N.W.2d 317, 320 (1973); *Collins v. Itoh*, 160 Mont. 461, 468-69, 503 P.2d 36, 40-41 (1972); *Butler v. Berkeley*, 25 N.C. App. 325, 342, 213 S.E.2d 571, 581-82 (1975); *Jacobs v. Theimer*, 519 S.W.2d 846, 848 (Tex. 1975); *Bly v. Rhoads*, 222 S.E.2d 783 (Va. 1976).

129. The court also suggested a fourth reason for the modification of the standard. Under the law of the District of Columbia, the customary practice of the medical profession is only evidentiary, and not probative of the standard of care. 464 F.2d at 785. The applicability of this as justification for revision of the standard in other jurisdictions will, of course, depend upon the rules of evidence of each jurisdiction. For a critical account of the three reasons given in *Canterbury* for aban-

. . ."¹³⁰ and replacing it with a standard framed in terms of information that is material to the decisionmaking process of the reasonable man. First, starting from the assumption that the underlying rationale for the informed-consent doctrine is to permit the patient to exercise choice concerning the risks to which he is willing to subject himself and which he would prefer to forego, the court concluded that "[r]espect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."¹³¹ To permit the physician to determine what information is to be disclosed by reference either to his own personal standards or to standards of the medical profession is to undercut the patient's right to have available to him information he might find relevant to the decision that he must make. Second, the court stated that it is entirely possible, if not likely, that a standard of disclosure based upon the custom of the medical profession is a facade for nondisclosure,¹³² because it is not clear that there is "any discernible custom reflecting a professional concensus [sic] on communication of option and risk information to patients . . ."¹³³ Fi-

doing the professional standard of disclosure see Schneyer, *Informed Consent and the Danger of Bias in the Formation of Medical Disclosure Practices*, 1976 WIS. L. REV. 124, 150-55, which concludes that the best reason for the change from a professional to a lay standard of disclosure is the bias toward underdisclosure in the medical profession.

130. 464 F.2d at 783.

131. *Id.* at 784; *accord*, *Wilkinson v. Vesey*, 110 R.I. 606, 624-25, 295 A.2d 676, 688 (1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 245, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972).

132. In *Hunter v. Brown*, 4 Wash. App. 899, 484 P.2d 1162 (1971), *aff'd*, 81 Wash. 2d 465, 502 P.2d 1194 (1972), the defendant-physician had testified that the "risks are minimal, and they are never mentioned to a patient." *Id.* at 902, 484 P.2d at 1164. The trial judge had therefore "felt that he was compelled to dismiss Mrs. Hunter's case because she produced no evidence of a medical standard of disclosure." *Id.*

133. 464 F.2d at 783; *accord*, *Wilkinson v. Vesey*, 110 R.I. 606, 623, 295 A.2d 676, 687 (1972); *Scaria v. St. Paul Fire & Marine Ins. Co.*, 68 Wis. 1, 12, 227 N.W.2d 647, 653 (1975). Courts that have subsequently considered this question have concurred in this view, and have supplemented it with the rationale that since disclosure in a particular case depends substantially upon the facts of that case—facts not known to the medical profession generally—there can realistically be no professional standard of disclosure. *See, e.g.*, *Wilkinson v. Vesey*, *supra* at 623, 295 A.2d at 687.

One study of this problem is reported in Hagman, *The Medical Patient's Right to Know: Report on a Medical-Legal-Ethical, Empirical Study*, 17 U.C.L.A.L. REV. 758, 765-66 (1970). Physicians, in response to the question, "Was Dr. D right in telling P only what he did?" responded to hypothetical cases as follows:

nally, the court found it to be inappropriate to establish the bounds of duty by reference to a profession's own standard of conduct where the professional's "activity does not bring his [special] medical knowledge and skills peculiarly into play."¹³⁴ Because the materiality of information to a patient's decision is not a matter of medical judgment, the standard of materiality, and thus of disclosure,¹³⁵ must be set by law rather than by professional custom:

When medical judgment enters the picture . . . prevailing medical practice must be given its just due. In all other instances, however, the general standard exacting ordinary care applies, and that standard is set by law. In sum, the physician's duty to disclose is governed by the same legal principles applicable to others in comparable situations, with modifications only to the extent that medical judgment enters the picture.¹³⁶

A fair statement of the rule that emerged—and there are several different statements in the *Canterbury* case alone—is that the physician is required to disclose all information about a proposed treatment which a reasonable person in the patient's circumstances would find material to his decision either to undergo or to forego treatment.¹³⁷ The scope of the duty to disclose is to be determined by "the patient's right of self-decision,"¹³⁸ rather than by the custom or practice either of the particular physician making the disclosure or by the larger medical profession.

	Question 1		Question 2	
	"Yes"	"No"	"Yes"	"No"
a) "medically?"	52	101	67	67
b) "ethically?"	38	111	64	69
c) "legally?"	29	117	40	78

Id. at 765 n.30, 766 n.34. This illustrates that there is substantial disagreement as to what risks are required to be disclosed as a matter of good medical practice, ethically, or legally.

134. 464 F.2d at 785.

135. See note 137 *infra*.

136. 464 F.2d at 785.

137. See *id.* at 786-87. The court adopted as the test of materiality that proposed by Waltz & Scheuneman, *supra* note 64, at 640: "A risk is . . . material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy." 464 F.2d at 787; *accord*, Wilkinson v. Vesey, 110 R.I. 606, 627, 295 A.2d 676, 689 (1972).

The *Canterbury* court rejected as a measure of the physician's duty of disclosure that which the particular "patient would consider important to his decision," stating that this cannot be known to the physician with "complete exactitude." The court felt, however, that "on the basis of [the physician's] medical training and experience he can sense [what] the average, reasonable patient" would want to know. 464 F.2d at 787.

138. *Id.* at 786.

By imposing a "lay" or "objective" standard, *Canterbury* substantially enhanced the prospects for the compensation of the medical-accident victim. The lay standard of disclosure, by eliminating the need to obtain expert testimony,¹³⁹ removed one of the more substantial barriers to getting to the jury. In addition, and probably of far more significance, the jury, rather than being bound by any single expert witness's testimony or having to decide between conflicting expert testimony, itself determines the adequacy of disclosure. Therefore, factors extraneous to the actual rules of decision—most notably the egregiousness of the plaintiff's injuries—may more directly enter into the jurors' individual and collective decisionmaking processes.

2. *Therapeutic Privilege*

Although the doctrine of informed consent requires disclosure of relevant information to patients—whether relevancy is judged by a lay or professional standard—a patient's consent to treatment will still be recognized as valid when less than full disclosure has occurred if full disclosure would have had a deleterious effect upon the patient's emotional condition. Under these circumstances, the physician is said to have a "therapeutic privilege" to withhold information from the patient.¹⁴⁰ Despite the fact that the invocation

139. There may still be a need to obtain expert testimony concerning what the risks are of a particular procedure, as opposed to expert testimony as to whether admitted risks must be disclosed. See *Morgenroth v. Pacific Medical Center, Inc.*, 54 Cal. App. 3d 521, 534-35, 126 Cal. Rptr. 681, 689 (1st Dist. 1976); *Pierce v. Dowman*, 135 Ga. App. 783, 783, 219 S.E.2d 8, 9 (1975); *Wilkinson v. Vesey*, 110 R.I. 606, 626, 295 A.2d 676, 688 (1972); *Miller v. Kennedy*, 11 Wash. App. 272, 284, 522 P.2d 852, 861 (1974), *aff'd*, 85 Wash. 2d 151, 530 P.2d 334 (1975).

140. The precise definition of the privilege varies considerably among jurisdictions, as does the formulation of the informed-consent requirement to which it is an exception. Several good discussions of the privilege exist. See Comment, *Informed Consent: The Illusion of Patient Choice*, *supra* note 64; Note, *Restructuring Informed Consent*, *supra* note 64, at 1564; Waltz & Scheuneman, *supra* note 64, at 641-43. The legal origins of the therapeutic privilege are unclear, Note, *Restructuring Informed Consent*, *supra* note 64, at 1564-65 n.95, although it seems first to have been adverted to in *Twombly v. Leach*, 65 Mass. (11 Cush.) 397, 405-06 (1853) ("Upon the question whether it be good medical practice to withhold from a patient . . . a knowledge of the extent and danger of his disease, the testimony of educated and experienced medical practitioners is material and peculiarly appropriate.").

Paradoxically, the medical profession seems to have recognized a privilege to *withhold* information long before there was any firmly established obligation to *disclose* information. The two earliest articles discussing the privilege—Lund, *The Doctor, the Patient, and the Truth*,

of the privilege undercuts the patient's right of self-determination, some courts have reasoned that the erosion of this value is more than offset by the augmentation of the patient's health.¹⁴¹ Further, it is said that the physician's obligation to "do no harm" "must take precedence at times over the duty to tell the patient the truth."¹⁴²

On its face the therapeutic privilege bestows substantial latitude upon the physician to withhold information from the patient. Carried to its extreme, the privilege embodies the paternalistic notion, completely antithetical to the doctrines of consent and informed

19 TENN. L. REV. 344 (1946), and Smith, *supra* note 79—appeared at a time when very few cases had imposed upon a physician an affirmative duty of disclosure. See note 78 *supra*.

141. See Note, *Restructuring Informed Consent*, *supra* note 64, at 1565-66 (invocation of privilege "should be permitted only when there is a clear showing that the patient's interest in not hearing is greater than his interest in making his own decision"). In *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 499 P.2d 1 (1972), the court recognized that "[t]he rules imposing upon a doctor the duty to inform . . . may present dangers to patient and physician alike, and if extravagantly interpreted might in some degree impede the advancement of medical science or operate to deprive the patient of the most modern therapy and latest scientific developments . . ." *Id.* at 27, 499 P.2d at 10. It concluded, however, that this drawback does not justify the abrogation of the duty. It has also been suggested that "a complete disclosure . . . could so alarm the patient that it would, in fact, constitute bad medical practice," *Williams v. Menahan*, 191 Kan. 6, 8, 379 P.2d 292, 294 (1963), that might even be actionable. See note 90 *supra*.
142. *Watson v. Clutts*, 262 N.C. 153, 159, 136 S.E.2d 617, 621 (1964); *accord*, *Lester v. Aetna Cas. & Sur. Co.*, 240 F.2d 676, 679 (5th Cir. 1957); *Shetter v. Rochelle*, 2 Ariz. App. 358, 365-66, 409 P.2d 74, 81-82 (1965), *modified*, 2 Ariz. App. 607, 411 P.2d 45 (1966); *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 578, 317 P.2d 170, 181 (1957); *Nishi v. Hartwell*, 52 Hawaii 188, 191-92, 473 P.2d 116, 119 (1970); *Grosjean v. Spencer*, 258 Iowa 685, 694, 140 N.W.2d 139, 144-45 (1966); *Ball v. Mallinkrodt Chem. Works*, 53 Tenn. App. 218, 227-28, 381 S.W.2d 563, 567-68 (1964).

There is some empirical evidence that full disclosure "does no harm" to the patient. In a study of 100 patients who were to undergo angiography (a procedure in which a dye is injected into the arteries to study circulation), only 2 refused treatment after full disclosure of the risks. Twenty-seven of the 100 indicated that full disclosure made them less comfortable about going ahead with the procedure. In a related study, 103 of 132 patients answered "no" to a question asking them whether they "[w]ould . . . have preferred that we [withhold] information concerning possible complications." Alfidi, *Informed Consent—A Study of Patient Reaction*, 216 J.A.M.A. 1325 (1971). See also Alfidi, *Informed Consent and Special Procedures*, 40 CLEV. CLINIC Q., Spring, 1973, at 21 (similar study with similar results); Rosenberg, *Informed Consent—A Reappraisal of Patients' Reactions*, 119 CALIF. MED. 64 (Nov., 1973).

consent, of "doctor knows best,"¹⁴³ permitting the substitution of the physician's judgment for the patient's.¹⁴⁴ In practice, the courts have been quite tolerant of physicians withholding information on their mere representation that to have informed the patient would have unduly upset him.

Recognizing that the therapeutic privilege had the potential to "devour the disclosure rule itself,"¹⁴⁵ the *Canterbury* court considered the application of the privilege and promulgated standards for its appropriate invocation, departing significantly from the traditional attitude toward the privilege. The privilege, the court stated, is not to be used to permit the physician to substitute his judgment for the patient's. Where the physician expects that full disclosure would cause the patient to forego treatment, a proper case for its application does not exist. Rather, the privilege properly operates only when the communication of information to the patient, based on sound medical judgment, would cause the patient to become so distraught that he would not be able to make a rational decision.¹⁴⁶

The reformulation of the therapeutic privilege in *Canterbury* will have a twofold effect on the compensation of medical-accident victims. Physicians who withhold information from patients, whether intentionally or negligently, will be forced to contend with a legal rule permitting such withholding only under very narrow circumstances.¹⁴⁷ However, litigation also will occur over the ap-

143. Smith, *supra* note 79, at 351.

144. Note, *Restructuring Informed Consent*, *supra* note 64, at 1564-71.

145. *Canterbury v. Spence*, 464 F.2d 772, 789 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).

146. *Id.* *Canterbury* specified the conditions under which the privilege should not operate, but failed to explain expressly when the privilege should operate. Since the court indicated, however, that the objective of disclosure is to promote "the patient's right of self-decision," *id.* at 786, the privilege should properly operate when disclosure would interfere with the patient's right of self-decision.

That there is a fine line between withholding information because it would so upset the patient that he could not make a rational decision, and withholding information because disclosure would result in a decision against treatment, is well illustrated by the examples in Lund, *supra* note 140.

147. If the therapeutic privilege is invoked, is the physician obliged nevertheless to disclose the information withheld from the patient to some other interested person such as a close relative? In discussing another exception to the duty to disclose, the so-called "emergency" exception, the *Canterbury* court stated that in an emergency, when informed consent is impractical, "the physician should, as current law requires, attempt to secure a relative's consent if possible." 464 F.2d at 789. Although the court did not address the necessity of disclosure to a close

propriate rules for the application of the new, narrower privilege announced in *Canterbury*. Because the court's discussion of the privilege was quite limited—the facts of the case do not even appear to have raised the issue and hence the entire discussion is dictum—it will take further litigation to polish the rough edges of the privilege. In the past, little room for maneuvering existed once the physician testified that he had withheld information because it would have harmed the patient.¹⁴⁸ Now, however, there will be additional room for the plaintiff to maneuver through tactics, either factual or legal, or both.¹⁴⁹

There remains the question of what the appropriate standard for withholding information ought to be. Should the physician's right to withhold information from the patient be determined by the exercise of professional judgment, or in accord with a lay standard of what information would emotionally harm a reasonable person in like circumstances? Conceptually, the problem of what information the physician may withhold is the converse of what in-

relative when the therapeutic privilege is invoked, other courts have suggested that less than full disclosure under such circumstances will not be tolerated. See, e.g., *Darrah v. Kite*, 32 App. Div. 2d 208, 212, 301 N.Y.S.2d 286, 292 (1969); cf. *Steele v. Woods*, 327 S.W.2d 187, 198 (Mo. 1959). But see *Nishi v. Hartwell*, 52 Hawaii 188, 198-99, 473 P.2d 116, 122-23 (1970). See also *Hagman*, *supra* note 133, at 791.

Because the legitimate reasons for invoking the therapeutic privilege are absent when the information is to be disclosed to a third party, the privilege should have no application under such circumstances. Disclosure to a third party may, however, raise ethical, and possibly legal, issues for the physician who is under an obligation not to disclose confidential information about the patient. See American Medical Association, *Principles of Medical Ethics*, OPINIONS AND REPORTS OF THE JUDICIAL COUNCIL iii-vii, ¶ 9 (1969), reprinted in *J. KATZ*, *supra* note 68, at 314, 315. See generally, Boyle, *Medical Confidence—Civil Liability for Breach*, 24 N. IR. L.Q. 19 (1973); Furner & Thomason, *Physician-Patient Confidences: Legal Effects of Computerization of Records*, 31 ALA. LAWYER 193 (1970); Annot., 20 A.L.R.3d 1109 (1968); 28 OKLA. L. REV. 658 (1975).

148. Moreover, "[a]vailable evidence indicates that physicians' decisions to withhold information are based on hearsay rather than on actual experience with the effects of full disclosure and that the physician's own emotional reluctance to confront the patient with stark diagnoses and risks often prevents disclosure." Note, *Restructuring Informed Consent*, *supra* note 64, at 1566.
149. Expert testimony concerning the appropriate invocation of the privilege does not appear to be foreclosed even by the restrictive formulation of *Canterbury*. Psychiatric testimony may be admitted to establish the patient's emotional state at the time when disclosure would have been made. Expert testimony, however, will no longer be dispositive of the issue of whether the privilege was properly exercised. *Id.* at 1569 n.105.

formation he must disclose. A court, when confronted with the issue of the appropriate standard for the application of the therapeutic privilege, should therefore follow the same rule that it applies in determining whether to hold the physician to a lay or professional standard of disclosure. Thus, to the extent that the lay standard of disclosure announced in *Canterbury*¹⁵⁰ is adopted by other jurisdictions, a correspondingly narrow therapeutic privilege should also develop.¹⁵¹

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150. The *Canterbury* court did not articulate a standard against which the operation of the privilege is to be judged. Its statement that "[t]he critical inquiry is whether the physician responded to a *sound medical judgment* that communication of the risk information would present a threat to the patient's well-being," 464 F.2d at 789 (emphasis added), could be taken to mean that expert testimony is required to determine whether the privilege was properly invoked. But the court's strenuous insistence upon a lay standard for determining what information must be *disclosed* to the patient is hard to reconcile with its favoring a professional standard for determining what information may be *withheld*. The overall tone of the opinion implies that a lay standard would be deemed as appropriate to the withholding of information as it was to the *disclosure* of information. For a discussion of the possible standards of disclosure see *Restructuring Informed Consent*, *supra* note 64, at 1567-68.
151. The California supreme court may have rejected a narrow therapeutic privilege. Its statement in *Cobbs v. Grant* is at best puzzling and at worst contradictory:

A disclosure need not be made beyond that required within the medical community when a doctor can prove by a preponderance of the evidence he relied upon facts which would demonstrate to a reasonable man the disclosure would have so seriously upset the patient that the patient would not have been able to dispassionately weigh the risks of refusing to undergo the recommended treatment.

8 Cal. 3d 229, 246, 502 P.2d 1, 12, 104 Cal. Rptr. 505, 516 (1972). The statement first seems to indicate that the appropriateness of invoking the privilege should be measured against the practices of the medical community (professional test), but then it implies that the privilege is properly applied only if a reasonable man (lay test) would have withheld information. Because the statement is obiter dictum, the court was probably not unduly concerned with clarifying this seeming ambiguity. Yet California physicians presumably would be interested in such a clarification. One plausible interpretation is that the test is to be a professional one as to the *content* of the information that is to be disclosed (or withheld) when the privilege is properly invoked, but the propriety of invoking the privilege is to be judged according to a lay standard.

Wilkinson v. Vesey did not discuss the issue of therapeutic privilege, but merely recognized that "[t]he imposition of a duty of making disclosure is tempered by the recognition that there may be a situation where a disclosure should not be made because it would unduly agitate or undermine an unstable patient." 110 R.I. at 628, 295 A.2d at 689. In support of this statement, it cited three cases—*Stauffer v. Kar-*

Regardless of what standard is used to measure the appropriateness of the exercise of the privilege, there remains the question of which party is to bear the burden of proof. Traditionally the plaintiff bears the risk of nonpersuasion on the issue of the adequacy of disclosure, because it is one of the elements of the cause of action.¹⁵² Reasoning from this premise, it has generally been assumed that where the therapeutic privilege is invoked, because it essentially speaks to the adequacy of disclosure, the burden of proof on the privilege rests on the plaintiff.¹⁵³

abin, 30 Colo. App. 357, 363-64, 492 P.2d 862, 865 (1971); *Di Filippo v. Preston*, 53 Del. 539, 173 A.2d 333 (1961); and *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093 (1960)—only the first of which explicitly held that the validity of the exercise of the privilege is to be tested by professional standards. The other two cases did not have occasion to consider this question, though both held that the duty to disclose was to be measured by professional standards.

The *Canterbury* opinion itself states that “[t]he critical inquiry is whether the physician responded to a sound medical judgment that communication of the risk information would present a threat to the patient’s well-being.” 464 F.2d at 789 (emphasis added). It is not clear whether the “soundness” of medical judgment is to be determined by reference to some general professional standard, or by reference to the subjective judgment of the defendant-physician who made the decision to withhold the information. The *Canterbury* court, in its discussion of the standard by which to measure affirmative disclosure, rejected both of these standards as inappropriate. *Id.* at 787. The inconsistency apparently escaped the attention of the court.

152. See, e.g., *Aiken v. Clary*, 396 S.W.2d 668, 675-76 (Mo. 1965).

153. As is the case with the allocation of the burden of proof in general, the few courts that have considered the problem in the context of therapeutic privilege have for the most part failed to distinguish between the burden of production and the burden of persuasion. See generally F. JAMES, *supra* note 43, §§ 7.5-8. One exception is *Stauffer v. Karabin*, 30 Colo. App. 357, 364, 492 P.2d 862, 865 (1971), in which the court held that the plaintiff has the burden of producing evidence of his uninformed status at the time consent was given, and that once this burden is met, the defendant bears the burden of persuading the trier of fact that the nondisclosure “conformed with community medical standards of care or national standards . . .” and implied that the therapeutic privilege might constitute such a standard. See also *Martin v. Bralliar*, — Colo. App. —, 540 P.2d 1118, 1121 (1975). Several courts have either expressly held or suggested that the burden of proof on therapeutic privilege is on the doctor. See *Cobbs v. Grant*, 8 Cal. 3d 229, 245, 502 P.2d 1, 12, 104 Cal. Rptr. 505, 516 (1972); *Small v. Gifford Memorial Hosp.*, 133 Vt. 552, 557, 349 A.2d 703, 706 (1975); *Holt v. Nelson*, 11 Wash. App. 230, 241, 523 P.2d 211, 218 (1974); *Trogun v. Fruchtmann*, 58 Wis. 2d 569, 604, 207 N.W.2d 297, 315 (1973). Other courts have suggested that the burden is on the plaintiff. *Charley v. Cameron*, 215 Kan. 750, 757, 528 P.2d 1205, 1210 (1974); *Getchell v. Mansfield*, 260 Ore. 174, 182-83, 489 P.2d 953, 957 (1971); *Longmire v. Hoey*, 512 S.W.2d 307, 310 (Tenn. App. 1974).

Canterbury analyzed this issue more closely than had any previous case and came to the realization that, essentially, the therapeutic privilege is an affirmative defense by which the physician first admits that disclosure was less than ordinarily would be deemed adequate and then seeks to justify the degree of disclosure that actually occurred. Therefore, because the allocation of the burden of proof is primarily an issue of fairness and policy rather than one susceptible to mechanical resolution,¹⁵⁴ *Canterbury* looked to the equities of the issue to allocate the burden.

Two factors weighed heavily in *Canterbury's* allocation of the burden to the defendant-physician. First, before the matter of therapeutic privilege even becomes an issue in the case, the plaintiff must have adduced some evidence that disclosure was inadequate. Thus, placing the burden of proof regarding therapeutic privilege on the defendant still would not require him to risk an adverse directed verdict should he fail to come forth with any explanation whatever. Second, the fact that "any evidence bearing on the privilege is usually in the hands of the physician alone . . . [r]equire[s] him to open the proof on the privilege . . . consistent with judicial policy laying such a burden on the party who seeks shelter from an exception to a general rule and who is more likely to have possession of the facts."¹⁵⁵ This result honors the therapeutic privilege as an exception to the general rule of full disclosure, rather than as a presumptively acceptable manner for physicians to behave which must be overcome by the plaintiff in individual cases.¹⁵⁶

One commentator has stated that "[a]fter the patient has satisfied the elements necessary to prevail, the burden of going forward shifts to the physician, who must introduce evidence explaining the reason for withholding the information." Zaslow, *Informed Consent in Medical Practice*, 22 PRACTICAL LAWYER 13, 25-26 (Apr., 1976). This clearly goes too far, in that it implies that if the defendant fails to introduce evidence justifying the invocation of the therapeutic privilege, there must be a directed verdict for the plaintiff. The failure to justify the therapeutic privilege, assuming that it is pleaded, should merely permit the plaintiff to get to the jury.

154. 9 J. WIGMORE, EVIDENCE § 2486, at 275 (3d ed. 1940).

155. *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972). The burden of proof on therapeutic privilege should be the same whether or not the test of the appropriateness of its invocation is lay or professional. See, e.g., *Stauffer v. Karabin*, 30 Colo. App. 357, 364, 492 P.2d 862, 865 (1971) (applying a professional test to the therapeutic privilege and placing the burden of proof on the defendant-physician).

156. Comment, *Informed Consent: The Illusion of Patient Choice*, supra note 64, at 514. Even where the courts are reluctant to apply a therapeutic privilege as narrow as that announced in *Canterbury*, it is still not inconsistent to place the burden of proof on the defendant-physi-

Even in those jurisdictions which might adopt a professional standard by which to measure the appropriateness of the application of the therapeutic privilege, plaintiffs will still have some room to maneuver with factual tactics. There will be disputes as to whether the physician actually exercised sound medical judgment in concluding that disclosure would have been harmful to the plaintiff—that is, whether or not he conformed to the practice that other physicians would have employed under like circumstances.¹⁵⁷

The narrow therapeutic privilege articulated in *Canterbury*, even if not universally adopted in other jurisdictions, is still likely to suggest to plaintiffs that the privilege need not be as broad as the medical profession might like,¹⁵⁸ nor as broad as it has been in practice.¹⁵⁹ Because of the close conceptual relationship between the privilege and the fundamental duty to disclose, it is likely that the rules that shape the latter in a given jurisdiction will determine

cian. See *Cobbs v. Grant*, 8 Cal. 3d 229, 246, 502 P.2d 1, 12, 104 Cal. Rptr. 505, 516 (1972).

157. See Note, *Restructuring Informed Consent*, *supra* note 64, at 1567-70.

158. See note 148 *supra*. No scholarly or judicial attention seems to have been directed toward eliminating the privilege altogether and attempting to reconcile the patient's right to information with the physician's obligation to do no harm through the mechanism of waiver. The courts have recognized that the patient may give up the right to have information disclosed, see *Cobbs v. Grant*, 8 Cal. 3d 229, 246, 104 Cal. Rptr. 505, 516, 502 P.2d 1, 12 (1972); *Putenson v. Clay Adams, Inc.*, 12 Cal. App. 3d 1062, 1083-84, 91 Cal. Rptr. 319, 333 (1st Dist. 1970), and this view has been supported by even the most ardent critic of the paternalistic potential of the informed-consent doctrine. See Goldstein, *supra* note 64, at 692. *But see Aden v. Younger*, 57 Cal. App. 3d 662, —, 129 Cal. Rptr. 535, 543, —, P.2d — (4th Dist. 1976). Presumably, a waiver is valid only if it is voluntary and knowing. See *Miranda v. Arizona*, 384 U.S. 436, 475, 479 (1966). Thus, in the medical context, the doctor must not have conditioned the availability of medical care upon nondisclosure, and he must have informed the patient that the patient has the right to have information disclosed. To minimize the risk of upsetting the patient, the doctor might prepare the patient as follows:

There is some information about your treatment that you may wish to know, and I will tell you about it if you like. There's a chance that this information may upset you, and if you'd rather that I not go into details, please say so. And if you'd like I'll discuss it with your spouse [or other family member] instead.

See *Irvin, Now, Mrs. Blare, About the Complications . . .*, 40 MED. ECON., July 29, 1963, at 102 (parody of disclosure required by doctrine of informed consent), reprinted in J. KATZ, *supra* note 68, at 393. It is, of course, possible that even the limited disclosure that "this information may upset you" will harm the patient. But to require such a minimal disclosure does not seem an unreasonable compromise between the competing interests of the patient's right to disclosure and the doctor's obligation not to harm the patient. *But see Aden v. Younger, supra*.

159. See authorities cited note 140 *supra*.

the former. Yet plaintiffs who focus on this crucial connection between the two will of necessity emphasize to the courts that the therapeutic privilege is properly invoked only when the disclosure of full information would have harmed the plaintiff. To the extent, then, that courts are made to realize that the privilege cannot be used to permit the physician to substitute his judgment for the patient's—that is, to withhold information when the physician believes that its disclosure would result in a decision to forego treatment—inquiry will have to be made into the validity of the physician's judgment.

3. Causation

What *Canterbury* gave to plaintiffs with one hand, it partially took away with the other. During the 1960's, the assimilation of the cause of action for inadequate disclosure to the cause of action for negligence presented a serious obstacle to the compensation of medical-accident victims. The primary difficulty was the establishment of the standard of disclosure by the profession, which meant both that the profession could impose a restrictive standard of disclosure and that proof of the standard had to be by expert testimony. *Canterbury*, by changing the standard of care from a professional to a lay one and thereby eliminating the need for expert testimony to establish the standard, eliminated this obstacle, and consequently focused attention on another problem that had been lurking in the shadows all along—the element of causation.

Although *Canterbury* substantially diminished the plaintiffs' problem, even under an informed-consent theory, of establishing the duty to which physicians are held—albeit a duty to disclose, rather than a duty to use reasonable care in the practice of medicine—it reinforced, if not created, another barrier to compensation. Because mere breach of duty would not establish liability in a cause of action sounding in negligence, the plaintiff was also compelled to demonstrate the existence of legal causation between the breach of duty and the ensuing damages.¹⁶⁰

160. *Canterbury v. Spence*, 464 F.2d 772, 790-91 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972). Here, perhaps more than anywhere else, is the form of action crucial. If the absence of a legally valid consent is viewed as rendering the ensuing treatment a trespass to the person, then the legal wrong consists in the very performance of the procedure. PROSSER, *supra* note 2, § 32, at 165; *Shetter v. Rochelle*, 2 Ariz. App. 358, 366, 409 P.2d 74, 82 (1965), modified, 2 Ariz. App. 607, 411 P.2d 45 (1966). For a comprehensive analysis of the distinction see *Trogun v. Fruchtmann*, 58 Wis. 2d 569, 596-600, 207 N.W.2d 297, 311-13 (1973); C. FRIED, *MEDICAL EXPERIMENTATION* § 2.1 (1974); Goldstein, *supra* note 64, at 690-98; *Plante*, *supra* note 98. If, however, the appropriate form of action for the lack of a legally valid consent is negligence, the de-

Prior to *Canterbury*, courts had given very little attention to causation in informed-consent cases.¹⁶¹ While courts considering the problem both before¹⁶² and after¹⁶³ *Canterbury* agreed that

parture from that standard is not actionable unless it is the proximate cause of the ensuing injury. The legal wrong is thus conceived as being "injury-to-the-patient-resulting-from-inadequate-disclosure," whereas the trespass action views the legal injury as the "failure-to-convey-adequate-information." See PROSSER, *supra* note 2, § 32, at 165; 1 HARPER & JAMES, *supra* note 4, § 3.10, at 235; Goldstein, *supra* note 64, at 691. "Proof of proximate cause in [negligence] cases requires, initially, a showing that the unrevealed risk which should have been made known has materialized." *Downer v. Veilleux*, 322 A.2d 82, 92 (Me. 1974).

Waltz and Scheuneman claim that "[t]his basic principle of tort law [i.e., a causal connection between the failure to disclose and the injury resulting from the occurrence of an undisclosed risk] has been alluded to more frequently by commentators than courts in the medical malpractice area," and that *Shetter v. Rochelle*, *supra*, and *Aiken v. Clary*, 396 S.W.2d 668 (Mo. 1965), "are the only reported medical cases that have stated the principle clearly." Waltz & Scheuneman, *supra* note 64, at 646 n.69. It should not be surprising that the courts have paid scant attention to the necessity for a causal connection between the failure to disclose and the injury, since this requirement such a well-established principle of negligence law. See *Davis v. Rodman*, 147 Ark. 385, 227 S.W. 612 (1921), in which the court refused to impose liability upon a physician who had failed to warn a family that the condition from which two of the children were suffering was a contagious disease (typhoid fever), on the ground that there was no proof that the defendant's omission was the proximate cause of the remainder of the family members' contracting of the disease.

161. For example, in *Shetter v. Rochelle*, 2 Ariz. App. 358, 409 P.2d 74 (1965), *modified*, 2 Ariz. App. 607, 411 P.2d 45 (1966), the court seemed unaware of the problem of the appropriate test to be used to determine causation. In the following excerpt from its opinion, the court unconsciously intermingled the two tests:

The fact that the plaintiff proceeded to have this operation upon her other eye by another surgeon, presumably after she was fully informed of the inherent risks to this operation, is some evidence that disclosure by the defendant of inherent risks would not have deterred her from having the earlier operation. The risks of injury are not so great as to most reasonable persons to decline to have such a beneficial operation performed

Id. at 367, 409 P.2d at 83 (emphasis added). At first the court implied ("disclosure . . . of . . . risks would not have deterred her") that a subjective standard is the test of causation, but in the next sentence it invoked an objective test (whether "[t]he risks . . . are . . . so great . . . to most reasonable persons").

162. *Shetter v. Rochelle*, 2 Ariz. App. 358, 367, 409 P.2d 74, 83, *modified*, 2 Ariz. App. 607, 411 P.2d 45 (1965); *Natanson v. Kline*, 186 Kan. 393, 410, 350 P.2d 1093, 1106 (1960); *Aiken v. Clary*, 396 S.W.2d 668, 676 (Mo. 1965); *Sharpe v. Pugh*, 270 N.C. 598, 604, 155 S.E.2d 108, 113 (1967).
163. See note 168 *infra*.

causation exists only when disclosure of risks to the patient would have resulted in a decision to forego treatment,¹⁶⁴ most courts failed to address the problem of whether causation is to be found by reference to an objective (reasonable man) or subjective (the particular patient) standard. Many commentators assumed that the subjective test should be applied,¹⁶⁵ and the courts concurred, although seemingly unaware of the issue.¹⁶⁶

Canterbury, however, rejected the subjective test on the grounds that "[i]t places the physician in jeopardy of the patient's hindsight and bitterness . . . [and] places the factfinder in the position of deciding whether a speculative answer to a hypothetical question is to be credited."¹⁶⁷ Just as other jurisdictions have begun to adopt the reasoning and holding of the *Canterbury* decision requiring that the adequacy of disclosure be measured against a lay, rather than a professional, standard, so too have they followed *Canterbury* on the issue of causation.¹⁶⁸

164. 464 F.2d at 791.

165. See Plante, *supra* note 98, at 666-67; Comment, *Informed Consent in Medical Malpractice*, *supra* note 67, at 1411; Comment, *Informed Consent as a Theory of Medical Liability*, *supra* note 64, at 885; 75 HARV. L. REV. 1445, 1448-49 (1962). But see Shartsis, *supra* note 64, at 547; Waltz & Scheuneman, *supra* note 64, at 646-48; Note, *Failure to Inform as Medical Malpractice*, *supra* note 118, at 773. Although the test of causation was assumed to be subjective to the patient, if his testimony that he would have forgone the procedure was "inherently incredible," or his "veracity is impeached," or "there is proof that he actually knew of the danger all along," the trier of fact is not bound by his testimony. Plante, *supra* note 98, at 667.

166. See note 161 *supra*.

167. 464 F.2d at 790-91. The Cobbs court, following similar reasoning, also adopted the objective test of causation. Cobbs v. Grant, 8 Cal. 3d 229, 245, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972) ("we doubt that justice will be served by placing the physician in jeopardy of the patient's bitterness and disillusionment"); accord, Funke v. Fieldman, 212 Kan. 524, 512 P.2d 539 (1973); Fogal v. Genesee Hosp., 41 App. Div. 2d 468, 344 N.Y.S.2d 552 (1973); Scaria v. St. Paul Fire & Marine Ins. Co., 68 Wis. 2d 1, 227 N.W.2d 647 (1975). The *Canterbury* formulation relies heavily upon that suggested by Waltz & Scheuneman, *supra* note 64, at 646-48.

168. See Karp v. Cooley, 493 F.2d 408, 422 & n.18 (5th Cir.), cert. denied, 419 U.S. 845 (1974); Bowers v. Garfield, 382 F. Supp. 503, 505-06 (E.D. Pa.), *aff'd*, 503 F.2d 1398 (1974); Riedinger v. Colburn, 361 F. Supp. 1073, 1078 (D. Idaho 1973); Cobbs v. Grant, 8 Cal. 3d 229, 246, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972); Funke v. Fieldman, 212 Kan. 524, 537, 512 P.2d 539, 550 (1973); Zeleznik v. Jewish Chronic Disease Hosp., 47 App. Div. 2d 199, 207, 366 N.Y.S.2d 163, 171-72 (1975); Fogal v. Genesee Hosp., 41 App. Div. 2d 468, 474-75, 344 N.Y.S.2d 552, 560 (1973); Martin v. Stratton, 515 P.2d 1366, 1369 (Okla. 1973) (by implication); Small v. Gifford Memorial Hosp., 133 Vt. 551, 349 A.2d 703,

The unwillingness of the courts to view inadequate disclosure of information alone as a harm to the patient, and the corresponding insistence upon the need to demonstrate that "but for" inadequate disclosure¹⁶⁹ the patient would not have consented to treat-

707 (1975); *Holt v. Nelson*, 11 Wash. App. 230, 236-37, 523 P.2d 211, 216 (1974); *Miller v. Kennedy*, 11 Wash. App. 272, 288-92, 522 P.2d 852, 864-65 (1974), *aff'd*, 85 Wash. 2d 151, 530 P.2d 334 (1975); *Scaria v. St. Paul Fire & Marine Ins. Co.*, 68 Wis. 2d 1, 15-16, 227 N.W.2d 647, 655 (1975); *Trogun v. Fruchtman*, 58 Wis. 2d 569, 603, 207 N.W.2d 297, 315 (1973).

For an example of a forerunner to the test of causation adopted in *Canterbury* see *Cooper v. Roberts*, 220 Pa. Super. 260, 266-69, 286 A.2d 647, 650-51 (1971).

As with the lay standard of disclosure, see note 128 *supra*, there are still strong pockets of resistance to the adoption of the rules laid down in *Canterbury*. Several jurisdictions still adhere to a subjective test of causation. See *Poulin v. Zartman*, 542 P.2d 251, 275 (Alas. 1975); *Riedisser v. Nelson*, 111 Ariz. 542, 544, 534 P.2d 1052, 1054 (1975); *Morgenroth v. Pacific Medical Center, Inc.*, 54 Cal. App. 3d 521, 533-35, 126 Cal. Rptr. 681, 688-89 (1st Dist. 1976); *Goodwin v. Aetna Cas. & Sur. Co.*, 294 So. 2d 618, 620 (La. App. 1974); *Wilkinson v. Vesey*, 110 R.I. 606, 628-29, 295 A.2d 676, 690 (1972); *Jacobs v. Theimer*, 519 S.W.2d 846, 848 (Tex. 1975). In addition, some courts have not yet recognized or acknowledged that there is even any issue as to the appropriate test of causation. See *Poulin v. Zartman*, *supra*; *Riedisser v. Nelson*, *supra*; *Goodwin v. Aetna Cas. & Sur. Co.*, *supra*; *Wilkinson v. Vesey*, *supra*; *Jacobs v. Theimer*, *supra*.

169. See generally 2 HARPER & JAMES, *supra* note 4, § 20.2; PROSSER, *supra* note 2, §§ 41, 42.

The objective and subjective tests of causation, as applied by the courts, are both "but for" tests. That is, the plaintiff must prove that but for the inadequate disclosure, a reasonable person (objective test), or the plaintiff (subjective test), would not have consented to treatment. One alternative, clearly at the other extreme, is that there be no test of causation at all, with a mere showing of failure to disclose being liability-grounding. This, of course, is not entirely a question of causation, but also pertains to the nature of the duty owed by the physician, as well as the nature of the harm suffered by the patient. Under this rule, the duty owed is that of disclosure per se, and the harm that occurs is not the bad results from the treatment, but the failure to disclose.

An intermediate position is that of requiring that the patient demonstrate not that he or a reasonable person would have forgone treatment had adequate disclosure been made, but that the information that was withheld was material to the decisionmaking process (either of the plaintiff or of a reasonable person). This test has been applied by the Supreme Court in determining whether there has been a violation of § 14(a) of the Securities Exchange Act of 1934, and of Rule 14a-9 issued thereunder, which require the disclosure of material facts in proxy statements. To establish such a violation, one need not prove that undisclosed material information caused the shareholder to vote in favor of a proposal. The Court has recognized that,

ment, constitutes the strongest judicial resistance to broadening the role that the doctrine of informed consent is to play in compensating victims of medical accidents. The added unwillingness to apply a subjective test of causation further thwarts the ability to obtain compensation for injuries not occasioned by medical negligence.

More important, these trends undermine a fundamental purpose of the informed-consent doctrine—the protection and promotion of

[a]s an abstract proposition, the most desirable role for a court in a suit of this sort, coming after the consummation of the proposed transaction, would perhaps be to determine whether in fact the proposal would have been favored by the shareholders and consummated in the absence of any misstatement or omission.

TSC Indus., Inc. v. Northway, Inc., 96 S. Ct. 2126, 2132 (1976). Because “such matters are not subject to determination with certainty,” *id.*, however, the Court held that a violation occurs if material information is merely withheld or misstated. The standard of materiality is then defined in such a way as to presume that the undisclosed information caused the stockholder to vote as he did without actual proof thereof:

[A]n omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote. . . . It does not require proof of a substantial likelihood that disclosure of the omitted fact would have caused the reasonable investor to change his vote. What the standard does contemplate is a showing of a substantial likelihood that, under all the circumstances, the omitted fact would have assumed actual significance in the deliberations of the reasonable shareholder.

Id. at 2133; cf. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 2281-82 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974). This test bears a close resemblance to the “substantial factor” formula of causation, under which a defendant is liable for harm done to the plaintiff only if his conduct was “a material element and a substantial factor in bringing it about.” PROSSER, *supra* note 2, § 41, at 240.

If courts were to adopt the position that the mere breach of the duty to disclose gave rise to a cause of action, without the need for a showing that failure to disclose was the proximate cause of the plaintiff's decision to consent to treatment, there probably would not be, in cases where there was no consequent physical injury to the patient, a rash of lawsuits for failure to disclose, since only nominal damages would be available. See note 63 *supra*. Where, however, the undisclosed risk did materialize, but the plaintiff was unable to prove “but for” causation between the nondisclosure and the injury, an emotional appeal to the jury concerning the materialized risk might lead to the awarding of damages for the physical injury under the guise of compensation for the dignitary harm. This is presently not possible in jurisdictions requiring a “but for” test of causation, because the failure to prove “but for” causation keeps the case from the jury. Only where consent was also totally lacking, and a count in battery was alleged, could the plaintiff get to the jury and stand a chance of obtaining damages for the physical injury in the guise of damages for the dignitary harm.

human dignity.¹⁷⁰ Because the doctrine is premised on the right of the individual to make decisions concerning the kind of medical care (if any) that he wishes to undergo or forego, regardless of the soundness of his reasons,¹⁷¹ the subjective test of causation is far more consonant with the underlying rationale for informed consent than is the objective test.¹⁷² By conditioning the availability of compensation on the congruence between the patient's own decision and what a "reasonable" person would have decided under the same or similar circumstances, the objective test undercuts the patient's right of self-determination.

It is not difficult to understand why this development has occurred. As *Canterbury* indicates, and as other cases have agreed,¹⁷³

170. The objective standard of causation is one example of what Professor Joseph Goldstein regards as a fundamental misunderstanding and misapplication of informed consent: "In the name of respect for human dignity, the current concept [of informed consent] has been subtly construed to deny it . . ." Goldstein, *supra* note 64, at 691.

One of the reasons for permitting persons to make foolish decisions is that it is paternalistic to do otherwise. *Id.* But there is also a practical reason—namely, that of the difficulty of defining what is "foolish," even in the limited context of providing medical care. Doctors themselves often do not obtain routine or other needed medical care. *Am. Med. News*, Apr. 5, 1976, at 17, col. 2. That persons educated to make "wise" decisions about medical care often do not follow their own professional advice evidences disagreement within the medical profession—let alone between doctors and patients—as to the wisdom of particular courses of action.

171. See *Cooper v. Roberts*, 220 Pa. Super. 260, 266-67, 286 A.2d 647, 650 (1971); *Canterbury v. Spence*, 464 F.2d 772, 780 n.15, 790 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *In re Yetter*, 62 Pa. D. & C.2d 619, 624 (Northampton County 1973) (a decision that is "foolish and irrational to an outside observer" does not warrant being overridden). *But see* note 189 *infra*. See also Goldstein, *supra* note 64, at 693-96; Waltz & Scheuneman, *supra* note 64, at 642; Note, *Physicians and Surgeons*, 75 HARV. L. REV. 1445 (1962); Comment, *Informed Consent as a Theory of Medical Liability*, *supra* note 64; Comment, *Informed Consent: The Illusion of Patient Choice*, *supra* note 64, at 504; *Faretta v. California*, 422 U.S. 806 (1975).

172. See, e.g., *Scaria v. St. Paul Fire & Marine Ins. Co.*, 68 Wis. 2d 1, 15, 227 N.W.2d 647, 655 (1975) ("The plaintiffs argue that the objective standard is unfair in that it deprives the patient of the right to make his own decision for whatever reasons he alone may deem appropriate."). See also Note, *Informed Consent and the Dying Patient*, *supra* note 64, at 1642.

173. See note 167 *supra*. See also *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1281-82 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974) (testimony by mother of child who contracted polio from immunization that she would have refused the immunization if she had been warned of the danger, is self-serving, but presumption of reading and refusal arises where warning not given); *Technical Chem. Co. v. Jacobs*, 480 S.W.2d 602, 604-05 (Tex. 1972), *rev'g* 472 S.W.2d 191 (Tex. Civ. App. 1971)

it is highly unlikely that a medical-accident victim would thwart his own opportunities for obtaining compensation—no matter how much good faith we are willing to ascribe to him—by testifying that had he been properly informed, he would have withheld his consent.

There is, however, a serious problem with the court's reasoning. Under an objective test of causation, the plaintiff still will be able to testify as to what he actually would have done had he been properly informed. Although such testimony will no longer be dispositive of the causation issue, the jury will be able to consider the plaintiff's subjective views.¹⁷⁴ *Canterbury*, in rejecting a subjective test of causation, was skeptical of the plaintiff's ability to admit, after the fact, that he would have elected treatment even if adequate disclosure had been made. For the same reason that the *Canterbury* court was skeptical, it is reasonable to assume that the jurors will also be skeptical. Because it is the jury's function to evaluate all the evidence and to weigh the credibility of witnesses,¹⁷⁵ it would have ample opportunity to employ this natural skepticism. Thus the fear of the court is overstated, if not entirely misplaced.

D. Disclosure or Understanding: The Next Assault?

There are aspects of the doctrine of informed consent that hardly have begun to be explored by the courts. One of the most notable is the extent to which a patient must "understand" the information that has been disclosed to him before his consent is legally valid.

(whether plaintiff's failure to read a label, which did not contain a warning, was a cause of his injury is a jury question).

174. *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 31, 499 P.2d 1, 13 (1972). The Washington supreme court, in applying a subjective test of causation, held that the plaintiff need not specifically testify on the causation issue in order to establish proximate cause between the undisclosed information and the decision to undergo treatment, stating that such testimony adds little to the credible proof. *Id.* at 31, 499 P.2d at 13. Despite the court's unwillingness to credit plaintiff's own testimony on causation, it was still not willing to reject, as was the *Canterbury* court, a subjective test of causation.
175. F. JAMES, *supra* note 43, § 7.7, at 253. The courts might adopt in informed-consent cases the same rule that has been adopted with respect to causation in products liability cases where the plaintiff alleges a failure to warn. Some courts, noting that a plaintiff's testimony as to whether he would have refrained from using the product had a warning been given is likely to be self-serving, have established a rebuttable presumption that, but for the failure to warn, the plaintiff would not have used the product. See *Reyes v. Wyeth Laboratories*,

Many courts have failed to distinguish between the physician's giving of information on the one hand, and the patient's receiving it on the other. Judicial opinions use words like "inform," "disclose," "tell," "know," and "understand" almost interchangeably without any apparent realization that the physician's disclosure of information does not assure the patient's understanding of that information.¹⁷⁶ One example suffices to illustrate:

[B]efore a patient will be deemed to give an *informed* consent, it may be necessary that he *know* the alternative methods of treatment available to him and the inherent dangers and possibilities of success of such alternatives If a patient's decision is to be a *knowing* and *intelligent* one, he must *understand* in addition to the risks of the suggested surgery, the possible results of the failure to chance it. A complete *understanding* of the consequences of foregoing the operation would seem necessarily to include a *consideration* of the alternative treatment for the patient's disease or condition.

Some jurisdictions considering the duty of a physician to *disclose* to a patient the hazards of surgery have given broad discretion [I]n Pennsylvania a consent is "*informed*" only if the patient *knows* what is apt to happen to him¹⁷⁷

498 F.2d 1264, 1281-82 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Technical Chem. Co. v. Jacobs*, 480 S.W.2d 607 (Tex. 1972). This presumption has been criticized as inappropriate in cases where the plaintiff has no real alternative, such as where the product involved was a polio immunization required for enrollment in the public schools. Note, *Mass Immunization Cases: Drug Manufacturer's Liability for Failure to Warn*, 29 VAND. L. REV. 235, 259 (1976). The presumption may be properly applied in the typical medical-care case, however, because there are alternatives to undergoing most risky medical procedures, including that of choosing no treatment at all.

176. See Fellner & Marshall, *Kidney Donors—The Myth of Informed Consent*, 126 AM. J. PSYCH. 1245 (1970); Olin & Olin, *Informed Consent in Voluntary Mental Hospital Admissions*, 132 AM. J. PSYCH. 938 (1975). See also *Project, Interrogation of Draft Protesters*, 77 YALE L.J. 300, 310-19 (1967); J. KATZ, *supra* note 68, at 609-74 (discussion of the conscious and unconscious, and internal and external factors that affect understanding).

177. *Dunham v. Wright*, 423 F.2d 940, 944 (3d Cir. 1970) (emphasis added) (applying Pennsylvania law). A discussion of the *Dunham* case in the subsequent Pennsylvania case of *Cooper v. Roberts*, 220 Pa. Super. 260, 286 A.2d 647 (1971), merely compounds the confusion:

The Third Circuit Court of Appeals in *Dunham v. Wright* . . . found that a charge which instructed the jury that in order for there to have been an "informed and knowledgeable" consent, the physician should have advised the patient of the consequences of the operation as well as the alternative possibilities accurately reflected Pennsylvania law and was fair to the plaintiff

Gray [Gray v. Grunnagle, 423 Pa. 144, 223 A.2d 663 (1966)] and *Dunham* make it clear that the primary interest of Pennsylvania jurisprudence in regard to informed consent is that of having the patient informed of all the material facts from

This confusion in language¹⁷⁸ betrays a deeper uncertainty on the part of the courts as to the true nature of the obligation imposed

which he can make an intelligent choice as to his course of treatment

Id. at 265-66, 286 A.2d at 649-50.

Although under Pennsylvania case law it is not clear whether the physician's duty is merely to disclose or to assure some level of understanding before being entitled to rely on the patient's consent, this problem seems to have been eliminated (though possibly unintentionally) by a recent legislative enactment defining "informed consent":

"Informed consent" means for the purposes of this act and of any proceedings arising under the provisions of this act, the consent of a patient to the performance of health care services by a physician or podiatrist: Provided, That prior to the consent having been given, the physician or podiatrist has informed the patient of the nature of the proposed procedure or treatment and of those risks and alternatives to treatment or diagnosis that a reasonable patient would consider material to the decision whether or not to undergo treatment or diagnosis

PA. STAT. ANN. tit. 40, § 1301.103 (Supp. 1975).

178. The source of the problem may be largely semantic. The word "informed" can function as either a verb or an adjective. See 1 WEBSTER'S NEW INTERNATIONAL DICTIONARY 1276 (2d ed. 1959). When used as a verb (*e.g.*, D has informed P of "X"), the connotation is that information has been transmitted from one person to another. When used adjectivally (*e.g.*, P is informed of "X"), the primary connotation is that P is knowledgeable about "X", or more specifically that P has understood "X." There may also be an inferential secondary connotation that before this cognitive integration could occur, information necessarily had to have been transmitted to the person who is now said to understand it, though this conclusion denies the possibility of original thought.

The confusion in the cases stems from the failure of the courts to distinguish clearly between the two different meanings of "informed." The following example from a New Mexico case illustrates this point:

The real basis for the rule requiring disclosure is to give the patient a basis upon which to exercise judgment as to whether he will consent to the treatment. Without the disclosure by the doctor it is said that the patient is not informed and that, therefore, any consent obtained is ineffectual.

Woods v. Brumlop, 71 N.M. 221, 227, 377 P.2d 520, 624 (1962). To state that the patient is not "informed" is to imply either (1) that information has not been transmitted to the patient (the verbal sense of "informed"), or (2) that information has not been understood by the patient (the adjectival sense of "informed").

In the *grammatical* context in which "informed" is used in the above excerpt, the word functions as an adjective, and therefore the consent is not valid. But in the *logical* context of the case, the reason that the consent was ineffectual is that adequate disclosure did not occur (which means that the patient could not have understood the information without having acquired it some other way. See note 107 *supra*).

by the doctrine of informed consent, and even more fundamentally with the purposes served by the doctrine itself.¹⁷⁹

Even the one court that has recognized this issue—*Canterbury*—did not satisfactorily resolve it. Judge Robinson noted that the phrase “informed consent” is used in two different ways:

The doctrine that a consent effective as authority to form [*sic*; perform (?)] therapy can arise only from the patient's understanding of alternatives to and risks of the therapy is commonly denominated “informed consent.” . . . The same appellation is frequently assigned to the doctrine requiring physicians, as a matter of duty to patients, to communicate information as to such alternatives and risks.¹⁸⁰

He then explained the distinction between the patient's understanding of information and the physician's disclosure of information:

In duty-to-disclose cases, the focus of attention is more properly upon the nature and content of the physician's divulgence than the patient's understanding or consent. Adequate disclosure and informed consent are, of course, two sides of the same coin—the former a *sine qua non* of the latter. But the vital inquiry on duty to disclose relates to the physician's performance of an obligation, while one of the difficulties with analysis in terms of “informed consent” is its tendency to imply that what is decisive is the degree of the patient's comprehension. As we later emphasize, the physician discharges the duty when he makes a reasonable effort to convey sufficient information although the patient, without fault of the physician, may not fully grasp it. . . . Even though the factfinder may have occasion to draw an inference on the state of the patient's enlightenment, the factfinding process on performance of the duty ultimately reaches back to what the physician actually said or failed to say.¹⁸¹

If this were all, *Canterbury* could be said to stand for the proposition that as long as reasonable disclosure is made to the patient by the physician, the fact that the patient may not have understood it does not denote any breach of duty on the part of the physician. But ignoring his own caution “that uncritical use of the ‘informed

In order to have conveyed the intended logical meaning—namely, that consent is ineffectual when there has been inadequate disclosure—the court should have written, “Without the disclosure by the doctor, any consent obtained is ineffectual,” or, “If the patient has not been informed (of the hazards of treatment), any consent obtained is ineffectual.” Through sloppy syntax, the court confused the meaning it intended to convey.

179. See note 68 *supra*.

180. 464 F.2d at 780 n.15.

181. *Id.* The first sense of “informed consent” seems to be related to the battery theory of informed consent, and the second sense of the phrase traces its origins to the negligence theory of informed consent. See note 111 *supra*.

consent' label can be misleading,"¹⁸² Judge Robinson immediately obfuscated the issue when he stated that the purpose of disclosure of therapeutic alternatives and their hazards is "[t]o enable the patient to chart his course understandably [sic]."¹⁸³

If the function of the informed-consent doctrine is to safeguard the individual's right of self-determination, even his right to make what might be considered "foolish" decisions¹⁸⁴—which is what *Canterbury* asserts¹⁸⁵—the proper concern is exclusively with the information disclosed by the physician.¹⁸⁶ This of course in no way prohibits the state, through the legal requirement of informed consent, from *encouraging* that the decisions that patients make be "rational."¹⁸⁷ If, however, the function of informed consent is to *assure* "rational"¹⁸⁸ decisionmaking, then the focus of judicial concern must also be on the patient's comprehension of the information that has been disclosed. Although considerable judicial lipservice is given to promoting individual self-determination, and to permitting patients to make and requiring physicians to honor decisions that may seem unwise, the holdings of many cases suggest a great deal of judicial intolerance for decisions viewed as unreasonable in outcome.¹⁸⁹ Some courts have left the door open, through their loose

182. 464 F.2d at 780 n.15.

183. *Id.* at 781. Presumably the court meant "understandingly."

184. See note 171 *supra*.

185. See *Canterbury v. Spence*, 464 F.2d 772, 780 n.15, 790 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).

186. See generally Goldstein, *supra* note 64.

187. See note 68 *supra*.

188. *Canterbury* appears to be the only case to have expressly discussed this problem. Other courts, however, have made statements that bear on the issue, and at least one has suggested that the purpose of disclosure of information is to *assure* that the patient understands the risks of the procedure. See *ZeBarth v. Swedish Hosp. Medical Center*, 81 Wash. 2d 12, 29, 499 P.2d 1, 11 (1972) (*semble*) (duty to inform imposed upon physician "so that the patient's choice will be an intelligent one"); *Cobbs v. Grant*, 8 Cal. 3d 229, 245, 520 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972) ("[T]he patient's right of self-decision . . . can be effectively exercised only if the patient possesses adequate information to *enable* an intelligent choice." (emphasis added)).

When the courts use the term "rational," it is not clear whether they are referring to the *process* by which decisions are made, or the outcome of the decision itself. Roth, Meisel & Lidz, *Tests of Competency to Consent to Treatment*, 134 AM. J. PSYCH. — (1977).

189. Cases involving the refusal, for religious reasons, of blood transfusions, are the most typical. These cases are collected and discussed in Annot., 9 A.L.R.3d 1391 (1966), and in Library of Congress, Congressional Research Service, *Court Decisions Involving the Right to Refuse Blood Transfusions* (Ehlke ed. 1973) (No. JC 585 B; 73-87 A). In the most celebrated of these cases, *Application of the President & Directors of Georgetown College, Inc.*, 331 F.2d 1000 (D.C. Cir.),

language, to the argument that the mere disclosure of risks to the patient, without the patient's understanding thereof, is inadequate.¹⁹⁰

cert. denied, 377 U.S. 978 (1964), the court demonstrated its intolerance of not only the outcome that probably would have ensued (*i.e.*, death) had the refusal of a blood transfusion been permitted to stand, but also of the patient's reason for refusing treatment:

The President of Georgetown University, Father Bunn, appeared and pleaded with Mr. Jones [the husband of the patient] to authorize the hospital to save his wife's life with a blood transfusion. Mr. Jones replied that the Scriptures say that we should not drink blood, and consequently his religion prohibited transfusions. The doctors explained to Mr. Jones that a blood transfusion is totally different from drinking blood in that the blood physically goes into a different part and through a different process in the body. Mr. Jones was unmoved. I thereupon signed the order allowing the hospital to administer such transfusions as the doctors should determine were necessary to save her life.

Id. at 1007; *accord*, *Powell v. Columbian Presbyterian Medical Center*, 49 Misc. 2d 215, 267 N.Y.S.2d 450 (Sup. Ct. 1965). If the reasonableness of a refusal is to be measured against the standards of the medical profession, there is little left to be protected by a rule that lets the patient choose in the first instance. There might just as well be initial acquiescence to medical decisionmaking. Although the court in the *Georgetown* case in part justified its decision on the ground that a husband has no right to refuse life-saving treatment for his spouse, *see Application of President & Directors of Georgetown College, Inc.*, *supra* at 1008, there is fairly persuasive evidence that the wife had also refused treatment on her own volition. The court, however, discounted this refusal, stating that "[i]t was obvious that the woman was not in a mental condition to make a decision." *Id.* at 1007.

This attitude is not limited to blood transfusions. *See generally* Byrn, *Compulsory Lifesaving Treatment for the Competent Adult*, 44 *FORDHAM L. REV.* 1 (1975); Cantor, *A Patient's Decision to Decline Life-Saving Medical Treatment: Bodily Integrity Versus the Preservation of Life*, 26 *RUTGERS L. REV.* 228 (1973); Goldstein, *supra* note 64, at 690-98; Sharpe & Hargest, *Lifesaving Treatment for Unwilling Patients*, 36 *FORDHAM L. REV.* 695 (1968); *Symposium, Euthanasia*, 27 *BAYLOR L. REV.* 1 (1975); Comment, *Unauthorized Rendition of Lifesaving Medical Treatment*, 53 *CALIF. L. REV.* 860 (1965); Comment, *Compulsory Medical Treatment: The State's Interest Re-evaluated*, 51 *MINN. L. REV.* 293 (1966); Note, *The Dying Patient: A Qualified Right to Refuse Medical Treatment*, 7 *J. FAM. L.* 644 (1968); Comment, *Is There a Right to a Natural Death?*, 9 *NEW ENG. L. REV.* 293 (1974); Note, *Informed Consent and the Dying Patient*, *supra* note 64.

190. *See, e.g.*, *Dunham v. Wright*, 423 F.2d 940, 944-45 (3d Cir. 1970); *cf.* *Demers v. Gerety*, 85 N.M. 641, 645, 515 P.2d 645, 649 (Ct. App. 1973), *rev'd and remanded on other grounds*, 86 N.M. 141, 520 P.2d 869, *rev'd and remanded after retrial*, 87 N.M. 52, 54, 529 P.2d 278, 280 (Ct. App.), *cert. denied*, 87 N.M. 47, 529 P.2d 273 (1974); *Gravis v. Physicians & Surgeons Hosp.*, 427 S.W.2d 310, 311 (Tex. 1968); *Grannum v. Berard*, 70 Wash. 2d 304, 422 P.2d 812 (1967).

Although informed-consent cases do not expressly hold that patients must understand the information before their consent will be considered valid,¹⁹¹ there is some support for this view. Justice Cardozo's dictum that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body"¹⁹² is often echoed in the contemporary informed-consent cases.¹⁹³ The judicial statements acknowledging that the decision

191. The U.S. Department of Health, Education, and Welfare has proposed regulations that would govern research conducted with subjects of compromised capacity, and ensure voluntary and knowledgeable consent to treatment. See 38 Fed. Reg. 31737 (1973) (original proposal); 39 Fed. Reg. 30647 (1974) (revised proposal); 40 Fed. Reg. 33526 (1975) (adopting in part and revising prior proposals). A comment received on the definition of "informed consent" in the original proposal, 38 Fed. Reg. 31737, 31740 (1973), "suggested the addition of language concerning . . . assurance that the subject comprehends the disclosure." 39 Fed. Reg. 30647, 30649 (1974). In rejecting this suggestion, the Department of Health, Education, and Welfare noted that the "suggestion goes beyond requirements for informed consent as they have generally been articulated by the courts." *Id.*

It should be noted that there is empirical evidence to indicate that patients' understanding of the information disclosed to them before consent is obtained is not very substantial. See note 113 *supra*.

192. *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914).

193. See *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 241-42, 502 P.2d 1, 9, 104 Cal. Rptr. 505, 513 (1972); *Natanson v. Kline*, 186 Kan. 393, 407-08, 350 P.2d 1093, 1104 (1960); *Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 433-34, 88 N.W.2d 187, 190 (1958); *Wilkinson v. Vesey*, 110 R.I. 606, 619-20, 295 A.2d 676, 685 (1972); cf. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 578, 317 P.2d 170, 181 (1st Dist. 1957); *Mitchell v. Robinson*, 334 S.W.2d 11, 18 (Mo. 1960). What this dictum often means in practice is that the *refusal* of treatment by a person who is not of "sound mind" (or who is "incompetent") is either ignored by the physician or overridden by the court. See, e.g., *Fraser, A Judge Orders Cancer Surgery*, N.Y. Times, Dec. 30, 1973, § 1, at 31, col. 1 (city ed.) (patient who refused to acknowledge that she had cancer, and had been diagnosed as a chronic paranoid schizophrenic deemed incapable of choice); *Illson, Court Orders Doctors to Feed a Woman Who Wants to Die*, N.Y. Times, Oct. 25, 1975, at 33, col. 4 (city ed.); *Walsh, Amputation or Death, Doctor Tells Judge*, Pittsburgh Press, June 4, 1975, at 1, col. 1 (refusal of treatment by daughter carrying out expressed wishes of 67-year-old patient overruled); Pittsburgh Press, Feb. 7, 1976, at 1, col. 3 (judge rules for amputation for 96-year-old woman who is not "lucid" and is unable to consent); cf. *In re Yetter*, 62 Pa. D. & C.2d 619 (Northampton County 1973) (although patient was "incompetent," court refused to order surgery because of patient's prior "competent" refusal).

The Supreme Court of New Jersey has indicated that it will apply a balancing test—one which weighs the patient's interest in privacy

of a person of unsound mind is legally ineffective do not seem to be directed explicitly toward patients who do not *in fact* understand the information that is disclosed to them. There does not seem, in other words, to be any explicitly articulated requirement that the physician attempt to ascertain the patient's level of understanding. Instead the courts seem, through their use of the unsoundness-of-mind exception, to be establishing a requirement of a *potentiality* for understanding, rather than of actual understanding. Instead of looking to the patient's competency to perform a particular act—in this case, to make a decision about a specific kind of medical treatment—the unsoundness-of-mind standard disqualifies a person from making a decision about treatment if he is incompetent in a generalized way.¹⁹⁴

against the state's interest in preserving life—where a patient refuses treatment:

In many of those cases the medical procedure required (usually a transfusion) constituted a minimal bodily invasion and the chances of recovery and return to functioning life [are] very good. We think that the State's interest *contra* weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims. Ultimately there comes a point at which the individual's rights overcome the State interest.

In re Quinlan, 70 N.J. 10, —, 355 A.2d 647, 664 (1976). The problem with this test is that it reverses the presumption of bodily integrity underlying the informed-consent cases, and places on the party opposing treatment the burden of proof of demonstrating that the individual's interest in refusing treatment outweighs the state's interest in compelling it.

Although the "incompetent" refusal of treatment by a patient is often subjected to judicial scrutiny, there seem to be few reported cases in which a patient's "incompetent" consent to treatment has been challenged. It is only when such a consent achieves a substantial degree of notoriety that it is brought to the public's attention. Physicians have little hesitancy about honoring a patient's consent to treatment, even if "incompetent," because it accords with the physician's own view of the proper course of action. See, e.g., *Kaimowitz v. Michigan Dep't of Mental Health*, 1 MENTAL DISABILITY L. REP. 147 (1976) (consent to experimental brain surgery overridden).

194. In *Reif v. Weinberger*, 372 F. Supp. 1196 (D.D.C. 1974), the court enjoined regulations governing sterilization operations paid for with federal funds. It held that the sterilization could be undertaken only with the "voluntary, knowing, and uncoerced consent" of the patient. *Id.* at 1201. It absolutely prohibited, however, the sterilization of "incompetent" persons, on the ground that "[n]o person who is mentally incompetent can meet these standards . . ." *id.* at 1202, and stated that the term "voluntary," "at least when important human rights are at stake, entails a requirement that the individual have at his disposal the information necessary to make his decision and the mental competence to appreciate the significance of that information." *Id.* at 1202. This language implicitly recognizes that the disclosure of

There is also a small group of cases more directly suggesting that the consent of patients who actually have not understood the disclosure of information is not valid authorization for treatment. In each of these cases the plaintiff claimed that he or she was under the influence of some therapeutically administered sedative medication that compromised the cognitive faculties. The courts have held that if this claim can be established, and it can be shown that the patient was thereby disabled from understanding information about the procedure, the consent is invalid.¹⁹⁵ However, there is a division as to whether the burden is on the plaintiff to establish lack of understanding,¹⁹⁶ or whether the fiduciary nature of the doctor-patient relationship requires the physician to attempt to ascertain the patient's level of understanding and to refrain from proceeding with treatment where comprehension is compromised.¹⁹⁷

A final source of support for the view that the physician has an obligation to ascertain the patient's level of understanding re-

information does not guarantee its comprehension. Additionally, the court clearly insisted upon the patient's understanding of the information, as well as its disclosure, in order for the consent to be valid. The court subsequently refused to approve modified federal regulations because, *inter alia*, they lack a requirement that "the attending physician [certify] that the patient has truly given informed consent *with full understanding . . .*" *Relf v. Mathews*, 403 F. Supp. 1235 1239 (D.D.C. 1975) (emphasis added).

Another way of viewing this matter is that if the patient seems to be so unlike the "reasonable man" of tort law that he is unable to make a rational decision, then the physician will not be permitted to rely upon the patient's decision as valid authorization for treatment. The requirement of a generalized competency thus becomes a threshold of understanding, which, if not met by the patient, deprives him of his right to make his own decision about medical treatment. Conversely, the physician who relies upon the refusal of such a person—*i.e.*, an "incompetent" refusal—may incur liability for failure to obtain proxy consent to render medically necessary treatment, or to proceed without consent in an emergency. See *Jackovach v. Yocom*, 212 Iowa 914, 927-29, 237 N.W. 444, 451 (1931); *Steele v. Woods*, 327 S.W.2d 187, 198 (Mo. 1959); *Kennedy v. Parrott*, 243 N.C. 355, 362-63, 90 S.E.2d 754, 759 (1956).

One problem with the unsoundness-of-mind standard, besides its inherent imprecision, is that some persons who may appear quite derailed may in fact be able to articulate clear, rational, and compelling decisions to consent to or refuse treatment.

195. See *Demers v. Gerety*, 85 N.M. 641, 515 P.2d 645 (Ct. App. 1973), *rev'd and remanded on other grounds*, 86 N.M. 141, 520 P.2d 869 (1974); *Gravis v. Physicians & Surgeons Hosp.*, 427 S.W.2d 310 (Tex. 1968); *Grannum v. Berard*, 70 Wash. 2d 304, 422 P.2d 812 (1967).
196. *Grannum v. Berard*, 70 Wash. 2d 304, 422 P.2d 812 (1967).
197. *Demers v. Gerety*, 85 N.M. 641, 646-47, 649-50, 515 P.2d 645, 650-51, 653-54 (Ct. App. 1973), *rev'd and remanded on other grounds*, 86 N.M. 141, 520 P.2d 869 (1974).

sides in the meaning of the word "consent" as it is used in the law of torts generally. According to Harper and James, "'consent' indicates an 'assent' given under circumstances which make it legally effective."¹⁹⁸ One kind of circumstance under which an assent—that is, "an expression or manifestation of willingness to suffer a particular interest-invasion"¹⁹⁹—is ineffective is where the person giving the assent is incapable of expressing a rational will.²⁰⁰ The physician who relies upon such an "assent" will find that it does not rise to the level of a "consent." Thus it could be said that to avoid liability, the physician has a duty to assure himself that

198. 1 HARPER & JAMES, *supra* note 4, § 3.10, at 233.

199. *Id.*

200. *Id.* at 234-35. The Restatement of Torts defines consent similarly: "A person of full capacity who freely and without fraud or mistake manifests to another assent to the conduct of the other is not entitled to maintain an action of tort for harm resulting from such conduct." RESTATEMENT OF TORTS § 892, at 486 (1939). Comment b indicates that an assent based upon a mistake of fact, including the consequences of the other person's conduct, does not constitute a consent. Comment e states that "[t]he manifestation of assent by a person . . . so mentally defective that he does not understand the nature or effect of an act done is not a defense to an action for such act." *Id.* at 490.

A proposed revision of this and related sections makes even clearer that a mistake of fact known to the actor renders ineffective a consent:

If the person consenting to the conduct of another is induced to do so by a substantial mistake as to the nature of the invasion of his interests or the extent of the harm to be expected from it, and his mistake is known to the other . . . the consent is not effective as to the expected invasion or harm.

RESTATEMENT (SECOND) OF TORTS § 892B(2) (Tent. Draft No. 18, 1972). The comments to this section also indicate that where the mistake that induces the consent is known to the actor (whether a mistake as to the nature of the interest-invasion or as to the nature of the harm reasonably to be expected therefrom), the consent does not shield the actor from tort liability. *Id.* comments d & e. Neither the Restatement nor the tentative revision, however, expressly addresses the problem of whether a mistake of fact occurs merely when inadequate or incorrect information has been provided by the actor, or when the consenting person misunderstands adequate and correct information. But, the tentative draft states, "to be effective, consent must be by one who has the capacity to consent . . ." *Id.* § 892A(2)(a). The comment to this subsection states that the consent of a child or a mentally deficient person "may still be effective if he is capable of appreciating the nature, extent and probable consequences of the conduct consented to . . ." but not otherwise. *Id.* § 892A(2), comment b. This seems to imply that there must be some subjective understanding of the nature of the conduct and the consequences, and that mere disclosure of information about the conduct and its consequences is inadequate to shield the actor from liability.

In discussing informed consent to medical treatment, the Restatement does not further elucidate upon this problem, but merely uses

the patient has achieved the requisite level of understanding (whatever that level may be)²⁰¹ of the information that has been disclosed.

Enterprising courts and lawyers faced with a situation in which there has been adequate disclosure, but little understanding by the plaintiff, may therefore be amenable to the suggestion that "the physician could be held responsible for taking reasonable steps to ascertain whether the information presented has been understood"²⁰² The desirability of such a requirement for the practice of medicine, for the well-being of patients, and for the multitudinous social interests served by the doctrine of informed consent²⁰³ is not here in issue.²⁰⁴ Rather, what is clear is that for the medical-accident victim who is unable to prove medical negligence, the ambiguity of the nature of the physician's obligation under the developing doctrine of informed consent will invite further litigation aimed at broadening the physician's obligation to include a reasonable effort to ascertain whether the patient understands the information that has been disclosed.

E. Informed Consent and Strict Liability

At first glance, liability grounded upon the physician's failure to obtain the patient's informed consent does not seem to be equiv-

the phrases it employs elsewhere, without defining them precisely: "[C]onsent to an operation is binding if the patient is *made aware* of the nature of the operation or treatment and of the extent of the harm normally to be expected." *Id.* § 892B(2), comment *i* (emphasis added). Query whether "made aware" means "made to understand" or "provided with information."

201. The problems of ascertaining when and the extent to which a person understands something are immense. The added administrative burden of such a requirement might ultimately make it unworkable.

In one proposal, Miller and Willner recommend that the patient be given a kind of written examination, after information has been disclosed, to determine if he understands sufficiently. See Miller & Willner, *The Two-Part Consent Form*, 290 *NEW ENG. J. MED.* 964 (1974). One virtue of this procedure is that it demonstrates that the physician has made a good-faith effort to ascertain the level of the patient's understanding. But the proposal raises far more questions than it answers. For example, does the ability to answer questions correctly necessarily test understanding, or merely ability to recall? Furthermore, it would be very difficult to establish the requisite level of understanding, assuming that we were able to specify what we mean by "understanding." See Ingelfinger, *Informed (But Uneducated) Consent*, 287 *NEW ENG. J. MED.* 465 (1972).

202. Capron, *supra* note 64, at 414. See also Waltz & Scheuneman, *supra* note 64, at 643-45.

203. See note 68 *supra*.

204. See pp. 150-51 *infra*.

alent to strict liability. A true system of strict liability, in rudimentary form, requires only proof by the plaintiff that the medical treatment was the cause of the bad results.²⁰⁵ To impose liability under the doctrine of informed consent, the plaintiff must meet this rudimentary requirement of strict liability, but there is an additional requirement that must be satisfied. The plaintiff must also show that the physician failed to disclose information to the patient adequate to enable him to make an intelligent choice to undergo treatment, and that but for this failure, plaintiff would not have consented to treatment. Thus, under the informed-consent doctrine there must be inquiry into the adequacy of disclosure and the reasonableness of the decision to forego treatment had adequate disclosure been made, both of which are to be measured in accordance with accepted rules of *negligence* liability.

Yet despite the assimilation of the cause of action for informed consent to a negligence form of action, to the extent that informed consent permits the injured patient to obtain compensation without having to establish negligence in the traditional sphere of medical practice, the doctrine does constitute a vital link with strict liability. By permitting the patient to impose liability upon the physician for bad results not caused by negligent medical practice, but caused by inadequate disclosure of information, there is at the very least a substantial abandonment of medical negligence as the basis for liability, and a corresponding movement toward a system of liability without regard to fault.

On closer examination, there is an even more striking similarity between informed consent and strict liability. When the layers of rhetoric and procedural formality are stripped away, it is apparent that the doctrine of informed consent closely approximates strict liability for medical accidents.

An illustrative basis for comparison is strict liability in tort for injuries from a defective product. To hold a seller or manufacturer strictly liable for personal injuries, the plaintiff must prove essentially that his injuries were caused²⁰⁶ by a product manufactured

205. Prosser, *supra* note 24, at 840. See generally 2 HARPER & JAMES, *supra* note 4, § 12.2.

206. 1 FRUMER & FRIEDMAN, *supra* note 24, § 11.01[1], at 198.12. "A defendant cannot be [held strictly] liable unless his conduct is an actual cause of the plaintiff's harm—that is, unless the plaintiff would not have been injured but for the defendant's conduct." Comment, *Torts—Proximate Cause in Strict-Liability Cases*, 50 N.C.L. REV. 714, 715 (1972).

Causation in products liability cases consists of two elements—causation-in-fact and proximate cause—either or both of which the plain-

or sold by the defendant which was in a defective condition making it unreasonably dangerous for use.²⁰⁷ If these basic elements of the cause of action can be established, the defendant will be held liable unless he is able to establish a recognized defense to strict liability, such as abnormal use²⁰⁸ or assumption of risk.²⁰⁹

Allowing for the relevant differences between medicine and commerce, this is how the informed-consent doctrine operates for

tiff must prove. Causation-in-fact refers to whether the defendant's product caused the injury that the plaintiff incurred, whereas proximate cause refers to whether the defect (which may be a failure to warn) in the defendant's product was responsible for the plaintiff's injury. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1279-80 (5th Cir.), cert. denied, 419 U.S. 1096 (1974). Proximate cause, however, may be inferable as a matter of law—that is, it is not always a question of fact whether the plaintiff would have refrained from using the injurious product had he been adequately warned; that he would have will sometimes be presumed. *Id.* at 1281-82. See also note 175 *supra*.

207. 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.

The literature dealing with liability for injuries from products is so vast that there does not seem to be any single comprehensive bibliography. Some of the major works are cited in Vetri, *Products Liability: The Developing Framework for Analysis*, 54 ORE. L. REV. 293, 293 n.2 (1975), and McNichols, *The Kirkland v. General Motors Manufacturers' Products Liability Doctrine—What's in a Name?*, 27 OKLA. L. REV. 347, 351 n.25 (1974).

208. PROSSER, *supra* note 2, § 102, at 667-68; Prosser, *supra* note 24, at 824-26.

209. See RESTATEMENT (SECOND) OF TORTS § 402A, comment *n* at 356 (1965). See also PROSSER, *supra* note 2, § 102, at 667-71; Prosser, *supra* note 24, at 839.

Assumption of risk in products liability cases is not always discussed as such because it tends to merge into the requirement that the plaintiff prove that the defect was latent. Thus, in *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 59, 64, 377 P.2d 897, 901, 27 Cal. Rptr. 697, 701 (1963), the court stated that a cause of action for strict liability in tort was made out if plaintiff proved "defect in design and manufacture of which [he] was not aware." See generally 2 FRUMER & FRIEDMAN, *supra* note 24, § 16A[5][f].

medical-accident victims. To hold a doctor liable, the plaintiff must prove that his injuries were caused by the conduct of the doctor. The doctor's conduct must have been "defective," not in the sense that this term is used in the law of negligence to denote a departure from a standard of care, but in the sense that it posed an "unreasonably dangerous" risk to the patient.²¹⁰ The very failure to warn may constitute the defective condition that makes the conduct

210. The question of when a product is unreasonably unsafe has occupied a good many writers. . . . [The] terminology [of the Second Restatement of Torts § 402A] may perhaps leave something to be desired, since it is clear that the "defect" need not be a matter of errors in manufacture, and that a product is "defective" when it is properly made according to an unreasonably dangerous design, or when it is not accompanied by adequate instructions and warning of the dangers attending its use.

PROSSER, *supra* note 2, § 99, at 659.

Some courts have rejected the "unreasonably dangerous" requirement, holding that strict liability in tort may apply even to products that are unavoidably unsafe. See *Anderson v. Fairchild Hiller Corp.*, 358 F. Supp. 976, 978-79 (D. Alas. 1973); *Cronin v. J.B.E. Olson Corp.*, 8 Cal. 3d 121, 132-35, 501 P.2d 1153, 1161-63, 104 Cal. Rptr. 433, 441-43 (1972); *Glass v. Ford Motor Co.*, 123 N.J. Super. 599, 602-03, 304 A.2d 562, 564-65 (1973).

A defect in design of a product, as well as a defect in manufacture, calls into play strict liability in tort. This has raised the extremely difficult metaphysical and practical question of what a defect is, see 2 FRUMER & FRIEDMAN, *supra* note 24, § 16A[4][e], and has also permitted negligence principles to creep into strict liability through the back door. See Fischer, *Products Liability—The Meaning of Defect*, 39 Mo. L. Rev. 339 (1974). Some courts have held that where the defect alleged is in the design, the plaintiff must show that the defendant failed to use reasonable care in the development of the design. Comment, *Products Liability: Is § 402A Strict Liability Really Strict in Kentucky?*, 62 Ky. L.J. 866, 867-74 (1974) (discussing *Jones v. Hutchinson Mfg. Co.*, 502 S.W.2d 66 (Ky. 1973)). Other courts, however, have held that strict liability for defective design should not turn on negligence in the design process. See, e.g., *McCormack v. Hanksraft Co.*, 278 Minn. 322, 337-39, 154 N.W.2d 488, 500 (1967); *Schipper v. Levitt & Sons*, 44 N.J. 70, 91-93, 207 A.2d 314, 326 (1965); *MacDougall v. Ford Motor Co.*, 214 Pa. Super. 384, 387-88, 257 A.2d 676, 678 (1969); *Pizza Inn, Inc. v. Tiffany*, 454 S.W.2d 420, 423-24 (Tex. Civ. App. 1970).

The problem is analogous to the issue of what information is required to be disclosed under the doctrine of informed consent. A failure to warn of any information about a risk that materializes does not necessarily lead to the imposition of liability on the defendant-doctor. Only if the information would have been "material" to a "reasonable" person in the plaintiff's position does liability attach for nondisclosure. See also note 211 *infra*. The adequacy of disclosure under the doctrine of informed consent is measured by reference to reasonableness, in the same manner that some courts determine whether or not there was a defect in design.

unreasonably dangerous.²¹¹ The doctor, like the manufacturer or seller in products liability cases, may avoid liability if the patient

211. RESTATEMENT (SECOND) OF TORTS § 402A, comment *j*, at 353 (1965); see, e.g., *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1088 (5th Cir.), *cert. denied*, 419 U.S. 869 (1973) (failure to warn of lung disease from inhaling asbestos dust); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 1121, 1129 (9th Cir. 1968) (failure to warn of possibility of contracting polio by taking polio vaccine); *Boains v. Lasar Mfg. Co.*, 330 F. Supp. 1134, 1137 (D. Conn. 1971) (failure to warn of possibility of injury from inherent defect in meat grinding machine); *Mountain v. Proctor & Gamble Co.*, 312 F. Supp. 534, 536-37 (E.D. Wis. 1970) (failure to warn of allergic response to shampoo); *Canifax v. Hercules Powder Co.*, 237 Cal. App. 2d 44, 53-54, 46 Cal. Rptr. 552, 558 (3d Dist. 1965) (failure to warn of fuse burning time; dynamite explosion); *Crane v. Sears, Roebuck & Co.*, 218 Cal. App. 2d 855, 860-61, 32 Cal. Rptr. 754, 757 (4th Dist. 1963) (failure to warn of low flash point of paint surface preparer; plaintiff "caught on fire"); *Jonescue v. Jewel Home Shopping Serv.*, 16 Ill. App. 3d 339, 344-45, 306 N.E.2d 312, 316 (1973) (failure to warn of dangers of drinking household cleaner); *Berkebile v. Brantly Helicopter Corp.*, 225 Pa. Super. 349, 353-55, 311 A.2d 140, 143 (1973) (failure to warn adequately of method of operating helicopter in event of power failure; pilot killed in crash). See also Annot., 53 A.L.R.3d 239 (1973).

The rationale for this has been stated as follows:

Modern, and rapid, advances in technology have resulted in the production and commercialization of more and more highly sophisticated products in virtually every field of manufacturing. Many users and consumers of these sophisticated products lack the knowledge, experience, and skill to fully comprehend the true nature of such complex items.

The very nature of a manufactured item, therefore, may be a potential source of physical harm to the user unless he or she is made aware of the potential danger.

Accordingly, the manufacturer's duty is not just to use reasonable care in designing or manufacturing his product. There may be a duty to warn even though the product is perfectly made.

1 FRUMER & FRIEDMAN, *supra* note 24, § 8.01, at 143. This is equally true of medical practice, which has become increasingly technologized, sophisticated, and unfamiliar to the average patient. The Restatement, however, cautions that products, such as drugs, that are incapable of being made entirely safe, are not defective or unreasonably dangerous if accompanied by a proper warning and directions for use. RESTATEMENT (SECOND) OF TORTS § 402A, comment *k*, at 353 (1965). See also Twerski, Weinstein, Donaher & Pehler, *The Use and Abuse of Warnings in Products Liability—Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495, 517-21 (1976).

Similarly, in medical accidents, the liability-grounding conduct is the physician's failure to warn of "material" risks, or of risks that are not common or not actually known to the patient. See text accompanying note 107 *supra*. This is the equivalent of the duty in products liability cases to warn of "latent" dangers, but not of "patent" ones. See 1 FRUMER & FRIEDMAN, *supra* note 24, § 8.04. Manufacturers, like

assumed the risk of the doctor's conduct. Assumption of risk occurs when the doctor warns of the risks of the treatment and the patient consents to the treatment anyway.²¹² Although the burden of proof is allocated differently in informed-consent cases than in products liability cases—in the former it is the plaintiff who must establish as an element of his cause of action that there was inadequate disclosure and hence no assumption of risk,²¹³ and in the lat-

doctors, will not be held liable for injuries to users of their products where the injury results from a common, known risk. *Fanning v. Le-May*, 83 Ill. 2d 209, 230 N.E.2d 182 (1967) (common knowledge that a rubber shoe heel and sole will slip when wet). See generally 2 FRUMER & FRIEDMAN, *supra* note 24, § 16A[4][d], at 3-302 to -303. When risks are "common," or actually known to the plaintiff, the plaintiff assumes the risk thereof despite the physician's failure to warn. *Cobbs v. Grant*, 8 Cal. 3d 229, 245-46, 502 P.2d 1, 12, 104 Cal. Rptr. 505, 516 (1972). The same is true when the patient requests that he not be informed of risks—that is, when he waives his right to make an informed decision. *Id.*; *Putensen v. Clay Adams Inc.*, 12 Cal. App. 3d 1062, 91 Cal. Rptr. 319 (1st Dist. 1970); *Kaplan v. Haines*, 96 N.J. Super. 242, 232 A.2d 840 (1967), *aff'd*, 51 N.J. Super. 404, 241 A.2d 235 (1968); *Goldstein*, *supra* note 64, at 692; *Hagman*, *supra* note 136, at 785; Note *Restructuring Informed Consent*, *supra* note 64, at 1562 *et seq.*

The failure of a manufacturer to warn of the risks of a product will not always give rise to liability. A warning is required only if "the seller . . . has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the . . . danger." RESTATEMENT (SECOND) OF TORTS § 402A, comment j, at 353 (1965). See also 1 FRUMER & FRIEDMAN, *supra* note 24, § 8.03[1]. That only negligent failures to warn create liability, even under the so-called "strict" liability provision of the Restatement, has the effect of bringing negligence principles into strict liability theory through the back door. *Fischer*, *supra* note 210. *But see Jackson v. Coast Paint & Lacquer Co.*, 499 F.2d 809, 812 (9th Cir. 1974) (failure to warn is not to be tested by negligence principles). In this respect, strict liability for medical accidents under the informed-consent doctrine is no less "strict" than strict liability in tort for defective products, since under the informed-consent doctrine, physicians are liable only for negligent failure to warn. See p. 124 *supra*. For a discussion of the relationship between "defect," "assumption of risk," and "appropriateness of use" see *Calabresi & Hirschhoff*, *supra* note 11, at 1061-67.

212. Although the equivalence of "informed consent" and assumption of the risk may be inferred from the informed-consent cases, no court has stated the proposition directly. Cf. *Steele v. Woods*, 327 S.W.2d 187, 196 (Mo. 1959) ("the refusal of treatment, after reasonable explanation as to its necessity . . . is a complete defense of the doctor who is accused of negligence in not giving the treatment"); *accord*, *Carey v. Mercer*, 239 Mass. 599, 600-01, 132 N.E. 353, 354 (1921).
213. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 245-46, 502 P.2d 1, 12, 104 Cal. Rptr. 505, 516 (1972); *Martin v. Bralliar*, — Colo.

ter it is the defendant who must establish as an affirmative defense that the plaintiff assumed the risk²¹⁴—the basic rules of liability are remarkably similar.²¹⁵

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- App. —, 540 P.2d 1118, 1120-21 (1975); *Charley v. Cameron*, 215 Kan. 750, 756-57, 528 P.2d 1205, 1210 (1974); *Wilkinson v. Vesey*, 110 R.I. 606, 625-26, 295 A.2d 676, 688 (1972); *Longmire v. Hoey*, 512 S.W.2d 307, 310 (Tenn. App. 1974); *Small v. Gifford Memorial Hosp.*, — Vt. —, 349 A.2d 703, 706 (1975); *Trogun v. Fruchtmann*, 58 Wis. 2d 569, 693-04, 207 N.W.2d 297, 315 (1973).
214. *Shuput v. Heublein Inc.*, 511 F.2d 1104, 1106 (10th Cir. 1975); *Hastings v. Dis Tran Prods., Inc.*, 389 F. Supp. 1352, 1359 (W.D. La. 1975); *Hügel v. General Motors Corp.*, 34 Colo. App. 145, 544 P.2d 983, 988 (1975); *Parzini v. Center Chem. Co.*, 136 Ga. App. 396, 400, 221 S.E.2d 475, 479 (1975); *Collins v. Musgrave*, 28 Ill. App. 3d 307, 311-12, 328 N.E.2d 649, 652 (1975); *Berkebile v. Brantly Helicopter Corp.*, — Pa. —, 337 A.2d 893, 901-02 (1975); *Rourke v. Garza*, 530 S.W.2d 794, 800 (Tex. 1975). See generally 2 HARPER & JAMES, *supra* note 4, § 21.7, at 1190-91; 3 FRUMER & FRIEDMAN, *supra* note 24, § 46.02[5], at 16-80.
215. That a system of strict liability for medical accidents—whether developed through the doctrine of informed consent or otherwise—has not as yet been worked out in great detail does not mean that there is no place for such a system. See Epstein, *Defenses and Subsequent Pleas in a System of Strict Liability*, 3 J. LEGAL STUD. 165 (1974). The virtue of a judicially adopted system of strict liability is its flexibility, since no more change need be made in a case than is necessitated by the facts before the court. A case-by-case approach avoids two of the major pitfalls of most of the statutory and private-law no-fault proposals: the inflexibility of paying compensation according to predetermined schedules, and the problem of defining compensable events. See J. O'CONNELL, *supra* note 7 ("elective" no-fault); Havighurst & Tancredi, *supra* note 37, at 71-72, 75-88; Rubsamen, *No-Fault Liability for Adverse Medical Results—Is It a Reasonable Alternative to the Present Tort System?*, 117 CALIF. MED. 78 (1972).

The common law's flexibility, necessary to achieve strict liability for medical accidents, is amply evidenced by the long-developing shift from negligence to strict liability as a basis for compensating victims of defective products. See Prosser, *supra* note 27; Prosser, *supra* note 24. The flexibility and effectiveness of the judicial process is also illustrated by the movement toward a *fault* basis for tort liability:

Absolute liability for one's acts is today the exception; there must commonly be some tinge of fault, whether willful or negligent. Time was, however, when absolute liability was the rule. . . . These changes . . . have been wrought by judges. The men who wrought them used the same tools as the judges of today.

B. CARDOZO, *supra* note 96, at 26-27 (footnotes omitted). Presumably, the flexibility of the judicial process is bidirectional. Cf. Note, *Hospital Liability in the New York Court of Appeals: A Study of Judicial Methodology*, 61 COLUM. L. REV. 871, 899 (1961) ("[T]he original formulation of the [charitable] hospital immunity rule resulted from a judicial policy determination. It would be anomalous to say that this policy determination could not also be reexamined by the judiciary in light of changed circumstances."). See also Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 467 (1897).

Why not then rid ourselves of this confusing and obscuring phrase "informed consent"? Concerning the development of the law of strict liability for defective products, Prosser wrote:

[I]t gradually became apparent that "warranty," as a device for the justification of strict liability to the consumer, carries far too much luggage in the way of undesirable complications, and is more trouble than it is worth. The suggestion was therefore a sufficiently obvious one, that we get rid of the word, which was originally adopted only because it provided a theory ready at hand to accomplish the desired result.²¹⁶

Although the phrase "informed consent" has caused untold confusion in the law of liability for medical accidents²¹⁷—as did "warranty" in the law of products liability²¹⁸—not the least of which has been its concealment of the drift toward strict liability, there are quite different policy considerations at stake.

Ridding the case law of this phrase would be acceptable as a means of removing the cloak that presently obscures the movement toward strict liability only if it did not also entail dispensing with the requirement that the physician disclose information to the patient. The effect of the disclosure requirement may be to impose liability without fault, but its purpose is to permit medical patients to wield intelligent decisionmaking power within the doctor-patient relationship.²¹⁹ The independent policy consideration that patients

216. PROSSER, *supra* note 2, § 98, at 656. See also Prosser, *supra* note 27, at 1133-34.

217. See *Canterbury v. Spence*, 464 F.2d 772, 780 n.15 (D.C. Cir.), 409 U.S. 1064 (1972) ("uncritical use of the 'informed consent' label can be misleading"). Plante, *supra* note 98, at 671-72.

218. See, e.g., *B.F. Goodrich Co. v. Hammond*, 269 F.2d 501, 505 (10th Cir. 1959); *Crystal Coca-Cola Bottling Co. v. Cathey*, 83 Ariz. 163, 166-69, 317 P.2d 1094, 1096-97 (1957); *Nichols v. Nold*, 174 Kan. 613, 622-31, 258 P.2d 317, 324-31 (1953); *Le Blanc v. Louisiana Coca Cola Bottling Co.*, 221 La. 919, 925 n.3, 60 So. 2d 873, 875 n.3 (1952); *Worley v. Proctor & Gamble Mfg. Co.*, 241 Mo. App. 1114, 1119-21, 253 S.W.2d 532, 536-37 (1952); *Madouros v. Kansas City Coca-Cola Bottling Co.*, 230 Mo. App. 275, 282-83, 90 S.W.2d 445, 449 (1936); *Markovich v. McKesson & Robbins, Inc.*, 106 Ohio App. 265, 273-75, 149 N.E.2d 181, 187-88 (1958); *La Hue v. Coca-Cola Bottling, Inc.*, 50 Wash. 2d 645, 647, 314 P.2d 421, 422 (1957). See generally Prosser, *supra* note 27, at 1124-34.

219. See Section IV-D *supra*. Professor Goldstein has argued persuasively that we could rid ourselves of the confusing term "informed consent" and still preserve the goals it was originally designed to serve. See Goldstein, *supra* note 64. In fact, since "[t]he concept has been employed to emphasize a patient's or subject's actual state of mind, knowledge, or understanding in giving (not denying) consent, rather than to emphasize and force attention on the conduct required of the therapist or experimenter in the process of informing the citizen for decision," *id.* at 690-91, abandonment of the term would facilitate a return to the original purpose.

be permitted and encouraged to make intelligent choices about medical care might be severely compromised if the stated purpose of disclosure were to become subsidiary to the compensation of medical-accident victims without regard to fault. Although a system of strict liability for medical accidents can exist without the disclosure requirement, individual self-determination and rational decisionmaking cannot.

The phrase "informed consent" therefore serves an important purpose apart from the method of determining liability, which was not the case with "warranty." Though "warranty" may have carried too much luggage, "informed consent" carries luggage vital to the promotion of individual self-determination and rational decisionmaking about matters of medical care. It should not be abandoned lightly, even if the cost is to retard the advance on the citadel.

To a large extent the development of informed consent has been dictated by the ends it is said to serve—those of promoting individual autonomy and protecting bodily integrity. But its development has also been affected by the skirmishes fought over the compensation of medical-accident victims. The desire to circumvent the requirement of having to establish medical negligence has served as a strong incentive to medical-accident victims to attempt to shape the doctrine of informed consent to meet immediate needs. Thus, rather than being invoked exclusively to protect the individual's dignity, it has also been invoked—and has therefore been shaped and applied—to protect the accident victim's economic interests.²²⁰

Although the doctrine of informed consent bears many structural similarities to strict liability in tort, doctors are not actually being held strictly liable for bad results. However, aggressive plaintiffs' counsel may seize upon the informed-consent doctrine, and by exploiting its flexibility and ambiguity push the courts closer to strict liability. Even in cases where consent has been given and disclosure has been made, the plaintiff, merely by alleging that disclosure was inadequate, is afforded an opportunity for

220. It has been said that "[t]he object of changing the law [of consent to medical treatment] is not to get doctors into court, but to get them to change their practices." Note, *Restructuring Informed Consent*, *supra* note 64, at 1569. Though this may be theoretically so, in practice it seems that one of the major objectives of changing the law is to get the doctor into court, and to impose liability upon him, not so much for the specific or general deterrent effect that the imposition of liability may have upon medical practices, but to make whole the medical-accident victim. One of the consequences of the constant state of flux in which the law of consent to medical treatment has been for the last two decades has been the formulation of new rules that have made compensable hitherto uncompensable medical accidents.

recovery not available in negligence alone. Although the fight may be uphill, continual changes in the standard of disclosure, the test of causation, the rules for the operation of the therapeutic privilege, and the necessity *vel non* for patient understanding, afford plaintiffs an opportunity to get to the jury not otherwise available. This is precisely how each of the landmark "informed consent" cases was made in the past, and how new ones will be made in the future.

V. THE HEAD-ON ASSAULT ON THE CITADEL

Although the doctrine of informed consent, especially in its present formative period, is a highly flexible one permitting judges and juries extensive leeway in awarding compensation, a large proportion of medical-accident victims is still unable to obtain compensation under this theory of liability. Only where there has been inadequate disclosure does a possibility for compensation exist. If there is inadequate disclosure and the patient consents to treatment, or if there is inadequate disclosure and the patient refuses treatment, liability may attach if the inadequate disclosure was the cause of the patient's decision. But if disclosure is adequate and the patient either accepts or refuses treatment, the warning given by the doctor concerning the risks of treatment or of foregoing treatment forecloses liability under the informed-consent doctrine. Equally significant is the case in which the physician makes a nonnegligent decision about the patient's condition involving an omission of treatment. In such situations there often will be no warnings of the consequences of foregoing treatment, since no treatment is contemplated.

The patient who suffers bad results under either of these circumstances—that is, when there is adequate disclosure or when there is a nonnegligent omission of treatment and consequently no disclosure of the risks of foregoing it—is still worse off than another patient who incurs precisely the same injuries from negligently rendered or omitted medical care. The problem that caused our initial concern—the differential treatment of medical-accident victims, depending upon whether the accident occurred as a result of negligence or not—remains unresolved as long as the doctor has complied with his duty to warn and the patient has assumed the risk of treatment.

Other efforts have been made in judicial forums to breach the citadel of negligence for medical-accident victims. Although many of these efforts have met with quite limited success, if not downright failure, the viability of head-on attacks on the negligence requirement (to be distinguished from the surreptitious attacks

launched under the banners of *res ipsa loquitur* and informed consent) remains an open question.

Patients whose injuries have resulted from transfusions of contaminated or infected blood have persistently pursued these avenues of assault, as have those whose injuries have resulted from a drug or a medical device. But the courts have, for the most part, been unreceptive to these claims, tending to treat the provision of blood, the prescription of a drug, or the use of a medical device, as a "service" rather than a "sale," thus making unavailable a warranty of strict liability theory.²²¹

Other patients injured by drugs and devices have sought to impose liability not only upon their physicians but on the drug or

221. See Annot., 45 A.L.R.3d 1364 (1972) (blood transfusions); Annot., 45 A.L.R.3d 928 (1972) (drugs); Annot., 54 A.L.R.3d 258 (1973) (drugs and devices).

There has been a great deal of judicial reluctance to apply strict liability in tort to services, or to products supplied as incidental to a service. PROSSER, *supra* note 2, § 104, at 679. In 1971, Prosser stated that such efforts had "entirely failed." *Id.*; accord, Comment, *Sales-Service Hybrid Transactions: A Policy Approach*, 28 Sw. L.J. 575, 583 & *passim* (1974). See generally Farnsworth, *Implied Warranties of Quality in Non-Sales Cases*, 57 COLUM. L. REV. 653 (1957); Note, *Products and the Professional: Strict Liability in the Sale-Service Hybrid Transaction*, 24 HASTINGS L.J. 111 (1972); Note, *Implied Warranties and Service Contracts*, 39 NOTRE DAME LAWYER 680 (1964); Comment, *Continuing the Common-Law Response to the New Industrial State: The Extension of Enterprise Liability to Consumer Services*, 22 U.C.L.A.L. REV. 401 (1974) [hereinafter cited as Comment, *Extension of Enterprise Liability*]; Comment, *Strict Liability for Services, Chevron v. Sutton*, 4 N.M.L. REV. 271 (1974). But see Note, *Strict Liability: A "Lady in Waiting" for Wrongful Birth Cases*, 11 CAL. W.L. REV. 136 (1974).

The sales-service distinction was originally made in the case of blood transfusions in *Perlmutter v. Beth David Hosp.*, 308 N.Y. 100, 123 N.E.2d 792 (1954). The vast body of literature on this subject is collected in Comment, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform*, 24 AM. U.L. REV. 367, 368-69 n.7 (1975).

Courts have been more willing to impose liability upon commercial blood banks than upon hospitals, because blood banks are more clearly involved in the "sale" of blood than hospitals, where the provision of blood is incidental to a "service." See, e.g., *Community Blood Bank, Inc. v. Russell*, 196 So. 2d 115 (Fla. 1967). Some states have enacted statutes prohibiting the imposition of liability, under a strict liability or breach of warranty theory, for the provision of blood. In some cases, such statutes have had the effect of overruling case law that had applied such theories. Franklin, *Tort Liability for Hepatitis: An Analysis and a Proposal*, 24 STAN. L. REV. 439, 474-75 n.203 (1972) (collecting statutes).

device manufacturers. Suits grounded in negligence have had to contend with many of the same problems of privity that existed in other areas of products liability, but just as the privity barrier has been surmounted elsewhere,²²² so has it also with drugs and devices.²²³ More recently, plaintiffs have also sought to hold the drug manufacturer strictly liable for failing to warn the physician who prescribed the drug of its side effects, and these efforts have met with general success.²²⁴

A single recent development in the effort to overrun the citadel of negligence by medical-accident victims is more significant than the sum of all these other efforts because it is aimed at the very foundation of the cause of action in negligence, and has occurred in the heart of medical practice, rather than in the periphery of drugs, blood transfusions, and medical devices.

222. Prosser, *supra* note 27; Prosser, *supra* note 24.

223. With respect to drugs see, e.g., *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1st Dist. 1960). See generally Annot., 79 A.L.R.2d 301 §§ 37, 38 (1961). With respect to devices see, e.g., *Bowles v. Zimmer Mfg. Co.*, 277 F.2d 868 (7th Cir. 1960). See generally Rubin, *Manufacturer and Professional User's Liability for Defective Medical Equipment*, 8 AKRON L. REV. 99 (1974).

Ostensibly because there was a "sale" rather than a provision of a medical "service," the courts have not been as hesitant to apply breach of warranty theory and strict liability in tort against manufacturers as they have against physicians. See, e.g., *Silverhart v. Mount Zion Hosp.*, 20 Cal. App. 3d 1022, 1028-29, 98 Cal. Rptr. 187, 190-91 (1st Dist. 1971); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 980, 5 Cal. Rptr. 381, 393 (2d Dist. 1971); *Gottsdanker v. Cutter Laboratories*, *supra*. The courts' receptivity to the application of strict liability and warranty to manufacturers may be due to the presumption that manufacturers have "deep pockets," and to a belief in manufacturers' ability to practice deterrence and cost-spreading. Thus, in *Magrine v. Krasnica*, 94 N.J. Super. 228, 227 A.2d 539 (County Ct. 1967), *aff'd sub nom.*, *Magrine v. Spector*, 100 N.J. Super. 223, 241 A.2d 637 (1968) (per curiam), *aff'd*, 53 N.J. 259, 250 A.2d 129 (1969) (per curiam), the New Jersey courts refused to hold a dentist strictly liable for a patient's injuries suffered when a hypodermic needle broke in the patient's jaw. Although relying heavily on the fact that the dentist was merely a user of the needle, was not in the business of selling such needles, and did not promote its use, there can be no doubt that the dentist, unlike the manufacturer of the needle, could not "fairly be assumed to have [had] substantial assets and volume of business, and a large area of contacts over which the risk [could] be widely spread." *Id.* at 238, 227 A.2d at 545. See generally C. CALABRESI, *supra* note 11, at 39-67.

224. See generally Annot., 53 A.L.R.3d 239 §§ 8(a), 10, 14 (1973). When an individualized doctor-patient relationship is absent, such as in a mass-immunization program, the manufacturer's duty is to the patient. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1295 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 131 (9th Cir. 1968). See generally Note, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235 (1976).

Ordinarily, the standard of care in medical malpractice is determined by reference to how a reasonable member of the profession would act in like circumstances.²²⁵ It was this point that was at issue in *Canterbury*, regarding the test of the adequacy of disclosure, and it was only because the court held that no special expertise is required to determine what information about treatment is material to a patient that it rejected the profession's standard as the legal standard of care.²²⁶ The court implied that it would have abided by the profession's standard of care if it had determined that the materiality of information is a matter requiring professional expertise.²²⁷

Yet in the recent case of *Helling v. Carey*,²²⁸ which either may be aberrant²²⁹ or may signal a new trend in medical-accident cases, the Supreme Court of Washington invaded even this sacrosanct area of deference to the medical profession. In *Helling*, the plaintiff developed glaucoma, a disease of the eye which causes severely impaired vision and, ultimately, blindness.²³⁰ For more than nine years, she had been a regular patient of the defendants, who were specialists in the treatment of disorders of the eye, having first consulted them for nearsightedness and on ten other occasions for what were described as eye "irritations." The defendants believed that the plaintiff's visual problems were related solely to complications associated with the contact lenses that they had prescribed for the nearsightedness. Not until the eleventh consultation did they consider that the plaintiff's visual problems were related to anything other than the contact lenses. On that occasion one of the defend-

225. *Toth v. Community Hosp.*, 22 N.Y.2d 255, 262, 239 N.E.2d 368, 372, 292 N.Y.S.2d 440, 447 (1968). Malpractice cases thus differ from other negligence cases, in which "customary performance may help to appraise the defendant's conduct but does not conclusively determine whether it was reasonable . . ." 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 8.04, at 200 (1973). See generally PROSSER, *supra* note 2, § 33, at 166-69; King, *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213 (1975).

226. See pp. 93-95 *supra*.

227. 464 F.2d at 784-85.

228. 83 Wash. 2d 514, 519 P.2d 981 (1974) (en banc).

229. The Court of Appeals of Washington, in one of the two cases citing *Helling v. Carey*, concluded that "the holding there was intended to be restricted solely to its own 'unique' facts, i.e., cases in which an ophthalmologist is alleged to have failed to test for glaucoma under the same or similar circumstances." *Meeks v. Marx*, 15 Wash. App. 571, —, 550 P.2d 1158, 1162 (1976). See also *Hood v. Phillips*, 537 S.W.2d 291, 293-94 (Tex. Civ. App. 1976) (rejecting *Helling* as authority for the rule that a doctor's performance is not to be judged by its conformance "with the general practice of reasonable physicians utilizing the same treatment").

230. See 3 R. GRAY, *ATTORNEY'S TEXTBOOK OF MEDICINE* ¶¶ 55B.00-.70 (3d ed. 1976).

ants performed a test that was positive for glaucoma. By this time the plaintiff had lost her peripheral vision, and her central vision was drastically reduced.

After consulting other physicians, the plaintiff brought suit against her original ophthalmologists.²³¹ Expert testimony of witnesses called by both the plaintiff and the defendant to establish the profession's standard of care unanimously indicated that it was not routine practice to perform glaucoma tests on patients under 40 years of age, because in that age group the disease occurs at the low rate of approximately 1 in 25,000 persons. Testimony also revealed, however, that the professional standards require a pressure test even in those under 40 "if the patient's complaints and symptoms reveal to the physician that glaucoma should be suspected."²³²

The jury verdict for the defendant eliminated the possibility of the appeal turning on the factual question of whether the plaintiff's complaints and symptoms should reasonably have led the defendants to suspect glaucoma and administer a pressure test, even though the plaintiff was under 40. Rather, if compensation were to be made available at the appellate level, the standard of care itself had to be addressed.²³³ To do so, the court was confronted by the rule that the medical profession ordinarily establishes its own standard. Yet it was able to circumvent this rule through appropriate invocation of two legal demigods, Holmes and Hand.

At the turn of the century, Justice Holmes said of the standard of care: "What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not."²³⁴ And in equally, if not more, famous words, Hand reminded us that

231. That there was no allegation of a failure to disclose information to the plaintiff is understandable, since it is not reasonable to require a physician to inform a patient of the risks, benefits, alternatives, and consequences of forgoing a treatment that is not even contemplated. Liability must attach, if at all, for the doctor's failure to have contemplated and proposed the treatment.

232. 83 Wash. 2d at 516, 519 P.2d at 982.

233. The court rejected the plaintiff's argument that the trial court had improperly refused to charge the jury that "by reason of their special ability, knowledge and information, [defendants] were negligent in failing to give the pressure test to the plaintiff at an earlier point in time . . ." *Id.* at 517, 519 P.2d at 982. Because the defendants did not have any greater special ability, knowledge, or information than ophthalmologists in general—that is, more than others in the group to whom the standard of care applied—the court held that they could not be held to a higher standard. *See id.*

234. *Id.* at 518-19, 519 P.2d at 983 (quoting *Texas & Pac. Ry. v. Behymer*, 189 U.S. 468, 470 (1903) (Holmes, J.)).

"a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission."²³⁵ With the aid of these precedents, the court was able to swallow whatever misgivings it might have had and announce that "[u]nder the facts of this case reasonable prudence required the timely giving of the pressure test to this plaintiff."²³⁶

The "facts of this case" that the court referred to as justifying its refusal to accept the professional standard of practice as the legal standard of care, were that the test necessary to avert the harm that befell the plaintiff was simple, harmless, and inexpensive,²³⁷ and that the harm itself, blindness, was serious.

Helling achieved, through selective choice of precedent, the compensation of a medical-accident victim. In so doing, it left intact the form of the negligence requirement, but simultaneously so dramatically changed its substance as to raise a substantial question about the continued viability of consistently compensating medical-accident victims exclusively on a negligence principle.²³⁸

235. *Id.* at 519, 519 P.2d at 983 (quoting *The T.J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932) (Hand, J.)).

236. *Id.* at 519, 519 P.2d at 983.

237. *But see* Charfoos, *Helling: The Law of Medical Malpractice Rewritten*, 2 OHIO N.L. REV. 692, 696-98 (1975) (arguing that the tonometry test that the *Helling* court found had been improperly omitted is not without risk) (citing Bradford, *A Unique Decision*, 2 J. LEGAL MED., Sept.-Oct., 1974, at 52). There is also evidence that the test may not be reliable. See Heilmann, *On the Reversibility of Visual Field Defects in Glaucomas*, 78 TRANS. AM. ACAD. OPHTHALMOL. & OTOLARYNGOL. 304 (1974); H. SCHEIE & D. ALBERT, *ADLER'S TEXTBOOK OF OPHTHALMOLOGY* 341 (8th ed. 1969), cited in Charfoos, *supra* at 698. Moreover, though the test may be inexpensive for any given patient, it may be quite expensive relative to the cost of the harm that it is able to prevent. See Note, *Comparative Approaches to Liability for Medical Maloccurrences*, *supra* note 37, at 1147 n.38. See also Spaeth, *Is Screening for Glaucoma Worthwhile?*, 292 NEW ENG. J. MED. 1299 (1975).

238. It has been suggested that the decision is not at all inconsistent with the rule permitting the medical profession to establish its own standard of care by reference to customary practice. Since the basis for the rule is that laymen are not competent to decide whether a doctor exercised reasonable care, the rule operates only when the matter in issue is too technical for laymen to judge. Since the question raised in *Helling* was "relatively simple," there is no reason why the standard of care should have been established by resort to customary practice. 44 U. CIN. L. REV. 361, 364-65 (1975). *But see* authorities cited note 237 *supra*.

Three justices of the nine-member court, concurring in an opinion of Justice Utter, pierced the formalistic veil in which the majority enshrouded its result. Though agreeing that liability ought to be imposed upon the defendants, their basis for doing so was stated more openly. The concurring justices, like the majority, believed that the reason for imposing liability was that the test the defendants had failed to administer to the plaintiff was simple, harmless, and inexpensive.²³⁹ But whereas the rationale—perhaps “rationalization” is a more apt description—given by the majority for reaching its result was that ultimately it is for the courts and not the profession to establish the standard of care, the concurring justices employed a more innovative and straightforward analysis.

Because of the apparent absence of wrongdoing²⁴⁰ on the part of the defendant doctors, it seemed to the concurring justices unnecessarily stigmatizing to impose liability on the ground of negligence. Rather than predicating liability upon blameworthiness and implicitly assigning blame where in fact it was absent, the justices chose to predicate liability upon a social policy supportable by the facts of the case. The doctrine of strict liability avoids both the stigmatization of the defendants and the ratiocinations of the majority justices. What the court was really doing, observed the concurring opinion, was choosing to shift the costs of an unfortunate event from the victim (plaintiff) to parties (the defendants) who were in a better position to bear or to spread the cost.²⁴¹

But even the concurring justices failed to note—though there was no necessity for their doing so—that the same conditions exist in all statistical-risk medical-accident cases. As a class, and probably in the vast majority of individual instances, doctors are situated to bear the costs of accidents more easily, and are able to spread the costs by prorating their insurance premiums to all of their patients through the fees charged for their services. Certainly the features of this case which the concurring justices found to warrant strict liability—(1) conformance with the profession’s standard of care, (2) problems of proof where events are not matters of common experience, (3) a precise definition of the injurious activity to permit cost allocation, and (4) a financially responsible defend-

239. See *Helling v. Carey*, 83 Wash. 2d 514, 520, 519 P.2d 981, 984 (1974).

240. The concurring opinion suggests that there was an absence of “moral” wrongdoing on the part of the defendants. *Id.* at 520, 519 P.2d at 984. The majority and concurring opinions make clear, however, that there was also an absence of wrongdoing in the sense that there was no departure from the profession’s standard of care.

241. *Id.* at 520, 519 P.2d at 984.

ant²⁴²—are present in most statistical-risk medical-accident cases. In fact, all except the first of these criteria ordinarily are present in *all* medical accidents.

Problems of proof are omnipresent, for it is this factor which ordinarily creates the often impenetrable barrier to success in suits grounded in negligence. For the most part, the competent medical practitioner is able to obtain insurance against medical accidents.²⁴³ The only element that is questionable is the precision with which the accident-causing activity can be identified. In many situations, an act of medical commission or omission can be identified as the cause of the accident, though in many others there is a substantial amount of admixture between the patient's pre-existing condition and the unsuccessful medical intervention.²⁴⁴

242. *Id.* at 521-22, 519 P.2d at 984-85. Four conditions must be met for the judicial imposition of strict liability in the absence of a controlling statute: (1) the defendant must be aware of the abnormally dangerous nature of the activity in which he engages; (2) the damage that is threatened by the activity for which liability is sought to be imposed must be well defined; (3) there must be a well-defined class of persons threatened by the defendant's abnormally dangerous activity; and (4) the harm must occur from the defendant's activity. PROSSER, *supra* note 2, § 79. Though each of these conditions is met in medical accidents, the application of strict liability to medical accidents is not without substantial problems. See authorities cited note 254 *infra*.

243. *But see* note 31 *supra*.

244. The most difficult practical problem of strict liability for medical accidents lies in determining what kinds of bad results were caused by the natural course of the illness or injury that originally brought the patient to the doctor, and what kinds were iatrogenically caused—that is, caused by the medical intervention made to deal with the particular illness or injury.

Take . . . the patient who presents with a mild febrile illness which is treated with aspirin, then goes home and develops a fatal meningitis? What if the fever was low grade, the sore throat mild and these occurred when a number of patients in the community were manifesting epidemic virus respiratory infections? Were the patient's parents carefully instructed to contact the physician within 24 hours and did they then not do so? Is it reasonable to suppose that the meningitis wasn't present at all when the patient was first seen, developing only later from the upper respiratory infection? It is one thing to talk about a "deviation from expected results" where there has been surgical operation, but how can one talk about the "expected results" in this meningitis case without analyzing every facet of the presenting problem and subsequent course?

Rubsamen, *supra* note 215, at 87. See also J. O'CONNELL, *supra* note 7, at 70-111 & app. III (1975); Cooper, *Sweden's No-Fault Patient-Injury Insurance*, 294 NEW ENG. J. MED. 1268, 1268-69 (1976); Havighurst & Tancredi, *supra* note 37, at 75-88; Keeton, *supra* note 31, at 614-15; O'Connell, *supra* note 29, at 790-93; Comment, *Extension of Enterprise Liability*, *supra* note 221, at 424-30; Note, *Comparative Approaches to*

There are other indications that the issue really at stake in *Hel-ling* was whether there is to be strict liability for medical accidents, rather than who is to establish the standard of care. The fact that the tonometry test, which the court held should have been used by the defendants, may not be as riskless, inexpensive, and reliable²⁴⁵ as both the majority and concurring opinions suggest, casts doubt upon the assertion that the defendants acted unreasonably even when judged by a *lay* standard. If there is doubt about the reasonableness of the failure to employ the test, then the imposition of liability can only be on the basis of strict liability—the court's efforts to camouflage this result notwithstanding.

Furthermore, the plaintiff failed to raise at trial the issue on which the majority decided the case on appeal. The concurring opinion noted this and excused it:

Where this court has authoritatively stated the law, the parties are bound by those principles until they have been overruled. Acceptance of those principles at trial does not constitute a waiver or estop appellants from adapting their cause on appeal to such a rule as might be declared if the earlier precedent is overruled.²⁴⁶

But the fact is that the rule of law upon which the majority claimed to decide the case—that the standard of care is for the courts to determine, and customary professional conduct, while evidence of the proper standard, is not dispositive of the issue—had previously been adopted by the Supreme Court of Washington only eight years earlier. In *Mills v. Inter Island Telephone Co.*,²⁴⁷ the court stated:

We think it is important that the parties and the trial court recognize that even if the industry has not accepted [a particular standard of care] or used it, the issue of negligence is not to be determined *simply* and *solely* by a reference to what is commonly done in the industry. It is possible that the entire industry has been negligent in its practices. See *The T.J. Hooper*, 60 F.2d 737 (2 Cir. 1932); Prosser, [The Law of Torts] § 32, p. 136 [(3d ed. 1964)].

Liability for Medical Maloccurrences, *supra* note 37, at 1153-54. *But cf.* *Canterbury v. Spence*, 464 F.2d 772, 795 (D.C. Cir.) ("A Tortfeasor takes his victim as he finds him . . ."), *cert. denied*, 409 U.S. 1064 (1972).

One legislative no-fault proposal takes a rather simplistic view of the causation problem, providing no-fault benefits "for loss from any injury suffered as a result of health care services provided . . ." S. 215, 94th Cong., 1st Sess. § 1711(a) (1975). The process of administrative regulation by which these broad terms will necessarily have to be interpreted is akin to the judicial definition that would be necessary under a judicially constructed system of strict liability.

245. See note 237 *supra*.

246. 83 Wash. 2d at 522, 519 P.2d at 985.

247. 68 Wash. 2d 820, 416 P.2d 115 (1966).

Especially, this may be true if the cost and ease of precautions that may be taken are weighed against the severity of the risk to be guarded against. See Prosser, *op. cit.*, *supra*, § 30, p. 122.²⁴⁸

Not only had the "court . . . authoritatively stated the law," but it had even relied upon one of the same authorities, *The T. J. Hooper*, that it did in *Helling*.

Thus the fact that the theory upon which the case was decided was the law of Washington prior to the decision in the *Helling* case, and despite the concurring opinion's assertion to the contrary, the plaintiff's failure to raise this claim in her pleadings and at trial would ordinarily have led the court to find that the claim had been waived.²⁴⁹ Its failure so to hold is further evidence of its desire to provide compensation for the victim of a medical accident on the basis of the factual or emotional appeal of the case, rather than on the basis of pre-existing principles of law.

The commentary²⁵⁰ to date on *Helling v. Carey*—which has been described as sending off "shock waves . . . [which] have already begun to spread and may be expected to permeate all areas of pro-

248. *Id.* at 833, 416 P.2d at 123. The *Mills* case involved an appeal from the dismissal of the action on defendant's motion for summary judgment. Plaintiff's decedent died when an airplane in which he was riding became, on a landing approach, entangled in power and telephone wires owned in part by the defendant. The issue for decision on appeal was whether a document signed by plaintiff in an agreement with another tortfeasor (since dropped as a defendant), styled a "covenant not to sue," released the claim against the present defendant. Plaintiff, however, had also moved for partial summary judgment in part on the issue of whether defendant as a matter of law "was negligent in failing to mark its poles and wires so that they were clearly visible to pilots approaching the airfield for a landing . . .," *id.* at 832, 416 P.2d at 123, in conformity with a standard issued by the United States Department of Commerce and the Civil Aeronautics Administration. Since it granted defendant's motion and dismissed the action, the trial court did not rule on this motion. In response to the defendant's claim that the standard was not accepted by the industry, the court felt compelled to speak to the relationship between custom and the legal standard of care.

249. See *Ivan's Tire Serv. Store, Inc. v. Goodyear Tire & Rubber Co.*, 10 Wash. App. 110, 125-27, 517 P.2d 229, 239 (1973), *aff'd*, 86 Wash. 2d 513, 546 P.2d 109 (1976). See generally F. JAMES, *supra* note 43, § 11.3, at 526-28.

250. Charfoos, *supra* note 237; King, *supra* note 225, at 1244-57; Comment, *The Role of Custom in Medical Malpractice Litigation*, 55 B.U.L. REV. 647 (1975); 20 N.Y.L.F. 669 (1975); 6 TEXAS TECH. L. REV. 279 (1974); 44 U. CIN. L. REV. 361 (1975); 11 WILLAMETTE L.J. 152 (1974). *But cf.* 28 VAND. L. REV. 441, 448 n.43 (1975).

fessional negligence litigation in time,"²⁵¹—has almost exclusively viewed the case as raising the issue of who is to set standards of professional practice, the professions or the courts. While unquestionably this is a significant issue in *Helling*, when viewed in the context of other developments in the law of medical accident liability, the fundamental issue of policy seems to be whether compliance with or deviation from any standard of care, by whomever set, is to be determinative of whether medical-accident victims are to receive compensation for their injuries—that is, whether there is to be strict liability for injuries from medical accidents.

The overall lack of success of the direct efforts involving blood transfusions, drugs, and medical devices, to breach the negligence stronghold and impose strict liability upon doctors, indicates that the war over compensating medical-accident victims will probably continue to be carried out for the foreseeable future through the use of guerilla tactics and flanking maneuvers such as the informed-consent doctrine. As has occurred over the past half century or more in the area of products liability, slow inroads may first be made under warranty theories when injuries may be characterized as being occasioned by a defective "good" rather than by a "service." This has already begun to occur with injuries caused by blood transfusions, drugs, and medical instruments. Though the courts have on the whole been unreceptive to a forthright application of strict liability, they have been somewhat more willing to apply breach-of-warranty theories, though even here the majority of jurisdictions that have considered the theory have rejected it.²⁵²

251. Stieglitz, *Liability of Accountants and Investment Counselors*, 15 *FOR THE DEFENSE*, Sept., 1974, at 92. See also 29 *THE CITATION*, May 1, 1974, at 17-18.

252. Although the courts have been less than enthusiastic about openly applying strict liability, there have been some legislative proposals to create a system of strict liability for medical accidents. Senators Inouye and Kennedy have introduced a bill in the Senate, entitled the *National Medical Injury Compensation Insurance Act of 1975*, which would, in part, permit the Secretary of Health, Education, and Welfare to enter into contracts with health-care providers to provide both traditional tort liability insurance and no-fault insurance. See S. 215, 94th Cong., 1st Sess., § 1701 (1975). No-fault benefits would be available "for loss from any injury suffered as a result of health care services provided by an insured," *id.* § 1711(a), and for economic and non-economic losses. *Id.* § 1713. See also S. 482, 94th Cong., 1st Sess. (1975) (also introduced by Senators Inouye and Kennedy, providing for a national medical malpractice insurance and arbitration system, the use of which would be a prerequisite to the filing of a traditional tort suit). The provisions of this bill are discussed in Note, *Comparative Approaches to Liability for Medical Maloccurrences*, *supra* note 37, at 1158-60. Other federal proposals for dealing with the problem

Thus, against this background of overall judicial hostility toward widening the possibilities of forthrightly compensating medical-accident victims under strict liability and breach-of-warranty theories, the case of *Helling v. Carey* (and especially the concurring opinion) may signal another significant breach in the negligence fortress.²⁵³

VI. STRICT LIABILITY AND THE DOCTOR-PATIENT RELATIONSHIP

Strict liability for medical accidents is presently in an incipient stage of development. Should it be nipped in the bud and limited to situations in which the doctrine of informed consent is properly applied? Should it be expanded beyond the bounds of that doctrine as suggested by the concurring opinion in *Helling*? Or should it be eliminated altogether, by legislative fiat if necessary?

Whether or not strict liability for medical accidents would promote the goals of accident law better than the present negligence system has been debated substantially, though inconclusively,²⁵⁴ in

of compensating medical-accident victims, none of which proposes a no-fault system, are S. 188, 94th Cong., 1st Sess. (1975); H.R. 1378, 94th Cong., 1st Sess. (1975); and H.R. 6100, 94th Cong., 1st Sess. (1975).

253. In response to *Helling*, the Washington legislature enacted a statute providing that:

In any civil action for damages based on professional negligence against a hospital which is licensed by the state of Washington or against the personnel of any such hospital, or against a member of the healing arts . . . , the plaintiff in order to prevail shall be required to prove by a preponderance of the evidence that the defendant or defendants failed to exercise that degree of skill, care and learning possessed by other persons in the same profession and that as a proximate result of such failure the plaintiff suffered damages, but in no event shall the provisions of this section apply to an action based on the failure to obtain the informed consent of a patient.

WASH. REV. CODE § 4.24.290 (Supp. 1975). The legislative history indicates that the statutory intent is to "re-establish the pre-*Helling* standards of negligence that have been developed through case law in Washington. (See *Pederson v. Dumochel* [72 Wash. 2d 73, 431 P.2d 973 (1967)] and *Hayes v. Hulswit*, [73 Wash. 2d 796, 440 P.2d 849 (1968)].)" 51 WASH. L. REV. 167, 168 n.6 (1975). It continues by explicitly stating that the effect of the bill is to require the "medical malpractice plaintiff to show that the defendant failed to exercise the degree of skill, care and learning possessed by others in the same profession and that such failure caused damages." *Id.* It is not at all clear that the statute will have its intended effect. *Id.* at 183-85.

254. Analysis and choice of a system of compensating accident victims has been complicated by the lack of unanimity as to what the proper goals

recent years.²⁵⁵ Because this debate has been part of the larger one over how best to compensate accident victims and to promote the goals of accident law,²⁵⁶ little concern has been paid to the unique aspects of medical accidents and to what effect strict liability might have on the doctor-patient relationship.

The doctor-patient relationship partakes of many aspects of an arms-length consumer relationship.²⁵⁷ There is often a disparity

of accident law are. See *Extension of Enterprise Liability*, *supra* note 221, at 430.

255. See G. CALABRESI, *supra* note 11; Brown, *Toward an Economic Theory of Liability*, 2 J. LEGAL STUD. 323 (1973); Calabresi, *Optimal Deterrence and Accidents*, 84 YALE L.J. 656 (1975); Calabresi & Hirschhoff, *supra* note 11; Calabresi & Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972); Diamond, *Accident Law and Resource Allocation*, 5 BELL J. ECON. & MANAGEMENT SCI. 366 (1974); Diamond, *Single Activity Accidents*, 3 J. LEGAL STUD. 107 (1974); Epstein, *A Theory of Strict Liability: A Comment*, 2 J. LEGAL STUD. 151 (1973); Epstein, *supra* note 215; Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29 (1972); Posner, *Strict Liability: A Comment*, 2 J. LEGAL STUD. 205 (1973).
256. J. O'CONNELL, *supra* note 7, at 72-73, 92-94, 189-94 & *passim*; CENTER FOR THE STUDY OF DEMOCRATIC INSTITUTIONS, *MEDICAL MALPRACTICE: A DISCUSSION OF ALTERNATIVE COMPENSATION AND QUALITY CONTROL SYSTEMS* (1971); Carlson, *Conceptualization of a No-Fault Compensation System for Medical Injuries*, 7 LAW & SOC'Y REV. 329 (1973); Ehrenzweig, *Compulsory "Hospital-Accident" Insurance: A Needed First Step Toward the Displacement of Liability for "Medical Malpractice,"* 31 U. CHI. L. REV. 279 (1964); Ford, *The Fault with "No Fault,"* 61 A.B.A.J. 1071 (1975); Franklin, *supra* note 221; Havighurst "Medical Adversity Insurance"—*Has its Time Come?*, 1975 DUKE L.J. 1233; Havighurst & Tancredi, *supra* note 37; HEW, *MEDICAL MALPRACTICE*, *supra* note 4, at 30; Keeton, *supra* note 31; Lanzone, *Products Liability and Professional Liability No-Fault: A Defense Lawyer's Views*, 47 N.Y. ST. B.J. 185 (1975); O'Connell, *supra* note 29, at 778, 785-86; O'Connell, *No-Fault Insurance for Injuries Arising from Medical Treatment: A Proposal for Elective Coverage*, 24 EMORY L.J. 21 (1975); Roth & Rosenthal, *Non-Fault Based Medical Injury Compensation Systems*, in HEW, *MEDICAL MALPRACTICE*, *supra* note 4, at 450 app.; Rubsamen, *supra* note 215; Comment, *Extension of Enterprise Liability*, *supra* note 221, at 424-430; Note, *Comparative Approaches to Liability for Medical Maloccurrences*, *supra* note 37.

Because a system of no-fault compensation for medical accidents would probably provide compensation to a larger number of persons than does the present system, it might be fairer, but also far more expensive. Mechanic, *Some Social Aspects of the Medical Malpractice Dilemma*, 1975 DUKE L.J. 1179, 1192-94. The increased costs of a more broadly based system of compensation might be offset, however, by eliminating or restricting damages for pain and suffering, as has been done with no-fault automobile insurance.

257. See generally S. SHINDELL, *THE LAW IN MEDICAL PRACTICE* ch. 2 (1966);

of bargaining power between the parties, arising from the doctor's superior knowledge of medicine and from the patient's suffering. Providing medical care is the means by which the doctor earns his living, and the extent to which it is dispensed on a charitable basis has substantially declined in recent decades with the advent of private and governmental insurance. Medical care is increasingly being provided by large, impersonal institutions nominally under the direction of physicians, but actually under the direction of a shared authority of doctors, hospital administrators, technicians, and assorted other professionals and paraprofessionals.²⁵⁸

Yet the doctor-patient relationship has an added, and probably essential, dimension lacking in purely commercial relationships. No matter how commercialized medicine may become, this dimension will always remain, because the very subject matter of the doctor-patient relationship is the human body. Because of the irreplaceable, personal, and some would say sacred,²⁵⁹ nature of this subject matter, additional responsibilities are placed on the doctor which neither the vendor of goods nor the provider of services is morally or legally obligated to bear.

First of all, the doctor-patient relationship is one depending in large part for its efficacy on the patient's trust in the doctor.²⁶⁰ Although other professional relationships depend upon trust, rarely does a lack of trust have the same far-reaching consequences for

Epstein, *Medical Malpractice: The Case for Contract*, 1976 A.B. FOUNDATION RESEARCH J. 87, 93-94.

258. See generally R. DUFF & A. HOLLINGSHEAD, *SICKNESS AND SOCIETY* (1968); Field, *The Doctor-Patient Relationship in the Perspective of "Fee-for-Service" and "Third-Party" Medicine*, in *PATIENTS, PHYSICIANS, AND ILLNESS* 222 (E.G. Jaco ed. 1972); Freidson, *Client Control and Medical Practice*, in *PATIENTS, PHYSICIANS, AND ILLNESS*, *supra* at 214; Georgopoulos & Mann, *The Hospital As an Organization*, in *PATIENTS, PHYSICIANS, AND ILLNESS*, *supra* at 304; Mechanic, *Problems in the Future Organization of Medical Practice*, 35 *LAW & CONTEMP. PROB.* 233, 235-39 (1970).
259. See P. RAMSEY, *supra* note 68; Pope Pius XII, *The Moral Limits of Medical Research and Treatment*, 44 *ACTA APOSTOLICAE SEDIS* 779 (1952), reprinted in J. KATZ, *supra* note 68. The almost universal view of the human body as sacred may explain in part why early medical practice was often performed by priests. J. FLETCHER, *MORALS AND MEDICINE* 3 (paper ed. 1960).
260. It is well recognized that much of the benefit of medical intervention is attributable to what is referred to as the "placebo effect" of the doctor-patient relationship. In fact, "throughout much of the history of medicine, until the 19th century, the placebo effect was the most a physician was able to offer his patients . . ." Benson & Epstein, *The Placebo Effect—A Neglected Asset in the Care of Patients*, 232

the client as it does in the doctor-patient relationship where the patient's life may be at stake.²⁶¹

Yet while the doctor-patient relationship is heavily dependent upon trust, this dependence is not total. Because the patient, not the doctor, must bear the consequences, both good and bad, of medical treatment, it is in the first instance the patient's right to determine what is to be done to his body.²⁶²

Thus in evaluating the applicability of strict liability to medical accidents, consideration must be given not only to the effect that it might have on the realization of the goals of accident law, but also to the effects strict liability is likely to have on these two other factors unique to the doctor-patient relationship: trust and self-determination. These effects are speculative; nevertheless, an attempt at evaluation should not be forsaken.

1. "*Defensive*" *Medicine*. Ideally, medical decisions ought to be made only on the basis of medical considerations (supplied by the doctor) and personal value preferences (supplied by the patient). However, it is often stated, and it is certainly logical to assume,

J.A.M.A. 1225 (1975). The trusting nature of the doctor-patient relationship is more than a matter of efficacy. It is also an ethical issue. Guttentag, *Ethical Problems in Human Experimentation*, in *ETHICAL ISSUES IN MEDICINE* 208 *et seq.* (F. Torrey ed. 1968); P. RAMSEY, *supra* note 68, at 1-58.

An excellent discussion of the doctor-patient relationship making clear the necessity for trust between doctor and patient, and especially of the doctor by the patient, may be found in Note, *Restructuring Informed Consent*, *supra* note 64, at 1535-51.

The erosion of the patient's trust in the physician is probably one of the primary factors in the patient's decision to bring suit against the doctor. 1 LOUISELL & WILLIAMS, *supra* note 3, ¶¶ 5.03, 5.08; Frankel, *Medico-Legal Communication*, 6 WILLAMETTE L.J. 193, 202 (1970). This is especially plausible in light of the fact that relatively few iatrogenically injured patients bring suit against their doctors. In large part, this is because the medical-accident victim often is not aware that his condition has been worsened by the medical intervention. The conspiracy of silence by doctors who refuse to testify for plaintiffs in malpractice cases, *see* text accompanying notes 36-39 *supra*, extends to an unwillingness to inform their own or other patients of iatrogenically induced bad results. J. O'CONNELL, *supra* note 7, at 33-39. *See also* Havighurst & Tancredi, *supra* note 37, at 73.

261. The criminal lawyer in a capital case occupies a position similar to that of the physician, though of course relatively few doctor-patient encounters entail even a remote possibility that death of the patient will ensue.

262. Cf. *Faretta v. California*, 95 S. Ct. 2525, 2541 (1975). *See also* text accompanying note 66 *supra*.

that doctors also have one eye on the risk of incurring legal liability for bad results,²⁶³ and therefore they tend to practice what is termed "defensive" medicine²⁶⁴—that is to perform procedures, especially diagnostic ones, which are only marginally medically indicated, but which from a juror's hindsight view may seem unreasonable to have omitted.

The imposition of liability on a no-fault basis may remove this consideration from medical decisionmaking, or reduce its importance. Because liability will attach for bad results, whether negligently caused or not, the doctor will be freer to choose the most medically sound course of treatment, and possibly encouraged to choose a treatment which minimizes the possibility of bad results of the statistical-risk variety. A more trusting doctor-patient relationship may then exist, in which the doctor views the patient less adversarially, and the patient believes that the doctor is exercising his best medical judgment.

2. *The Bias in Favor of Medical "Omissions."* Another extraneous consideration may be eliminated from the practice of medicine if strict liability is imposed for nonnegligent omissions as well as for nonnegligent commissions. As long as strict liability for medical accidents exists only as a consequence of the operation of the

263. Judicial recognition of this phenomenon has been used as a rationale by some courts to limit the degree of disclosure required by the physician:

To adopt the minority rule of *Canterbury* would result in requiring every doctor to spend much unnecessary time in going over with every patient every possible effect of any proposed treatment. The doctor should not have to practice his profession with the knowledge that every consultation with every patient with respect to future treatment contains a potential lawsuit and his advice and suggestions must necessarily be phrased with the possible defense of a lawsuit in mind.

Butler v. Berkeley, 25 N.C. App. 325, 342, 213 S.E.2d 571, 581 (1975). See also *Ross v. Hodges*, 234 So. 2d 905, 909-10 (Miss. 1970).

264. "Defensive medicine consist[s] of medically unjustified care provided by the physician for the purpose of reducing the possibility of a malpractice suit . . ." *Project, The Medical Malpractice Threat: A Study of Defensive Medicine*, 1971 DUKE L.J. 939, 942. This study concludes that "[t]he threat of malpractice suit does induce physicians to overutilize the diagnostic tests and procedures in particular cases, but . . . the practice is not extensive and probably not a contributing factor to the rising costs of medical care." *Id.* at 964. But see Sagall, *Medical Malpractice: Are the Doctors Right?*, 10 TRIAL, July/Aug., 1974, at 59, 60, suggesting that reports on the extent of the practice of defensive medicine are exaggerated. Query whether the performance of medical diagnostic procedures not justified by medical considerations is actionable, perhaps as a breach of contract, as negligence, or as fraud by the doctor on the patient.

informed-consent doctrine, liability for the failure to perform a medical procedure will continue to be grounded in negligence, and therefore will be less widespread than liability for bad results from acts of commission. This asymmetry may create another nonmedical bias in the practice of medicine, though this time in favor of the nonperformance of medical procedures in those situations where the necessity for the procedure is unclear.

If, however, strict liability is applied to omissions as well as to commissions (as suggested by the *Helling* concurring opinion), this factor, which ought to be irrelevant in the practice of conscientious medicine, will disappear. By not having to worry about the differential prospects of liability, the doctor may be more inclined to act on the basis of medical judgment alone. To the extent that this encourages doctors to speak more openly with patients about the various options, this may enhance the opportunity for patient self-determination and for a trusting relationship.

3. *Effect on Disclosure of Information.* Strict liability for medical accidents firmly planted on considerations of justice and efficiency rather than flowing indirectly from the doctrine of informed consent may create an incentive for doctors to withhold information from patients. If doctors were to be held strictly liable for bad results even if they had made adequate disclosure, the incentive for disclosure would be lost and the possibilities for rational patient-decisionmaking undermined. However, if a cause of action for the dignitary harm of inadequate disclosure²⁶⁵ were to be recognized, this outcome might be mitigated. Furthermore, even if strict liability is to be applied independently of the informed-consent doctrine, there still ought to be a duty to warn of material dangers as there is in the law of products liability.²⁶⁶

4. *The Stigma of Liability.* Strict liability, unlike negligence liability, does not rest on a finding of wrongdoing (either moral or legal) on the part of the defendant. By eliminating the stigma that presently flows from a plaintiff's verdict,²⁶⁷ physicians may be less inclined to fight malpractice suits tooth-and-nail even when their insurance carrier has recommended settlement of a claim.²⁶⁸ In addition to reducing the administrative costs of a medical accident-victim-compensation system, liability strictly imposed for bad

265. See Goldstein, *supra* note 64. See also J. FLETCHER, *supra* note 259, at 60-64.

266. See note 211 *supra*.

267. 1 LOUISELL & WILLIAMS, *supra* note 3, ¶ 1.01, at 3-4; *Project*, *supra* note 264, at 951-52, 965.

268. Demy, *Practice and Malpractice (One Doctor's Viewpoint)*, 1973 MED. TRIAL TECH. Q. 61, 67; O'Connell, *supra* note 29, at 756.

results instead of for wrongdoing would no longer constitute an indictment of the doctor's professional expertise, and therefore might lead to a more trustful relationship with patients.

5. *The Adequately Warned, Consenting, but Injured Patient.* As long as assumption of risk remains a defense to actions for strict liability in tort, the patient who has been warned of the risks of treatment and who consents to bear them will go uncompensated, while the patient who suffers the same injury as a result of negligent medical practice will be able to obtain compensation. This disparate outcome might lead to bitterness on the part of one class of medical-accident victims, and could further undermine the trust that patients place in doctors and in the law.

To the extent that this is true, the adverse effect on the doctor-patient relationship is bound to be less than it presently is from the disparate treatment of victims of negligently caused injuries and statistical-risk-caused injuries. Merely because strict liability may not eliminate all unfairness is no reason to prevent it from eliminating a large quantity of unfairness. The better solution is not to abolish strict liability altogether, but to eliminate the defense of assumption of risk,²⁶⁹ possibly on the ground that an individual

269. [E]ven when a danger is fully known and comprehended plaintiff is not barred from recovery simply because he chooses deliberately to encounter it

He may be contributorily negligent if he does so under circumstances which make the choice unreasonable. But that is because his encountering the risk is *negligent* and *not* because it is *voluntary*.

2 HARPER & JAMES, *supra* note 4, § 21.1, at 1165 & n.17. Applying this rule would not always bar the plaintiff to whom adequate disclosure has been made and who has consented to treatment from maintaining an action in strict liability. Only in those cases where the decision to undergo treatment could be viewed as "unreasonable" would the defense operate, thus reintroducing negligence principles into strict liability theory. See also note 210 *supra*.

Harper and James believe that assumption of risk is a vestige "of laissez faire and its concomitant philosophy of individualism which has passed its prime . . . [and] is likely to lose more ground as notions of social insurance gain strength and techniques for effecting broad distribution of enterprise liability are developed." 2 HARPER & JAMES, *supra* note 4, § 21.3, at 1174-75. Though advocating abolition of the defense in general, they believe it should be retained where the plaintiff expressly agrees to assume the risk and where the defendant is under no obligation to protect the plaintiff from the risk. See *id.* § 21.3, at 1191. This is not the case in the medical-accident context, because the defendant is under a duty to use reasonable care to protect the plaintiff from the risk of harm even when disclosure of it is made. Furthermore, any attempt to relieve the defendant of liability by the plaintiff's express agreement may be void as against public

should not be forced to make a choice between certain, present suffering from a potentially treatable condition, and foregoing compensation for possible future suffering from a statistical risk, in order to exercise his right of self-determination.

On balance, it is difficult to discern the impact that strict liability would have on the nature of the doctor-patient relationship and on the goal of encouraging rational decisionmaking by patients. But strict liability probably would make the doctor no more wary of the patient, and no more influenced by legal rather than by medical considerations, than does negligence liability, nor would it seem to make the patient any less trustful of the doctor. Strict liability would only undercut the goals of the informed-consent doctrine if the courts were to refuse to recognize a cause of action for injury to dignity caused by inadequate disclosure of risks and other information about treatment.

The greatest threat posed by a system of strict liability for medical accidents, which does not depend upon the doctrine of informed consent, is to the values promoted by informed consent.²⁷⁰ In the name of grounding compensation for medical accidents on a more equitable foundation than negligence theory may be able to provide, the ends served by informed consent may be first subtly, then dramatically subverted. Perhaps the most dramatic example of this subversion would be the enunciation of a rule that the patient's consent is not valid unless he "understands" the information that is disclosed, by whatever standard understanding is to be gauged. If such a requirement were to be recognized, the old-style paternalism that insisted that doctors make decisions for patients because patients are not *able* to understand, would be replaced by a neopaternalism which would deprive a patient of the right to decide if he could not *in fact* understand.

policy where the plaintiff suffers from a disadvantage in bargaining power. PROSSER, *supra* note 2, § 68, at 442. In Professors Calabresi's and Hirschoff's view, assumption of risk is "a kind of plaintiff's strict liability." Calabresi & Hirschoff, *supra* note 11, at 1065 & *passim*. This view embodies the judgment that the plaintiff is in a better position than the defendant to determine which party is able to avoid an accident at the least expense. In other words, assumption of risk reflects, at its essence, the determination that the accident victim was better able to compare the risks and benefits of the accident-causing activity than was the injurer, and therefore ought to bear the costs of the accident.

Ultimately, the applicability *vel non* of assumption of risk in strict liability cases, as elsewhere, is a matter of policy, *see* PROSSER, *supra* note 2, § 68, at 454-57, and cannot be settled by the application of mechanical rules.

270. *See* note 68 *supra*.

The often complementary but sometimes competing goals served by the informed-consent doctrine and by strict liability are each important in themselves. Neither should be sacrificed to the attainment of the other. It would be ironic if the informed-consent doctrine, which spawned strict liability for medical accidents, were to contain the seeds of its own destruction, and equally tragic if in the pursuit of the humane urge to compensate medical-accident victims without regard to medical negligence, courts were to take measures that would spell the death of the doctor's duty to disclose and the patient's right to chart his own course.

VII. CONCLUSION

The persistent efforts of lawyers and judges have shaken the very foundation of the system of compensating medical-accident victims based on negligence. Although there has been an outright rejection of strict liability for medical accidents by some courts,²⁷¹ and despite the black-letter law that a doctor is not an "insurer" of the care he provides,²⁷² there has been a slow, surreptitious,²⁷³

271. See note 221 *supra*. No case, however, has explicitly sought to apply a theory of strict liability for bad results in the absence of a blood transfusion, drug, or medical device.

272. Prosser, *supra* note 2, § 32, at 162. But see Markham, *The Doctrine of Informed Consent—Fact or Fiction?*, 10 FORUM 1073, 1076-77 (1975) ("The terrible injustice of the rule [in *Canterbury v. Spence*, requiring disclosure of a 1% risk of paraplegia in connection with a laminectomy] is that it makes . . . the physician an insurer of a successful medical outcome."). In this regard, strict liability must be distinguished from absolute liability. The adoption of strict liability for injuries resulting from defective products does not make the manufacturer or seller an insurer of the user's safety. *Suvada v. White Motor Co.*, 32 Ill. 2d 612, 623, 210 N.E.2d 182, 188 (1965); *Cintrone v. Hertz Truck Leasing & Rental Servs.*, 45 N.J. 434, 452, 212 A.2d 769, 779 (1965); *Dippel v. Sciano*, 37 Wis. 2d 443, 460, 155 N.W.2d 55, 63 (1967).

Strict liability has never meant that the party held strictly liable is to be a general insurer for the victim no matter how or where the victim comes to grief. General insurance was not the rule in classical instances of strict liability, such as ultra-hazardous activities, or in legislatively mandated instances, such as workmen's compensation, and it is not the rule in the recent instances of application such as products liability.

Calabresi & Hirschhoff, supra note 11, at 1056. Similarly, a physician, under strict-liability principles, is liable only for injuries to the patient caused by his medical conduct, and not for injuries traceable to the underlying illness or injury for which the patient sought treatment. See pp. 56-57 *supra*.

273. "Although Harper and James applaud this trend of accident law toward more compensation, others have bitterly resented it. To them, it was not only distorting the law of torts but doing it surreptitiously, without fairly facing the issues." J. O'CONNELL, *supra* note 7, at 66

but perceptible advance toward strict liability for medical accidents. The initial impetus, procedural in appearance, but substantive at its core, has come from a liberalized application of *res ipsa loquitur*. Another has been the development of an entirely distinct basis for liability—the doctrine of informed consent. Recently the citadel of negligence has been breached head-on, though in a concurring opinion, by the Supreme Court of Washington in *Helling v. Carey*.

But still the citadel stands, its ultimate collapse foreseeable, probably inevitable, yet distant. In the meantime, the inequities and deficiencies persist. We can improve little on Prosser's observation made in a similar context some time ago: "The assault upon the citadel . . . is proceeding in these days apace."²⁷⁴

(citing Cooperrider, Book Review, 56 MICH. L. REV. 1291 (1958)). A government report reaches a similar conclusion within the specific context of medical accidents:

The Commission FINDS that some courts have applied certain legal doctrines for the purposes of creating or relieving the liability of health professionals. The Commission further FINDS that such special doctrines, or the application thereof, are no longer justified.

The Commission RECOMMENDS that legal doctrines relating to the liability of health professionals should be applied in the same manner as they are applied to all classes of defendants, whether they be favorable or unfavorable to health professionals.

HEW, MEDICAL MALPRACTICE, *supra* note 4, at 31.

274. Prosser, *supra* note 27, at 1099.