Nebraska Law Review

Volume 63 | Issue 4 Article 9

1984

Malpractice Revisited: Of Medical Errors, Social Transformations, and Tort Standards

Barry R. Furrow
University of Detroit School of Law, Barry.R.Furrow@drexel.edu

Follow this and additional works at: https://digitalcommons.unl.edu/nlr

Recommended Citation
Barry R. Furrow, *Malpractice Revisited: Of Medical Errors, Social Transformations, and Tort Standards*, 63 Neb. L. Rev. (1984)
Available at: https://digitalcommons.unl.edu/nlr/vol63/iss4/9

This Article is brought to you for free and open access by the Law, College of at DigitalCommons@University of Nebraska - Lincoln. It has been accepted for inclusion in Nebraska Law Review by an authorized administrator of DigitalCommons@University of Nebraska - Lincoln.

Barry R. Furrow*

Malpractice Revisited: Of Medical Errors, Social Transformations, and Tort Standards

TABLE OF CONTENTS

I. Introduction 811
II. Medical Errors: Refining the Tort Standard of Care ... 814
A. Physician Fault—The Negligence Standard 815
B. Professional Shortcomings and Medical Innovation 818
1. Standard-neutral 819
2. Standard-forcing 819
3. Standard-freezing 821
4. Standard-diffusing 821
C. Medical Innovation and Evolving Standards of Care 822
1. The Out-of-Touch Practitioner 823
2. The Reluctant Practitioner 824
3. The Faithful Follower 825
4. The Innovative Practitioner 827
D. Work Setting Errors 828
III. Conclusion 833

> Like the Octopus, which is essentially blind in the absence of movement but strikes at every shadow that moves by, the social scientist not only notices whatever moves but usually considers it bad. Thus it is with malpractice. Malpractice law is held in low repute largely because it has recently changed.[1]

* Associate Professor of Law, University of Detroit School of Law. A.B. 1967, J.D. 1971, Harvard University. Editor-in-Chief, *Law, Medicine & Health Care*.

1. THE ECONOMICS OF MEDICAL MALPRACTICE 283 (S. Rottenberg ed. 1978).

I. INTRODUCTION

Powerful forces are at work transforming modern medicine. Technological advances, new institutional structures, changing modes of payment, and new categories of allied health professionals can each claim an important impact on medical practice.[2] Malpractice litigation is another such transforming force promoting changes in medical practices. Tort litigation is a major current in a sea of pressures, and is much more than a simple problem bobbing in the wake of other major changes. Several emerging areas of litigation, such as wrongful life suits, are symptomatic of the emergence of technological medicine which creates "zones of transition."[3] These zones of transition present difficult problems

2. Third party reimbursement practices represent a powerful force converging on medical practice, but one which this article will not discuss in depth. The desire for reimbursement leads to an understandable clamor by subgroups such as nurses and other health professionals as they demand recognition as independent providers. If new allied health professionals are recognized, they are likely to be held to the higher standard of practice of the traditional medical specialities to which they are most related.

The third party payor's listing of approved billable treatments may prove to be a mixed blessing. If a defendant's mode of treatment or diagnosis is on an approved list for purposes of reimbursement, that list may be evidence in defense of the propriety of treatment in a particular case; however, such a list may then deny an evidentiary shield to the defendant who uses an effective but unlisted approach. Third party reimbursement promises a complex and bewildering array of problems.

The most recent change in reimbursement practice comes from new Medicare reimbursement regulations. New prospective payment legislation requires Medicare to fix prices in advance on a cost-per-case basis, using 467 categories called "diagnosis-related groups" (DRG's). The hospital is the central instrument of this policy, which promises to complicate treatment decisions in substantial ways. One commentator notes:

> Once physicians begin to encounter this process— reacting to new incentives to reduce lengths of stay, limit laboratory tests, and adopt policies to reduce the use of inpatient services—a whole set of other questions arises dealing with quality, access, and appropriateness of treatment. Balancing these conflicting demands will be a tall order.

Iglehart, *Medicare Begins Prospective Payment of Hospitals*, 308 NEW ENG. J. MED. 1428, 1432 (1983). Physicians are already afraid of increased malpractice exposure as a result of the new Diagnosis Related Groups (DRG) prospective payment system. The AMA in a recent report stated:

> There is a sense of foreboding . . . because of the anticipated pressure by hospitals to curtail the ordering of diagnostic procedures and shorten hospital lengths of stay. Both could result in increased claims for failure to order medically necessary diagnostic procedures and premature discharge.

MEDICAL LIABILITY ADVISORY SERVICE 2 (Dec. 1983).

3. This phrase was coined by Bruce Watson in an unpublished paper, Liability for Failure to Acquire or Use Computers in Medicine (unpublished paper on file with the author) [hereinafter cited as Watson].

for those practicing medicine. This article will briefly trace some transforming forces on medical practice, develop major categories of medical errors, and then analyze the inner workings of tort doctrine as it affects medical practice.

Discussions of professional regulation tend to downplay the role of malpractice litigation, portraying it as useful only for the sanctioning of gross violations of professional norms. In fact, such litigation should be viewed as a form of microregulation of undesirable practices. Such microregulation has substantial positive benefits, such as improved medical disclosure of risks to patients,[4] increased hospital sensitivity to iatrogenic events,[5] and closer monitoring of drug use. The impact of malpractice litigation on the behavior of medical professionals has been the subject of much debate among economists,[6] lawyers and doctors; but some general conclusions have emerged. One recent analysis concluded, with regard to incentives provided by malpractice suits:

> [I]t is not implausible that the current non-trivial incidence of injury due to negligence would be at least 10 percent higher, were it not for the incentives for injury prevention, created by the one in ten incidents of malpractice that result in a claim. If so, the malpractice system, despite its costs, is worth retaining.[7]

Tort liability is first of all a system of quality control, and must be evaluated by its successes in deterring bad medical practices. Compensation is a secondary systemic goal, since it can be achieved more effectively and at lower cost through other mechanisms.[8] Recent studies of malpractice claims have reached several interesting conclusions. First, most extreme criticisms of the system are unfounded, and the number of malpractice claims falls far short of the number of incidents of malpractice.[9] The data does not reveal the existence of a malpractice crisis. Rather, as one

4. Novack, *Changes in Physicians' Attitudes Toward Telling the Cancer Patient*, 241 J.A.M.A. 897, 898 (1979) (noting that, in 1961, 12 percent of surveyed physicians generally told a patient about a cancer diagnosis, and, by 1977, 98 percent reported a general policy of telling the patient).

5. Steel, *Iatrogenic Illness on a General Medical Service at a University Hospital*, 304 NEW. ENG. J. MED. 638 (1981). A new speciality within hospital administration, risk management, illustrates this sensitivity.

6. L. Pocinki, S. Dogger, & B. Schwartz, *The Incidence of Iatrogenic Injuries*, in DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, APPENDIX: REPORT OF THE SECRETARY'S COMMISSION ON MEDICAL MALPRACTICE 50, 51 (D.H.E.W. Pub. No.(os) 73-89) (1973) [hereinaftercited as L. Pocinki]; THE ECONOMICS OF MEDICAL MALPRACTICE, *supra* note 1; Danzon, *An Economic Analysis of the Medical Malpractice System*, 1 BEH. SCIENCES & LAW 39 (1983); Schwartz & Komesar, *Doctors, Damages and Deterrence: An Economic View of Medical Malpractice*, 298 NEW ENG. J. MED. 1282 (1978).

7. Danzon, *supra* note 6, at 53.

8. Schwartz & Komesar, *supra* note 6, at 1282.

9. Danzon, *supra* note 6, at 51.

commentator has observed, "only very recently have malpractice insurance costs become large enough to be interesting."[10] In fact, the current system may provide significant incentives for changes in medical practice. One economist noted: "A finding that malpractice premiums are being shifted and that defensive medicine is being practiced is not damning evidence against the system. Indeed, one purpose of a tort system is to change the way medicine is practiced."[11] Liability insurance may therefore provide too much insulation to physicians from the deterrent impact of sanctions.[12] Second, it is not evident from the data that claims strike physicians like lightning, unpredictably and randomly. To the contrary, one study concluded that "claims are far from random. Past claim history is as good a predictor of future claim experience as medical specialty."[13] Third, peer review as a means of controlling negligent medical practice is not likely to be effective.[14] Malpractice litigation, therefore, has a significant and productive function in assuring quality control.

Discussions of medical malpractice often culminate in the adoption of one of two extreme views: the trial lawyer's view that injured patients deserve compensation, with the treating physician as the best source of compensation; and the physician's view that such suits unfairly penalize judgmental errors while raising the costs of practicing medicine. The economist's viewpoint—that, from a quality control perspective, malpractice suits are useful—draws our attention to the central issues: How do the inner workings of tort doctrine affect or reduce the level of various medical errors? Can we improve tort rules to better promote litigation that will reduce medical errors, particularly those which cause a large share of injuries? Can we divert litigation theories away from the individual physician and toward the hospital, the product supplier, or the health care institution, when errors are traceable to the culpability of the latter?

---

10. Burghardt, *Medical Malpractice and the Supply of Physicians*, in THE ECONOMICS OF MEDICAL MALPRACTICE, *supra* note 1, at 122.
11. THE ECONOMICS OF MEDICAL MALPRACTICE, *supra* note 1, at 282.
12. Danzon, *supra* note 6, at 51.
13. *Id.* at 44.
14. As one commentator has noted:

> The potential for success of peer review is based on some further assumptions: that it is possible for peers to evaluate performance quality, that they have the will and the mechanism to bring malefactors to account, and that sanctions are available to punish misdeeds. All are required if self-regulation is to succeed in protecting the public. But there are, in fact, difficulties and obstacles in each of these areas, and in many respects the assumptions are unwarranted."

Haug, *The Sociological Approach to Self-Regulation*, in REGULATING THE PROFESSIONS, 61, 64-65 (R. Blair & S. Rubin eds. 1980).

II. MEDICAL ERRORS: REFINING THE TORT STANDARD OF CARE

Iatrogenesis, defined as the undesirable side effects of medical intervention, is not a new phenomenon. The major study undertaken by the Department of Health, Education and Welfare in 1973 noted that a substantial percentage of adverse medical outcomes occur as the result of treatment.[15] Other studies have concluded that many surgical deaths are avoidable.[16] Two recent studies have focused upon surgical mishaps[17] and upon iatrogenic illness in a general medical service at a university hospital.[18]

The first study, surveying avoidable adverse outcomes from colonic surgery, concluded that "[t]he penalties for such misadventures turned out to be severe, with 10 times the mortality, seven times the average cost, and four times the length of hospitalization expected in average patients undergoing comparable but uncomplicated colonic surgical procedures."[19] Of 56 types of errors that occurred, 31 were "those of unnecessary, contra-indicated, or technically defective surgical activity."[20] Other sources of the medical "errors" identified by the authors, admittedly in an impressionistic fashion, were misplaced optimism, a sense of unwarranted urgency, the urge for perfection, and the use of vogue therapies: all errors of commission.[21]

The second study, of general medical services at a university hospital, monitored 815 patients during a five month period in

15. L. Pocincki, *supra* note 6, at 51.
16. A study, jointly sponsored by the American College of Surgeons and the American Surgical Association, concluded that 796 of the 1,696 deaths or complications arising out of 1,493 surgical operations examined were avoidable. C. CHILD, THE CRITICAL INCIDENT STUDY OF SURGICAL DEATHS AND COMPLICATIONS 1973-1975 (1975), *discussed in Study on Quality of Surgery is Unveiled*, MEDICAL WORLD NEWS, Jan. 26, 1976, at 24-25. *See also* Brody, *Incompetent Surgery Is Found Not Isolated*, N.Y. Times, Jan. 27, 1976, at 1, col. 6. A study of the death rate in Los Angeles County during a doctors' work slowdown confirmed a drop in the death rate, which has been linked to the sharp reduction in the amount of elective surgery performed during the slowdown. *See* Wash. Post, October 20, 1978, at A6, col. 5.
17. Couch, *The High Cost of Low-Frequency Events*, NEW ENG. J. MED. 634-37 (1981).
18. Steel, *supra* note 5, at 638-42.
19. Couch, *supra* note 17, at 634.
20. *Id.* at 635.
21. *Id.* at 637. However, from a legal standpoint, the errors of commission do not appear to have involved negligence. The authors were concerned about their findings, and proposed that a legal safeguard was needed against malpractice suits for errors in judgment, *i.e.*, "error simply related to flawed reasoning" as opposed to negligence. *Id.* Malpractice suits only succeed, according to the authors, in driving into concealment the "forces that could help to reveal and control epidemiologic sources of error." *Id.*

1979.[22] Of these, 290 (36 percent) had one or more iatrogenic illnesses, seventy-six (9 percent) had major complications, and of the fifteen who died (2 percent of all patients and more than 5 percent of those with complications), iatrogenic illness was believed to be a contributing cause. The intervention categories were drugs, diagnostic and therapeutic procedures, and miscellaneous. The overall conclusion was that "the risk incurred during hospitalization is not trivial" and "the risk of a serious problem may well have increased" in the last twenty years.[23] Causes of this hospitalization risk included routine monitoring of a range of physiologic characteristics, often leading to earlier interventions than might have occurred in the past, use of a wide range of potent drugs, and therapeutic procedures in general.[24]

The level of patient harm demonstrated by these recent studies raises the question of whether malpractice litigation can be used to accomplish risk reduction. Tort litigation can be a central force in promoting change. An analysis of types of medical errors may suggest possible alterations in tort doctrine to better deal with iatrogenesis.

A. Physician Fault—The Negligence Standard

Malpractice, in the area of professional tort liability, refers to that category of acts or omissions which are "faulty"[25] or negligent.[26] Traditionally, negligence suits have been brought against the physician who has diagnosed or treated the plaintiff, with the issue being whether his conduct deviated from the professional standard of practice within his specialty. In a non-malpractice negligence suit, a defendant can present evidence of a "customary practice" which he would claim to have followed in the particular

22. Steel, *supra* note 5, at 638.
23. *Id.* at 641.
24. *Id.* While no opinion as to negligence was offered, strong suggestions were made for better mechanisms "to assess the hazards of hospitalization in an ongoing manner," for an intensified search for means to reduce the frequency and severity of iatrogenic events, and for a shared concern for deficiencies in medical review within the hospital. *Id.*
25. If the harm to the patient is intentionally caused, the defendant's conduct will still be judged by the professional or ethical norms of practice of the profession. These cases are often dramatic, such as that of Dr. Nork, who performed countless sugical procedures which he was incompentent to perform and knew to be unnecessary. Gonzales v. Nork, No. 228566 (Cal. Super. Ct., Sacramento County, Nov. 19, 1973). For excerpts, see S. LAW & S. POLAN, PAIN AND PROFIT: THE POLITICS OF MALPRACTICE 215-45 (1978).
26. Tort rules have traditionally attempted to render the plaintiff whole, after he has suffered injury at the hands of another, by forcing the defendant to pay compensation. This is justified on the principle that the defendant can in fairness be taxed because of his fault.

case. The trier of fact is free to accept or reject this standard, and may find the defendant liable in spite of evidence that he followed a customary practice.[27] In malpractice cases, however, the customary practice of the profession determines the standard of care against which an individual's behavior is judged. The standard is "what is customary and usual in the profession."[28] The trier of fact is not allowed to reject the customary practice as improper. The medical profession, therefore, has the privilege of setting its own standard of conduct merely by adopting and acknowledging its own treatment practices.[29]

The justification for this deference to customary medical practice has been the courts' perceived lack of expertise in judging another profession, and their fear of imposing liability based upon an uneducated judgment. Even if the customary medical practice is inadequate, dangerous, or out-of-date, the plaintiff has lacked a doctrinal basis for attacking the standard itself. Thus, the standard is proven by evidence of actual patterns of medical practice without any normative evaluation as to whether the existing practice is either effective or useful. One critic of the customary practice standard has observed:

> The controlling standard thus would be defined exclusively in terms of medical procedures that have occurred with sufficient regularity in the past to become unmistakably etched into the practice of the profession. This raises the spectre of the past elevated to prologue in the scientifically dynamic and fluid field of medicine.[30]

The suggestion has been made that the standard should be "accepted practice" in lieu of customary practice, thereby allowing practices that are approved by the leaders of the profession, even if not customarily followed. This model would allow for the evaluation of a standard by reference to the state of the art in diagnosis and treatment. Even without historical antecedents, conduct might be evaluated as sound professional practice on the basis of current medical literature. Such an evaluation could rely heavily on expert witnesses' testimony concerning the best practice.[31]

Two exceptions to the general rule regarding proof of the standard of care bridge the gap between the traditional "customary practice" test and the accepted practice proposal. First, the "re-

27. *See* The T.J. Hooper, 60 F.2d 737 (2d Cir. 1932); Marsh Wood Prods. Co. v. Babcock & Wilcox Co., 207 Wis. 209, 240 N.W. 392 (1932).
28. W. PROSSER, LAW OF TORTS § 32, at 165 (4th ed. 1971). *See generally* J. KING, THE LAW OF MEDICAL MALPRACTICE IN A NUTSHELL 36-80 (1977).
29. W. PROSSER, *supra* note 28, § 30.
30. King, *In Search of a Standard of Care for the Medical Profession—The 'Accepted Practice' Formula*, 28 VAND. L. REV. 1213, 1236 (1975).
31. Chumbler v. McClure, 505 F.2d 489, 492 (6th Cir. 1974) (standard not determined "solely by a plebiscite").

spectable minority" rule allows for variation in clinical judgment, holding that "a physcian does not incur liability merely by electing to pursue one of several recognized courses of treatment."[32] As long as the patient is informed of treatment alternatives in compliance with informed consent requirements, the physician is protected. However, distinctive practices must be supported by at least a respectable minority within the professional group if the judge is to be willing to direct a verdict rather than leave the question for the jury to resolve based upon the conflicting testimony of the proponents of the two opinions.[33] Second, a "best judgement" rule has been allowed in some cases, postulating that a physician must act in a manner consistent with his best judgment.[34] Clearly, the defendant physician must be able to articulate a reasoned defense of the treatment decision in order to convince the trier of fact to override the standard of care.

On rare occasions, courts have even recognized that a customary medical practice may be negligent. In *Helling v. Carey*,[35] the Washington Supreme Court held that the defendant opthalmologists were negligent as a matter of law in failing to administer a simple glaucoma test to a patient under the age of forty, despite uncontradicted expert testimony that it was universal practice not to do so. However, *Helling* and the few cases that have overridden the customary practice rule[36] have all involved a therapy or diagnostic procedure that was readily understandable by lay persons. This has allowed the trier of fact to weigh—without expert testimony—the relative risk of injury caused by the procedure, and by its omission. These cases have not been followed by most jurisdictions, because courts are normally reluctant to replace the standards of care established within the profession with judicially contrived standards, especially in complex cases. However, courts may be willing to critically evaluate the customary practice where a plaintiff can produce some evidence indicating that the practice is out-of-date or ineffective and, therefore, dangerous.

The failure of a physician to follow an accepted or customary

32. Downer v. Veilleus, 322 A.2d 82, 87 (Me. 1974).

33. Hamilton v. Hardy, 37 Colo. App. 375, 549 P.2d 1099 (1976).

34. Toth v. Community Hosp., 22 N.Y.2d 255, 262-63, 239 N.E.2d 368, 372-73, 292 N.Y.S.2d 440, 447 (1968) (physician must follow his best judgment, even if it requires precautions in addition to those customarily followed in community).

35. 83 Wash. 2d 514, 519 P.2d 981 (1974).

36. *See* Lundahl v. Rockford Memorial Hosp. Ass'n, 93 Ill. App. 2d 461, 465, 235 N.E.2d 671, 674 (1968) ("what is usual or customary procedure might itself be negligence"); Favalora v. Aetna Casualty & Sur. Co., 144 So. 2d 544 (La. Ct. App. 1962). *See also* Note, *An Evaluation of Charges in the Medical Standard of Care*, 23 VAND. L. REV. 729, 742 (1970).

standard of medical practice may be attributable to: the inattentiveness of the physician on a particular occasion, even though he is an otherwise skillful, well-trained doctor; a failure of medical education or training, or of the physician to keep abreast of his field;[37] or the personal inability of a physician, who is operating outside of his sphere of competence, to deal with a particular problem. However, the tort system holds a physician accountable for intentional or negligent deviations from medical practice, whatever the excuse. These errors imply that the physician has failed to perform at the level that his profession requires. This category of medical error is, thus, measured by the benchmark of a profession-wide standard, focusing upon the individual practitioner and his deviation from accepted professional practice. The types of errors likely to be detected are those of the unethical or slipshod doctors, who are probably responsible for only a small, although significant, percentage of harm to patients.

B. Professional Shortcomings and Medical Innovation

Deficiencies within a medical specialty may cause iatrogenic harm. These deficiencies may include problems of scientific ignorance, inadequate evaluation of diagnostic instruments and procedures before use, or failure to educate members. A medical specialty may be in its infancy, so that knowledge about etiologies of illness and techniques of treatment is incomplete. Those therapeutic techniques that are available may not yet have been perfected to the point where substantial risks of side effects can be eliminated.

Although injury to a patient may be caused by the shortcomings of a particular therapist in a given case, it is not the individual's failure, but rather that of the profession as a whole that can fairly be said to have caused injury. We single out the individual physician for liability, but it is really a mirror image of vicarious libility we are imposing; while the profession is collectively at fault, it is the individual therapist who is inevitably penalized for those collective shortcomings.[38] The causes cited by the studies suggest that errors in this category (e.g., vogue therapies, multiple drug administration) account for a significant percentage of the iatrogenic harms suffered.[39]

Where medical errors are related to professional shortcomings (e.g., too rapid diffusion of vogue treatments, or excessive reliance

37. Darling v. Charleston Community Mem. Hosp., 33 Ill. 2d 326, 211 N.E.2d 253 (1965), *cert. denied*, 383 U.S. 946 (1966).

38. *See* Gorovitz & MacIntyre, *Toward a Theory of Medical Fallibility*, 1 J. MED. & PHIL. 51 (1976).

39. Couch, *supra* note 7, at 636; Steel, *supra* note 5, at 639.

on unproven diagnostics) we need to ask how tort standards and proof requirements can be altered to reduce medical errors. Four effects of a tort standard are possible, and the choice of one over another depends on one's perception of dominant sources of medical error.

1. Standard-neutral

The first approach—labeled the standard-neutral approach—is closest to the present customary practice standard. As a statistical matter, this tort standard simply mirrors whatever the profession does. The position of neutrality by courts in determining the professional standards, as discussed above, means that the profession is dominant in setting standards, and is able to provide a safe harbor from tort liability for any practitioner who follows the practice— regardless of its effectiveness.

2. Standard-forcing

The second approach—standard-forcing—operates at two levels. First, courts have on rare occasions set the appropriate standard of practice in spite of evidence indicating that the customary practice is either to the contrary or is less demanding. *Helling v. Carey* is a good example of a rare judicial attempt to force the level of practice higher. Second, where a new speciality is emerging, such as genetic counseling, the lack of a consensus standard means that some defendants will be found liable because they were unable to justify their practice by reference to general practice.

The process of developing a consensus as to a physician's standard of care is a complex one, and is of particular concern to practitioners in new speciality areas. Concern has been expressed that litigation will drive out new practitioners, and expose others to unmanageable expenses.[40] The litigation process contains its own safeguards, however. Individual plaintiffs must prove their cases, presenting evidence and persuading the trier of fact that they should prevail. To do this, plaintiffs must use expert witnesses. Unless plaintiffs can find experts who will testify as to the existence of established standards of care for any given treatment or mode of diagnosis, the floodgates of litigation are unlikely to let in more than a trickle of suits against physicians in new specialty areas. As standards evolve, however, such expertise will certainly be more available to plaintiffs. It is precisely this chain of events that illustrates the indirect pressure of tort litigation on the medical

40. *See* Taub, *Wrongful Life—The Problems Are Not Just Semantic: A Reply to Furrow*, 10 L. MED. & HEALTH CARE 208, 210 (1982).

profession: the threat of suits will eventually force the medical community to attempt to develop a professional consensus as to what constitutes proper treatment.[41] The process of developing standards helps the medical profession reduce its risk of tort liability in two significant ways. First, articulation and dissemination of

41. The wrongful birth and wrongful life suits pose interesting questions involving medical technology. The dramatically improved ability of physicians to make diagnoses based upon such techniques as amniocentesis and ultrasound is at the root of such litigation and has spawned new specialties such as genetic counseling. *See* Fraser, *Introduction: The Development of Genetic Counseling*, in GENETIC COUNSELING: FACTS, VALUES AND NORMS (1979). Many of the cases illustrate "zones of transition," with diagnostic error at the root of the litigation. In Curlender v. Bio-Science Labs, 106 Cal. App. 3d 811, 165 Cal. Rptr. 477 (1980), a child born with Tay-Sachs disease sued a physician and medical testing laboratories for negligently conducting certain genetic tests on the parents. The court recognized a need to encourage "careful genetic counseling and medical procedures" in light of the increase "of the medical knowledge and skill needed to avoid genetic disaster." Having considered the principles applicable to the suit by the infant plaintiff against the testing laboratory, the court concluded:

> We have no difficulty in ascertaining and finding the existence of a duty owed by medical laboratories engaged in genetic testing to parents and their as yet unborn children to use ordinary care in administration of available tests for the purpose of providing information concerning potential genetic defects in the unborn.

Id. at 822, 65 Cal. Rptr. at 488.

The second case, *Schroeder v. Perkel*, 87 N.J. 53, 432 A.2d 834 (1981), involved a suit brought by the parents of two children born with cystic fibrosis against the pediatricians who treated the first child but who failed to diagnose her condition in time for parents to prevent, or to abort, the second pregnancy. Cystic fibrosis cannot be detected in a fetus through amniocentesis; however, the simple, safe and highly reliable "sweat" test may be performed on the child shortly after birth. A positive result indicates that the parents are carriers of the disease and that future children may also be afflicted with cystic fibrosis. Here, the treating physician never administered the sweat test, despite the symptoms shown by the first child. By the time the parents consulted a second specialist who performed the test and diagnosed the condition of the first child, Mrs. Schroeder was eight months pregnant with a second child.

Curlender and *Schroeder* illustrate a trend toward judicial allowance of recovery for misdiagnosis of genetic defects. The increase in this type of litigation reflects advances in the understanding of genetic defects and improvements in diagnostic methods for predicting their occurrence. These cases illustrate the connection between improved medical knowledge and diagnostic procedures, and expanded tort liability. For a thorough discussion of the problems, see Capron, *Tort Liability in Genetic Counseling*, 79 COLUM. L. REV. 618 (1978); Note, *Father and Mother Know Best: Defining the Liability of Physicians for Inadequate Genetic Counseling,* 87 YALE L.J. 1488 (1978). For an extended debate on the merits of wrongful life litigation, see Furrow, *Impaired Children and Tort Remedies: The Emergence of a Consensus*, 11 L. MED. & HEALTH CARE 148 (1983); Furrow, *Diminished Lives and Malpractice-Courts Stalled in Transition*, 10 L. MED. & HEALTH CARE 100 (1982); Taub, *supra* note 40.

standards will educate those in a new specialty, so as to minimize negligence through ignorance. Second, defendants can take advantage of the real areas of uncertainty by having experts testify on their own behalf. Collection of data and pressure toward consensus will be encouraged even by scattered litigation, for such suits do not go unobserved; rather, they receive a great deal of exposure through the medicolegal and medical presses. While the threat of law suits raises the anxiety levels of professionals within the practice of medicine, such anxiety can be productive if it forces new specialty areas to develop standards.[42]

3. Standard-freezing

If any deviation from customary professional practice is held to be negligent *per se*, then a standard-freezing effect exists, in which an ossified customary practice can remain in effect long past its prime. Exceptions such as the "best judgment" rule, the "respectable minority" rule, or "acceptable practice" would be narrowly construed, if allowed to operate at all. Most courts, however, are not inclined to follow such a rigid approach, since in most jurisdictions some flexibility is built into the standard-setting process through the establishment of doctrines protecting individual judgment.

4. Standard-diffusing

The final approach—standard-diffusing—requires the court to be liberal in its application of the exceptions to the customary practice doctrine, as well as its application of evidentiary rules that would allow medical treatises and journals supporting the defendant's use of newer diagnostic or treatment approaches to come into evidence. As our previous discussion suggests, a standard-diffusing approach should be avoided, since one of the larger sources of iatrogenesis and medical error is the rapid diffusion of questionable techniques into use.

Of the four standards discussed, the standard-neutral approach seems preferable to the other alternatives. However, judicial use of a standard-forcing approach may be warranted in rare instances where the professional practice is clearly inadequate or out-of-date. The dissemination of complete and accurate information gained through clinical research, and its proper use by practition-

42. For an interesting study on the effects of tort law on medical practice, see Comment, *Where the Public Peril Begins: A Survey of Psychotherapists to Determine the Effects of Tarasoff*, 31 STAN. L. REV. 165 (1978) (concluding that *Tarasoff* had produced substantial anxiety and had effected some changes in therapists' practice).

ers, is fundamentally a problem of medical education, for which tort litigation is merely a stage on which to act out the drama of harmful vogue therapies.

C. Medical Innovation and Evolving Standards of Care

The physician is the principal decisionmaker regarding the implementation of most medical innovations, as he is the front-line agent in diagnosing and treating patients. Therefore, in developing a taxonomy of medical errors, it is necessary to develop some understanding of how medicine incorporates innovation, and how tort law treats, or should treat, these "zones of transition."[43] Diagnostic techniques provide an excellent example for testing how innovation should be treated, both in medicine and in law suits involving medical technology.

Medicine increasingly relies upon new techniques and technologies of diagnosis, as doctors clamor for more data. Manufacturers respond with an array of techniques and devices, and clinical researchers suggest new approaches. Technologies such as ultrasound, automated clinical analyzers, and heart monitoring systems are now commonly used, and further advances in diagnostic imagery can be expected in the next decade.[44] This proliferation of diagnostic tools and techniques is understandable, for diagnosis is critical to the proper treatment of the patient and continues to be a major source of physician error.[45]

The swift diffusion of new technological innovations into practice is fueled by many factors, including: medical ethics, the need of a physician to do something in the face of patient needs, the value society places on technology generally, the nature of medical training, and reimbursement policies.[46] Research findings are of great importance, since there is evidence that most physicians regularly read and take note of the new approaches to diagnosis or

43. Watson, *supra* note 3.
44. *See* 210 SCIENCE 227 (1980) (entire issue, no. 4467, devoted to new medical technologies, providing an overview of recent developments in instrumentation).
45. Data for the period between 1973 and 1980, collected by the St. Paul Fire & Marine Casualty Ins. Co., the nation's largest medical malpractice insurer, reveals that failure to diagnose was alleged in 25 percent of cases brought for malpractice. 6 MEDICAL MALPRACTICE LIABILITY ADVISORY SERVICE 2 (1981). Data from the Department of Health, Education and Welfare, for suits between July and October of 1976, reveal that about 25 percent of all claims, and about 50 percent of claims against internists and general practitioners, alleged diagnostic error, while inadequate testing claims were by far the most numerous in non-surgical cases. *Id.*
46. Young, *Communications Linking Clinical Research and Clinical Practice*, BIOMEDICAL INNOVATION 177 (1981).

treatment that are published in medical periodicals. While skepticism of these research findings is appropriate, one critic has observed that such skepticism is not common.[47] In spite of the lack of evidence of efficacy, practitioners have fostered rapid adoption of new technologies such as CT scanning and coronary after-surgery and respirator therapy. In addition, the data and opinions available to practitioners are often inadequate to allow them to evaluate research findings, in that the studies themselves may have significant defects; the studies may lack information as to how to translate limited clinical research findings into practice; the practitioner may not be aware of the unique nature of clinical trials; or little guidance may be given to the practitioner for evaluating controversy over earlier studies.[48]

Despite the pitfalls of technological advances, a physician must utilize new diagnostic technologies as part of his professional obligation to his patients. He is "bound to keep abreast of the times."[49] However, the physician's relationship to a standard of practice is considerably more complex than the general statements in the caselaw suggest. Keeping "abreast of the times" is far too vague a standard when the rate of medical change is accelerating well beyond a level known even twenty years ago. Individual physicians respond to this accelerating technological change in varying ways. A physician may fall within one of four technological-response categories.

1. The Out-of-Touch Practitioner

The out-of-touch practitioner has failed, for a variety of reasons, to adopt the mainstream standard of care of diagnostic testing. It is an old and recurrent problem in the caselaw.[50] An erroneous diagnosis may be merely an error of judgment for which a physician is not liable; however, where an erroneous diagnosis results from the physician's failure to administer standard tests, the physician may be deemed to have breached the standard of care and found to be negligent. As one court said:

---

47. *Id.* at 182.
48. *Id.* at 190.
49. Pike v. Honsinger, 155 N.Y. 201, 210, 49 N.E. 760, 762 (1898).
50. In *Peterson v. Hunt*, 197 Wash. 255, 84 P.2d 999 (1938), the defendant physician made a vaginal examination of the plaintiff and concluded that she was pregnant. However, it was later determined that she was not pregnant but had an ovarian cyst. At trial, the plaintiff sought to admit into evidence testimony showing that the rabbit test for pregnancy was 96 percent effective and was well recognized in the local area; however, the evidence was excluded. On appeal, the exclusion of the evidence was held to constitute prejudicial error since it was material in deciding whether the defendant was negligent in failing to use the test earlier in the treatment.

> If a physician, as an aid to diagnosis, i.e., his judgment, does not avail himself of the scientific means and facilities open to him for the collection of the *best* factual data upon which to arrive at his diagnosis, the result is not an error of judgment but negligence in failing to secure an adequate factual basis upon which to support his diagnosis or judgment.[51]

Failure to recognize a new standard of medical practice represents the classic malpractice situation. Where the deviation from a standard of care can be shown, recovery is likely if the proper proof is presented. For example, since amniocentesis is now normally administered to pregnant women over the age of 35, a physician's failure to inform his patient of the availability of such a procedure may lead to liability if a defective child is subsequently born.[52] Also, the failure of a practitioner to use computers to assist in diagnosis may lead to liability. During the zone of transition between experimental uses of a new technology and its diffusion into widespread use, a physician probably has little risk of liability. However, once the diagnostic tool has come into widespread use and is made affordable, the threat of liability is very real.[53]

2. The Reluctant Practioner

Unlike the out-of-touch practitioner, a reluctant practitioner has knowledge of the existence of medically accepted procedures or techniques but may refuse to adopt them. Such would be the case where a doctor refuses to use fetal monitors during labor, or to recommend their use to his patient, when such use has become standard practice. Under the traditional malpractice rule, this deviation from the standard may be conclusive as to liability unless the physician is able to convince the jury that the general acceptance by his profession of such monitoring is not justified.[54] The physician may attempt to discredit the standard by using statistics to show that the efficacy of the procedure is unproven in light of its costs and in terms of increased Caesarean sections. He may, thus, invoke the "best judgment" rule as a defense—a rule that states that a physician should use his or her own best judgment when the commonplace medical practice is dangerous.[55] In

51. Clark v. United States, 402 F.2d 950, 953 (4th Cir. 1968) (quoting Smith v. Yohe, 412 Pa. 94, 105, 194 A.2d 167, 173 (1963)).
52. Phillips v. United States, 508 F. Supp. 544 (D.S.C. 1981); Berman v. Allan, 80 N.J. 421, 404 A.2d 8 (1979).
53. *See* Watson, *supra* note 3.
54. Capron, *supra* note 40, at 671.
55. *See* Toth v. Community Hosp., 22 N.Y.2d 255, 239 N.E.2d 368, 292 N.Y.S.2d 440 (1968). "There is no policy reason why a physician, who knows or believes there are unnecessary dangers in community practice, should not be required to take whatever precautionary measures he deems appropriate." *Id.* at 263, 239 N.E.2d at 373, 292 N.Y.S.2d at 447. The institutional pressure, from hospital administrators, to adopt new technologies may also stem from fears

proffering this defense, the practitioner will face an uphill battle in trying to justify his deviation from the generally accepted standard.

3. The Faithful Follower

The third technological-response category of physicians is that of the faithful follower. Such a physician is one who religiously adopts the current mainstream practice and acts reasonably in his belief that proper research has been done to justify a new procedure. However, in three situations, the physician's blind adoption of mainstream techniques may be inappropriate.

First, the current practice of physicians within the specialty may lag behind improvements suggested by current research findings. Practitioners may not hear about new research findings, thereby failing to adopt valid, innovative technologies. For example, psychotherapists who use Electro Convulsive Therapy (ECT) persist in using bilateral electrode placement, despite evidence that unilateral placement reduces adverse effects, particularly those of memory cognitive malfunctions.[56] An emerging consensus by researchers may not be adopted by practitioners for reasons related to the nature of their practice, or because they do not keep up with the literature. In cases where the plaintiff can present evidence as to the emerging consensus, courts have been willing, on occasion, to treat compliance with a customary practice as only partial, not conclusive, evidence of the standard of care.[57]

Second, the mainstream technology, particularly in the diagnostic area, may lead the physician to rely excessively on the technology for his data, causing him to relinquish other, more traditional, clinical and diagnostic checks on error. Faulty lab results may go undetected,[58] or more subtle problems may escape

---

of malpractice litigation and a perception that monitors provide a shield against liability.

56. B. FURROW, MALPRACTICE IN PSYCHOTHERAPY 59 (1980).

57. *See* United States v. Simon, 425 F.2d 796, 805-06 (2d Cir. 1969). The *Simon* court held that professionals may be liable for acts a jury considers detrimental to the public interest whether or not professional organization guidelines have been adhered to. Compliance was considered persuasive, but not conclusive. The professionals in *Simon* were accountants who sought to use their adherence to generally accepted accounting principles as a complete defense. While it may be that courts will accord more deference to medical professionals than to other professional groupings, cases like *Helling* suggest that where the professional practice has pernicious effects, courts will override the practice. Helling v. Carey, 83 Wash. 2d 514, 519, 519 P.2d 981, 983 (1974).

58. Price v. Neyland, 320 F.2d 674 (D.C. Cir. 1963). The rate of error in testing laboratories has been described as "massive." *See* Culliton, *Clinical Labs: Bills Aimed at Correcting "Massive" Problems*, 192 SCIENCE 531 (1976). *See*

notice because traditional cross-checks have fallen into disuse. The medical profession's current reliance on computerized axial tomography (CAT) scanners in diagnosing certain brain lesions illustrates this problem.[59] Since the use of CAT scanners became a standard of practice within four years after its introduction, debate has centered on its swift diffusion into mainstream use before its efficacy and costs were properly evaluated. One report, looking beyond cost, noted that the scanner may even have a detrimental effect on therapy, since its accuracy in detecting brain lesions is high (although not perfect), and so further steps are usually needed to ensure that all lesions are detected. The use of the CAT scanner tends to cut short the diagnostic workup and cause some treatable lesions to be missed.[60]

Technologies of diagnosis, in particular, can develop a life of their own. Excessive reliance on the computer, the X-ray machine, the electrocardiograph, causes the treating physician to neglect his own senses. The dependence on diagnostic information from complex, automated devices may be counterbalanced by physician recognition that overreliance upon laboratory tests can lead to liability, at least where cross-checks are available and are not used.[61]

Finally, the mainstream practice may have diffused too quickly into professional use. As in the case of gastric freezing of duodenal ulcers,[62] a technique's adverse effects should be sufficient to alert the doctor to the hazards of following a particular customary prac-

---

also Levitt, *Growth of Technology, and Corporate Profitmaking in Clinical Laboratories*, 8 J. HEALTH, POLITICS, POLICY & LAW 732 (1984).

59. INSTITUTE OF MEDICINE, COMPUTED TOMOGRAPHIC SCANNING (1977). The consensus on CT scanners is that they are now indispensable to radiologists. *See* Kolata, *Consensus on CT Scans*, 214 SCIENCE 1327 (1981) (noting that CT scans may be overused in a variety of situations).

60. Davis, *Some Limitations of Computed Tomography in the Diagnosis of Neurological Diseases*, 127 AM. J. ROENTGENOLOGY 111, 121 (1976).

61. In Price v. Neyland, 320 F.2d 674 (D.C. Cir. 1963), a mistake was made in the diagnosis and management of a child born of parents with an Rh factor blood incompatibility. Based upon incorrect laboratory tests, the physician misdiagnosed the jaundice that the infant showed, and he failed to give followup tests. The court quoted, with approval, medical testimony that "where laboratory tests are inconsistent with clinical findings, the laboratory tests should re-run . . . ." *Id.* at 677.

Excessive reliance on computer-assisted diagnosis, in lieu of other traditional crosschecks, may ultimately lead to liability if the program malfunctions or is erroneously programmed for a certain disease or symptom. *See* Hall, *Psychiatrists' Computer Use Stirs Debate*, Wall St. J., Dec. 6, 1983, at 31, col. 2.

62. Fineberg, *Gastric Freezing: A Study of the Diffusion of Equipment-Embodied Technology*, in MEDICAL TECHNOLOGY AND THE HEALTH CARE SYSTEM 173 (1979).

tice. Evidence of such adverse affects may be obtained through the testimony of an expert or through periodicals and treatises.[63] Where the medical literature discussing the adverse effects of a particular procedure is clearly accessible, the imposition of tort liability might change the mainstream practice by highlighting the technique that is ineffective or dangerous, and by bringing the new results to the attention of other practitioners. Studies suggest that if negative results from clinical tests become available *after* a medical speciality has adopted a technique, practitioners will gradually abandon the practice.[64] The threat of litigation would encourage the widespread abandonment of harmful practices, and underscore the lack of efficacy or hazards inherent in particular diagnostic and treatment techniques.[65]

4. The Innovative Practitioner

Typically, the innovative physician wants to use a new procedure or diagnostic device that has not yet been incorporated into the professional standard. He may be liable if the procedure has received little support in the medical literature, and if it does not work properly. Even full disclosure of the experimental nature of the procedure or device to his patients may not protect the physician from liability. Sound policy reasons dictate that full disclosure should not be a defense to liability in this area. Use of a new untested procedure or technique on a patient amounts to an experimentation. Such experimentation has been termed "nonvalidated practice," since the primary attribute of the novel practice is "lack of suitable validating of [their] safety [and] efficacy."[66] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, discussing physician innovation, wrote:

63. *See* FED. R. EVID. 803(18). The problem is that either the expert has to rely on the periodical, or else the judge must take judicial notice under FED. R. EVID. 201; this requires a clearly reliable authority—a publication "recognized as a standard authority by the medical profession." *See* Hemingway v. Ochsner Clinic, 608 F.2d 1040 (5th Cir. 1979) (text written by two nurses was not shown to be reliable); Generella v. Weinberger, 388 F. Supp. 1086 (E.D. Pa. 1974) (statements from a respected medical publication, when independently used as evidence of truth therein asserted, are inadmissible as violative of hearsay rule).

64. Finkelstein, Schectman, Sondik & Gilbert, *Clinical Trials and Established Medical Practice: Two Examples,* in BIOMEDICAL INNOVATION 213 (1981).

65. Others have proposed national bodies to evaluate and regulate innovative procedures. *See, e.g.*, Necheles, *Standards of Medical Procedure Become Accepted?*, 10 L. MED. & HEALTH CARE 15 (1982). Unfortunately, no such national body presently exists.

66. Levine, *Clarifying the Concepts of Research Ethics*, 29 HASTINGS CENTER REP. 21 (1979).

> Radically new procedures . . . should . . . be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal reseach project.[67]

The hospital may also face liability if unscreened experimental procedures carried out by staff physicians result in injury.[68]

Innovation, in the context of the complexity of modern medical practice, properly belongs in a controlled environment. Where sufficient literature is available to suggest that controlled tests have validated the procedure, a physician's risk of liability is diminished, and a "respectable minority" within the specialty area will quickly emerge to use the procedure or device. Thus, physicians are encouraged to become familiar with the merits of clinical testing, the evaluation of results, and research protocols; those refusing to do so assume the risk of liability in adopting a technique that proves ineffective and dangerous.

D. Work Setting Errors

While solo practice has long been the ideal of medical practice, the movement toward group practice has been inexorable. Group physicians constituted 1.2 percent of the profession in 1940, 2.6 percent in 1946, 5.2 percent in 1959, and 12.8 percent in 1969. By 1975, over 18 percent of all active physicians practiced in groups of three or more. By 1980, 88,000 physicians, or about 25 percent of the doctors in private practice, worked in groups.[69] Other institutional groups, in which physicians practice together, have also emerged. Health Maintenance Organizations (HMO's) constitute the largest of such groups;[70] emergency centers and surgical centers are two

---

67. NAT. COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, BELMONT REPORT 3-4 (1978).

68. THE JOINT COMMISSION ON ACCREDITATION MANUAL FOR HOSPITALS, STANDARD IV (1982) (pertaining to the Medical Staff) provides:

> The Medical Staff shall provide mechanisms for the regular review, evaluation, and monitoring of medical staff practice and functions. Such mechanisms shall be designed to maintain high professional standards of care.

Id. at 106. Hospitals will need to develop policies to deal with potentially unvalidated diagnostic and treatment approaches. *See* Cowan, Hospital Responsibility for Innovative Therapy (unpublished paper on file with the author).

69. P. STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 425 (1982).

70. *Id.* at 415. *See also* Binford, *Malpractice and the Prepaid Health Care Organization*, 3 WHITTIER L. REV. 337 (1981); Bovbjerg, *The Medical Malpractice Standard of Care: HMO's and Customary Practice*, 1975 DUKE L.J. 1375, 1386 n.36.

other emerging forms of institutional groups.[71]

The growth of the modern hospital as the locus of medical practice is another significant force transforming American medicine.[72] Physicians have come to need hospital affiliation. By 1975, no physician would consider practicing without the resources that hospitals offered, and 25 percent of the 330,000 active physicians practiced fulltime in a hospital.[73] So rapid is the movement of doctors toward hospital affiliation that the hospital industry may end up dominated by "huge health care conglomerates."[74] Almost 80 percent of the incidents that lead to malpractice claims occur in hospitals, reflecting the primacy of the hospital as the locus of most medical practice.[75] The work setting of the hospital provides a context in which "persistent and powerful demands cause the individual to behave in a certain way regardless of his personal qualities."[76] These demands have resulted in peer pressure against questioning a colleague's judgment or informing on his errors. However, the incentive structure can be changed so as to facilitate the detection of errors.[77]

Large hospital practice has become the norm, as the larger hospitals have become dominant through the federal health planning process.[78] With hospitals growing more powerful, hospital administrators have also acquired greater power, developing "a natural community of interest with staff physicians whose modes of practice utilize sophisticated technologies and justify further institutional expansion."[79] One critic has contended that the investments in such large facilities lead to "rigidifying of medical practice around current patterns of treatment favored by the institution. The practice of medicine at the larger hospitals has set community expectations and medical standards."[80] The "coming

71. *See, e.g.* Zaremski & Fohrman, *The Emergicenter: Has Its Time Arrived?*, 11 L. MED. & HEALTH CARE 4 (1983).
72. *See* P. STARR, *supra* note 69, Ch. 5.
73. S. REISER, MEDICINE AND THE REIGN OF TECHNOLOGY 156 (1981).
74. *See* P. STARR *supra* note 69, at 428.
75. J. GUINTHER, THE MALPRACTITIONERS 7 (1978) (citing results of a study conducted by the Insurance Services Office).
76. E. FREIDSON, PROFESSION OF MEDICINE: A STUDY OF THE SOCIOLOGY OF APPLIED KNOWLEDGE 94 (1970).
77. *See* Havighurst & Tancredi, *Medical Adversity Insurance: A No-Fault Apporach to Medical Malpractice and Quality Assurance*, 613 INS. L.J. 69 (1974) (discussing an attempt to couple financial insurance incentives with risk disclosure). *See generally* INSTITUTE OF MEDICINE, BEYOND MALPRACTICE: COMPENSATION FOR MEDICAL INJURIES (1978).
78. Payton & Powsner, *Regulation Through the Looking Glass: Hospital, Blue Cross, and Certificate of Need*, 79 MICH. L. REV. 203, 273 (1980).
79. *Id.* at 274.
80. *Id.* at 275.

of the corporation"[81] has, therefore, already had significant effects on medical practice. The issue is whether tort rules should yield to this transformation of practice, or seek to control or direct it.

Judicial expansion of malpractice liability, making physicians accountable for a range of medical errors, has run counter to legislative reforms in the malpractice area. Over the past decade, state legislatures, responding to the so-called "malpractice crisis," have abrogated or restricted the operation of legal doctrines from res ipsa loquitur to informed consent.[82] But the courts have recognized the centrality of the hospital setting. Thus, hospitals have been subjected to an expansion of the *respondeat superior* doctrine and are held to be responsible for the negligence of the physicians practicing within them, even when the physicians are operating as independent contractors.[83] An alternative theory of "corporate negligence" has been premised on the hospital's duty to exercise ordinary care in supervising its staff.[84]

A judicial movement toward strict liability for hospital services, analogous to that which exists for some products, may also be developing. Some hospitals have been held liable for the harm caused by medical instruments used in treating patients.[85] Courts have usually distinguished the rendition of professional services from sale of goods.[86] In recent cases, however, courts have begun to examine the basis for strict liability in the medical context. In *Hoven v. Kelble*,[87] the Supreme Court of Wisconsin, while rejecting strict liability for medical services, noted the similarity between a consumer's purchase of products and the patient's request for medical treatment and care.

> The typical purchaser of medical services cannot evaluate the quality of care offered because medical services are complex and infrequently bought. The medical care market gives the purchasers little assistance in enabling the purchaser to evaluate what he or she is buying. It is generally the physician—not the patient—who determines the kind of services to be rendered and how often. . . . The physician is in a better position than the patient to determine and improve the quality of the services, and the patient's reliance on the doctor's skill, care and reputation is perhaps greater than the reliance of the consumer of goods.[88]

In *Johnson v. Sears, Roebuck & Company*,[89] a federal district

81. *See* P. STARR, *supra* note 69, at 428.
82. *See generally*, S. LAW & S. POLAN, *supra* note 25, at 97-119.
83. Beeck v. Tucson Gen. Hosp., 18 Ariz. App. 165, 500 P.2d 1153 (1972).
84. Darling v. Charleston Community Mem. Hosp., 33 Ill. 2d 326, 211 N.E.2d 253 (1965), *cert. denied*, 383 U.S. 946 (1966).
85. See Annot., 54 A.L.R. FED. 3D 258 (1971), for a list of cases.
86. *See* B. FURROW, *supra* note 56, at 82.
87. 79 Wis. 2d 444, 256 N.W.2d 379 (1977).
88. *Id.* at 468-69, 256 N.W.2d at 391 (footnote omitted).
89. 355 F. Supp. 1065 (E.D. Wis. 1973).

court held strict liability to be a permissible theory of recovery for defects in mechanical and administrative services in hospitals. The court assumed, without deciding, that strict liability would "not apply to professional medical services by doctors."[90] But it reasoned that such an exemption should not apply to "those services which hospitals perform for both doctors and patients," because of the "public interest" in having these services "performed properly."[91]

These cases represent a judicial willingness to invoke tort liability where the harmful results of a treatment are forseeable and avoidable. Courts are beginning to recognize that the hospital is in the best position to monitor the iatrogenic effects which are traceable to the hospital's rendition of services, and that expanded liability creates a substantial incentive to improve risk management programs. Expanded liability may, therefore, foster a movement by hospitals to keep better records, increase the frequency of conferences on adverse outcomes, increase consultations, and establish evaluation of procedures which not only consider cost factors, but also iatrogenic impact.

The tort law concept of foreseeability of harm provides the core justification for a concept of medical culpability that would encompass the three categories of medical errors discussed above. Foreseeability involves a prediction, at a time prior to the occurrence of an injury, of the type of injury that might result from a treatment error, its severity, and the probability that such an injury will occur.[92] Where harm is likely to occur and the victim has neither consented to nor can avoid the harm, "foreseeability of harm," as the dominant test of a duty to prevent injury, requires the actor to either take precautions or to face liability.

The focus of predictability of risk shifts the attention from the individual within a professional group to the capabilities of the group itself or, in the institutional setting, the hospital. Liability is linked to predictability and to the ability of the profession to alter

90. *Id.* at 1066.

91. *Id.* at 1067.

92. See Judge Learned Hand's famous statement of the negligence calculus in United States v. Caroll Towing Co., 159 F.2d 169 (2d Cir. 1947):

> [T]here can be no . . . general rule, when we consider the ground for liability. [T]he . . . duty . . . to provide against resulting injuries is a function of three variables: (1) The probability [of harm]; (2) the gravity of the resulting injury . . . ; (3) the burden of adequate precautions. Possibly it serves to bring this notion into relief to state it in algebraic terms: if the probability be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P: i.e., whether B is less than PL.

Id. at 173.

risks that it is able to predict.[93]

In each case, the test of foreseeability will depend on the increased ability of modern medicine to predict, through its new technologies and through the use of statistics, the risks involved in certain practices. As institutions come to know more precisely the extent of the risks associated with their activities, the ascription of responsibility and culpability becomes possible and fair.[94] Even if a medical provider cannot predict the whole range of risks associated with his administration of service, he is in a better position than the patient to detect and avoid as many of the risks as possible.[95]

Placing the responsiblity for medical malpractice with the hospitals would inevitably help to reduce the incidence of malpractice. It has been observed that if a hospital faces liability directly or vicariously for the negligence of its agents, it will tighten its control over their practice of medicine. "Under corporate management, there is also likely to be close scrutiny of mistakes, if only because of corporate liability for malpractice."[96] Technology provides the tools for monitoring a doctor's medical practice within the hospital, allowing the determination of patterns of unusual patient loss or excessive surgery rates, or other suspicious facts. As one hospital administrator has noted: "The large conglomerate can purchase and/or develop sophisticated quality-of-care control programs managed by statisticians."[97] The work setting thus becomes more

93. See O'Connell, *Expanding No-Fault Beyond Auto Insurance: Some Proposals*, 59 VA. L. REV. 749, 790-94 (1973), for an analysis of the connection between culpability and predictability of risk.

94. Twiss, *The Problem of Moral Responsibility in Medicine*, 2 J. MED. & PHIL. 330, 365 (1977). *See* Baram, *Technology Assessment and Social Control*, 180 SCIENCE 465 (1973).

95. Schwartz & Komesar, *Doctors, Damages and Deterrance: An Economic View of Medical Malpractice*, 298 NEW ENG. J. MED. 1282 (1978). *See generally* G. CALABRESIS, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS (1970).

96. *See* P. STARR *supra* note 69, at 447.

97. *Id.* Ironically, the computer may pose liability problems for the hospital at the same time that its capabilities provide better quality control. The issue is the legal standard by which to measure computer related errors: Are computer program services subject to a negligence standard, or are they products subject to strict liability?—The issue has not been resolved by the courts, but one recent commentary concludes:

> [W]hen hospitals, physicians, or programmers have considered the question of liability, they have tended to think in terms of negligence and malpractice. By creating, distributing, or even merely using computer programs, however, they may have moved toward the area of strict liability, formerly the domain of drug manufacturers, automobile manufacturers and other traditional industrial producers.

Brannigan & Dayhoff, *Liability for Personal Injuries Caused by Defective Computer Programs*, 7 AM. J.L. & MED. 123, 144 (1981).

important in reducing medical error; malpractice can become the spur, provided that expanding theories of liability cause the attention to be focused on the hospital and away from the individual practitioners.

III. CONCLUSION

The physician has, until now, been the principal decisionmaker regarding the implementation of most medical innovations. Regulatory policies to control the introduction of new technologies are often "all or nothing" propositions; they either prohibit the technology until a high standard of safety is met, as with the Medical Device Amendments of the Food, Drug and Cosmetic Act, or leave control to the informal pressures of the marketplace. Thorough premarket testing cannot always detect adverse reactions that are eventually exposed with the passage of time; malpractice suits thus become an important form of postmarket monitoring of the technology. Such suits, focusing on the practitioner's application of technology in the particular case, can subject the professional standard to the spotlight of review pertaining to its efficacy, potentially adverse effects, and its rate of diffusion into mainstream use. As one commentator has written:

> Physicians will inevitably make mistakes, but they should not err for the wrong reasons, such as misplaced reliance on fragmentary information, succumbing to the force of authority rather than depending on the strength of evidence, suspicion of population based studies, ignorance of the pitfalls and requirements for statistically and scientifically valid clinical research, a need to have the latest gadget, a desire to achieve prestige, defend a reputation, or gain financially.[98]

Other malpractice developments may also result in alteration of professional attitudes and practices. The doctrine of informed consent, while still bitterly resisted by some members of the medical profession,[99] has had an impact on medical disclosure practices, resulting in more clearly articulated disclosures by physicians of hazards and alternatives.[100] Legal rules, if they are seen as technical and are mechanically applied, are of little use; but when the values inherent in such doctrines as informed consent become internalized, there will be more changes and further reforms.

Tort law has a role to play in regulating medical errors. The malpractice suit can signal the need for change in the habits of the individual practitioner or in the institutional practices of the hospi-

98. Fineberg, *supra* note 62, at 191.

99. *See, e.g.*, Grudner, *On the Readability of Surgical Consent Forms*, 302 NEW ENG. J. MED. 900 (1980).

100. Doctrinal changes in tort law have altered the physician-patient relationship in the direction of fuller disclosure. *See* Novak, *supra* note 4, at 898.

tal. It may help to expose the ethical renegades. It may provide direct deterrent effects through dollar judgments and the nontangible costs of litigation. Litigation may articulate new duties, validating existing norms or promoting the centrality of new ones. It may announce new concepts of responsibility, requiring medical specialities to reexamine their diagnostic procedures and treatment modalities. It may alter the work setting, spurring improved quality control by expanding the liability of institutions which increasingly dominate health care delivery. Litigation has the advantage of not requiring legislation to put its reforms into operation. It can be triggered by a single plaintiff. Once the court's intervention is sought, it must act on the case before it.

The recent studies of iatrogenesis suggest that medical errors are a real and substantial problem but that the medical profession still seeks to avoid linking culpability with medical error. It is not uncommon to find the legal system blamed for medicine's own tardiness in implementing effective monitoring of iatrogenic harms. Malpractice suits may be the best source of regulation currently available for iatrogenic outcomes in the health care system. Proposals to reform the medical malpractice system will be inadequate if they ignore this primary need to deter bad medical practices.

The medical establishment needs to be made more aware of the risks it creates. Accordingly, future reforms must note the real problems of medical error and the incentives for correction provided by malpractice litigation. Any "no fault" system, national health insurance plan, or other legislative reform, must provide an alternative means of deterring iatrogenic outcomes.