Medical Liability and the Culture of Technology

Peter D. Jacobson

Printed in the United States of America.

0-9741239-5-1

The Project on
Medical Liability in Pennsylvania
funded by The Pew Charitable Trusts

Medical Liability and the Culture of Technology

Peter D. Jacobson

Other Reports of the Pew Charitable Trusts' Project on Medical Liability

Resolving the Medical Malpractice Crisis: Fairness Considerations
by Maxwell J. Mehlman
ISBN 0-9741239-0-0

Understanding Pennsylvania's Medical Malpractice Crisis: Facts about Liability Insurance, the Legal System, and Health Care in Pennsylvania
by Randall R. Bovbjerg and Anna Bartow
ISBN 0-9741239-1-9

Expertise in Medical Malpractice Litigation: Special Courts, Screening Panels, and Other Options
by Catherine T. Struve
ISBN 0-9741239-2-7

Lessons from History: State Constitutions, American Tort Law, and the Medical Malpractice Crisis
by John Fabian Witt
ISBN 0-9741239-4-3

Public Medical Malpractice Insurance
by Frank A. Sloan
ISBN 0-9741239-3-5

These reports are posted on the Project's Web site: www.medliabilitypa.org.

Table of Contents

Acknowledgments

I want to thank The Pew Charitable Trusts for funding support. Bill Sage suggested this topic and provided expert guidance throughout. I received excellent research assistance from Rachel Schneller, JD, MPH, Hemant Lanjewar, MHSA, and Rachel Turow, JD, MPH Candidate (2006). I also appreciate the very thoughtful comments I received in conversations with Haavi Morreim, PhD, and Phil Peters, JD.

Executive Summary

This paper explores the relationship between technology and medical liability. The analysis is based on several premises:

- Technology is the principal driver of health policy and health care delivery.
- Technology is the principal driver of negligence law.
- The history of medical malpractice liability tracks the development of medical technology.
- Culture is the most important factor driving the development and use of technology.

In short, the culture of technology drives medical liability. No solution to the recurrent medical liability crises is possible without dealing with the underlying culture of technology.

Technology and the Law

Technology has been the central component in shaping the contours of legal doctrine in negligence generally and medical liability specifically. The history of medical malpractice liability is a struggle between technological advances and injuries resulting when those advances fail.

Technological Change and Medical Liability

Along with improving health, technological advances create opportunities for error in diagnosis and treatment, and those errors may result in more visible and more

severe outcomes. The precision of new technologies means that momentary lapses can have major adverse consequences. Studies of specific technologies and liability indicate that claims increase when a new technology is introduced, and then level off over time. Studies of patients undergoing laparoscopic cholecystectomy, breast cancer patients, and neurologically impaired infants suggest that liability claims relating to technology are rising and comprise a growing portion of malpractice insurance payouts.

Explanatory Factors for Mediating the Use of Technology

American medicine thrives on the inexhaustible demand for high-technology medical interventions: a "culture of technology." Americans prize continued advances in technology and widespread availability of those innovations. Individual patient preferences for the latest technology bolster the general cultural propensity to favor technological solutions to medical problems. This puts added pressure on physicians to use the latest technology. Long-term cultural phenomena (i.e., a belief that technology can improve lives, unrealistic patient expectations, and a proclivity to sue when procedures fail) contribute to liability trends. Other factors include:

- Physician Attitudes: Self-image and competition for patients lead physicians to choose new technology if there is a perceived improvement in patient comfort or safety, even when clinical benefits are marginal or unproved.
- Physician Specialization: Technology makes subspecialty practice possible and creates its own demand for more technology.

- Research: Americans are willing to pay for progress, so research funding for technological innovation is likely to remain generous.
- Rapid Diffusion of Technology: Manufacturers' commercial incentives, combined with hospital competition for physician business, lead to rapid dissemination of technology, which in turn changes how medical care is organized and delivered.
- Selecting and Reimbursing New Technology: Rapidly evolving technology places a heavy burden on government and private insurers to evaluate and reevaluate medical interventions.
- Lack of Centralized Controls: Unlike many European countries, the United States does not directly regulate the availability of medical technology.

Recommendations for Change

There is no easy legal or policy solution to the technological imperative, especially as there is no one trajectory for how technology leads to litigation. As long as society demands technological innovation, physicians' liability exposure is an inevitable consequence.

- Incremental Reforms:
    - Change the legal standard of care to factor in costs and benefits, and allow physicians to weigh available resources in deciding whether to adopt certain technologies.
    - Impose caps on non-economic damages—an illusory fix.

- Improve the litigation process by making use of court-appointed experts and empowering an independent judicial panel to review and monitor expert testimony.

- Systemic Reforms:
  - Adopt a no-fault approach in cases of indeterminate causation in order to reduce incentives to practice defensive medicine.
  - Adopt enterprise (institutional) liability to improve accountability for quality and reduce medical errors. But shifting responsibility to the institution does not solve the problem of technology-induced liability; it only changes the financing mechanism.
- Technology Assessment: Developing a much more robust technology assessment process should be a key policy objective.
- Changing the Culture of Technology:
  - A more forthright debate about the cultural aspects of technology is needed.
  - Dialogue between medical leaders and the public could temper expectations about what medical technology is capable of achieving.
  - Physicians should communicate to individual patients that technology offers only a limited solution to many medical problems.

Introduction

This report explores the central but often unappreciated role medical technology plays in recurring medical malpractice insurance crises. During the past 30 years, the country has witnessed three separate malpractice crises. Each crisis has led to incremental reforms, but fundamental alterations in how medical professional liability is determined have remained elusive. In the current crisis, physicians and liability insurers blame exorbitant and irrational jury verdicts for the rise in medical malpractice insurance premiums, while plaintiffs' attorneys blame insurers who under-price premiums to expand market share when investment income is strong and then overcharge when investment income declines. No doubt, as the Congressional Budget Office (CBO, 2004) observes, there is plenty of blame to go around (including the medical profession's inadequate self-regulation).

Not only is technology the principal driver of health policy through its impact on cost, access, and quality, but technology is also the primary driver of negligence law.

Medical technology has not been prominently featured in the ongoing liability debate. Not only is technology the principal driver of health policy through its impact on cost, access, and quality, but technology is also the primary driver of negligence law. The history of medical malpractice liability parallels the development of medical technology. As one medical historian puts it, "…the development and implementation of new technologies and procedures have played a consistent and central role throughout the

history of malpractice litigation" (DeVille, 1998, p. 197). For any malpractice reform effort to be effective, it must take account of how technology influences and is influenced by malpractice liability.

The report adopts the Institute of Medicine's broad definition of technology as "techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered" (IOM, 2000, p. 53). This definition excludes diagnoses and interventions that rely mainly on physician observation and deduction, as well as errors or misdiagnoses based on provider misjudgment (i.e., adverse drug interactions). There are at least two different kinds of medical technology that affect physicians: technology that directly shapes patient care (such as new diagnostic tools or medical devices), and information technology (such as on-line medical data bases or telemedicine). A further distinction could be made between low-technology equipment (e.g., hospital beds) and high-technology equipment (e.g., CT scans), but malpractice litigation almost always involves high-technology equipment.

Technology is both savior and culprit: savior in extending length and improving quality of life; culprit in causing rapid increases in health care expenditures and considerably more exposure to liability.

In a sense, technology is both savior and culprit: savior in extending length and improving quality of life; culprit in causing rapid increases in health care expenditures

and, for physicians, considerably more exposure to liability. Because there is no single dominant technology, there is no single appropriate legal or health policy response. What might be effective for one technology might not work for another. For a novel direct technology, such as a full body scan, a technology assessment process might be the most effective policy approach. For an application of information technology, such as telemedicine, the key issue might be defining a standard of care.

The following section looks at the historical relationship between technology and law. Next, the report examines the reciprocal effects of technological change on liability trends and of liability trends on continued technological innovation. In the final section, the report describes the culture of technology that permeates American medicine, and offers suggestions for policy and legal change.

Technology and Tort Law

Technology has been the central component shaping the contours of legal doctrine in the law of negligence generally and medical liability specifically. The influence of technology on the development of legal rules is not only an observation about the past, but is likely to dictate the future as well. Among others, cyberspace and genetic technology will affect the legal environment well into the 21st century. A similar phenomenon is also likely to dominate international law, with technological advances shaping international legal regimes in ways that depart from past efforts (Picker, 2001).

General Tort Law[1]

Tort suits are civil claims for injury not arising from a contract, such as claims alleging negligence. At its simplest, tort law sets standards of behavior that individuals and businesses are expected to meet in avoiding the unreasonable risk of harm to third persons. Although all states use the same general framework, each state's court system has established its own body of common law principles, some of which have been modified by the state's legislature. This means that legal doctrine will vary across states, so that what is a tort in one state may not be a tort in another.

To win a negligence case, the plaintiff must prove the following four elements by a preponderance of the evidence: that a duty of due care exists; that the defendant breached the duty; that the defendant's conduct caused the injury; and that the injury produced actual damages. To ascertain the scope of the duty of due care, courts often

[1] Part of this section is taken from Jacobson (2002, Chapter 2).

look to custom in the industry, or, in the absence of custom, will set the standard based on notions of reasonableness. Weighing the defendant's conduct against the way a "reasonable person" would have acted under the circumstances allows the jury to make an informed decision about whether the defendant's activity met the community's standard of due care or created an unreasonable risk of harm.

By deferring to industry custom, courts give the marketplace considerable flexibility to determine how and when to introduce the latest technology or new safety advances. Not every conceivable safety precaution must be taken—only those that are justified by the costs of injury prevention. Thus, the utility or social value of the conduct must be balanced against the risks.[2] In negligence cases, the courts are free to ignore industry custom and impose more stringent standards of care if the industry is slow to adopt technologies or systems that would avoid injury.[3] For example, if an industry fails to adopt a cost-effective technology, such as airbags in automobiles, the courts could overrule industry norms and impose liability.

Negligence law is fundamentally a creature of technology; really, it is the common law's response to technology.

[2] *United States v. Carroll Towing Co*., 159 F2d. 169 (2d Cir. 1947); Restatement (Third) of Torts: Gen. Principles, Art. 4 (1999).
[3] See, e.g., *The T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932), *cert. denied*, 287 U.S. 662 (1933).

One of the hallmarks of the common law is that it develops incrementally in response to changing economic and social conditions. For instance, the emergence of railroads in the 19th century and the attendant social consequences (e.g., increased injuries to workers and bystanders alike) drove the development of modern negligence principles. Likewise, the development of mass produced goods in the 20th century led courts to adopt strict liability for defective products in the 1960s (i.e., liability without regard to fault) (Jacobson and Pomfret, 1999).

A consistent factor in these examples is technology. As one scholar has noted,

> Negligence law is fundamentally a creature of technology; really, it is the common law's response to technology. Advances in technology can easily cause corresponding increases in the number of negligence claims. Revolutions in an industry's technology will often impose tremendous new loads on the negligence system (Grady, 1988, p. 293).

At the same time, there is a life-cycle to technology. At first,

> there are few suits until a particular technology is performed frequently and both the profession and the public believe that it generates predictable results and substantial benefit….This phenomenon helps explain why patients only infrequently sued physicians during the period when surgery was least effective, and perhaps the most dangerous (De Ville, 1998, pp. 201-202).

Eventually, the initial technological advance leads to inflated expectations and litigation when the expectations are not met. As a general proposition, new technologies "…take risk from nature and transform it into potential liability—liability that will become

actual" when their use falls below the standard of care (Grady, 1988, p. 295). Subsequent improvements then limit risk and reduce injuries.

To the extent that the pace of new technological innovations quickens (as in the late 20th and early 21st centuries), negligence claims are likely to explode. As corrective technologies emerge, those claims will be reduced (Grady, 1988; Grady, 1992). Another factor will be how the courts respond to this life-cycle. As long as courts permit negligence claims to proceed, new technology will increase liability exposure. But if courts provide immunity to new innovations, liability exposure may be postponed or reduced. We can observe this pattern most clearly in briefly reviewing the development of legal doctrine in response to the railroads (Jacobson and Pomfret, 1999).

Although historians disagree about many aspects of how negligence principles were developed in U.S. common law, it seems clear that accidents involving the railroads were the precipitating factor. Tort, insofar as we think of it as a regime imposing on strangers a general duty of care, was not a coherent concept prior to railroads and industrialization. Earlier suits for damages tended to be based on the relationship between the parties, often arising out of status, property, or contract considerations. Thus, courts would periodically "discover" (the common law was viewed as something "discovered" rather than fashioned) new duties between employers and employees, innkeepers and guests, or passengers and coach operators. A common carrier, for

example, was held strictly liable for injuries to his passenger because of the relationship between them.

After a period of immunizing the railroads from liability, in part because courts were reluctant to interfere with an emerging industry and in part because established doctrinal rules did not seem to apply, the courts developed modern negligence principles to hold the industry responsible for the harm it caused. By the second half of the 19th century, negligence was fixed as the proper rubric under which to analyze claims against the railroads. The same framework was soon applied to a wide range of interpersonal and business-related activities, including lawsuits against physicians.

Medical Negligence

The history of medical professional liability is a struggle between technological advances and injuries resulting when those advances fail. In fact, the first wave of medical malpractice lawsuits, between 1820 and 1850, was fueled by advances in treating bone fractures (Table 1). This pattern would consistently replicate itself over the succeeding years (Mohr, 1993). By the late 1800s, it was apparent that rapid technological change enhanced physicians' stature, but exposed them to litigation: "… innovation often ran through the cycle of advancement, inflated expectations, limited successes, and lawsuits" (De Ville, 1990, p. 217).

The first wave of medical malpractice lawsuits, between 1820 and 1850, was fueled by advances in treating bone fractures.

Table 1: Brief History of Medical Liability and Technology

Beginning of 19th Century	
1820s – 1850s	First wave of medical malpractice suits inspired by technological advances in treating bone fractures
1840s	Medical Malpractice creates breach between lawyers and physicians • Litigation against physicians becomes common • Contingency fees and jury system aided rise
Second Half of 19th Century	
	Negligence framework established: the common law's response to technology
1890s	Technical advances increase physician prowess but also expose them to greater liability
Early-Mid 20th Century	
	Lawsuits continue to increase in frequency as advances in medicine make it more effective and more dangerous for physicians.
	Innovations in radiography and orthopedics lead to greater liability in those areas
	Development of strict liability principles applicable to manufacturers—rarely applied to physicians
Late 20th Century	
	Pace of technology quickens
	Acceleration of new technology exposes many new medical mistakes, adding to frequency of medical malpractice claims and award severity
	Recurrent medical liability crises dominated by rising malpractice insurance premiums
21st Century	
	Technology's role becomes ever-increasing in medical practice and liability

Technical advances in medical care would seem to increase positive patient outcomes and improve satisfaction, yet they are not risk-free: “Physicians could be penalized for adopting a new practice too soon, but they were also under immense pressure, intellectually, professionally, and legally, to keep pace with rapidly evolving medical technology” (De Ville, 1990, p. 221). In their attempts to be entrepreneurial and aggressive, physicians often experimented with new procedures. Innovative, sometimes radical techniques raised expectations of a cure, while the general public did not often understand the attendant risks. The only recourse for a patient who suffered an adverse outcome was to ask a court to hold the physician accountable. Malpractice litigation emerged as a serious rift between American physicians and lawyers in the 1840s, as legal practitioners identified such actions as a potential growth area. Before that decade, litigation against physicians was rare in the United States, although the concept of medical malpractice already had been imported from England and used against medical charlatans. Ironically, trained physicians supported this early litigation (Mohr, 1993).

The initial cause of tensions between doctors and lawyers was their confrontation over medical testimony. Most physicians feared court appearances, even when they were not named as defendants (Mohr, 1993; Morantz-Sanchez, 1999). Physicians began to resent the role of attorneys and the court in questioning their medical judgment. The nature of the adversarial legal system exposed expert witnesses to withering cross-

examination, which was especially effective in an era of limited scientific support for clinical theories.

> Expert witnesses as often as not made professional knowledge look shaky rather than strong… The insanity issue had evoked a popular backlash rather than continued public support; and suits against shabby medical treatments, which might have helped drive quacks from the field, had instead ignited a continuing, even growing, firestorm of malpractice indictments against the regulars themselves (Mohr, 1993, p. 236).

With the development of contingent fee arrangements and the increasing use of the American jury system to set common law standards, the legal world was poised to sanction physicians for any departure from prevailing practice norms (Mohr, 2000). By the end of the 19th century, the promise of a separate field of medical jurisprudence based on cooperation between the medical and legal professions seemed shattered.

Medical advances came to delineate the standard of care for the "better" practitioners.

One reason physicians were subjected to cross-examination was that new techniques allowed well-trained physicians to take on more difficult cases. Medical advances came to delineate the standard of care for the "better" practitioners. In the case of a compound fracture, a less qualified practitioner whose only skill was amputation might decline the case altogether. An educated physician, by contrast, could attempt to save the limb. Often the result was that the treated limb was shortened and had some

loss of function. The new, higher standards became the basis for lawsuits when patients unhappy with this outcome looked to the courts for compensation. Educated physicians could also have the medical texts they relied on used against them to define standards from which they were deviating.

In this way, physicians became "ironic victims of their own medical advancement" (Mohr, 1993). As physician capabilities and training expanded:

> Rather than pay their doctors for doing as well as they could under the conditions at hand, an increasing number of patients instead sued their doctors for failing to prevent or for apparently inflicting permanent disabilities and deformities; for failing to deliver on an implied contract of full recovery or restoration (Mohr, 1993, p. 112).

Innovations in radiography and orthopedics were particularly susceptible to lawsuits. Indeed, the spread of x-ray technology in the first part of the 20th century illustrates this point. Radiography undoubtedly advanced patient care, but soon became the largest source of malpractice liability, in both claim frequency and award severity, as patients claimed that they had received excessive radiation or that the roentgenologist had failed to interpret the films properly. "Radiographic tests also opened to exposure other sorts of medical mistakes that were previously difficult to demonstrate in court" (Mohr, 2000, p. 1734. See also, De Ville, 1998; Howell, 1995). This pattern of new technology raising expectations for health and physician

Innovations in radiography and orthopedics were particularly susceptible to lawsuits.

intervention and exposing new types of medical mistakes accelerated in the latter part of the 20th century (Jacobson, 1989).

As these historical developments were unfolding, the courts began adapting the negligence framework described above to help resolve the burgeoning litigation. In formulating legal principles to guide malpractice lawsuits, courts used the rules developed for railroad accidents, with one important exception. In medical liability cases, the standard of care is not general reasonableness but customary and usual practice established by physician testimony and medical treatises. This means that the medical profession itself sets the standard of care—far greater deference than the law provides to any other industry or profession. A typical statement of the law is that each physician must "exercise that degree of skill ordinarily employed, under similar circumstances, by the members of [the] profession."[4] The primary reason why medical liability diverged from general negligence is deference to professionalism; courts do not feel capable of second-guessing medical practice (Prosser, 1978; Peters, 2000).

Most courts presume that a physician's failure to adhere to customary practice constitutes negligence. If there is more than one recognized course of treatment, most courts allow some flexibility in what is regarded as customary (known as the respectable minority rule). In relatively rare instances, courts will allow a plaintiff to challenge the adequacy of customary medical practice, resulting in a higher standard of care than that

[4] *Lauro v. The Travelers Insurance Co,* 261 So.2d 261 (La. 1972).

determined appropriate by the profession. In general, the same level of care must be provided to all patients, regardless of individual (as opposed to community-wide) resource constraints.

The Effects of Technology on Medical Liability

As we enter the 21st century, technology develops faster and plays an even greater role in medical practice and medical liability exposure than in prior eras. During the last thirty years, an unprecedented number of innovations have had great clinical and economic importance for U.S. medicine. Millions of people have been able to live longer, better-quality lives because of new treatments, new surgical procedures, new drugs, and vastly improved diagnostic techniques. Medical technology has played a major role in conquering many dreadful and incurable disease conditions. But it has also brought forth new challenges for health care administrators and policy makers, including a propensity for litigation.

Technology affects the medical system in two ways: new technologies often substitute for older technologies in the therapy of established patients—called the "treatment substitution effect;" and they lead more people to be treated for disease—termed the "treatment expansion effect."

The General Liability Propensity

Technology affects the medical system in two ways: new technologies often substitute for older technologies in the therapy of established patients—called the "treatment substitution effect;" and they lead more people to be treated for disease—termed the "treatment expansion effect" (Cutler and McClellan, 2001).

In the aggregate, health has improved as medical spending has increased, with medical technology playing a central role in improved mortality and morbidity rates (Cutler and McClellan, 2001). But unregulated dissemination of new technologies and techniques has resulted in a general propensity to stimulate malpractice liability litigation.

Unregulated dissemination of new technologies and techniques has resulted in a general propensity to stimulate malpractice liability litigation.

Technological advances create opportunities for error in both diagnosis and treatment, and those errors may result in more visible and more severe injuries. Diagnostic technology in common use may not always improve medical outcomes but paradoxically contributes to a higher legal standard of care. In obstetric and gynecologic practice, the failure to employ genetic testing, electronic fetal monitors, ultrasonography, and new information technologies can create liability, as can improperly interpreting the results. Absent a diagnostic test, for instance, the failure to detect prostate cancer through a biopsy might not result in either a lawsuit or a damage award. Just as important, physicians and institutions are vulnerable to claims that they failed to adopt cutting-edge technological innovations, though these claims are likely to be less frequent than claims

Diagnostic technology in common use may not always improve medical outcomes but paradoxically contributes to a higher legal standard of care.

regarding misuse and failure to use when technology is available.

Technology also helps create unrealistic patient expectations that every newborn child will be perfect or can become so. The ability to save a severely injured, low birth-weight infant, when that same infant would not have survived 20 years ago, carries with it the potential for litigation that seeks to blame the obstetrician for any permanent disability.[5] To put it another way:

> …when medical technology is crude, the law of negligence is forgiving. With crude technology, only a major error by a doctor will make a significant difference in the patient's progress. In the 1990s, however, good medicine often makes a difference (Grady, 1992, p. 1070).

Even noteworthy technological advances that generally improve health outcomes are not immune from exposing physicians to liability. Take, for example, the recent disclosure that drug-coated coronary artery stents have been linked to blood clots that can cause a heart attack. Coronary stents have been a remarkable advance in preventing heart injury, and it was widely expected that newer generations of stents would continue to improve clinical outcomes. Regrettably, the Food and Drug Administration (FDA) has received reports that 34 stent recipients have suffered blood clots, with 5 deaths (though the FDA has not ascertained that clots caused the deaths). The manufacturer claims that the risk is quite small (50,000 patients have received the stent in question) and "cautioned

[5] See, e.g., *Brownsville Pediatric Association v. Reyes*, 68 S.W.3d 184 (Tex.App. 2002), for a graphic depiction of how the failure to use technology can result in permanent harm to a neonate and a large jury verdict against the physician.

that some of the clots happened after doctors improperly used the [technology]…by choosing stents that were too small, implanting them improperly or not giving patients appropriate anti-clotting medicine afterward."[6]

To be sure, the stent situation is representative of how medical knowledge changes, and perhaps litigation is simply the price of progress. And while "medical services and new medical technologies create value that people desire" (Chernew, Hirth, and Cutler, 2003, p. 23), the value comes at a high cost to society and physicians. In this instance, stent technology diffused without adequate physician training in how to use it properly. There is little doubt that litigation will soon follow.

The precision of new technologies means that momentary lapses can have serious consequences, even if the probability of harm is low.

Perhaps most significantly, medical innovations are increasingly complex. The precision of new technologies means that momentary lapses can have serious consequences, even if the probability of harm is low (De Ville, 1998, p. 203): "The cost of momentary lapses of concentration is typically greater in the new technology, because the promise of benefit is greater, but also because the procedure itself is sometimes more dangerous." The more advanced the technology, the greater the skill needed to use it appropriately and successfully. While that complexity allows physicians to undertake

[6] Associated Press, New Heart Stent Linked to Blood Clots, 8 July 2003 (http://www.msnbc.com/news/936250.asp?0cv=CB10).

procedures previously unavailable, the potential costs of errors are that much greater: "…each new technique ha[s]…the potential…of introducing new patient dangers and new grounds for litigation…." (Mohr, 2000, p. 1734).

General advances in surgery are particularly liability-inducing. Danzon (1987) found that the number of surgical procedures per capita was a statistically significant explanation of claim frequency and award severity. Minimally invasive surgery, for example, reduces recovery time but requires careful training and monitoring for error. Laparoscopic cholecystectomy (for gallstone disease) replaced an open surgical procedure that had low complication rates. When patients availed themselves of the minimally invasive alternative, however, some suffered major injuries to the common bile duct or the liver, resulting in a wave of unwelcome litigation. Consider the following description of a 58 year-old surgeon's first use of laparoscopic cholecystectomy, when he mistakenly cut into the patient's liver (apparently without lasting harm): "This was new terrain, requiring new tricks to compensate for not being able to touch what he was cutting, for not being able to plainly see where his instruments were" (Gester, 1993, p. 1280).

Recently, the safety of American health care has come under attack, with the Institute of Medicine attributing between 44,000 and 98,000 deaths annually to medical error (IOM, 2000). Technology contributes significantly to the problem, as evidenced by high error rates in technical specialties such as vascular surgery, cardiac surgery, and

neurosurgery (Leape et al., 1993; Kacmar, 1997). The IOM report, *To Err is Human: Building a Safer Health System*, highlights how advances in technology contribute to medical error. On one level, technology prevents error by replacing fallible humans with automated systems. But learning to implement new technologies is hazardous; the IOM report observes that "all technology introduces new errors, even when its sole purpose is to prevent errors" (IOM, 2000, p. 151). Technology can also make medical procedures "opaque" to operators, who may be overwhelmed by complexity and therefore unable to assess the situation and make corrections (see, e.g., Gaster, 1993).

There is no one trajectory for how technology might lead to litigation, especially with regard to determining the standard of care. … In the ABMT cases, the dominant legal issue was whether the procedure's widespread use among community oncologists overrode the absence of scientific evidence that it was effective. In contrast, the new body scan diagnostic technology, equally unproven, primarily raises issues of unnecessary surgery resulting from false positive findings.

Advanced technology may also have indirect effects on litigation.[7] By driving up life expectancy, new technology increases the number of encounters with physicians, and therefore opportunities for error. Because physicians are more willing to intervene if potentially life-saving technology is available, frail patients may suffer serious harm that

[7] I am indebted to Phil Peters for suggesting this approach.

would otherwise not be attributable to medical care. What complicates matters further is that there is no one trajectory for how technology might lead to litigation, especially with regard to determining the standard of care. Compare, for example, high-dose chemotherapy with autologous bone marrow transplant (ABMT) and "whole body scans." In the ABMT cases, the dominant legal issue was whether the procedure's widespread use among community oncologists overrode the absence of scientific evidence that it was effective. In contrast, the new body scan diagnostic technology, equally unproven, primarily raises issues of unnecessary surgery resulting from false positive findings.

Technology is largely responsible for the rapid expansion of institutional liability over the past several decades. Surgical technology in particular created a demand for inpatient care (and health insurance) among patients wealthy enough to afford private physicians, prompted the development of accreditation standards that obligated hospitals to supply services of definable quality, and generated revenues sufficient to attract tort plaintiffs and persuade judges and legislatures to revoke "charitable immunity." A major source of present-day liability risk for hospitals is the failure to maintain adequate technology to meet patient needs (Jacobson, 1989). Institutions are considerably more likely to be held liable for lack of adequate equipment than physicians, though very few cases have been decided (Sage, 2003c).[8] In particular, institutional efforts to reduce cost

[8] See, e.g., *Hall v. Hilbun*, 466 So.2d 856 (Miss. 1985).

may be subjected to close scrutiny in tort litigation. Finally, institutions may be held vicariously liable for a physician's misuse of technology within the facility.

Specific Technologies

Aside from the general liability propensity, it is instructive to consider how specific technologies raise liability concerns. As part of this project, I attempted to obtain information from malpractice insurance carriers regarding technology-related claims to address two key issues. First, do a few technologies account for a significant portion of liability risk in any given year? Second, what is the overall contribution of technology to claim frequency and award severity? The answers to these questions are important because they would illuminate what types of technology policy responses might be effective to relieve pressure on the malpractice system, perhaps by developing special liability arrangements for key technologies. Unfortunately, very little data are available in the form needed to address these questions. Studies conducted by the Physician Insurers Association of America (PIAA) reveal some interesting trends, but fall short of providing clear policy direction (Table 2).

PIAA studied three specific procedures at different points in time: neurological impairment in newborns, laparoscopic injury, and breast cancer (PIAA 1998, 2000, 1994, 2002, 1995). Each represents a different type of technology claim. For breast cancer, the issue is failure to screen for and detect disease. For laparoscopic surgery, the issue is error using therapeutic technology. And for neurological impairment, the issue is failure

to properly interpret new monitoring devices available during routine procedures. Although PIAA has not published a synthesis of these studies, a PIAA analyst suggested that technology claims are on the rise and are consuming a greater portion of insurance claim payments.[9] In her view, new technology makes errors more obvious and causation of injury more likely.

Table 2: PIAA Data

	Claim	Frequency of Claims	Mean Award	% Of Claims Paid[10]
Laparoscopic Cholecystectomy	Error In Use; Improperly Performed Surgery	1990-94: 331 1995-99: 869	$136,000 $236,384	54% 50%
Neurologically Impaired Infants	Failure to Interpret Diagnostic Technology	1985-97: 3466	$568,283	47%
Breast Cancer	Failure to Detect or Diagnose	1985-2001: 3437	$217,500 (1995) $438,047 (2002)	41%
Anesthesia Monitoring	Anesthesia-related Injury and Substandard Care	1988: 1004 Substantial declines after guidelines used	$10,000 - $6 million*	62%

*$10,000-$6 million is a range; the data do not offer a mean.

[9] Personal communication with Robin Traywick, PIAA, December 2002.
[10] % of claims paid relative to total number of claims filed. (31% is the national average.)

This is consistent with the view that claims increase upon the introduction of a new technology, but then level off over time, in part because "a new procedure is typically more complex and exacting than previous treatment" methods (De Ville, 1998, p. 202). But these data have several limitations. First, PIAA only reports paid claims, so the averages tend to overstate indemnity. Second, the data are self-reports from PIAA member companies. Not all members submit data on each of the surveys, so it is difficult to make any broad generalizations about the findings.

Laparoscopic Cholecystectomy. Laparoscopic cholecystectomy produces both treatment substitution and treatment expansion effects. Before minimally invasive surgical techniques were developed, removing the gallbladder required painful and disfiguring abdominal surgery with a lengthy recovery period, and was done only when absolutely necessary. The new procedure reduces all of these effects, which results in much greater frequency of use. However, less visibility and unfamiliar instruments occasionally lead surgeons to injure the common bile duct, perforate the bowel, lacerate the liver, or cut

Laparoscopic cholecystectomy produces both treatment substitution and treatment expansion effects. … These risks result in more malpractice claims and larger damage awards.

the iliac artery. These risks result in more malpractice claims and larger damage awards than in the era before laparoscopic cholecystectomy was available.[11]

From 1990 to 1994, before minimally invasive techniques entered widespread use, PIAA received 750 claims relating to gallstone surgery, and made indemnity payments of approximately $42 million. In 1995-1999, the number of claims rose to 1,426, with indemnity payments of around $104 million. In the latter period, 60% of claims involved allegations of improperly performed cholecystectomies, which PIAA attributes to both higher numbers of cholecystectomies being performed and a greater risk of complications from the laparoscopic technique. Tellingly, the rate of paid claims involving cholecystectomy (50%) vastly exceeds PIAA's overall rate of paid claims (31%), and the average indemnity payment is 26% higher.

One reason for these results is that the procedure has a higher severity index than the conventional procedure (4.25 to 3.94 in the 1994 survey, rising to 4.9 for all claims in the 2000 report, rising to 5.19 for all paid claims). The National Association of Insurance Commissioners (NAIC) publishes the severity index, with codes from 1 (emotional injury) to 9 (death). A severity index of 4 is classified as a major temporary injury without permanent effects. In the laparoscopic studies, the severity index means that

[11] See, e.g., *Dunning v. Barnes*, 2002 Del. Super. LEXIS 487 (malpractice claim for the transection of the common bile duct); *Lucas v. Collins*, 743 N.E.2d 847(Mass. App. Ct. 2001) (malpractice claim for bifurcation of the cystic artery due to inadequate cauterization); *Oakden v. Roland*, 988 P.2d 1057 (Wyo. 1999) (malpractice suit for injury to common hepatic duct due to misuse of bent suction probe during laparoscopic cholecystectomy); *Mercker v. Abend*, 561 S.E.2d 351 (Ga. Ct. App. 2003) (malpractice action filed due to persistent bile leakage and removal of a portion of patient's liver as a result of perforation of the cystic duct during laparoscopic cholecystectomy).

many injured patients require an additional surgical procedure that results in no lifelong debilitation (PIAA, 1994, pp. 12-13; PIAA, 2000, pp. 14-15).

Breast Cancer. In PIAA's three breast cancer surveys, the dominant claim is failure to diagnose, which implicates two different effects of technology. Improved diagnostic technology creates liability if it is not used properly.[12] Improved therapeutic technology increases liability for delay, however caused. Diagnostic technologies as well as mammography also allow mass screening, which is otherwise impractical.

PIAA identifies certain trends across the studies. Radiologists were named in 33% of claims in 2002, up from 24% in 1995. By contrast, claims against obstetrician-gynecologists declined from 38.6% in 1990 to 23% in 1995 and 2002. Between 1995 and 2002, the median paid indemnity claims rose a robust 45.3% (from $301,460 to $438,047). PIAA suggests two reasons for the increase. One is that the average delay in diagnosis rose from 12.7 months in 1990, to 14 months in 1995, and to 16.3 months in 2002. The other is that negative or equivocal first mammograms

Diagnostic technologies as well as mammography also allow mass screening, which is otherwise impractical.

[12] See, e.g., *Walter v. Bruhn*, 40 Fed. Appx. 244 (7th Cir. 2002) (malpractice claim for failure to diagnose breast cancer by ordering a biopsy in the presence of a growing lump and negative mammogram); *Primus v. Galgano*, 187 F. Supp. 2d 1 (D.Mass. 2002, affd. 2003 U.S. App. LEXIS 9803 (1st Cir. 2003) (malpractice claim alleging substantial disfigurement as a result of failure to diagnose breast cancer and the need for radical mastectomy); *Kreppel v. Guttman Breast Diagnostic Institute*, 2000 U.S. Dist. LEXIS 4559 (S.D.N.Y. 2000) (malpractice claim for failure to diagnose a peculiar density in a mammogram as breast cancer and the resulting metastatic breast cancer and death of the patient).

rose from 68% in 1990, to 80% in both 1995 and 2002. According to PIAA, "This result is rather surprising as it would seem that diagnostic accuracy should be improving given the advances in technology of mammography equipment" (PIAA, 2002, p. 6).

Perhaps. But it may also indicate that technological advances create more opportunities for missed diagnoses; certain lesions were simply undetectable using earlier technologies. Thus, of the 1,077 individual physician claims in the 2002 survey, 703 (or 65%) were brought because of a negative mammogram report, "physical findings failed to impress," or "mammogram misread." Most importantly, the percentage of misread mammograms rose from 22.7% in 1995 to 37.8% in 2002 (resulting in over $57 million in indemnity payments). Since there is no reason to believe that radiologists are any less capable of interpreting films now than they were in the past, improved technology seems to have created expectations of more precise readings than may be justified.

Neurologically Impaired Infants. The claims data for neurologically impaired infants present a more complex picture than the other two areas. One reason is that causal attribution for negligence is notoriously difficult in these cases. Indeed, physicians argue strenuously that most adverse birth outcomes result from unknown etiologic factors as opposed to negligence. Another interpretive problem is that the comparison data across the 1987 and 1997 studies are less complete than the two studies already discussed. Because these claims represented PIAA's largest single area of claim

frequency and award severity as of 1997, it is worth attempting to understand technology's role.

Technology intrudes at two points in pregnancy—antepartum testing, and monitoring during labor. According to the PIAA data, interpretation of an antepartum test or procedure is a factor in 16.7% of all cases. The failure to perform a test or procedure occurs in an additional 19.8% of all cases. In both instances, diagnostic ultrasound is the primary technology involved. During labor, the use of electronic fetal monitors (EFMs) seems to be the driving factor in litigation.[13] PIAA concludes that "Abnormalities detected through electronic fetal monitoring resulted in a case payment value 71% higher than when no abnormality was detected (PIAA, 1997, p. 5)." Yet it is not clear whether payments are higher because the obstetrician caused the recorded abnormality or because the physician failed to respond to it.

Technology intrudes at two points in pregnancy—antepartum testing, and monitoring during labor.

[13] See, e.g., *Tucker v. Lain*, 798 So. 2d 1041 (La. App. 2001) (malpractice suit brought for failure to properly read EFM strips resulting in brain damage in infant); *Adventist Health System v. Florida Birth-Related Neurological Injury*, 2004 Fla. App. LEXIS 21 (malpractice suit brought for brain damage suffered due to oxygen deprivation at birth); *Tavares v. New York City Health and Hosptials Corp*., 2003 N.Y. Misc. LEXIS 1217 (2003) (malpractice suit alleging brain damage of the fetus due to the physician's departure from customary practice in ignoring lack of engagement of the fetus' head and signs of distress on fetal monitoring strips); *Wareing v. U.S.*, 943 F. Supp. 1504 (S.D. Fla. 1996) (malpractice claim resulting from failure to recognize signs of high risk pregnancy and failure to read fetal monitoring strips, resulting in the brain damage of the fetus at birth); *Smith v. Saraf*, 148 F. Supp. 2d 504 (D.N.J. 2001) (wrongful birth suit claiming that failure to perform routine prenatal tests prevented parents from receiving information about birth defects in their son, which might have led to the decision to terminate the pregnancy).

Two comparisons between the 1997 and 1987 studies are particularly relevant to the role of technology. In the 1997 survey, fetal distress appears in 88% of cases, up from 41% in 1987. PIAA suggests that this resulted from the substantially increased use of EFMs. There is also a marked increase in the use of diagnostic ultrasound (88% in 1997, up from 32% in 1987). PIAA makes no attempt to attribute the rise in average indemnity payments to these two issues, yet it seems reasonable to conclude that advances in technology have actually exposed physicians to higher liability claims.

One explanation is that EFM often cannot prevent adverse fetal events. A report just released by the American College of Obstetrician Gynecologists (ACOG) indicates that many instances of hypoxic-ischemic encephalopathy (HIE) in newborns, a more precise term for what is often called cerebral palsy (CP), result from factors that cannot be detected during labor.

> Only 19% of cases of neonatal encephalopathy met what were very nonstringent criteria for intrapartum hypoxia, with another 10% experiencing a significant intrapartum event that may have been associated with intrapartum hypoxia....[O]f all cases of neonatal encephalopathy, 69% had only antepartum risk factors, 25% had both antepartum and intrapartum risk factors, 4% had evidence of only intrapartum hypoxia without identified preconceptional or antepartum factors that might have contributed to neonatal encephalopathy, and 2% had no identified risk factors....Thus, approximately 70% of neonatal encephalopathy is secondary to events arising before the onset of labor" (ACOG, 2003).

If HIE is not caused by events during labor, technology utilized during labor clearly cannot prevent fetal injury. For example, the "use of nonreassuring fetal heart

rate patterns to predict subsequent cerebral palsy had a 99% false-positive rate." In other words, even advanced technology needs to be deployed at the appropriate time in order to be effective. As another example, a recent story indicates that a new, $411,000 patient monitoring system failed to alert nurses that two patients needed urgent attention. Both patients died, and the facility shut down the bedside monitoring systems. It is likely that litigation will follow (Weber and Ornstein, 2003).

Anesthesia Monitoring. The use of clinical practice guidelines can both influence the legal standard of care and improve patient safety. Physicians who follow the guidelines can use that as a defense. Indeed, Hyams et al. (1996) found that following guidelines deters the initiation of litigation. Of course, the failure to follow recognized guidelines can correspondingly result in liability. As several observers have argued, however, it is unlikely that courts will rely solely on guidelines to set the standard of care. Instead, the trend appears to be that judges will allow the jury to weigh them as one piece of evidence in determining liability. Judges recognize that physician judgment inheres in any clinical situation, competing and conflicting guidelines may exist, the guideline development process is itself uncertain, and direct physician testimony may be equally relevant. In addition, technology may diffuse faster than professional societies can develop appropriate guidelines.

One technology, anesthesia monitoring, nevertheless demonstrates the potential for guidelines to reduce liability exposure. During the 1970s, liability claims against

anesthesiologists resulted in higher claims frequency and award severity than any other category. In response, anesthesiologists developed the Harvard Anesthesiology Practice Guidelines (Eichhorn et al., 1986). Following their widespread adoption, both claims frequency and award severity against anesthesiologists declined dramatically (Lee and Domino, 2002; Cheney et al., 1989). One study found that "anesthesiology monitoring guidelines reduced losses at Harvard facilities from $5.24 per anesthetic in the period from 1976 to 1985 to somewhere between $.78 and $2.00 per anesthetic" (Holzer, 1990). Another noted that one Massachusetts insurer closed 27 anesthesia-related claims between 1976 and 1986, but faced no claims in 1988, after the anesthesia guidelines were implemented (Pierce, 1990).[14] Several insurers also lowered their insurance rate classifications based on the guidelines' overall success in reducing claims.

Pulse Oximetry. Another technology that is paradigmatic for the patient safety movement is pulse oximetry during labor and delivery. Especially during surgical delivery, pulse oximetry reduces injury by alerting the anesthesiologist to poor oxygenation. By providing an evidentiary trail that demonstrates maternal well-being, it also shifts legal liability for any hypoxic injury to the newborn away from the anesthesiologist and toward the obstetrician. In this sense, the technology is both

[14] However, see, *Breeden v. Anesthesia West*, 656 N.W.2d 913 (Neb. 2003) (malpractice claim for brain damage that resulted from negligent administration of anesthesia and use of anesthesia monitoring); *Denton Regional Medical Center v. Lacroix*, 947 S.W.2d 941 (Tex. Ct. App. 1997) (malpractice claim for brain injury resulting from anesthesia administered by a nurse anesthetist as not in compliance with guidelines). In *Denton*, lack of compliance with guidelines was a key argument the plaintiff used, and considered seriously by the court, to prove malpractice. The court in *Breeden* relied on both expert testimony and past precedent to determine the standard of care.

protective and deflective.[15] Once again, technology is both savior and culprit where potential liability is concerned.

Studies of sedation involving children also indicate a dramatic beneficial effect of pulse oximetry on patient safety. A study by the American Academy of Pediatrics looked at injury to children sedated in hospital and non-hospital settings. "When a serious adverse sedation event occurred in a non-hospital-based facility, 93% of children suffered death or permanent neurologic injury as the outcome, a 2.5-fold increase compared with children sedated in hospital-based venue" (Cote, 2000). Similarly, 30.2% of complications in a hospital setting resulted in death and 30.2% resulted in prolonged hospitalization without injury, whereas 82.1% of those in a non-hospital setting resulted in death and only 7.1% led to prolonged hospitalization without injury.

Pulse oximetry reduces injury by alerting the anesthesiologist to poor oxygenation. By providing an evidentiary trail that demonstrates maternal well-being, it also shifts legal liability for any hypoxic injury to the newborn away from the anesthesiologist and toward the obstetrician.

Many injuries in non-hospital settings could have been prevented with proper monitoring:[16] "The rank order of severity of adverse outcome and the incidence of death

[15] I am indebted to Bill Sage for the phrase "both protective and deflective."
[16] See, e.g., *Suttle v. Lake Forest Hospital*, 733 N.E.2d 726 (Ill. App. 2002), upholding a $10.9 million jury verdict for failing to monitor maternal and fetal blood pressure rates.

and permanent neurologic injury were significantly less in children monitored with pulse oximetry compared with those not monitored at all" (Cote, 2000). The data showed that

> adverse outcome is not related to patient characteristics but rather to failure to rescue the patient from a developing adverse event, [that pulse oximetry] is the single most helpful monitoring device for detecting impending life-threatening events … [and that it] should be required for every patient sedated for a procedure because it provides an early warning of developing oxygen desaturation to everyone present.

Information Technology. Medical research and the internet now provide physicians with more information than they have ever been able to utilize in the past. Online databases of medical literature, such as Medline, allow the physician immediate access to information that can influence treatment and possibly save lives (Kacmar, 1997). The medical profession may soon reach a point where a physician can put a patient's symptoms into a web-based form and the computer will offer a diagnosis. The physician also will be able to "chat" on-line with other doctors about the patient's symptoms to receive opinions from experts who previously would have been unavailable due to geography or time constraints. Clearly, techniques such as these call into question what constitutes reasonable care. If a physician does not utilize new information or is negligent in

If a physician does not utilize new information or is negligent in gathering the results, this could qualify as substandard care and expose the physician to liability.

gathering the results, this could qualify as substandard care and expose the physician to liability.

Suppose, for example, a radiologist relies on the digital transmission of a film to advise another physician about a possible malignancy, but the transmission blurs the image. Both the treating and consulting physicians are likely to be sued if the incomplete image leads to an incorrect diagnosis. Likewise, computerized systems for entering physicians' orders to a hospital's nursing staff pose liability risks for individual physicians and institutions if the information is misentered or not properly used. It seems likely that physicians will rely heavily on PDAs to store and retrieve information to "check patient diagnoses and treatment regimes against clinical practice guidelines" (Terry, 2002, p. 47). As Nicolas Terry observes, institutions and physicians could be held liable for failing to upgrade the new "smart systems," and for any resulting injuries. At this point, there is not enough litigation to discern any patterns or trends.

Recent Cases in Three States

Reported cases from 2001-2003 in three states considered by the AMA to be "in crisis" —West Virginia, New Jersey, and Pennsylvania – reveal a picture consistent generally consistent with the PIAA studies. Technology was at issue in 43% of reported medical malpractice cases. Plaintiffs won over 50% of these cases, more than historical win rates in malpractice cases of 20-50%. Technology cases often resulted in high damage awards, especially for pain and suffering.

In *McRae v. St. Michael's Medical Center*,[17] the plaintiff broke her leg after slipping on ice at work. Because the bones were completely shattered, the treating surgeon requested an external fixation device, which the hospital provided. During the operation, the physician determined that the fixation device supplied was too big, and eventually repeated the surgery using internal fixation. The plaintiff was unable to work and endured months of physical therapy followed by additional operations. The plaintiff sued the physician for failing to verify that proper hardware was available, continuing the surgery when he discovered it was not, and not using proper hardware during the second surgery. The jury awarded the plaintiff $1,175,000 for pain and suffering, $214,000 for past lost income, and $407,000 for future lost income. The jury award was affirmed on appeal.

[17] 794 A.2d 219 (N.J. Super. 2002).

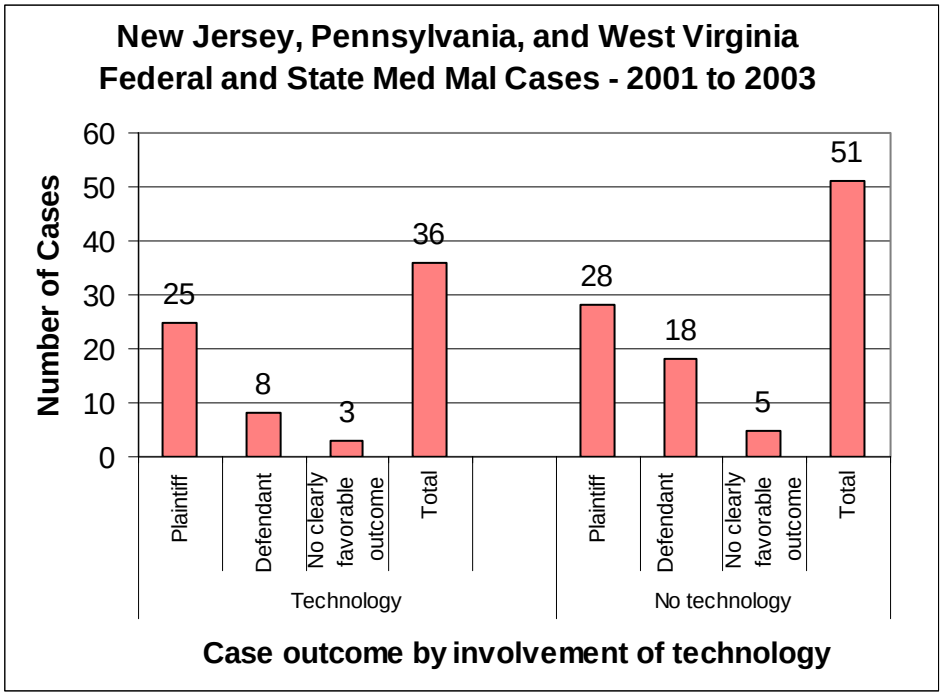
In *Cruz v. Northeastern Hospital*,[18] the plaintiff alleged that ignoring a fetal monitor injured her newborn son, who experiences seizures and has an IQ of 52. The plaintiff experienced distress during delivery, including leakage of amniotic fluid and a high fever. She was placed on fetal monitoring, but later claimed that the defendants did not heed the monitor's warnings, which directly contributed to her son's impairment. The jury awarded the plaintiffs $10,811,431, which was affirmed on appeal.

In *Mahoney v. Podolnick*,[19] the family of a patient who died from stomach cancer sued his physician for failure to recommend immediate endoscopy, biopsy, or surgery when a tumor was observed on abdominal x-rays. The jury awarded $700,000 in economic damages and $50,000 for pain and suffering.

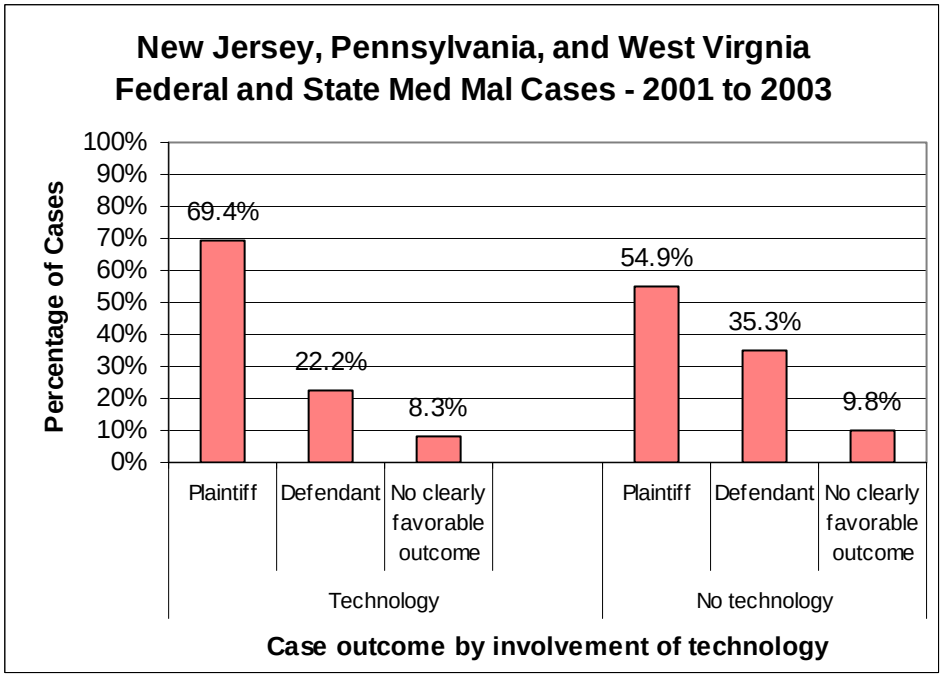
Other birth injury claims included failure to use available fetal monitoring technology,[20] failure to detect or order more sophisticated ultrasound to detect spina bifida,[21] and failure to undertake prenatal tests.[22] In breast cancer cases, claims included failure to diagnose and failure to properly read mammograms.[23] Other surgical claims involved faulty insertion of a prosthetic mitral valve.[24]

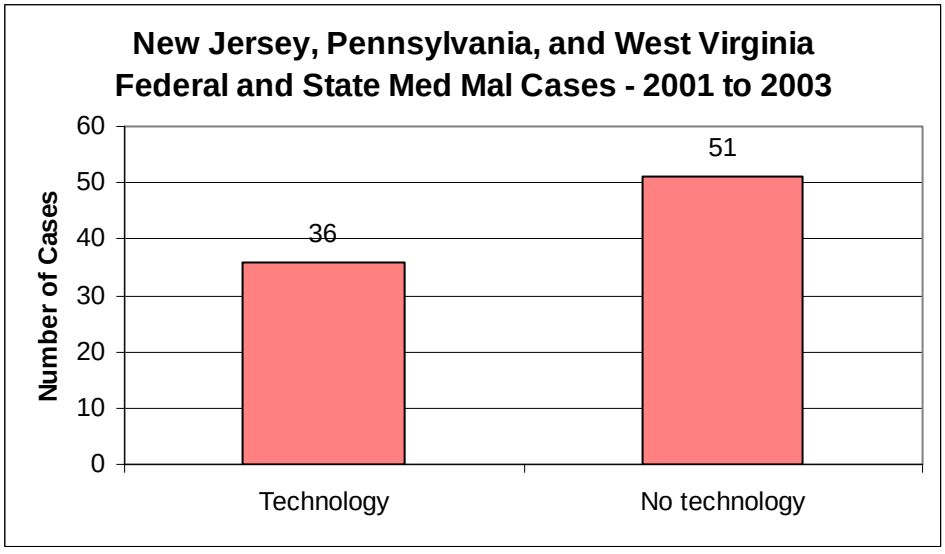
[18] 810 A.2d 602, 606 (Pa. Super. 2002).
[19] 773 A.2d 1102 (N.J. 2001). See also, *Callum v. Scott*, 58 Pa. D. & C.4th 1, 3 (Pa. Ct. Com. Pleas 2002), for a claim alleging failure to diagnose.
[20] *Das v. Thani*, 795 A.2d 876 (N.J. 2002).
[21] *McKenney v. Jersey City Medical Center*, 771 A.2d 1153 (N.J. 2001).
[22] *Geler v. Akawie*, 818 A.2d 402 (N.J. Super. 2003).
[23] See, e.g., *Newell v. Ruiz*, 286 F.3d 166 (3d Cir. 2002).
[24] *Brambley v. McGrath*, 788 A.2d 861 (N.J. Super. 2002).

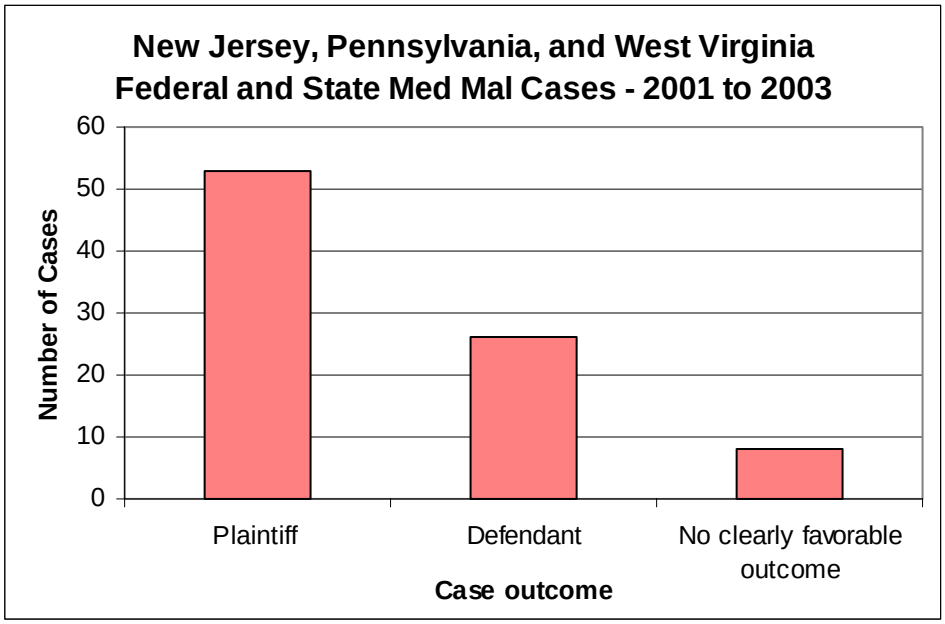
Not all technology claims resulted in large damage awards. In *Rachlin v. Edmison*,[25] the plaintiff claimed that a laser procedure (bilateral photo-refractive keratotomy) intended to improve her vision and eliminate the need for contacts, instead worsened her eyesight. For a variety of reasons, especially the inability to show that the procedure had caused the plaintiff's injuries, the court granted summary judgment for defendants.



[25] 57 Pa. D.& C.4th 190 (Pa. Ct. Com. Pleas 2001).


New Jersey, Pennsylvania, and West Virgnia
Federal and State Med Mal Cases - 2001 to 2003
Percentage of Cases
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
69.4%
22.2%
8.3%
54.9%
35.3%
9.8%
Plaintiff
Defendant
No clearly favorable outcome
Plaintiff
Defendant
No clearly favorable outcome
Technology
No technology
Case outcome by involvement of technology


New Jersey, Pennsylvania, and West Virginia
Federal and State Med Mal Cases - 2001 to 2003
Number of Cases
60
50
40
30
20
10
0
36
51
Technology
No technology


New Jersey, Pennsylvania, and West Virginia
Federal and State Med Mal Cases - 2001 to 2003
Number of Cases
60
50
40
30
20
10
0
Plaintiff
Defendant
No clearly favorable outcome
Case outcome

The Effects of Medical Liability on Technology

One of the interesting dynamics in the relationship between technology and liability is that it operates in both directions. The previous section explored the liability implications of new technologies pose for physicians. Another aspect is how liability affects technological innovation. The adverse effects of liability on technology may be mediated by market forces as well as by changes in the legal standard of care. Product liability litigation—usually involving pharmaceuticals or medical devices—showcases these issues.

Product Liability

Most of the past policy and scholarly attention has been on whether product liability litigation impedes technological innovation. For example, many policymakers and opponents of product liability law attribute the shortage of vaccines and new contraceptives (among other products) to excessive liability. Fears of liability, according to this line of reasoning, have inhibited manufacturers from developing products that would otherwise be beneficial. Yet there is no conclusive evidence that product liability litigation has undermined product development (Garber, 1993; 1998).

One of the interesting dynamics in the relationship between technology and liability is that it operates in both directions.

Product liability typically involves a different set of defendants, legal theories, and economic effects than conventional malpractice litigation. These lawsuits allege

strict liability, as opposed to negligence, and are usually brought against product manufacturers. Under strict liability, a manufacturer can be held responsible for a defective product whether or not the defect was the result of carelessness.

For many years, individual plaintiffs injured by medical devices have successfully brought product liability actions against device makers (Citron, 1994).[26] But unlike medical malpractice litigation, many product liability lawsuits are initiated as class actions on behalf of all individuals who have been injured by the product. Plaintiffs' attorneys have a financial incentive to litigate these cases as class actions because of the potential for very large settlements. Vaccines and contraceptives are particularly high-risk products susceptible to class action litigation. In fact, litigation on this scale has forced several device manufacturers into bankruptcy. The search for solvent defendants has sometimes led to litigation against suppliers of raw materials, leading those more diversified companies to refuse to sell products to makers of medical products. In turn, this can reduce the production and use of other medical devices.

In reaction to these events, Congress enacted the Biomaterials Access Assurance Act of 1998. The law allows for liability of a supplier in three situations: 1) when the supplier registered, or was required to register, as a medical device manufacturer under the Federal Food, Drug, and Cosmetics Act; 2) when the Secretary of Health and Human

[26] See generally *Dyer v. Danek Medical, Inc.*, 115 F. Supp. 2d 732 (N.D.Tex. 2000) (lawsuit against manufacturer for injury from defective spinal fusion fixation device); *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831 (D.Md. 2000) (lawsuit against manufacturer for injury resulting from defective breast implant).

Services issues a declaration that the supplier was required to register as a medical device manufacturer; or 3) when the supplier is "related by common ownership or control" to a medical device manufacturer and the court finds it necessary to impose liability on the supplier because the manufacturer is judgment proof or insolvent. The law's goal is to protect biomaterials suppliers by preserving manufacturing of medical devices and reducing litigation.

Liability can also affect the use of technology by health care providers. In their search for solvent defendants, individuals may initiate litigation against physicians and hospitals, especially in cases involving biomaterials such as pedicle screws. If courts were to impose strict liability on physicians for administering defective drugs or inserting defective devices, this could substantially discourage the use of biomaterials and other technologies. Litigation over allegedly defective implants demonstrates the interaction between manufacturer and physician product liability exposure.

TMJ Implants. In the early 1990s, DuPont was the subject of many lawsuits for its role as the supplier of Teflon for temporomandibular joint (TMJ) implants, which turned out to be defective. Lawsuits against the Vitek Corporation, the manufacturer of the implants, led to the company's bankruptcy declaration. Plaintiffs then moved on to DuPont. Even though DuPont was not directly involved with the manufacturing of the implants, DuPont "sustained substantial monetary losses resulting from the jaw implant litigation, which compelled the company to discontinue supplying biomaterials"

(Kerouac, 2001). This result highlights the struggle between technology and product liability. Patients demand the most advanced medical devices, but are quite willing to litigate in the event of adverse outcomes.

Yet most courts have drawn the line at applying strict liability principles to the health care setting (Roubal, 1998). In *Cafazzo v. Central Medical Health Services*, for example, the Pennsylvania Supreme Court declined to apply strict liability in a suit against a hospital and an oral surgeon for injuries resulting from a defective TMJ implant because of the "peculiar characteristics of medical services," such as "the tendency to be experimental,…a dependence on factors beyond the control of the professional,…and a lack of certainty or assurance of the desired result."[27] In *Parker v. St. Vincent Hospital*, the court held that a hospital was not strictly liable for injuries caused by defective jaw implants because that would not serve any of the "policies supporting the imposition of strict products liability," or would result in other negative consequences.[28] These policies include: 1) placing the cost of injuries on an entity capable of spreading the costs of injury across all consumers; 2) simplifying the plaintiff's job of proving negligence; 3) giving an incentive to all members of the chain of supply to select products from the most reputable and responsible manufacturers; 4) fairness; and 5) giving an incentive to manufacturers to take greater care in manufacturing their product.[29] Nevertheless,

[27] 668 A.2d 521, 527 (Pa. 1995). See also, *Royer v. Catholic Medical Center*, 741 A.2d 74 (1999); *Hoff v. Zimmer*, 746 F. Supp. 872, 874-75 (W.D.Wis. 1990).
[28] 919 P.2d 1104, (1996).
[29] See also, *Cafazzo v. Central Medical Health Services*, 668 A.2d 521 (Pa. 1995).

physicians can still be held liable for substandard care in how they respond to problems caused by product defects.[30]

Silicone Breast Implants. Other medical devices have elicited an onslaught of litigation as well. Silicone gel breast implants have been the subject of considerable controversy since the early 1990s. In 1992, the FDA recalled silicone implants and limited them to use in formal research trials because of uncertain safety and the specter of class action lawsuits (Ference, 1998). Epidemiological studies completed since that time have failed to link silicone breast implants with illnesses such as cancer and autoimmune diseases (Angell, 1996). Because of the lack of hard scientific evidence linking the implants to disease, individual plaintiffs have had a difficult time winning awards in lawsuits against the manufacturers. But class actions have been more successful. In 1994, manufacturers of silicone breast implants reached a thirty-year, $4.25 billion settlement. The settlement forced Dow Corning into Chapter 11 bankruptcy, and Bristol-Myers Squibb, 3M, and Baxter reached a new settlement in 1995. Implant use remains under moratorium, although an FDA Advisory Committee has now recommended that the moratorium be ended.

[30] See, e.g., *Coffie v. U.S.*, 43 Fed. Appx. 808 (6th Cir. 2002), *cert. denied*, 537 U.S. 1211 (2003) (malpractice suit alleging pain and swelling due to failure to remove or inform patient of necessity to remove temporary TMJ implants); *Brawn v. Oral Surgery Associates*, 819 A.2d 1014 (Me. 2003) (malpractice suit for failure to inform patients of FDA warnings about proplast TMJ implants and failure to remove implants when patients presented with symptoms associated with degeneration due to proplast implants).

Physician Supply Characteristics

Policymakers, especially at the state level, are unquestionably sensitive to the potential economic consequences of malpractice liability crises. The policy issue is whether skyrocketing insurance rates are affecting physician practice and location decisions, and therefore the need for other health care products and services. Whether biomedical research will also be affected negatively is a particular concern in states with high liability awards and major academic medical centers.

There are reasons to question the effects of a liability insurance crisis on physician or research location or concentration decisions. Nothing indicates that previous crises, similar in intensity, resulted in systematic physician relocation away from crisis states. Opponents of the malpractice litigation system often cite the number of physicians who close their practices in crisis states. The problem is that there is no empirical proof that the closure results from liability fears. Litigation and liability insurance costs may well be factors, but other issues (including age, family factors, managed care penetration, competitive pressures) are at least as likely to influence practice location decisions.[31] The General Accounting Office (2003a, p. 5; 2003b) recently reported that evidence of "the direct loss or newly limited availability of a health care provider resulting largely from actions…in response to malpractice concerns" is unsubstantiated or inconclusive.

[31] Personal communication with Steven Garber, PhD, November 2002.

From an economic standpoint, location decisions are multi-dimensional. Family factors, professional opportunities, future earnings potential, spousal job opportunities, and many other issues play a role in where a physician might locate. Moving to a high-litigation area may be a deterrent and would certainly be an important factor in the decision. Nonetheless, there is no strong economic rationale for why it would be a dominant location motivator.[32]

At the same time, some data challenge this logic by suggesting that the current crisis may depart from the past. A March 2003 American Hospital Association (2003) survey found that 53% of hospitals in crisis states report difficulty recruiting physicians. Although a low response rate (22%) limits the survey's reliability, it indicates that the liability crisis is having some economic impact. Unfortunately, the study does not describe the type or location of facility, previous recruitment difficulties, or other financial pressures affecting location incentives. But Hellinger and Encinosa (2003) found that states with caps on damages show 12% greater growth in physicians per capita than states without caps. And early results from a recent physician survey indicate that the primary reason for retirement decisions is the increasing malpractice insurance burden. The survey did not ask physicians to rank the factors leading to their decision, so the finding must be tempered somewhat. In any event, the survey confirms physicians' deep dissatisfaction with the current liability system. According to Michelle Mello, the

[32] Personal communication with Steven Garber, PhD, November 2002.

survey asked physicians to state the primary factor motivating their decision.[33] While certainly valid methodologically, it might be more revealing to have physicians rank order the set of factors influencing their location or practice decisions (see, e.g., Jacobson and Rosenquist, 1996).

Even if physician practice patterns have not been altered much in the aggregate, the current crisis may well affect the availability of specialists such as obstetricians, emergency physicians, and neurosurgeons. An American Medical Association survey of 4,846 physicians nationwide (no response rate provided) shows that 58.5% of all respondents changed their practices in response to liability pressures.[34] The figures are higher for high-risk specialties such as emergency medicine, ob-gyn, and surgery (64.8% versus 56.8% for low-risk specialists), and higher in crisis states (61.4% versus 54%). A higher percentage reports ceasing to provide certain services than actually closing their practices. One might expect these fields to be especially susceptible to increasing liability from the use or misuse of technology. Furthermore, if specialists who depend on technology are limiting their practices, less technology will be purchased, which will ripple through the "medical-industrial complex." The vexing question is what actions state policymakers can take to avert concentrated physician departures and loss of technology and research clusters.

[33] Personal communication, June 2003.
[34] American Medical Association. Quantifying the Effects of Liability Woes. Amednews.com, April 21, 2003.

The Standard of Care

In the rapidly changing health care delivery environment, the development of new technologies raises two key questions regarding the legal standard of care. First, has new medical technology led courts to change the standard of care in medical malpractice actions? Second, as a normative matter, should technology alter the standard of care? Both questions must be addressed in the context of cost containment and the potential for liability to depress the use of technology. This section of the report addresses the first question; the second is discussed below.

During the second malpractice crisis in the mid-1980s, a central concern was whether expectations of medicine had changed such that physicians were being held to strict liability standards as opposed to the traditional fault-based negligence rule. At that time, I concluded that there was no basis in the reported judicial opinions to support the strict liability hypothesis (Jacobson, 1989). Nearly 15 years later, it seems timely to revisit that analysis. In the interim, there has been a profusion of technological advances, ranging from expanded imaging techniques to entirely new areas involving genetic technologies and biometric materials that could easily result in changed liability standards. Even so, the evidence remains overwhelming that courts have not ventured far from the medical negligence principles established early in the 20th century (despite considerable entreaties from legal scholars to adopt different standards). In case after case, the starting point is to analyze physician custom as established through physician

testimony. The standard of care remains what it has always been—a fault-based determination, not a strict liability regime.

Thus far, courts have largely rejected plaintiffs' arguments that providers should be held strictly liable as sellers of medical products or members of the chain of distribution of a medical device or instrument.[35] Instead, judges have limited plaintiffs' strict liability claims for defective medical devices to actions against manufacturers (Adler, 1994). If the product manufacturer is bankrupt, plaintiffs may be left without a remedy for injuries resulting from a defective medical device. But imposing a strict liability standard on physicians for product failures would seriously impede medical progress.

Courts have largely rejected plaintiffs' arguments that providers should be held strictly liable as sellers of medical products or members of the chain of distribution of a medical device or instrument.

Beyond the policy arguments set forth in the TMJ and similar litigation, courts have offered several reasons for not imposing strict product liability on physicians and hospitals. Most prominently, judges have rejected plaintiffs' arguments that the

[35] *North Miami General Hospital v. Goldberg*, 520 So. 2d 650 (Fla. Ct. App. 1988) (holding that strict liability may not be invoked against a hospital or physician in the use of a defective medical implement); *Hoff v. Zimmer*, 746 F. Supp. 872 (refusing to apply strict liability to a hospital or medical practitioner for injuries caused by medical instruments, drugs, or other substances used in treatment); *Hershley v. Brown*, 655 S.W.2d 671 (Ct. App. Mo. 1983) (refusing to hold a physician strictly liable for injuries resulting from a defective tubal ring sterilization instrument); *In re Breast Implant Product Liability Litigation*, 331 S.Ct. 540, 551 (1998) (holding that health care providers are not strictly liable for defect breast implants); *Porter v. Rosenberg*, 650 So.2d 79, 80 (Fla. Ct. App. 1992) (holding that a physician is not strictly liable for injuries resulting from a defective breast implant).

physician or hospital "sold" the product or device to the patient.[36] Traditionally, courts have only held entities strictly liable under a product liability theory if the entity is a manufacturer or seller of the product. Entities that provide services are only held liable if the plaintiff can prove negligence.[37] Therefore, an issue often raised in product liability actions against a hospital or physician is whether the transaction was a sale or a service.[38] As a general rule, courts have concluded that the transaction between a defendant and a patient should be treated as a service, notwithstanding the fact that a medical product is involved.[39] One court ruled that even an 85% hospital surcharge for a pacemaker does not convert the hospital into a seller as opposed to a service provider.[40] Courts reason that holding providers strictly liable would put health care beyond the financial reach of

[36] *Goldfarb v. Teitelbaum*, 540 N.Y.S.2d 263 (N.Y. App. 1989) (holding that the defendant dentist was not strictly liable for injuries resulting from a defective mandibular prosthesis because the insertion of the device was not a sale); *Podrat v. Codman-Shurtleff, Inc*., 558 A.2d 895 (Pa. Super. 1988) (refusing to impose strict liability after concluding that the hospital was not in the business of selling or supplying the product, but was providing professional services); *Weissman v. Dow Corning Corp.*, 892 F. Supp. 510, 518 (S.D.N.Y. 1995) (holding that physician is not a seller of liquid silicone used in a breast augmentation surgery and therefore is not strictly liable for the plaintiff's injuries); *Hector v. Cedars-Sinai*, 180 Cal. App. 3d 493, 504 (Cal. Ct. App. 1986) (holding that a provider is not strictly liable for injuries from a defective pacemaker because the provider is not a seller of the pacemaker).

[37] *Royer v. Catholic Medical Center*, 741 A.2d 74 (N.H. 1999) (no liability for providing a service absent proof of violating a legal duty).

[38] *Murphy v. E.R. Squibb & Sons, Inc*., 40 Cal. 3d 672, 677 (Cal. Ct. App. 1985) ("It is critical to the issue posed to determine if the dominant role of a pharmacist in supplying a prescription drug should be characterized as the performance of a service or the sale of a product."); *In re Breast Implant Product Liability Litigation*, 331 S.C. 540, 545 (1998); *McKenna v. Harrison Memorial Hospital*, 960 P.2d 486, 487 (Ct. App. Wash. 1998); *Hector v. Cedards-Sinai*, 180 Cal. App. 3d 493, 501 (Cal. Ct. App. 1986) ("The key to the court's conclusion is the characterization of hospitals as providers of professional medical services, not suppliers of products.").

[39] *Podrat v. Codman-Shurtleff, Inc*., 558 A.2d 895 (Pa. Super. 1988); *Royer v. Catholic Medical Center*, 741 A.2d 74 (1999); *St. Mary Medical Center, Inc. v. Casko*, 639 N.E.2d 312, 315 (1994).

[40] *Hector v. Cedars-Sinai Medical Center*, 180 Cal.App.3d 493 (Cal. App. 2nd Div. 1986).

many patients,[41] would inhibit the development of new medical techniques, and would place an excessive burden on physicians and hospitals to test and assure the safety of medical products.

What constitutes a minimum standard of care will naturally evolve with available innovations, and will depend on how expert witnesses testify about the use and availability of technology.

Technological change nonetheless is a major factor in how the negligence standard operates. Medical standards reflect innovative procedures, techniques, and equipment. What constitutes a minimum standard of care will naturally evolve with available innovations, and will depend on how expert witnesses testify about the use and availability of technology.

Technological change therefore gives the appearance of a less forgiving legal regime.

With the demise of the locality rule, which limited expert testimony to the standard of care in the defendant's community, plaintiffs have access to a wider array of experts. This potentially accelerates technology-induced legal change, because out-of-state or academic experts may practice to a different (that is, higher) standard. Technological change therefore gives the appearance of a less forgiving legal regime. The underlying public policy question, of course, is how quickly new technologies should be adopted by the average practitioner.

[41] *Hershley v. Brown*, 655 S.W.2d 671, 675 (Ct. App. Mo. 1983); *Parker v. St. Vincent Hospital*, 919 P.2d 1104 (Ct. App. N.M. 1996).

Explanatory Factors: The Culture of Technology

So far, I have argued that technology plays a crucial role in liability trends. In this part of the report, I will examine the factors driving the development and use (i.e., the supply and demand) of technology. Observers of the U.S. health care system frequently remark on the nation's culture of technology. Americans expect, indeed demand, both continued innovation and widespread (though not universal) availability. As one observer notes, "Technology has become the symbol of our culture and the symbol of progress" (Hoffman, 2002, p. 681). Another commentator explains technology's cultural hegemony as follows:

> Medical technology is so uniquely powerful that its impact is felt not only in daily life, but also in the way life is viewed….While Americans might decide to limit 'halfway' or exotic, science-fiction inspired technologies, such as artificial hearts or brain transfers into robotic bodies, it would appear unlikely they would ever approve limitations on medical research whose focus is to discover technologies…which not only maintain qualitative existence, but extend life (Smith, 2001, p. 286).

Once "discovered," a similar imperative leads to use, and to both favorable and unfavorable consequences. According to Joel Howell:

> Still today, the technologies that we use, the machines that we choose to make a part of patient care, are used in ways that reflect the underlying social concerns and beliefs of a society (Howell, 1995, p. 249).

Technological progress accounts for most of the growth in national health care expenditures, and has been the primary impetus for the development of hospitals and

other medical institutions. Medical technology diffuses rapidly, with few safeguards to assure efficacy and avoid social waste. Not surprisingly, the public wants it both ways—quick access to the latest technology, but also a mechanism for compensating the inevitable failures. That may not, strictly speaking, amount to an effective quality control mechanism, but it clearly predisposes patients suffering adverse outcomes to litigate.

Cultural Explanations

The nation's culture of technology underlies the relationship between law and medicine. No other factor plays such a powerful explanatory role in litigation trends or overall health policy, and both liability reform and health care reform are impossible without taking into account the cultural aspects of technology.

Historian Kenneth De Ville has been a leading proponent of the relationship between technology and medical liability. The importance of De Ville's work is its focus on the cultural determinants of the technological imperative as they influence liability trends. His explanatory framework for recurrent medical malpractice crises invokes both long-term cultural factors and short-term topical influences, and is a useful starting point for understanding litigation trends and for adopting appropriate policy responses (De Ville 1998).

Under long-term cultural trends, De Ville notes several factors: 1) an upward-sloping baseline proclivity to sue; 2) breakdown of community solidarity that discouraged litigation; 3) a rising secular belief that humans can improve their lives; 4) a

growing preoccupation with physical well-being; and 5) increased demand that there be a remedy for every wrong. Topical influences include: 1) attitudes toward the medical profession; 2) more sophisticated plaintiffs' attorneys; 3) increasing media coverage; 4) changes in legal doctrine; and 5) the absence of national health insurance. The inadequacy of health insurance deserves special attention as an incentive for litigation. When technology-laden medical care is needed following iatrogenic injury, the expense to someone lacking insurance can be devastating.

Three aspects of the cultural dimension discussed above particularly influence liability. One is the oft-noted phenomenon of success breeding unrealistic expectations that all medical interventions, particularly those relying on innovative technology, will be successful. As De Ville notes, "Inflated public expectations are common following periods of dramatic medical advancement…." (De Ville, 1998, p. 202). These expectations not only lead more patients to litigation, but they also encourage juries to award ever higher damages when the technology is perceived to have failed.

Cultural expectations put [pressure] on manufacturers and physicians to use the latest technology without adequately assessing its value.

A second aspect is the pressure cultural expectations put on manufacturers and physicians to use the latest technology without adequately assessing its value. We are in the midst of a technology-driven cycle, which suggests a continued rise in malpractice

litigation rates. This is particularly pernicious because early adapters will push reluctant physicians to adopt new technology before diffusion is appropriate. The cycle is reinforced by professional competition: "Having the latest technology offers substantial professional status to a physician group" (Chernew et al., 2003). The examples of electronic fetal monitors (EFMs) and high-dose chemotherapy with autologous bone marrow transplant (HDC-ABMT) for metastatic breast cancer patients show the dangers of premature technology diffusion. EFMs led to litigation over the failure to use the technology or properly interpret the results; the other led to litigation over the need to provide insurance coverage.

The third aspect is overconfidence in the scientific basis of technological innovation, which reinforces the lack of assessment by not putting pressure on the system to justify new technologies. As part of a project looking at the history of HDC-ABMT, one interview respondent noted that "The greatest failure of the last half of the 20th century has been the uncritical acceptance of medical innovation as *a priori* effective."[42] All of this no doubt leads to remarkable medical advances, but at a high cost.

The Demand for Technology

From the industrial revolution to modern computing and telecommunications, the advance of technology has been a major determinant of our social and economic well-being. Health care delivery is so manifestly a product of technology that it seems entirely

[42] Interview conducted by Richard A. Rettig, 30 June 2003.

appropriate to speak of a technological imperative in health care—"the lure of always pushing toward the greatest feat of technological performance or complexity which is currently available" (Pacey, 1983, p. 79). The seemingly inexhaustible demand for high-technology medical interventions has shaped the course of American health care for at least a century (Rothman, 1997). Health economists agree that technological advance is the major cause of rising expenditures (Fuchs, 1996). The era of traditional fee-for-service medicine, where physicians and facilities were reimbursed at usual and customary rates for each service provided to their patients, was not sensitive to health care costs. This led to the rapid diffusion and widespread use of new medical technology, even technologies with few benefits over their predecessors (cf., Howell, 1995, arguing that diffusion is much slower than commonly recognized). The predictable result was a rapid escalation of medical care costs. In many communities, civic pride, patient demand, and competition for physician allegiance created a technology arms race, in which each hospital rushes to acquire the latest equipment. This, of course, leads to considerable duplication and waste.

Compared with hospitals in most European countries, U.S. hospitals perform a far greater number of catheterizations, angioplasties, and bypass surgeries. Similarly, the United States has more high-tech equipment, such as magnetic resonance imaging (MRI) and computed tomography (CT) scanners, available than most other countries (Kim, Blendon, and Benson, 2001). Americans are more interested in new medical discoveries

than Europeans, though they are not much different when it comes to inventions in other scientific fields. Americans also have higher expectations for medicine and show greater resistance to imposing cost or other constraints on medical technology. These expectations will continue to rise as dramatically new technologies are introduced, many claiming unique effectiveness. Recent advances in genomics and proteomics, to give two prominent examples, fuel such hopes today (Heffler et al., 2001).

Tendency to equate more tests and procedures with higher quality care puts pressure on physicians to adopt the latest technology.

Individual patient preferences bolster the general cultural propensity to favor technological solutions to medical problems. Patients often want the newest drug or the most cutting-edge surgical procedure when they fall ill or are injured, even if they lack enthusiasm for the increased premiums and out-of-pocket payments needed to pay for such innovations (Heffler et al., 2001; see also, Danzon and Pauly, 2001). Patients' tendency to equate more tests and procedures with higher quality care puts pressure on physicians to adopt the latest technology (Barger-Lux and Heaney, 1986). All of this helps explain why direct-to-consumer advertising has become so important for the pharmaceutical industry.

A key aspect of technology diffusion is the eagerness physicians have about using the latest innovations. Studies trying to understand physician adoption of new

technologies repeatedly mention the reimbursement environment, concerns about quality of care, and patient preferences as the predominant factors. Even when the overall clinical benefits are marginal and the incremental cost substantial, physicians will opt for new technology if there is a perceived advantage in patient comfort or safety (Jacobson and Rosenquist, 1996). A recent study of new coronary artery disease (CAD) technology concludes that the potential for improved clinical outcomes and competition for patients are powerful forces driving physician adoption:

> Certain respondents stated that the medical profession as a whole was biased toward action—instead of inaction—when faced with an uncertainty whether or not to intervene, a behavior often referred to as the "technological imperative." This bias was augmented by a subset of physicians, "early adopters," who actively seek out and apply new technologies. Respondents generally believed that the behavior of early adopters was motivated by perceptions of the patients' best interests, although some respondents noted a potential for self-interest as a driving force for early adoption (Chernew et al., 2003).[43]

Similarly, a physician survey found that more than 75% of physicians who perform laparoscopic cholecystectomy do so because of better patient outcomes (Escarce et al., 1995). Competition among physicians and patient preferences are also cited as important for adoption (see also, Robinson, Garnick, and McPhee, 1987; Gawande, 2002). Non-adopters cite safety concerns in the absence of rigorous scientific evaluation.

[43] One respondent noted that "No one wants to be the one on the block who doesn't know the new technique."

Physician specialization reinforces physician demand for increasingly sophisticated technology. Technology makes subspecialty possible, such as microsurgery on different parts of the body. The IOM (2002, p. 30) report on medical errors indicates that specialization accounts for a great many of the errors studied: "The contribution of complexity and technology to such error rates is highlighted by the highly technical surgical specialties of vascular surgery, cardiac surgery, and neurosurgery."

The Supply of Technology

Demand alone, needless to say, does not explain technology trends. The pressure to develop and market innovative technologies is equally relentless. Rapid technological advances transform the way health care is organized, delivered, and financed. Improved diagnostic, surgical, and anesthetic techniques are resulting in better outcomes and speedier recoveries, which enable more care to be provided in lower-acuity settings (Myers and Burchill, 2002). New medical technology is no longer the exclusive domain of academic medical centers, but is disseminated to a broader set of hospitals and physician practices. Not only does this accelerate the pace of practice change, it perpetuates fragmentation in health care delivery.

Demand alone, needless to say, does not explain technology trends. The pressure to develop and market innovative technologies is equally relentless.

Manufacturers, patient advocates, and political figures can also be fervent advocates for expanding the supply of new technologies. Product manufacturers have especially strong economic incentives to encourage technology adoption and diffusion. For example, the goal of direct-to-consumer advertising is to exploit cultural attitudes predisposed toward technology and encourage patients to pressure physicians to prescribe or use the latest innovations. All the while, manufacturers bombard physicians with free samples, seminars, and deals to encourage the technology arms race.

Americans' higher interest in new medical discoveries and higher expectations for medicine are likely to translate into pressure on policymakers and health plans to spend more on new medical technologies, drugs, and medical research (Kim, Blendon, and Benson, 2001). The National Institutes of Health (NIH), the National Science Foundation (NSF), and other federal agencies spend billions of dollars annually on biomedical research. If past is prologue, the preference for ever more technology will trump rising costs at almost every turn, even in a slower economy. Most Americans believe that the frontier of medical miracles is endless, and thus far they have been willing to pay for progress (Iglehart, 2001).

Precise estimates of the nation's yearly investment in technology development and transfer are difficult to derive. According to one estimate, new technologies and practice patterns account for up to 90 percent of the sevenfold increase in health care spending since 1950 (Thorpe, 2002). Whatever the exact amount, it is large and growing.

Each year, the federal government invests billions of public dollars in medical technology research. For example, NIH funds areas such as bioengineering ($825.9 million), gene therapy ($379.7 million), and clinical research ($7.6 billion). Through legal mechanisms such as patent protections, this research funding is then translated into a variety of products and technologies for medical use. Federal policy encourages technology transfer so that private firms can license their inventions for purposes of commercialization. "Technology transfer is the movement of technology and other resources between non-profit entities, government laboratories, and the private sector for further research, development and commercialization" (McGarvey, 1999, p. 1097).

Inventions that arise from government funding are made available for commercialization through the Bayh-Dole Act of 1980. "Under the Bayh-Dole Act, funding recipients generally have the right to elect title to inventions made with federal funding. By giving funding recipients the benefit of their inventions, Congress sought to promote the utilization, commercialization, and public availability of federally-funded inventions" (McGarvey, 1999, p. 1098). This act ensures that the public will benefit from these technologies through the disclosure and patenting of all technologies developed with federal money. Likewise, the Food and Drug Administration Modernization Act also accelerates new drug and medical device approvals.

There are many industries that contribute to and benefit from the commercialization and production of medical technology. Even in its infancy, the

biotechnology industry is important because of its promise for developing useful medical technologies (especially drugs for diseases that currently have no available treatment), its powerful hold on the public's imagination, and the ethical and moral challenges it raises. Biotechnology encompasses three different techniques. Traditional biotechnology uses living organisms (or parts thereof) to produce or modify chemical compounds. Gene technology, or genetic engineering, uses DNA's properties to analyze and modify the genetic information. And reproduction biology includes traditional breeding techniques, in-vitro fertilization, and cloning of organisms.[44] Biotechnology accounts for a growing share of the world medical market. Currently, biotechnologies derived medicines account for 5% of the value of the world market, and are expected to rise to more than 15% by the year 2005.[45] According to industry figures, 20% of new medicines annually are biotechnology derived.[46]

There are many industries that contribute to and benefit from the commercialization and production of medical technology.

Collectively, the biotech products currently on the market or in late-stage clinical trials for use in cardiovascular or neurological care represent incremental and additive rather than breakthrough or disruptive technologies. But over the next decade,

[44] Biomedicine: Promises for Health, The Technology, http://www.phrma.org/publications/publications/biomed/technology.pdf, December, 03, 2000.
[45] Biomedicine: Promises for Health, The Achievements, http://www.phrma.org/publications/publications/biomed/achieve.pdf, December, 03, 2000.
[46] Id.

developments such as gene testing, gene therapy, and stem cell therapy will affect the health care industry in far more profound ways. For example, gene chips will render diagnosis faster and more accurate, and more health care may move to ambulatory settings as biotech therapies (typically drugs and injections) replace surgeries and other invasive procedures (Myers and Ehrlich, 2001).

Traditional pharmaceuticals continue to contribute to the technology boom. Between 1993 and 2003, Americans obtained more than 363 new medicines, biologics, and vaccines approved by the U.S. Food and Drug Administration to prevent or treat more than 150 diseases and conditions. In 2002, the industry's trade association, PhRMA, estimated that $26.4 billion were spent on domestic pharmaceutical research and development (R&D).[47] This comprised 18.2% of domestic pharmaceutical sales, which totaled around $145 billion.[48] These R&D funds include money spent on U.S. laboratories and funds granted out to other companies and research institutions. The development of new drugs works to shape the standards and practices of medical care, especially in pharmaceutical-dependent diseases such as Alzheimer's, Parkinson's, and AIDS.[49]

A third component of the medical technology industry is medical devices. A medical device is "an instrument, apparatus, implement, machine, contrivance, implant,

[47] Appendix: Detailed Results from the PhRMA Annual Membership Survey
[48] Id.
[49] A Decade of Innovation: Advances in the Pharmaceutical Treatment of Disease, http://www.phrma.org/publications/publications//2003-10-16.855.pdf

in vitro reagent, or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease."[50] Medical devices can be anything from thermometers to artificial hearts to at-home pregnancy test kits. They include implantable devices such as heart valves, diagnostic screening, and lab technologies, as well as dialysis machines. More than 20,000 firms worldwide produce over 80,000 brands and models of medical devices for the U.S. market.[51] Medical devices are rapidly changing due to advances in nanotechnology and mergers with biotechnology that widen their application. Medical devices are also a highly regulated industry. Each device must gain approval through the Food and Drug Administration's Center for Devices and Radiological Health.

Health care institutions, especially hospitals, have always played an important role in driving technology. A facility's use of the latest technology attracts both physicians and patients, giving rise to a medical arms race (Luft et al., 1986). With the advent of managed care in the late 1980s, many policymakers anticipated that managed care organizations (MCOs) would restrict the use of technology to control cost, either through utilization review or medical necessity determinations. In the mid-1990s, managed care was reasonably successful in controlling the increase in health care

[50] Federal Food, Drug and Cosmetic Act, § 201 (1997), http://www.fda.gov/opacom/laws/fdcact/fdcact1.htm.
[51] http://www.fda.gov/opacom/factsheets/justthefacts/5cdrh.pdf

utilization, but there is no indication that the industry's cost containment policies altered either the use or culture of technology.

Paradoxically, cost containment hastened the technology-driven shift of the locus of care from the inpatient sector to the outpatient sector. From 1980 to 1998, the share of total personal health expenditures attributable to hospital spending fell from 42% to 33%, while the share attributable to outpatient drug spending rose from 5% to 8% (Danzon and Pauly, 2001). For instance, technological advances led to treatment techniques like lithotripsy that enable kidney-stone patients to be treated on an outpatient basis. In the past, this treatment involved complicated surgery and a lengthy inpatient hospital stay. Similar technologies allow specialists, such as cardiologists, to establish specialty clinics and hospitals, giving patients access to the most advanced procedures without presenting at a tertiary hospital (GAO, 2003c). In turn, this deprives tertiary hospitals of important revenue sources.

Paradoxically, cost containment hastened the technology-driven shift of the locus of care from the inpatient sector to the outpatient sector.

Policy Controls

One explanation for rapid diffusion is that available policy levers to restrain its use have not

One explanation for rapid diffusion is that available policy levers to restrain its use have not worked.

worked. For example, technology assessment has been inadequate, and insurers have not insisted on cost-effectiveness as a criterion for reimbursement. In principle, coverage and reimbursement policies could act as a barrier to the premature dissemination of technology. In reality, these control mechanisms have rarely been effective. At best, the technology assessment (TA) processes employed by public and private payers have had only a modest effect on technology (Jacobson and Rosenquist, 1988). One reason is that courts do not always support coverage denials, even those based on scientific evidence. Another reason is that legislatures (both state and federal) often succumb to pressure from patient advocacy groups, making new therapies rapidly available through public programs and mandating coverage of controversial techniques by private insurers.

The widespread use of ABMT for metastatic breast cancer patients is a glaring reminder of the physical harm and financial waste that can result from uncontrolled adoption of new procedures.

The widespread use of ABMT for metastatic breast cancer patients is a glaring reminder of the physical harm and financial waste that can result from uncontrolled adoption of new procedures. Many clinical oncologists in the late 1980s and early 1990s recommended ABMT as a last-ditch therapy that represented the patient's only chance for survival. The problem was that ABMT had not been proven through randomized clinical trials to be more effective than standard chemotherapy. Absent that evidence, insurers balked at reimbursing what was a very expensive procedure. Several patients

filed suit to compel insurers to pay, and approximately 50% prevailed in court. Unfortunately, when the results of clinical trials finally became available, it turned out that the plaintiffs had "won" the right to undergo a punishing and ineffective procedure that in many cases actually resulted in worse outcomes than conventional chemotherapy (Mello and Brennan, 2001).

The rapid cycling of health care technology presents health care policymakers with complex, if not intractable challenges. With the breakdown of the certificate of need process that attempted to limit and "rationalize" hospital investments in technology, the only constraint seems to be health insurers' ability to hold back reimbursement. Yet even managed care has had only limited ability to "stand in the way of the innovation 'steamroller.'" In response to patient demand and physician resistance, MCOs have retreated from stringent coverage policies that were both unpopular and prone to litigation.

Policy Recommendations

A more deliberate connection between technology policy and liability policy is desirable. The goal of this section is to suggest policy reforms that support innovation without undermining the liability system's legitimate role in monitoring quality of care. Liability and innovation are not mutually exclusive concepts. Thoughtful reforms are needed to provide greater stability to the medical liability system while encouraging the broad and safe diffusion of new technologies.

It would be nice to conclude this report with a ringing endorsement of a set of legal and policy changes that would clearly support innovation without undermining the tort system's compensation and deterrence functions. But if that set existed, the changes would have been made long ago. Instead, policymakers should encourage and fund experimentation with a variety of options, both within and without the malpractice system, designed to help the public and the health care system come to terms with the culture of technology.

Table 3

Recommended Changes

- ***The Culture of Technology***: Need for a more forthright debate about the cultural aspects of technology between medical leaders and the public. Alter expectations about what medical technology is capable of achieving.
- ***Technology Assessment*:** Effective TA is a key policy objective.
- ***The Legal Standard of Care***: Change standard of care to incorporate costs/benefits. Allow physicians to weigh available resources when deciding to adopt technologies.
- ***Liability Doctrine***: Design a no-fault system in cases of indeterminate causation.
- ***Enterprise Liability***: Shifting responsibility to the institution does not solve the problem of technology-induced liability; it only solves the problem of who pays for the error.
- ***Expert Testimony***: Expert witnesses are necessary in establishing liability for the use of technology, but they have legitimate disagreements as to what constitutes appropriate care. Three solutions are possible—independent panel under the judiciary to review and monitor expert testimony, use of court-appointed experts, or developing specialized courts.

Legal Processes

Changes in Liability Doctrine. The tort system is a reflection of societal and community values—a battleground of social theory (Prosser, 1978). These values are ultimately reflected in how jurors respond to various claims and how legal doctrine develops (Prosser, 1978; Rustad and Koenig, 2002). With respect to the current operation of tort law, I do not think that fundamental changes in the standard of care are warranted. Changes at the margin that add flexibility to certain types of technology-based litigation would be preferable, but solutions may vary across technologies. At some point, it may also be advisable to replace the traditional negligence standard with a strict liability (or "no-fault") regime centered on hospitals or other health care enterprises.

Changes in the Standard of Care. The legal standard of care is the key intersection between law and medicine and one of the critical points of external accountability for medical practice. The standard of care is supposed to reflect customary practice. Even under the best of circumstances, however, the standard of care only approximates how physicians actually treat patients. For one thing, local area variations cast doubt on the existence of any easily developed or applied standard of care (Wennberg and Peters, 2002). For another, the law thinks about the standard of care as definitive, while physicians think about a spectrum (or probability distribution) of reasonable treatment options.

In cases involving controversial scientific procedures (such as ABMT) that have not yet come into widespread use, convincing results from RCTs would almost certainly determine the outcome. Absent such conclusive evidence, courts are left with considering an array of alternatives in setting the standard of care, none of which is likely to be dispositive. For example, clinical practice guidelines, which courts have used as one piece of evidence rather than determining the standard of care, are not available for many technologies (such as partial lung surgery). Indeed, given rapid technological diffusion, it is difficult to develop guidelines in the early adoption phases. As a result, there is often no agreement on what should be included in clinical practice guidelines, and many guidelines conflict with one another (Mello, 2001). This makes it difficult to rely on these mechanisms in setting the standard of care and leaves courts dependent on expert testimony, with its attendant problems.

The process of establishing the legal standard of care has come under increasing scholarly examination. In a recent symposium, attorneys, physicians, and judges discussed the merits of various empirical ways of assisting the courts in setting the standard of care. For instance, scholars debated the merits of conducting physician surveys to determine how respondents would treat the patient bringing the lawsuit (Cramm, Hartz, and Green, 2002; Ely, Hartz, and James, 2002). Another approach would be to analyze existing data sources (i.e., a comprehensive review of medical records) to illuminate how physicians treat the conditions leading to the litigation (Hall et al., 2002).

Still another effort would redefine the standard of care away from customary practice to what would be reasonable under the circumstances (Peters, 2002). Though none of the conference participants disagreed about the utility of empirical evidence, it was obvious that each of these methods suffers from a number of methodological, conceptual, and practical shortcomings (Lempert, 2002; Jacobson and Kanna, 2001).

Departures from the Professional Standard. Courts could simply abandon the professional custom standard and switch to the standard of care for non-medical liability cases, where deference to custom is not as strong. On occasion, courts have deviated from the professional paradigm in medical liability cases.[52] Two instances where courts have relied on resource constraints to establish a different standard are instructive. Neither departure has had much doctrinal impact, but the cases suggest directions courts might take in certain cases involving medical technology.

One of the very few medical liability cases to consider the cost-effectiveness of technology in setting the standard of care is *Helling v. Carey*.[53] The case involved the physician's failure to provide a glaucoma screening test to a patient under 40 years of age when professional custom was to screen only patients over 40 because of the low incidence of glaucoma in persons under 40. After the patient developed glaucoma, she sued the physician, arguing that since the screening test was relatively inexpensive and

[52] See, e.g., *Brune v. Belinkoff*, 235 N.E.2d 793 (Mass. 1968); *Smith v. U.S.*, 119 F. Supp.2d 561, 573-74 (D.S.C. 2000).
[53] 519 P.2d 981 (Wash. 1974). The case was subsequently superseded by the Washington State legislature.

accurate, it should have been provided regardless of the prevailing professional custom. While the court did not explicitly rely on a cost-effectiveness analysis (CEA), it noted the test's low cost relative to potential benefits as a reason for overruling professional custom. Some commentators have argued that the case represents the potential application of CEA in medical liability that might provide physicians with a defense in litigation alleging harm from the failure to use technology (Schwartz and Komesar, 1978). Other commentators have criticized *Helling* on the grounds that the test mandated by the court has a high false positive rate and that early detection does not always alter the outcome of glaucoma (Fortess and Kapp, 1985).

Nothing prevents the medical profession from factoring costs into customary care. While I doubt that such a shift will counteract the technological arms race, it may protect against liability for failure to use unproven technologies and thereby slow their diffusion.

Subsequent cases generally have rejected the *Helling* analysis, and have retained a standard of care based on professional custom. As I have argued elsewhere, nothing prevents the medical profession from factoring costs into customary care (Jacobson, 2002). While I doubt that such a shift will counteract the technological arms race, it may protect against liability for failure to use unproven technologies and thereby slow their diffusion.

A different departure from the standard model occurred in *Hall v. Hilbun*,[54] a case alleging negligence in post-operative care that considered the availability of technology rather than its effectiveness. The principal issue was whether a national rather than a local standard of care should apply despite differences in resources across hospitals and geographical regions. In adopting a national standard, the court distinguished between technical skills and knowledge, which should not vary, and resource availability, which varies substantially. The court determined that the duty of care would be "based upon the adept use of such medical facilities, services, equipment, and options as are reasonably available."

Under this standard, for example, a physician practicing in a rural area would not be faulted for failing to use a CAT scan if the equipment were not reasonably available. If this approach were to be adopted, it would permit physicians to weigh available resources as a factor in deciding whether to adopt particular technologies. Again, it might slow diffusion of unproven technologies. But, as noted earlier, courts might not be as reluctant to hold health care institutions liable under similar circumstances, which would have the opposite effect on diffusion.

A doctrinal fusion of these two paths, *Helling* and *Hilbun*, might permit defendants to incorporate CEA into an evolving standard of care that distinguishes between resource constraints and technical skill. Haavi Morreim (2001) has been a

[54] 466 So.2d 856 (Miss. 1985).

leading proponent of this approach. Morreim argues that both health plans and physicians owe patients the traditional standard of administrative or medical expertise concerning professional knowledge and skill. At least in theory, this would allow MCOs greater latitude in which technologies it would purchase and how it would use CEA and other cost containments strategies in deciding when to pay for technologies in individual situations.

A doctrinal fusion of these two paths, *Helling* and *Hilbun*, might permit defendants to incorporate CEA into an evolving standard of care that distinguishes between resource constraints and technical skill.

Changes in Expert Testimony. Malpractice litigation generally, and litigation over medical technology in particular, depend on expert testimony because of the complexity of clinical care. Critics of the tort system argue that expert witnesses can be "bought" and that jurors have no principled way of resolving disagreements between experts (Cramm, Hartz, and Green, 2002). Consider the expert witness problem in the diffusion of ABMT, where judges and juries were confronted with conflicting positions regarding the procedure's effectiveness: academic oncologists argued that only RCTs could determine the issue, while community oncologists were using it widely even without statistical proof.

A revealing exchange occurred in a recent Pennsylvania trial. On direct examination, the plaintiff's attorney asked his expert witness whether the defendant had ordered an ultrasound of the breast. The expert responded that:

> He did not order an ultrasound. He did not order any x-rays or mammogram….He did not order any other diagnostic studies *which some places now have available, such as MRI scans or anything.*[55]

The defendant objected to the testimony because it asserted that the physician should have used technology that was unavailable. The objection was overruled, and the witness went on to describe why the physician had breached the standard of care.

Another issue is the competence of experts to assess specialized medical practice and associated technologies. At least in the medical malpractice cases included in this sample, the U.S. Supreme Court's decisions encouraging lower court judges to exercise greater authority over expert testimony have had little effect at the state court level (Dixon and Gill, 2001; Bernstein, 2002; Kassirer and Cecil, 2002). Nevertheless, judges can ensure that only experts in the particular area that is the subject of the litigation should be permitted to testify. For example, primary care physicians should not be permitted to describe the standard of care in complex labor and delivery litigation. Even if judges were able to screen expert witnesses more effectively, a conceptual problem

[55] *Branch v. Ledesma,* 54 Pa. D. & C.4th (Pa. Ct. Com. Pleas 2001). See also, *Cruz v. Northeastern Hospital,* 801 A.2d 602 (Pa. Super. 2002).

remains. More often than not, experts have legitimate disagreements as to what constitutes appropriate care.

In response to concerns that expert physician testimony (for plaintiffs, not defendants) should be monitored, the AMA has established a process to sanction errant physicians. However, allowing the medical profession to control expert testimony smacks of self-interest, and recalls the "conspiracy of silence" that denied legal recourse to patients for much of the twentieth century. A better idea would be to convene an independent panel under the judiciary to review and monitor expert testimony, with input from the AMA and the ABA. Alternatively, one could expand the use of court-appointed experts. States could authorize some trial courts to appoint non-partisan experts while allowing the rest to retain the current approach. One model might be based on the RAND Institute for Civil Justice's work on federal court case management (Kakalil, 1996).

Systematic Changes

Perhaps the easiest way to engage policymakers with technology and liability is to frame the issue in terms of patient safety. Studdert and Brennan argue that a no-fault system based on enterprise liability "is thoroughly consistent with system-oriented quality improvement efforts" (Studdert and Brennan, 2001; IOM, 2002). There is considerable merit to this approach and to the demonstration program they recommend. Sage (2003a; 2003b) agrees with the related IOM strategy of encouraging various state-

based demonstration projects, adding that reforms driven by politics (e.g., caps on damages) are not likely to address the real problems in the malpractice system.

Enterprise Liability. How should malpractice law change in response to the technological imperative? Eventually, it probably needs to incorporate resource constraints in determining liability. One scholar suggests that new technology will compel two doctrinal changes: institutional liability and a shift from negligence to strict liability (Terry, 2002). Terry argues that "key technological and structural shifts facing our health care delivery system, adapted to reduce medical error, will confirm the final maturation of institutional duty default" (Terry, 2002, p. 43).

One scholar suggests that new technology will compel two doctrinal changes: institutional liability and a shift from negligence to strict liability.

This argument is premised on the view that technology use can be controlled at the institutional level. It is a questionable assumption, and not only because of intense physician opposition to such controls. No matter what role the institution (i.e., an MCO) plays in how technology is used, technology operates at both institutional and individual (physician) levels. For example, information technology, such as a computer system for data entry and data security, arguably functions at an institutional level. Even here, however, physicians will be integral to the system, and will be exposed to liability if it is used improperly (e.g., telemedicine). Other emerging

technologies, such as full body scans, PET scans, and stents, are used and interpreted by physicians, even if the institution has a financial stake in the technology. Many new technologies are jointly funded by physicians and institutions, making it harder to apportion liability just to an institution. Indeed, the IOM's prediction that new information systems will redefine the physician's role by performing functions previously only provided by a physician seems just as premature as predictions that nurse practitioners would supplant physicians' primary care role.

Besides, shifting responsibility to the institution does not really solve the problem of technology-induced liability; it only solves the problem of who pays for the error. To be fair, those who argue that institutional liability will result in greater accountability for quality of care, and hence fewer errors, have a point. However, proponents of an institutional liability model ignore the fact that, at least in the near term, neither the judiciary nor society is prepared for a world in which institutions provide medical care. Despite the Institute of Medicine's (2000) report that medical error results in some 44,000-98,000 deaths annually, there is little evidence in judicial opinions to suggest that liability doctrine has moved toward enterprise liability, defined as holding the health care institution primarily responsible for medical errors (Sage, 1997).

No-Fault/Strict Liability. No-fault liability systems have been a much-debated solution. In no-fault, claims relating to medical practice are resolved without regard to demonstrable negligence. Although I am not convinced that no-fault would change much

regarding liability and technology, there are two instances where it might be an advantageous approach.

The first involves indeterminate causation, where the underlying disease is the primary cause of injury but unused or misused technology prompts juries to impose liability. In these instances, no-fault can limit physicians' liability exposure without undermining the tort's system's general deterrence and compensation purposes. For example, a no-fault system could be implemented with a schedule of damages to guide decisionmakers. A damage schedule would suggest certain amounts for specific injuries, while allowing for discretion in individual circumstances.

Where the underlying disease is the primary cause of injury but unused or misused technology prompts juries to impose liability…. Fault can limit physicians' liability exposure without undermining the tort's system's general deterrence and compensation purposes.

Two states (Virginia and Florida) have established no-fault administrative regimes to compensate neurologically impaired neonates to avoid the hindsight bias that often induces juries to impose liability on obstetricians for failing to monitor labor appropriately. An evaluation of these programs concluded that they "maintained the availability of affordable obstetrical liability coverage for physicians" (Bovbjerg and Sloan, 1998, p. 120). Despite a low number of cases, the evaluators concluded that more

people received compensation through the administrative no-fault system than would have through the tort system.

Second, a no-fault system could remove some of the incentives for practicing defensive medicine, which frequently involves the deployment of expensive diagnostic technology. If physicians do not need to fear large jury verdicts, but could instead have disputes handled on a no-fault basis, whatever pressures physicians feel for ordering unneeded tests and procedures to protect against liability claims should be substantially reduced. Even handling negligence claims through alternative dispute resolution (i.e., mediation and arbitration) might generate some of these benefits if physicians feel that the reasons for their clinical decisions will obtain a fair hearing.

Collectivist (Insurance) Solutions. At a time when intense individualism dominates our political environment, it seems heretical even to suggest collectivist responses. By collectivist, I mean some sharing of the risks associated with the technological imperative. One possibility is to provide universal health insurance, which would remove the incentive patients now have to use the tort system to recover economic losses, especially ongoing health care costs, many of which relate to technology. Another is to provide subsidies to the specialists most affected by malpractice crises – such as surgeons and radiologists who are prime users of technology – to offset rapid increases in their malpractice insurance premiums. By contrast, current malpractice insurance rate-setting approaches, which set premiums according to legal risk associated with particular

specialties, exacerbate the financial burden and volatility of liability premiums for many physicians with technology-intensive practices (GAO, 2003a).

The Culture of Technology

There is no easy solution to the recurrent medical malpractice crises unless we deal with the underlying culture of technology. At the risk of being accused of harboring Luddite tendencies, I suggest that we need a much more forthright debate about the cultural aspects of technology. It may well be that the window of opportunity for a meaningful discussion of the technological imperative is not open at the moment. There is too much pressure throughout the medical system to adopt innovative technologies without adequate time to determine their appropriateness and effectiveness. But without some way to limit public expectations, physicians will never escape the dilemma technology imposes in a health care system as fragmented as ours. Patients want the latest technology (especially when they do not absorb the full costs), physicians and hospitals rush to provide lest they lose customers and revenues, and manufacturers happily oblige with new products.

There is no easy solution to the recurrent medical malpractice crises unless we deal with the underlying culture of technology.

Advances in technology will continue to influence legal doctrine, public policy, and health care delivery. Because of our collective cultural belief in medical progress, the supply and distribution of technology are inextricably linked to liability policy. In

view of the foregoing analysis, it seems unlikely that the current malpractice insurance crisis will reverse longstanding trends, which are all in the direction of expanded reliance on technology. Conventional tort reforms, such as caps on non-economic damages in medical malpractice cases, would likely facilitate physicians' use of technology, but enacting caps is unlikely to dissipate the technological imperative. Nor will caps appreciably reduce health care costs (CBO, 2004). Furthermore, geographic and specialty-based pockets of excessive liability could influence physician location decisions and interfere with research-based industrial development. About the only factor that could plausibly slow the technological juggernaut, however, is a sustained economic contraction.

Technology is also substantially responsible, both directly and indirectly, for what appears to be a slower recovery from the current malpractice crisis than was the case in decades past.

The medical malpractice system also owes much of its present instability to technological forces. If anything, these pressures will accelerate in the future, widening the gap between the demands on the malpractice system and what the system can offer in terms of quality assurance and compensation for injury. Technology is also substantially responsible, both directly and indirectly, for what appears to be a slower recovery from the current malpractice crisis than was the case in decades past. It is directly responsible because the cost of caring for individuals seriously injured by malpractice and of

compensating them for their continued suffering, has grown tremendously as medical science has improved. It is indirectly responsible because cost containment mechanisms that were created in part to control technology have reduced the health care system's financial resiliency to external shocks, including rapid increases in liability insurance costs.

It is directly responsible because the cost of caring for individuals seriously injured by malpractice and of compensating them for their continued suffering, has grown tremendously as medical science has improved.

The ways in which technology will affect medical practice, financing, and organization are too numerous for an easy fix. For example, doctrine that would resolve questions regarding the use of specific technologies is unlikely to respond to questions about how information systems are designed and implemented (cf., Terry, 2002, p. 51). In the ABMT cases, courts arguably should have overruled the professional standard of care because the underlying scientific evidence supporting its use was inadequate. But that approach would not work for EFMs, which require an improved technology assessment system. In any event, technology-driven medical practice rarely stands still, making it very

It is indirectly responsible because cost containment mechanisms that were created in part to control technology have reduced the health care system's financial resiliency to external shocks, including rapid increases in liability insurance costs.

difficult for anything but general legal doctrine to be developed and applied.

Even if some type of legal change is necessary, it is not sufficient—witness the past two decades of attempted reforms. As long as people overvalue technological advances, there is no reason to expect them to support major limitations on the availability of technology or to abjure litigation when technology fails.

Cultural change will not occur quickly. Physicians can play a significant role by communicating the limits of technological solutions to medical problems. This needs to occur during individual patient encounters and within professional societies. Patients need to hear from both medical leaders and their personal physicians that technology is not a magic bullet, and both should help the public cultivate realistic expectations of what medical care can achieve. For example, the Institute of Medicine might convene a committee to address the culture of technology in medicine and ways of informing the public about technology's limits. Recent IOM reports on patient safety and quality of care have been widely publicized and have led to broad public discussions and incipient policy changes. The media also bear responsibility for explaining the costs and risks, as well as the benefits, of technology. This is not to suggest that the media should avoid covering technological breakthroughs. The tendency to herald new innovations is understandable; the challenge is to offer sufficient information about their limitations.

Cultural adjustment requires concomitant policy change. In addition to more effective technology assessment and reimbursement policies, federal regulators need to

restrain unfounded claims by technology makers and appliers, whether direct-to-consumer advertising of pharmaceuticals or testimonial marketing by hospitals. There are serious issues of ethics and values that must be examined when placing limits on technology. When dealing with "last hope" interventions, such as ABMT for metastatic breast cancer patients, it is understandable that individuals will want not just aggressive therapy, but the latest technology available (even if it has not been shown to be effective in clinical trials). We must at least keep in mind individual patients' needs and demands. Perhaps the best we can do is to acknowledge the conflicting values and develop institutions to mediate the competing interests (Rettig et al., 2004; Sage, 2003c).

The tendency to herald new innovations is understandable; the challenge is to offer sufficient information about their limitations.

Technology Assessment. Developing a more robust technology assessment (TA) process has been a key policy objective for many years. Recent efforts to tie technology to patient safety offer a promising opportunity to reinvigorate TA with substantially stricter criteria for the dissemination of unproven innovations. Doing so has the potential to limit improper use and allow more time for training physicians and other health professionals. More importantly, TA can restrain the cultural imperative by relieving pressure on physicians to use the latest technology. As an essential complementary

measure, insurance coverage decisions and clinical practice decisions also should be based on demonstrated scientific benefit and cost-effectiveness.

Two aspects of the TA process are useful in slowing diffusion. First, TA can form the basis for determining whether an insurer will cover (i.e., reimburse health care providers for delivering) a particular technology. Second, TA can inform physicians' individual clinical decisions and insurers' determinations of medical necessity. Using rigorous TA also will place insurers in a better position to avoid litigation when they deny payment for procedures that have not been shown to be effective.

Since it is virtually impossible to conduct RCTs across the board, we need to develop agreement on processes to guide the standard of care for controversial technologies.

In general, there is a weak social commitment to insisting that medical practice be supported by evidence of effectiveness. Medical schools teach that randomized control trials (RCTs) constitute the gold standard for determining effective care, but the medical profession does not always seek or consult them before adopting new procedures and technologies. Apart from legal requirements that drugs and devices subject to FDA approval be evaluated through RCTs, there is no consistent process for using RCTs to rigorously evaluate medical procedures or technologies. The failure to assess EFM prior to its widespread diffusion illustrates the point. Since it is virtually impossible to conduct RCTs across the board, we need to develop agreement on

processes to guide the standard of care for controversial technologies. For example, insurers, provider groups, and government officials could agree on the most important new technologies to assess and develop mechanisms for funding and conducting the assessments (Rettig et al., 2004).

Congress should also consider whether certain medical procedures should be subject to the same kinds of pre-marketing approval as FDA regulations require for drugs and medical devices.

TA is not a panacea. It seldom determines definitively whether and how to provide a technology to a particular patient. Clear answers may not be available even with rigorous clinical trials. Many high profile issues, such as the efficacy of PSA tests for men and mammography screening for women under age 50, are likely to be in an ambiguous category, dominated by conflicting opinions. And rapidly evolving technology places a heavy burden on any systematic approach to evaluating medical interventions. Many technologies need to be evaluated, and reevaluation will often be necessary, since new evidence accumulates even for stable technologies.

Even so, federal legislation to address the problem would be appropriate. At a minimum, Congress should either reconstitute the federal Office of Technology Assessment (OTA), or otherwise enhance the government's technology assessment portfolio (i.e., at the Agency for Health Care Research and Quality). In addition, Congress should reinforce Medicare's process for assessing technology before

reimbursing for it and also encourage HHS to include cost-effectiveness analyses in the TA process. Congress should also consider whether certain medical procedures should be subject to the same kinds of pre-marketing approval as FDA regulations require for drugs and medical devices.

Coverage and Reimbursement. The need to compare the value to patients of new technologies with their effect on spending is a major source of tension among physicians, hospitals, patients, insurance companies, and government policymakers (Fuchs and Sox, 2001). To avoid the problem that a new technology can be effective, but at such a high cost that the expenditure would not be justified, definitions of medical necessity should explicitly take cost-effectiveness into account (NIHCM, 1994; see also, Eddy, 1996; Jacobson and Kanna, 2001). Medicare does not impose a cost-effectiveness requirement for reimbursement and its coverage policies can encourage the use of questionable procedures. For example, Medicare pays up to four times more for a scientifically untested back surgery technique known as spinal fusion than for the standard laminectomy surgery (Abelson and Petersen, 2003).

Medicare does not impose a cost-effectiveness requirement for reimbursement and its coverage policies can encourage the use of questionable procedures.

Managed care is in a stronger position to improve how technology is assessed and used, though health plans have not been particularly effective in this regard for two reasons. The primary problem is that

restrictions on technology may encourage physicians to "take their marbles and go elsewhere." The health care industry's increasing tendency to fragment along specialty lines suggests serious limits to what plans can achieve. Health plans also face patient opposition to limits on coverage denials. As I have argued elsewhere (Jacobson, 2002), the industry should make a concerted effort to develop transparent processes for determining how new technologies and procedures will be evaluated and what criteria will be used to monitor their use. Health plans can use these mechanisms to bring patients into a discussion about the need to place limits on resource (and technology) use.

As a check on potentially arbitrary denials of treatment, it is imperative that health plans implement independent medical review (IMR). IMR permits patients to challenge any denial of care by requesting review by an independent panel of physicians. If the panel decides that the treatment should be covered, the insurer is obligated to pay for it. Many states have now mandated IMRs, but health plans should implement them voluntarily even where not required.

Clinical Practice Guidelines. Another mechanism health plans can use to effectuate the above policies is to develop and implement clinical practice guidelines. Even though physicians are reluctant to use guidelines, evidence supports the conclusion that following professional guidelines reduces liability exposure. For example, robust guidelines led to a substantial decline in malpractice award frequency and severity for anesthesia claims (Lee and Domino, 2002).

Conclusion

Politics aside, a solution remains elusive largely because of the underlying culture of technology. Time after time, the technological imperative has trumped science, legal doctrine, or even the reality and inevitability of disease and mortality.

Malpractice crises have generated an enormous volume of commentary, empirical study, and reform proposals. Politics aside, a solution remains elusive largely because of the underlying culture of technology. Time after time, the technological imperative has trumped science, legal doctrine, or even the reality and inevitability of disease and mortality. Policymakers have been content to tinker at the margins with incremental policy and legal reforms, without seriously considering fundamental reforms that might address the problem systematically. Unrealistic public expectations, often encouraged by physicians and exacerbated by industry marketing practices, make it all but impossible for policymakers to slow the adoption and use of new technologies.

By focusing political attention on simplistic fixes, such as caps on damages, policymakers have lost sight of the broader factors responsible for the recurrent malpractice crises.

By focusing political attention on simplistic fixes, such as caps on damages, policymakers have lost sight of the broader factors responsible for the

recurrent malpractice crises. As long as society demands technological innovation, liability exposure is an inevitable consequence for physicians, hospitals, and other health care providers.

As long as society demands technological innovation, liability exposure is an inevitable consequence for physicians, hospitals, and other health care providers.

In the end, I expect the malpractice cycle to continue, in part because Americans refuse to accept resource limits. The insatiable demand for more and better technology has brought incredible innovation and exciting medical advances. So far, I think the public is basically saying that the cost, including the liability cost, is worth it. That physicians are increasingly saying something very different has yet to fully penetrate the public's consciousness. Until "my" doctor is no longer open for business, there's no reason to worry. In the meantime, keep those innovations coming. Much like the looming social crises of Medicare and Social Security, the public seems to believe that something can be done to alleviate malpractice crises without fundamentally changing the entitlement system. "So it goes" (as Kurt Vonnegut Jr. wrote despairingly in

Much like the looming social crises of Medicare and Social Security, the public seems to believe that something can be done to alleviate malpractice crises without fundamentally changing the entitlement system.

Slaughterhouse Five). Or, as my childhood hero, Alfred E. Neuman, so aptly put it, "What, Me Worry?"

References

Abelson, Reed and Melody Petersen. 2003. An Operation to Ease Back Pain Bolsters the Bottom line, Too, *New York Times*, 31 December.

Amercican College of Obstetrician Gynecologists. 2003. *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology.* Washington, DC.

American Hospital Association. March 2003. Professional Liability Insurance: A Growing Crisis—Results of the AHA Survey of Hospitals on Professional Liability Experience. www.aha.org, accessed on 19 May 2003.

Adler, Rachel B. 1994. Device Dilemma: Should Hospitals be Strictly Liable for Retailing Defective Surgical Devices? *Albany Law Journal of Science and Technology* 5:95-130.

Angell, Marcia. 1996. *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case.* New York: W.W. Norton.

Barger-Lux, M. Janet and Robert P. Heaney. 1986. For Better and Worse: The Technological Imperative in Health Care. *Social Science & Medicine* 22:1313-1320.

Bernstein, David E. 2002. Improving the Qualifications of Experts in Medical Malpractice Cases. *Law, Probability and Risk* 1:9-16.

Bovbjerg, Randall R. and Frank A. Sloan. 1998. No-Fault for Medical Injury: Theory and Evidence. *University of Cincinnati Law Review* 67:53-123.

Cheney, Frederick W., Karen Posner, Robert A. Caplan, and Richard J. Ward. 1989. Standard of Care and Anesthesia Liability. *Journal of the American Medical Association* 261:1599-1603.

Chernew, Michael E., Richard A. Hirth, and David M. Cutler. 2003. Increased Spending on Health Care: How Much Can the United States Afford? *Health Affairs* 22(4):15-25.

Chernew, Michael E., Peter D. Jacobson, Timothy P. Hofer, Keith D. Aronson, and Fendrick A. Mark. Why Managed Care Did Not Stop Health Care Cost Inflation, unpublished manuscript, revised and resubmitted to *Archives of Internal Medicine* 2003.

Citron, Paul. 1994. Medical Devices, Component Materials and Product Liability, in *Product Liability and Innovation: Managing Risk in an Uncertain Environment*. National Academy of Engineering.

Congressional Budget Office. 2004. *Limiting Tort Liability for Medical Malpractice*. Washington, DC.

Cote, Charles J., Daniel A. Notterman, Helen W. Karl, Joseph A. Weinberg, and Carolyn McCloskey. 2000. Adverse Sedation Events in Pediatrics: A Critical Incident Analysis of Contributing Factors. *Pediatrics* 105:805-814.

Cramm, Timm, Arthur J. Hartz, and Michael D. Green. 2002. Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know. *Wake Forest Law Review* 37:699-756.

Cutler, David M., and Mark McClellan. 2001. Is Technological Change in Medicine Worth It? *Health Affairs* 20(5):11-29.

Danzon, Patricia M. 1987. The Effects of Tort Reforms on the Frequency and Severity of Medical Malpractice Claims. *Ohio State Law Journal* 48:413-417.

Danzon, Patricia M. and Mark V. Pauly. 2001. Insurance and New Technology: From Hospital to Drugstore. *Health Affairs* 20(5):86-100.

De Ville, Kenneth A. 1990. *Medical Malpractice in Nineteenth Century America: Origins and Legacy* New York: New York University Press.

_____. 1998. Medical Malpractice in Twentieth Century United States: The Interaction of Technology, Law and Culture. *International Journal of Technology Assessment in Health Care* 14:197-211.

Dixon, Lloyd S. and Brian P. Gill. 2001. *Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision.* Santa Monica, CA: RAND, MR-1439-ICJ.

Eddy, David M. 1996. Benefit Language: Criteria That Will Improve Quality While Reducing Costs. *Journal of the American Medical Association* 275:650-657.

Eichhorn, John H., Jeffrey B. Cooper, David J. Cullen, Ward R. Maier, James H. Phillip, and Robert G. Seeman. 1986. Standards for Patient Monitoring During Anesthesia at Harvard Medical School. *Journal of the American Medical Association* 265:1017-1020.

Ely, John W., Arthur J. Hartz, and Paul A. James. 2002. Determining the Standard of Care in Medical Malpractice: The Physician's Perspective. *Wake Forest Law Review* 37:861-875, 873.

Escarce, Jose J., Bernard S. Bloom, Alan L. Hillman, Judy A. Shea, and J. Sanford Schwartz. 1995. Diffusion of Laparoscopic Cholecystectomy. *Medical Care* 33:256-271.

Ference, Apryl A. 1998. Rushing to Judgment on Fen-Phen and Redux: Were the FDA, Drug Manufacturers, and Doctors too Quick to Respond to Americans' Infatuation with a Cure-All Diet Pill for Weight Loss? *Albany Law Journal of Science and Technology* 9:77-110.

Fortess, Eric E. and Marshall B. Kapp. Medical Uncertainty, Diagnostic Testing, and Legal Liability. *Law, Medicine & Health Care* 13:213-218.

Fuchs, Victor R. 1996. Economics, Values, and Health Care Reform. *American Economic Review* 86:1-24.

Fuchs, Victor R. and Harold C. Sox, Jr. 2001. Physicians' Views of the Relative Importance of Thirty Medical Innovations. *Health Affairs* 20(5):30-42.

Garber, Alan M. Evidence-Based Coverage Policy. *Health Affairs* 20(5):62-82.

Garber, Steven. 1993. *Product Liability and the Economics of Pharmaceuticals and Medical Devices.* Santa Monica, CA: RAND, R-4285-ICJ.

_____. 1998. Product Liability, Punitive Damages, Business Decisions and Economic Outcomes, *Wisconsin Law Review* 1998:237-295.

Gaster, Barak. 1993. The Learning Curve. *Journal of the American Medical Association* 270:1280.

Gawande, Atul. 2002. *Complications: A Surgeon's Notes on an Imperfect Science.* New York: Metropolitan Books.

General Accounting Office. 2003a. *Medical Malpractice: Implications of Rising Premiums on Access to Health Care*. GAO-03-836, Washington, DC, August.

_____. 2003b. *Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates*. GAO-03-702, Washington, DC, June.

_____. 2003c. Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance. Washington, DC, GAO-04-167, October.

Grady, Mark F. 1988. Why Are People Negligent? Technology, Nondurable Precautions, and the Medical Malpractice Explosion. *Northwestern University Law Review* 82:293-334.

_____. 1992. Book Review: Better Medicine Causes More Lawsuits, and the New Administrative Courts Will Not Solve the Problem. *Northwestern University Law Review* 86:1068-1093.

Hall, Mark A., Roger Anderson, Rajesh Balkrishnan, Steven R. Feldman, Alan B. Fleischer, Jr., David Goff, and William Moran. 2002. Measuring Medical Practice Patters: Sources of Evidence From Health Services Research. *Wake Forest Law Review* 37:779-821.

Havighurst, Clark C. 1995. *Health Care Choices: Private Contract as Instruments of Health Care Reform.* Washington, DC: The AEI Press.

Heffler, Stephen, Katherine Levit, Sheila Smith, Cynthia Smith, Cathy Cowan, Helen Lazenby, and Mark Freeland. 2001. Health Spending Growth Up in 1999; Faster Growth Expected in the Future. *Health Affairs* 20(2):193-203.

Hellinger, Fred J. and William E. Encinosa. 2003. The Impact of State Laws Limiting Malpractice Awards on the Geographic Distribution of Physicians. Washington, DC, USDHHS, July.

Hoffman, Bjorn. 2002. Is there a Technological Imperative in Health Care? *International Journal of Technology Assessment in Health Care* 18:675-689

Holzer, James F. 1990. The Advent of Clinical Standards for Professional Liability. *Quality Review Bulletin* 16:71-79.

Howell, Joel D. 1995. *Technology in the Hospital: Transforming Patient Care in the Early Twentieth Century,* Baltimore. Maryland: The Johns Hopkins University Press.

Hyams, Andrew L., David W. Shapiro, and Troyen A. Brennan. 1996. Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective. *Journal of Health Politics, Policy and Law* 21:289-313.

Iglehart, John K. 2001. America's Love Affair With Medical Innovation. *Health Affairs* 20(5):6-7.

Institute of Medicine. 2000. *To Err is Human: Building a Safer Health System*, Washington, DC: National Academies Press.

_____. 2001. *Crossing the Quality Chasm—A New Health System for the 21st Century.* Washington, DC: National Academy Press.

_____. 2002. *Fostering Rapid Advances in Health Care: Learning From System Demonstration.,* Washington, DC: National Academy Press.

Jacobson, Peter D. and C. John Rosenquist. 1996. The Diffusion of Low Osmolar Contrast Agents: Technological Change and Defensive Medicine. *Journal of Health Politics, Policy and Law* 21:243-266.

_____. 1988. The Introduction of Low Osmolar Contrast Agents in Radiology: Medical, Economic, Legal, and Public Policy Issues. *Journal of the American Medical Association* 260:1586-1592.

Jacobson, Peter D. 2002. *Strangers in the Night: Law and Medicine in the Managed Care Era.* New York: Oxford University Press.

Jacobson, Peter D. and Matthew L. Kanna. 2001. Cost-Effectiveness Analysis in the Courts: Recent Trends and Future Prospects. *Journal of Health Politics, Policy and Law* 26:291-326.

Jacobson, Peter D. and Scott D. Pomfret. 1999. Establishing New Legal Doctrine in Managed Care: A Model of Judicial Response to Industrial Change. *University of Michigan Journal of Law Reform* 32:813-861.

Jacobson, Peter D. 1989. Medical Malpractice and the Tort System. *Journal of the American Medical Association* 262:3320-3327.

Kacmar, Donald E. 1997. The Impact of Computerized Medical Literature Databases on Medical Malpractice Litigation: Time for Another *Helling v. Carey* Wake-Up Call? *Ohio St. Law Journal* 58:617-654.

Kakalil, James S., Terrence Dunworth, Laural A. Hill, Daniel McCaffrey, Marian Oshiro, Nicholas M. Pace, and Mary E. Vaiana. 1996. *An Evaluation of Judicial Care Management Under the Civil Justice Reform Act.* Santa Monica, CA: RAND.

Kassirer, Jerome P. and Joe S. Cecil. 2002. Inconsistency in Evidentiary Standards for Medical Testimony: Disorder in the Courts. *Journal of the American Medical Association* 288:1382-1387.

Kerouac, James D. 2001. A Critical Analysis of the Biomaterials Access Assurance Act of 1998 as Federal Tort Reform Policy. *Boston University Journal of Science and Technology Law* 7:327-371.

Kim, Minah, Robert J. Blendon, and John M. Benson. 2001. How Interested Are Americans in New Medical Technologies? A Multicountry Comparison. *Health Affairs* 20(5):194-201.

Leape, Lucian L., Ann G. Lawthers, Troyen A. Brennan, and William G. Johnson. 1993. Preventing Medical Injury. *Quality Review Bulletin* 19(5):144-149.

Lee, Lori A. and Karen B. Domino. 2002. The Closed Claims Project: Has it Influenced Anesthetic Practice and Outcome? *Anesthesia Clinics of North America* 20:485-501.

Lempert, Richard. 2002. Following the Man on the Clapham Omnibus: Social Science Evidence in Malpractice Litigation. *Wake Forest Law Review* 37:903-924.

Luft, Harold S., James C. Robinson, Deborah W. Garnick, Susan C. Maerki, and Stephen S. McPhee 1986. The Role of Specialized Clinical Services in Competition Among Hospitals. *Inquiry* 23:83-94.

McGarey Barbara M. and Annette C. Levy. 1999. Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition. *Berkeley Technology Law Journal* 14:1095-1116.

Mello, Michelle M. 2001. Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation. *University of Pennsylvania Law Review* 149:645-710.

Mello, Michelle M. and Troyen A. Brennan. 2001. The Controversy Over High-Dose Chemotherapy With Autologous Bone Marrow Transplant For Breast Cancer. *Health Affairs* 20(5):101-117.

Mohr, James C. 1993. *Doctors and the Law: Medical Jurisprudence in Nineteenth Century America.* Baltimore, Maryland: The Johns Hopkins University Press.

_____. 2000. American Medical Malpractice Litigation in Historical Perspective. *Journal of the American Medical Association* 283:1731-1737.

Morantz-Sanchez, Regina M. 1999. *Conduct Unbecoming a Woman: Medicine on Trial in Turn-of-the-Century Brooklyn.* New York: Oxford University Press.

Morreim, E. Haavi. 2001. *Holding Health Care Accountable: Law and the New Medical Marketplace.* New York: Oxford University Press.

Myers, Chris and Todd Burchill. 2002. The Short Life of a Medical Device. *Health Forum Journal* 45(5):34-38.

Myers, Chris and Reuben Ehrlich. 2001. Biotech Frontiers. *Health Forum Journal* 44(6):20-23.

Pacey, Arnold. 1983. *The Culture of Technology.* Oxford, UK: Basil, Blackwell.

Peters, Philip G., Jr. 2002. Empirical Evidence and Malpractice Litigation. *Wake Forest Law Review* 37:757-777.

_____. 2000. The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium. *Washington & Lee Law Review* 57:163-205.

PIAA. 2002. *Breast Cancer Study (Third Edition).* Rockville, Maryland: Physician Insurers Association of America.

_____. 2000. *Laparoscopic Injury Study.* Rockville, Maryland: Physician Insurers Association of America.

_____. 1998. *Neurological Impairment in Newborns: A Malpractice Claim Study*. Rockville, Maryland: Physician Insurers Association of America.

_____. 1995. *Breast Cancer Study*. Rockville, Maryland: Physician Insurers Association of America.

_____. 1994. *Laparoscopic Procedure Study*. Rockville, Maryland: Physician Insurers Association of America.

Picker, Colin B. 2001. A View From 40,000 Feet: Law and the Invisible Hand of Technology. *Cardozo Law Review* 149-218.

Pierce, Ellison C, Jr. 1990. The Development of Anesthesia Guidelines and Standards. *Quality Review Bulletin* 16:61-64.

Prosser, William L. 1978. *Handbook of the Law of Torts* (4th ed.). Minneapolis: West Publishing Co.

Rettig, Richard A., Peter D. Jacobson, Cynthia Farquhar, and Wade M. Aubry. *Treating Breast Cancer: Conflicting Values*. Unpublished manuscript (2004).

Robinson, James C., Deborah W. Garnick, and Stephen J. McPhee. 1987. Market and Regulatory Influences on the Availability of Coronary Angioplasty and Bypass Surgery in U.S. Hospitals. *New England Journal of Medicine* 317:85-90.

Rothman, David J. 1997. *Beginnings Count: The Technological Imperative in American Health Care*. New York: Oxford University Press.

Roubal, Brett W. 1998. Protecting Suppliers of Safe Component Parts and Raw Materials Through the Component Part Doctrine and the Sophisticated Purchaser Doctrine: *In Re Temporomandibular Joint (TMJ) Implants Products Liability Litigation*. *Creighton Law Review* 31:617-664.

Rustad, Michael L. and Thomas H. Koenig. 2002. Taming the Tort Monster: The American Civil Justice System as a Battleground of Social Theory. *Brooklyn Law Review* 68: 1-122.

Sage, William M. 2003c. Managed Care's Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance. *Duke Law Journal* 53: 597-652.

_____. 2003a. Understanding the First Malpractice Crisis of the 21st Century, in *2003 Handbook of Health Law*, ed. Alice G. Gosfield. St. Paul, MN: West Group.

_____. 2003b. Medical Liability and Patient Safety. *Health Affairs* 22(4):26-36.

_____. 2003c. Unfinished Business: How Litigation Relates to Health Care Regulation. *Journal of Health Politics, Policy and Law* 28:387-419.

_____. 1997. Enterprise Liability and the Emerging Managed Health Care System. *Law and Contemporary Problems* 60:159-209.

Schwartz, William B. and Neil K. Komesar. 1978. Doctors, Damages and Deterrence. *New England Journal of Medicine.* 298:1282–1289.

Smith, George P., II. 2001. Setting Limits: Medical Technology and the Law. *Sydney Law Review* 23:283-296.

Studdert, David M. and Troyen A. Brennan. 2001. No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention. *Journal of the American Medical Association* 286:217-223.

Struve, Catherine T. 2003. Expertise in Medical Malpractice Litigation: The Question of Procedural Reform, New York: The Pew Charitable Trusts Project on Medical Liability in Pennsylvania.

Terry, Nicholas P. 2002. When the "Machine That Goes 'Ping'" Causes Harm: Default Torts Rules and Technologically-Medicated Health Care Injuries. *Saint Louis University Law Journal* 46:37-59.

Thorpe, Kenneth E. 2002. Cost Containment, in Kovner AR and Jonas S, eds. *Health Care Delivery in the United States, Seventh Edition.* New York: Springer Publishing Company, Inc., pp. 427-451.

Weber, Tracy and Charles Ornstein. 2003. "King/Drew Patient Monitors Shut Off Following Two Deaths." *Los Angeles Times* 10 September http://www.latimes.com/news/local/la-me-kingdrew10sep10,1,3521718.story, accessed on 11 September 2003.

Wennberg, John E. and Philip G. Peters, Jr. 2002. Unwarranted Variations in the Quality of Health Care: Can the Law Help Medicine Provide a Remedy/Remedies? *Wake Forest Law Review* 37:925-941.

The Author

Peter D. Jacobson, JD, MPH, is Associate Professor in the Department of Health Management and Policy, University of Michigan School of Public Health. He received his law degree from the University of Pittsburgh School of Law in 1970, and a Masters in Public Health from UCLA in 1988. Before coming to the University of Michigan, he was Senior Behavioral Scientist at RAND from 1988 to 1996. At the University of Michigan, he teaches courses on Law and Public Health and Health Law. His current research interests focus on the relationship between law and health care, law and public health, and public health policy.

In 1995, Professor Jacobson received an Investigator Award in Health Policy Research from the Robert Wood Johnson Foundation to examine the role of the courts in shaping health care policy. Currently, he is the principal investigator on a study of survival strategies for health care safety net providers. His articles on health care and public health topics have appeared in journals such as the *Journal of the American Medical Association, Health Affairs, Inquiry,* and *the Journal of Health Politics Policy and Law*. He is a member of the Board of Editors of the *Journal of Health Politics Policy and Law*.

Professor Jacobson has also published a series of articles on the development of legal doctrine in managed care litigation. His most recent book is *Strangers in the Night: Law and Medicine in the Managed Care Era* (Oxford University Press, 2002). He is also

the lead author of *Combating Teen Smoking: Research and Policy Strategies* (University of Michigan Press, 2001).

About the Project

The Project on Medical Liability in Pennsylvania (www.medliabilitypa.org) is a two-year program of research, consultation, and communication funded by The Pew Charitable Trusts that seeks to provide decision-makers with objective information about the ways in which medical, legal, and insurance-related issues affect the medical liability system, to broaden participation in the debate to include new constituencies and perspectives, and to focus attention on the relationship between medical liability and the overall health and prosperity of the Commonwealth.

The Pew Charitable Trusts (www.pewtrusts.org) serve the public interest by providing information, policy solutions and support for civic life. Based in Philadelphia, with an office in Washington, D.C., the Trusts make investments to provide organizations and citizens with fact-based research and practical solutions for challenging issues. In 2003, with approximately $4.1 billion in dedicated assets, the Trusts committed more than $143 million to 151 nonprofit organizations.

William M. Sage, M.D., J.D.
Columbia Law School
Series Editor and Principal Investigator

Susan M. Liss, Esq.
Executive Director