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MEDICAL MALPRACTICE AND NEW DEVICES: DEFINING AN ELUSIVE STANDARD OF CARE

Michael D. Greenberg[†]

ABSTRACT

Early adoption of a new medical device by a physician carries with it some degree of malpractice liability risk. The legal standard for malpractice varies from place to place, but generally requires an evaluation of the physician's conduct either against that of a hypothetical "reasonable physician," or else against professional custom. Where the use of a new device involves a significant departure from traditional modalities of care, and a bad clinical result follows, questions may arise about whether the legal standard for malpractice has been violated. We suggest that a liberal interpretation of the malpractice standard of care is appropriate, and even necessary to avoid the potential for perverse disincentives to technical innovation in medicine.

INTRODUCTION

Medical malpractice is one of the most controversial aspects of American tort law. Over the past 30 years, advocates for tort reform have encroached significantly on the traditional contours of negligence liability associated with the practice of medicine.¹ That

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¹ For an elegant and current summary of state statutory interventions in medical malpractice law, see Nat'l Conference of State Legislatures, Medical Malpractice Tort Reform, <http://www.ncsl.org/standcomm/sclaw/medmaloverview.htm>

shift has partly been grounded on arguments that tort is an inefficient or inappropriate way to compensate injuries, and that malpractice claiming is associated with negative externalities and broader social welfare effects that call into question the fundamental soundness of malpractice liability doctrine.² A related set of questions has been raised by the patient safety movement in the United States, and by research that suggests that at least some medically induced injuries may better be understood as resulting from complex medical care processes and inherent risk trade-offs, rather than from specific acts of malfeasance committed by specific providers.³ These sorts of systemic insights suggest new ambiguities connected with traditional legal concepts in medical malpractice, and particularly so regarding the standard of care required of practitioners. For judges and policy-makers, the implication is that traditional legal concepts and doctrines may need to be re-examined and fine-tuned, in recognition that those rules may sometimes have unintended consequences that reach beyond any discrete malpractice dispute or occurrence of medical injury.

An important example of this kind of problem involves the relationship between medical malpractice and new technology adoption. Negligence and malpractice doctrine generally make it clear that standards of care are evolutionary rather than static, and that providers have an obligation to stay abreast of new techniques and developments.⁴ By implication, the malpractice standard in 2008 is different from what it was in 1978, less because of any changes in the law than because of changes in medical knowledge and in new technologies. But the simple recognition that medical knowledge changes over time provides scarce insight into the reality that those changes do not occur seamlessly, but by fits and starts, with the serial introduction of a multitude of new drugs, new devices, and new techniques, each of which starts out as experimental agent with imperfectly known

(last visited Mar. 8, 2009). See also the summary discussion offered by the Am. Tort Reform Ass'n, *Medical Liability Reform*, <http://www.atra.org/issues/index.php?issue=7338> (last visited Mar. 8, 2009).

² See, e.g., David M. Studdert, Michelle M. Mello & Troyen A. Brennan, *Health Policy Report: Medical Malpractice*, 350 N. ENGL. J. MED. 283, 283 (2004).

³ See Stephen C. Schoenbaum & Randall R. Bovbjerg, *Malpractice Reform Must Include Steps to Prevent Medical Injury*, 140 ANNALS INTERNAL MED. 51, 51-53 (2004); Lawrence Gostin, *A Public Health Approach to Reducing Error: Medical Malpractice as a Barrier*, 283 JAMA 1742, 1742 (2000).

⁴ For a discussion of relevant case law, see generally Carter L. Williams, *Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?* 61 WASH. & LEE L. REV. 479, 508-12 (2004).

risks, and each of which involves a departure from what most physicians are doing, *ex ante*, in providing care for their patients. Broadly speaking, the malpractice standard of care assumes, and depends upon, this kind of innovation in medical treatment. Far less clear is how the standard of care applies to any particular instance where an injury is associated with services that are occurring on the event horizon of medical progress, and drawing on new technologies that have not yet been incorporated into the practice and experience of most physicians.

Legal ambiguity around what the standard of care really means, in this kind of circumstance, implies that physicians (and their lawyers) may genuinely not know the degree of malpractice liability risk that is associated with adopting a new clinical technology. By itself, that may present a problem for judges after the fact, in determining appropriate rules and incentives for apportioning liability fairly. More important, though, is the potential for far-reaching effects on physicians (and other care providers) in their willingness to adopt new technologies, given ill-defined but perceived malpractice liability risks associated with doing so.⁵ By implication, malpractice law may sometimes present a deterrent to medical innovation, and a market barrier to demand for new technologies, even where those technologies offer broad social benefits in the form of superior clinical outcomes and/or reduced administrative costs. At a minimum, judges and policymakers concerned with malpractice law need also to be cognizant of the wider context of the U.S. healthcare delivery system, within which tort rules may exert undesirable or unanticipated side-effects.⁶

The purpose of this paper is to address the basic question of how medical malpractice liability standards apply to physicians, in connection with their adoption of new medical equipment and devices. This paper also analyzes the logic suggesting that legal ambiguities in the malpractice standard of care might lead to systematic disincentives for physicians (or hospitals) in adopting new medical technologies, at least under some circumstances. In Part I, we review the basic legal

⁵ As one pair of commentators has pointed out, law sometimes exerts its effect on the healthcare system by influencing the perceptions and expectations of market actors, in ways that can change their business practices based on anticipated (but not necessarily realized) adverse legal outcomes. See M. Gregg Bloche & David M. Studdert, *A Quiet Revolution: Law as an Agent of Health System Change*, 23 HEALTH AFFAIRS 29, 39 (2004).

⁶ See MICHELLE M. MELLO, *MEDICAL MALPRACTICE: IMPACT OF THE CRISIS AND EFFECT OF STATE TORT REFORMS* (2006) for a discussion of empirical evidence concerning "defensive medicine" and adverse physician supply effects.

concepts and standards that underlie medical malpractice doctrine. In Part II, we discuss why new technology can present a special problem for analyzing whether malpractice has been committed. In Part III, we observe that U.S. case law has neglected to address this special problem head-on, but we nevertheless identify a series of potential steps that physician-adopters can take, and which common sense suggests would help to mitigate liability risks associated with using new medical technologies. In Part IV, we briefly consider how malpractice liability related to new devices and equipment might extend to hospitals, and by implication, to other corporate entities that are involved in the delivery of health care services. And in Part V, we discuss the potential for negative externalities associated with ambiguous malpractice standards and new technology adoption, and some related considerations for policymakers. In sum, we observe that American case law does not appear directly to have addressed the problem of malpractice risk associated with innovative new technology use; that this problem may nevertheless be more important than the dearth of case law would indicate; and that policymakers may largely be able to neutralize the problem, simply by making explicit to physicians what the standard of care truly requires in connection with adopting a new medical device.

I. MEDICAL MALPRACTICE AND THE LEGAL STANDARD OF CARE

Medical malpractice is a form of tort, or in other words, a civil claim in which an injured person requests damages from an alleged perpetrator, in compensation for a wrongful, harmful act. As with negligence-based torts more generally, a claim for medical malpractice generally requires that the plaintiff establish four basic legal elements in order to obtain a recovery. First, she must show that the defendant owed a duty of care to the plaintiff; second, that that duty was breached by the defendant; third, that the plaintiff was harmed (and experienced damages); and fourth, that the plaintiff's harm was caused by the defendant's actions.⁷ Inability to establish any of these elements will undermine a claim of negligence (or of medical malpractice), and will cause the plaintiff's case to fail.

In most medical malpractice cases, the duty prong is fairly straight forward. When a physician actually provides medical services to a patient, a professional duty of care is thereby established.⁸ The

⁷ See PROSSER AND KEETON ON THE LAW OF TORTS 164-65 (W. Page Keeton et al. eds., 5th ed. 1984).

⁸ For a discussion of the general rule and the complexities posed by tele-

damages and causation prongs in medical malpractice are also frequently straight forward (e.g., where a surgical error clearly results in a patient's injury or disfigurement). For current purposes, the most important (and complex) legal requirement for malpractice is breach: i.e., not only that a physician owed a duty of care to her patient, but that by her actions she somehow violated that duty. Establishing whether a breach has taken place requires a comparison between the physician's actions and a legal "standard of care," which represents what physicians are obligated by law to do in providing medical services to their patients. Determining how the legal standard of care applies to a particular clinical situation is sometimes ambiguous, and it usually involves tapping the expertise, opinions and testimony of other physicians.⁹

The basic legal standard of care in most general negligence cases is the "reasonable person" standard. In essence, the law asks the question: what would a reasonable person have done if faced with the same set of circumstances as did the defendant?¹⁰ Where the defendant's conduct is found not to be reasonable by comparison, then the defendant has breached the duty of care, and may be held liable for negligence (provided that the other legal requirements for the tort claim, including damages and causation, are also established). Clearly, determining what the "reasonable person" standard of care requires, in the context of a particular situation, is somewhat subjective. It depends on the *ex post* determination of judges and juries (collectively, reasonable people), based on their own experience and judgment, together with a review of the defendant's conduct, plus any other relevant evidence about what similarly situated persons would do when confronted with similar circumstances.¹¹

medicine, see Patricia C. Kuszler, *Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability*, 25 AM. J.L. & MED. 297, 307-18; Kip Poe, *Telemedicine Liability: Texas and Other States Delve into the Uncertainties of Health Care Delivery via Advanced Communications Technology*, 20 REV. LITIG. 681, 693 (2001).

⁹ See Ben A. Rich, *Medical Custom and Medical Ethics: Rethinking the Standard of Care*, 14 CAMBRIDGE Q. HEALTHCARE ETHICS 27, 27-28 (2005).

¹⁰ See PROSSER AND KEETON ON THE LAW OF TORTS, *supra* note 7, at 169; cf. *Vaughan v. Menlove*, (1837) 3 Bing. 467, 472 (N.C.) (U.K.) ("[G]ross negligence ought to be estimated by the faculties of the individual, and not by those of other men.").

¹¹ See generally Stephen G. Giles, *On Determining Negligence: Hand Formula Balancing, the Reasonable Person Standard, and the Jury*, 54 VAND. L. REV. 813 (2001) (discussing the role of judges and juries in applying the reasonable person standard and the Learned Hand formula).

Applying a negligence-based standard of care to situations involving technical or professional practice presents some special challenges. This is true, in part, because the intuitions of juries about what is "reasonable" may not be well-suited to evaluating professional or technical activities, which often fall outside the direct experience and competence of most jury members. The legal standard that applies to these situations shifts slightly. First of all, the standard for negligence (or malpractice) in a medical context is usually determined by reference to what a reasonable *physician* would have done—i.e., a person with the same kind of technical background, training, and expertise as the defendant.¹² Second, figuring out what that standard of care actually means in a particular malpractice case typically involves reviewing evidence about what sorts of clinical practices are customary in the field of medicine: i.e., to determine what a reasonable physician should do in a given situation, we seek evidence about what physicians typically do in practice.¹³

Different states have formulated the legal standard of care for malpractice in somewhat different ways.¹⁴ Traditionally, the law has been very deferential to physician custom in determining what qualifies as malpractice. In other words, whatever constituted usual or typical medical care in a region was often formally defined as reasonable conduct, and where a physician's treatment comported with professional custom, this was sufficient to avoid any breach in the duty of care.¹⁵ Although customary practice remains the legal

¹² See Ruth Ellen Smalley, Comment, *Will A Lawsuit A Day Keep the Cyberdocs Away? Modern Theories of Medical Malpractice as Applied to Cybermedicine*, 7 RICH. J.L. & TECH. 29 (Winter 2001), available at <http://www.richmond.edu/jolt/v7i3/article3.html>; see also Amy Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine: E-Health, Medical Errors, and Technology Add New Obstacles*, 23 J. LEGAL MED. 449, 470-73 (2002); cf. *McNeely v. M. & M. Supermarkets, Inc.*, 269 S.E.2d 483, 485 (Ga. Ct. App. 1980) (holding the ordinarily prudent person standard, rather than one of individual judgment, applied); *Stewart v. Jefferson Plywood Co.*, 469 P.2d 783, 786 (Or. 1970) (holding a person is negligent only if he or she, as an ordinary reasonable person, ought reasonably to foresee the exposure of another to an unreasonable risk of harm).

¹³ See Rich, *supra* note 9, at 27-28.

¹⁴ See generally Joseph H. King, Jr., *Reconciling the Exercise of Judgment and the Objective Standard of Care in Medical Malpractice*, 52 OKLA. L. REV. 49 (1999) (arguing that "[v]arious formulations for the standard of care in medical malpractice cases" exist; "these formulations remain essentially objective.") (footnote omitted); Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163 (2000) (recognizing the erosion of judicial consensus favoring deference to customary standards of care and an on-going shift in favor of reasonableness standards).

¹⁵ See Peters, *supra* note 14, at 164-70. Note that the "customary practice" standard is more deferential to medical expertise and judgment than the reasonable

standard for malpractice in many states, almost half of the states have adopted an objective "reasonable care" standard instead. Rather than being based on what the majority of medical practitioners actually do, this standard is based on what is "reasonable to expect of a professional given the state of medical knowledge at the time of the treatment in issue."¹⁶ The differences between these two versions of the malpractice standard of care are subtle, because in most instances, the customary practices of most physicians *do* correspond closely to an objective standard of reasonableness based on the current state of the art in medicine.¹⁷ In principle, though, an objective "reasonable care" standard gives judges and juries more latitude in reviewing medical knowledge and customs in deciding what the applicable malpractice standard should be in a given circumstance.

There are a number of other common law doctrines that contribute to defining the malpractice standard of care.¹⁸ Many jurisdictions recognize an "adverse outcomes" admonition or rule, which establishes that the simple fact of a poor outcome following a medical procedure does not itself imply that malpractice has occurred.¹⁹ Likewise, many jurisdictions also follow some version of an "acceptable alternatives" rule, which establishes that the standard of care in medicine is not unitary, and that there are many medical situations where multiple forms of treatment may be consistent with reasonable care.²⁰ In a related vein, there are also legal doctrines that allow for participation in clinical trials, and recognize that delivering experi-

person/ reasonable physician standard. *See id.* at 180-85.

¹⁶ *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996); *accord King*, *supra* note 14, at 51-55; *Peters*, *supra* note 14, at 180-85. *Cf. Vergara v. Doan*, 593 N.E.2d 185, 187 (Ind. 1992) (holding that the standard of care "uses locality as but one of the factors to be considered in determining whether the doctor acted reasonably."); *Shilkrett v. Annapolis Emergency Hosp. Ass'n*, 349 A.2d 245, 253 (Md. 1975) (holding a physician has a duty to use that degree of care and skill expected of similarly-situated reasonably competent practitioners, acting in the same or similar circumstances and considering "advances in the profession" together with all other relevant considerations).

¹⁷ *See* Richard A. Epstein, *The Path to The T.J. Hooper: The Theory and History of Custom in the Law of Tort*, 21 J. LEGAL STUD. 1, 1-6 (1992); *see also Peters*, *supra* note 14, at 188-90 (distinguishing between deviations from accepted, customary, practices as opposed to unacceptable or unreasonable practices).

¹⁸ For a summary of these doctrines and relevant case citations, *see Peters*, *supra* note 14, at 166-68 and *King*, *supra* note 14, at 56-63.

¹⁹ *See, e.g., Hirahara v. Tanaka*, 959 P.2d 830, 835 (Haw. 1998).

²⁰ *See id.* at 834; *see also Lama v. Borrás*, 16 F.3d 473, 478 (1st Cir. 1994); *Parris v. Sands*, 25 Cal. Rptr. 2d 800, 803 (Cal. Ct. App. 1993) (holding that absent unusual circumstances physicians lack a duty to inform a patient of a non-recommended course of treatment based upon views of other health care providers).

mental treatment in a clinical trial does not of itself constitute malpractice, even though such trials might otherwise be viewed as a departure from customary care.²¹ Finally, the legal doctrines governing malpractice standards of care also include a "duty to stay abreast," which means that physicians have an obligation to be aware of evolving practices in medical care, and to make appropriate use of new scientific knowledge in medicine as it emerges.²²

The specific legal standard for malpractice differs from state to state, not only in its degree of deference to custom in defining reasonable care, but also in terms of details like whether reasonableness is determined by reference to a local or national comparison group of physicians.²³ Regardless, all versions of the malpractice standard are ultimately based on an evaluation of the appropriateness of a physician's conduct, by comparison to what reasonable physicians either do, or should do, in similar circumstances. The latter is usually determined by reference to the customary practices of other physicians, as established through expert testimony.

II. NEW MEDICAL DEVICES AND THE MALPRACTICE STANDARD OF CARE

Given that medical practice is not static, and that new clinical interventions and technologies are constantly being developed, an obvious question arises regarding how these new developments get incorporated into the malpractice standard of care.²⁴ For purposes of illustration, we will focus here on an example case of treatment using a new medical device. We assume for the sake of argument that the device does not present any immediate, transparent new risks to patients. On the other hand, application of the device does involve a somewhat modified set of clinical practices from the status quo, and possibly entails a different set of clinical risks from those that a patient would have faced under conventional treatment.²⁵ If some-

²¹ See, e.g., *Karp v. Cooley*, 493 F.2d 408, 423-24 (5th Cir. 1974).

²² See *infra* note 43 and accompanying text.

²³ See generally John C. Drapp III, *The National Standard of Care in Medical Malpractice Actions: Does Small Area Analysis Make it Another Legal Fiction?*, 6 QUINNIPIAC HEALTH L.J. 95 (2003) (discussing the distinction between a local versus a national standard of care).

²⁴ See Sokol & Molzen, *supra* note 12, at 451-56.

²⁵ To clarify, we can imagine some new medical devices, like a hypothetical tongue depressor made out of carbon fiber composite rather than of wood, which would not pose any new risks to patients. By contrast, we could also imagine other new medical devices, like a hypothetical laser-laparoscopic machine for doing surgical procedures, which might or might not impose new risks in patient care, but which

thing goes wrong in connection with treatment using the new device, how does the malpractice standard of care then apply?

There is no simple, easy answer to this question. Again, the general standard of care in malpractice involves some variation on the reasonableness of a physician's conduct, usually as determined by comparison to what other physicians would do in similar circumstances. A narrow interpretation of this standard could put a heavy burden onto the early adoption of a specific new medical device, since most other physicians would not yet be using that device, and any departure from customary practice might plausibly be construed as unreasonable. But a more nuanced perspective on the standard of care would recognize that clinical practices obviously do change over time, and that physicians frequently do employ new technologies and new techniques. By implication, the reasonableness of using a new device cannot be judged simply from the fact that it has not yet been widely adopted. Rather, a "reasonableness" or even a "customary" analysis would have to reflect on the circumstances under which physicians generally adopt and use new devices, even where those adoptions entail a substantial change from customary care.

One of the issues that this scenario raises is a closer examination of the risk properties of a new medical device. It is easy to imagine some hypothetical devices that would have no impact on underlying clinical risks, or else that would be risk-superior to status quo treatment (i.e., by reducing the possibilities of harm or adverse outcome to patients). Even where such devices are new, it seems unlikely that anyone would construe their use by physicians as unreasonable—a new device that offers benefits with no incremental risks seems like a clearly desirable innovation, and one that would not harm patients in any event. By contrast, a new device that does carry incremental risks will be much more problematic under the malpractice standard of care. Even so, there may be circumstances where the adoption and use of such a device would still be reasonable under the law. But figuring out whether this is the case would presumably call for a close review of the risks and benefits posed by the device, how those apply to a particular clinical situation, and, in turn, how all of that comports with the use of new devices by physicians more generally. In practice, the risks associated with a new device will often be somewhat ambiguous to physicians, because experience with the new device will be limited. The greater the ambiguity in clinical risk, the more difficult it becomes for physicians to know how the malpractice standard

clearly would transform the clinical procedures that patients would undergo. For our discussion here, we are interested in the latter sort of device.

of care will apply. By corollary, the potential for malpractice liability becomes greater.

On a related point, it is also important to consider whether a new medical device entails a transformation in related processes or procedures of medical care. We could imagine, for example, a "new" surgical retractor, which differs only modestly from traditional retractors, and which does not really involve any qualitative shift in the kinds of surgical procedures that physicians perform. To the extent that the new device is not salient, does not change the way that physicians practice, and does not carry any unique clinical risks, then its use is unlikely by itself to violate the malpractice standard of care. But this is a very different hypothetical from a device which actually *does* introduce a major change into the way that physicians practice. Where the processes of clinical care shift as a function of adopting a new medical device, the impact of that device becomes much more salient, and it invites closer scrutiny regarding any new risks that device-enabled care may pose. Even in the latter case, adoption of the new device may still be "reasonable" and consistent with the malpractice standard, but it clearly carries more responsibility and greater potential for liability among adopting physicians.

American case law on negligence and medical malpractice is noteworthy for including a couple of landmark cases in which defendants were held liable for their failure to adopt new technologies or procedures, even when near universal custom did not involve using them.²⁶ The holdings in those cases reserved to the courts ultimate judgment in defining the reasonableness standard in relation to defendants' conduct, despite contrary evidence regarding what most similarly situated physicians (or in another canonical case, barge captains) felt was appropriate.²⁷ Although the specific precedents in these cases focused ultimately on judicial authority, and their legal validity today is questionable, the cases nevertheless illustrate two important points. First, they help to show that legal standards of care do change over time in response to new technology. Adoption of new medical devices may start out as a risky and liability-prone process, but with time and experience, those same devices can become increasingly

²⁶ See *The T.J. Hooper*, 60 F.2d 737, 737-38, 740 (2d Cir. 1932) (holding a tug boat operator liable for the loss of a barge that could have been averted through the use of a radio); *Helling v. Carey*, 519 P.2d 981, 981, 985 (Wash. 1974) (holding an ophthalmologist liable for an injury that could have been prevented through a glaucoma pressure test); cf. *Washington v. Wash. Hosp. Ctr.*, 579 A.2d 177, 180 (D.C. Cir. 1990) (holding a hospital liable for failing to use continuous oximetry technology to reduce the risk of anesthesia-related brain injury).

²⁷ See *Epstein*, *supra* note 17 at 32-36; *Peters*, *supra* note 14, at 170-72.

attractive, and eventually their adoption may become mandatory. Second, the cases suggest again that determinations about “reasonableness” and the malpractice standard depend on how broadly we construe the reference group against which a particular behavior (or new device adoption) is being judged. A narrow view regarding the adoption of a specific new device, where most physicians are continuing to practice in the conventional way, may suggest one outcome. A broader view may accommodate the reality that physicians sometimes do (and should) adopt new devices, and that modern medicine in fact depends on that kind innovation. This is a perspective on new devices that suggests a different, and more flexible, malpractice standard of care.

In sum, we note that a quick review of American case law generates very few appellate decisions that address directly the malpractice standard of care in relation to medically induced injuries that allegedly result from the application of new technologies. In one such case from Louisiana in 1993, a court upheld a liability ruling against a physician who had performed a femoral arteriogram using a new imaging technology, based on the principle that “*it is a breach of the standard of care . . . to subject a patient to a particular test or procedure which has any risk of injury . . . if that doctor knows or reasonably should know that the procedure will be of no benefit to the patient.*”²⁸ Other U.S. cases involving the “off-label” use of medical devices and pharmaceuticals have generated rulings suggesting that off-label usage can be relevant to determining the standard of care (and informed consent requirements), but that it is not dispositive, by itself, in establishing whether malpractice has taken place.²⁹ Importantly, U.S. case law has not established any distinct principles for evaluating the malpractice standard of care in the context of new medical devices or procedures, as opposed to other clinical situations involving alleged malpractice.³⁰ Neither have the courts established

²⁸ *Riser v. Am. Med. Int'l, Inc.*, 620 So.2d 372, 377 (La. Ct. App. 1993). In the case at issue, the defendant physician reportedly did believe that there was some potential benefit in the new procedure to the patient, but the record of expert evidence actually produced at trial failed to support his point of view. *Id.* at 377-78.

²⁹ *Cf. Richardson v. Miller*, 44 S.W.3d 1, 17 (Tenn. Ct. App. 2000) (holding a prescription drug’s labeling or its PDR reference, when introduced along with other expert evidence on the standard of care, is admissible to assist the trier-of-fact to determine whether the prescribed drug presented an unacceptable risk to the patient); *Blazoski v. Cook*, 787 A.2d 910, 918-22 (N.J. Super. Ct. App. Div. 2002) (holding that the defendant doctor “was not required to disclose to plaintiff [patient] the FDA investigational status of [a medical device] in order for plaintiff to have given an informed consent to the surgery”).

³⁰ Note, however, that British and European courts reportedly have devel-

any distinction between applicable malpractice standards connected with new devices that are believed to offer unique therapeutic benefit, as opposed to new devices whose primary advantage is reduced cost when compared to conventional treatment.

III. MITIGATING MALPRACTICE LIABILITY ASSOCIATED WITH NEW DEVICES

So far, we have established that the precise legal standard of care in malpractice differs somewhat from state to state, but that it is usually based on reasonableness or professional custom, and informed by reference to what other physicians would do when presented with similar circumstances. We have also established that the standard of care can be ambiguous as applied to the adoption by a physician of a new medical device. That ambiguity is partly a function of the risk implications of the device itself (which may not be well understood), but also of the way in which courts construe the legal standard for malpractice, and whether that standard is viewed more narrowly (e.g., with regard to treatment for a specific clinical condition), or more broadly (e.g., with regard to reasonable circumstances for physicians' adopting and using new technologies and techniques). By implication, then, the use of a new medical device by a physician can result in increased potential for malpractice liability, particularly where the device does impose new clinical risks, and/or involves a transformation in underlying processes of care. So given this potential for expanded liability, is there anything that physicians can do to mitigate their malpractice risks, consonant with their legal duties of care? Put another way, can we infer anything about what reasonable physicians would or should do generally, in connection with their adoption of new medical technologies?³¹

oped principles for determining the medical standard of care in connection with new device use (or "therapeutic experimentation"). See Dieter Giesen, *Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination*, 3 MED. L. REV. 22, 31-32 (1995). According to Giesen, the European legal standard in these cases tends to involve 3 questions. "[F]irst, was there a normal [medical] practice which the law would have accepted?" *Id.* at 28. "[S]econd[], did the doctor deviate from that practice?" *Id.* "[T]hird[] (and most importantly) was his deviation such as reasonable physicians exercising due care and skill would not have carried out?" *Id.* at 28-29.

³¹ Of course, one of the most important things that any physician can do to protect against malpractice risk is to consult with a lawyer about the specific legal malpractice standards and precedents that apply in her jurisdiction, and how those might relate to the adoption of a particular new device. Our discussion here focuses on other precautionary measures, consistent with "reasonable" conduct among physicians more generally.

The first, obvious criterion for using a new device appropriately involves knowing something about its safety and effectiveness. If a physician knows nothing about the new device, and has no idea whether it is safe or superior to conventional treatment alternatives, then by using the device the physician would be exposing her patients to an unknown set of risks. By contrast, where the physician has a clear understanding of the safety and effectiveness of the new device, and of the scientific evidence base that supports it, the physician is in a much better position to decide whether clinical use of the device is appropriate. In general, it seems intuitive that reasonable physicians would want to understand the scientific evidence base that supports a new device or new equipment as a predicate to employing it clinically. As a consequence, it is likely that obtaining and reviewing this kind of evidence about a new device may be implicit in the malpractice standard of care.

Note that in practice, all new medical devices in the U.S. will fall into one of several FDA classifications, of which the most burdensome is Class III. New Class III devices require pre-market approval by the FDA and supporting clinical trials because of otherwise insufficient information to ensure their safety and effectiveness.³² Where Class III device trials have been conducted, knowledge that a device has actually been approved by the FDA, together with familiarity with the scientific trial results and any labeling instructions, would seem like basic information that any reasonable physician would want to have about a new device. Likewise, a failure to receive FDA market approval would also be information that most physicians would want to know concerning a new device. The key idea is not the details of the FDA's regulatory mechanism, but rather that significant information about the safety and effectiveness of new devices may often be generated through FDA mandated trials. And again, where any kind of scientific evidence base exists describing the risks and benefits of a new device, a physician can likely help to protect herself under the malpractice standard simply by becoming familiar with that evidence base and drawing upon it in making treatment decisions.

Another potential avenue for physicians to protect themselves from device-related malpractice liability involves obtaining appropriate training and expertise prior to actually using a new device. Again, the idea is for physicians to do those things that are reasonably within

³² For a discussion on the background of the FDA regulatory scheme concerning new medical devices, see Ellen J. Flannery, *The Safe Medical Devices Act of 1990: An Overview*, 46 FOOD DRUG COSM. L.J. 129 (1991) and Howard M. Holstein, *The Safe Medical Devices Act of 1990: Product Approval Changes and Access to PMA Data*, 46 FOOD DRUG COSM. L.J. 153, 153 (1991).

their power in order fully to understand a new device, and thereby to use it safely and effectively. Presumably, the idea of obtaining appropriate training would apply most directly to complicated pieces of medical equipment, where optimal usage may require some degree of instruction or supervision to achieve. Clearly, whenever a new medical device entails clinical risks that can be mitigated by the skill of the practitioner, the physician presumably has some obligation to try to acquire such skill. Failure to do so might be viewed as reckless or unreasonable under the law, quite apart from any intrinsic risks associated with the device itself.

Still another protective step that physicians might take in using a new device would involve considering in detail any specific risks posed by that device in connection with particular types of procedures or patients.³³ In some ways, this goes back to the idea of becoming maximally familiar with what the scientific evidence base and the label instructions have to say about a new device. To the extent that a device is generally safe and appropriate to use but poses added risks or safety concerns in particular situations, then consideration of those sorts of risks could help both to prevent avoidable injuries and to protect a physician from liability after the fact. Again, the legal standard in malpractice involves asking what reasonable physicians would do when faced with similar circumstances. Deliberately and carefully using available information about risk in order to optimize treatment, while protecting vulnerable persons from harm, seems consistent with what medical doctors generally do in clinical practice, and is a straight-forward step towards limiting malpractice risks.

Finally, in current practice physicians almost universally seek informed consent from their patients prior to undertaking medical procedures on a non-emergency basis.³⁴ Particularly when clinical care draws on a new medical device, disclosure and informed consent may allow patients better to understand the nature of their treatment options, and to make any decisions about risks with advice from their doctors. Disclosure and consent also give patients the opportunity to decline treatment options they don't like, and to accept risks that they feel are appropriate. To the extent that the use of a new device is a salient focus for risk, or represents a meaningful departure from traditional treatment, incorporating a discussion about the device into

³³ This kind of information is typically included in the labeling and evidence-base required by the FDA in connection with the approval of Class III medical devices. See 21 C.F.R. § 812.5(a) (2008).

³⁴ For discussion of the common law duty of informed consent in medicine, see Paula Walter, *The Doctrine of Informed Consent: To Warn or Not To Warn?*, 71 ST. JOHN'S L. REV. 543, 545-49 (1997).

informed consent proceedings can give a physician another layer of security under the malpractice standard. Again, it seems fair to assume that across many different treatment contexts, reasonable physicians do not usually conceal significant risks of treatment from their patients, or usurp control over medical decision-making from otherwise competent adults.

IV. NEW DEVICES, MALPRACTICE, AND CORPORATE LIABILITY FOR HOSPITALS AND PRACTICE GROUPS

To this point, our discussion of malpractice liability and new medical devices has basically focused on physicians, as the authors of medical care and the persons ultimately responsible for prescribing and carrying out clinical interventions. But physicians are not the only set of parties who face potential malpractice liability in connection with new medical devices and equipment. Hospitals, ambulatory treatment facilities, and medical provider groups may also be involved in the adoption of new medical technologies, particularly where the acquisition of devices and equipment depends upon major, capital-intensive investments.³⁵ Without addressing the myriad legal and financial issues that these kinds of investments raise, we note that no discussion of malpractice liability would be complete without offering some observations about the potential liability impact on corporate entities involved in delivering health care services, most notably including hospitals. How do malpractice standards of care extend to these sorts of organizations, if at all?

Traditionally, hospitals were almost completely protected from malpractice-type liability under the doctrine of charitable immunity.³⁶ And even as that doctrine went out of favor in the mid-20th century, the staff organization of most hospitals was still designed to preserve the independence of physicians as medical practitioners, and to limit the scope of oversight or control exercised by hospitals. Although most employment relationships serve to make an employer responsible for torts committed by his or her workers within the scope of their

³⁵ In fact, the relationships between physicians, institutional providers, and insurers are complex, and in connection with medical technology acquisition, can involve a range of issues and problems going beyond malpractice (e.g., connected with Stark and anti-fraud statutes). We do not touch on these issues here, other than to acknowledge that the playing field for new medical technology adoption can be complicated, and may often involve other players in addition to physicians.

³⁶ *Thuy Wagner, Hospitals: Court Rejects Charitable Immunity Defense and Holds Hospital Liable: Keene v. Brigham & Women's Hosp., Inc.*, 26 AM. J.L. & MED. 319, 319 (2000).

employment, this was not typically true of doctors and hospitals because the former were regarded as independent contractors, and not as employees of the latter.³⁷ Thus, the basic organization of hospitals protected them against claims of medical malpractice or liability based on deficient or negligent care delivered by physicians. Decades ago, that same organizational protection would probably have protected hospitals against malpractice claims related to the use of new medical devices where those claims depended on a putative departure by a treating physician from the medical standard of care.

In more recent decades, though, several changes in the law and in the business organization of hospitals have made hospitals more vulnerable to a range of malpractice-related tort claims. Perhaps the most important change involves the employment status of physicians vis-à-vis hospitals: in the most recent 10 to 15 years, some hospital chains have engaged in aggressive reorganizations and acquisitions of medical practice groups, resulting in an increasing number of physicians entering formal employment relationships with hospitals. Where that is true, it implies that hospitals can potentially be held liable for malpractice committed by their employee-physicians regardless of whether the inappropriate use of new medical equipment is putatively involved. On a similar note, hospitals have also been subject to growing *vicarious liability* risks: In essence, as hospitals have held themselves out to their communities as direct providers of high-quality medical care, the courts have been increasingly willing to hold them responsible for acts of malpractice committed in their facilities, even where the physicians involved may not have been formal employees of the hospitals.³⁸

The scope of direct liability for hospitals has expanded over the last 20 years. In 1991, an important case on institutional liability established that hospitals have legal duties that fall into four basic categories: 1) the "maintenance of safe and adequate facilities and equipment", 2) selection and retention of competent physicians, 3) oversight of clinical practice, and 4) formulation and enforcement of policies to ensure quality of care.³⁹ Interestingly, this kind of logic suggests another avenue by which hospitals might become liable in connection with the adoption of new medical technologies and equipment. To the extent that new equipment requires maintenance

³⁷ See PROSSER AND KEETON ON THE LAW OF TORTS, *supra* note 7, at 509.

³⁸ See Kuszler, *supra* note 8, at 321; see also Nicolas P. Terry, *When the "Machine that Goes 'Ping'" Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries*, 46 ST. LOUIS U. L.J. 37, 39-43 (2002).

³⁹ *Thompson v. Nason Hosp.*, 591 A.2d 703, 707 (Pa. 1991); see also Terry, *supra* note 38, at 40.

and oversight, those functions may fall within the responsibility of the hospital to provide. Patient injuries sustained as a result of inadequate maintenance of new medical equipment could potentially support claims of liability against the hospital directly, as could claims of inadequate hospital policies to ensure that staff physicians are using the new equipment with proper training and expertise.⁴⁰ Collectively, these theories suggest that hospitals may also face significant liability risks in connection with new device adoption, both vicariously through their affiliated physicians, and directly through their own responsibilities to maintain safe facilities and enforce institutional quality-of-care initiatives.

Importantly, many of these theories of institutional liability for hospitals ultimately depend on a standard-of-care analysis similar to what we described above concerning physicians. Vicarious liability for malpractice committed by staff or employee-physicians depends on whether those physicians have committed malpractice under the law. And direct liability for appropriate maintenance and policies concerning new medical technology invokes its own standard of care, potentially based on what reasonable organizations would do in similar circumstances. All of the ambiguities concerning malpractice liability and new devices potentially apply in the context of hospitals as well—but so too do the basic prophylactic steps of requiring providers to glean all available knowledge and evidence about the risks and appropriate use of the new device, obtain appropriate training, and seek patient informed consent to any salient, incremental risks.

V. MALPRACTICE LIABILITY, NEW TECHNOLOGY, AND THE POTENTIAL FOR UNINTENDED CONSEQUENCES

As we have argued above, the precise contours of the malpractice standard of care are unclear in connection with the adoption of new medical technologies. Granted, there are a set of common-sense steps that most physicians would likely want to take before using new clinical technologies; steps that potentially could help protect against the imposition of malpractice liability after the fact. But even so, those steps do not ameliorate the basic legal ambiguity concerning new device adoption, and how the standard of care for physicians actually applies in those situations. Perhaps the most important policy issue that arises here is less how specific cases of alleged malpractice might

⁴⁰ See Terry, *supra* note 38, at 47-58.

be resolved under an ambiguous rule, but rather, the impact that an ambiguous rule might have on the behavior of physicians more broadly. Recall that the malpractice standard of care is generally intended to ensure that physicians fulfill their professional duties with appropriate care and skill. In the context of new technology, a key concern is that the standard may create perverse incentives that have little to do with preventing or compensating medical injuries, and far more to do with physicians' perceptions about the potential risks to themselves associated with medical innovation.

To better understand the potential for perverse incentives, it helps to consider new technology adoption more broadly, and how the calculus of costs and benefits associated with new technologies typically works. New medical technologies, in particular, are often quite costly to develop and expensive for physicians (and their patients) to obtain. Those costs are necessarily balanced by a set of benefits—otherwise, nobody would be willing to buy the new technology. Note that some new technologies are desirable for their clinical benefits: they either support therapeutic functions not previously available, or else provide risk-superior alternatives to existing treatments. Other new technologies may be desirable more for efficiency reasons: they may make it easier (and cheaper) for physicians to deliver treatment than by conventional means. Either way, in order for a new technology to be cost-effective in the marketplace, its benefits to consumers (in the simplest case, physicians and patients) need to outweigh its costs. This is true even where the technology also offers collateral benefits to a broader set of stakeholders. Thus, a new technology that is both more efficient and that saves lives compared to the status quo might plausibly result in a range of social welfare benefits, including reduced healthcare utilization and costs, reduced mortality and liability risks, improved long-term recovery and productivity among patients, etc. Regardless, in order to get off the ground, the technology minimally needs to pay for itself—i.e., those who bear the costs of the new technology will need to see benefits that equal or exceed those costs.⁴¹

⁴¹ Again, adopting new technology in medicine is often more complex than we describe here, since the acquisition of capital-intensive equipment may involve hospitals as well as physicians, and the cost-effectiveness of equipment for providers may also depend on insurers' reimbursement practices and perspectives regarding new technology. The financial relationships and incentives involved in medical technology adoption can become quite complicated. Nevertheless, the basic principle remains the same: new technology typically brings both costs and benefits: the benefits need to outweigh the costs for whomever is footing the bill, or else they have no reason to acquire it, and malpractice risk may represent a significant cost and disin-

In principle, the challenge posed by ambiguous malpractice liability is that it may escalate the risk to providers, and therefore the cost, associated with adopting new technology, quite apart from any underlying clinical risk associated with the technology itself.⁴² But clearly, that is not the intended purpose of malpractice doctrine. The aim of malpractice is not to create broad disincentives to innovation, but rather to ensure that providers use appropriate care and skill in delivering medical services, regardless of treatment modality. As we have already discussed, it is widely understood in the legal community that medical standards of care evolve over time, in response to new empirical research and scientific progress.⁴³ Perhaps less understood in the legal community are physicians' perceptions regarding innovation and malpractice risk, and the possibility that physicians' fears about ambiguous liability might deter them from considering new technologies that could otherwise be cost-effective and risk-reducing.⁴⁴ This kind of indirect result seems undesirable on its face,

centive to physicians in their calculus about whether or not to adopt.

⁴² Again, the underlying legal premise here is that a bad clinical outcome, when combined with a new and unorthodox mode of treatment, might be sufficient in itself to establish a malpractice claim. This is clearly a formulation of malpractice that distills the standard of care down to a very narrow gloss on professional custom: if the physician departs from conventional and widely accepted modes of treatment, then perhaps she takes on the risks of bad outcomes as a result. I have argued that this rationale is fundamentally flawed as an interpretation of law—nevertheless, to the extent that medical providers see this as a threat, then it becomes a powerful disincentive to adopting new technologies and new modes of treatment.

⁴³ For a discussion of the “duty to stay abreast,” See Williams, *supra* note 4 at 508-12. Several key precedents have imputed to physicians an obligation to take into account advances in medical science in their professional practice. See *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996); *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875 (N.Y. App. Div. 1982). Moreover, these cases echo *The T.J. Hooper* case in suggesting *another* problem in the standard of care doctrine around new technology: namely, that there is a tipping point beyond which emerging scientific knowledge can become the basis for a new standard of care, notwithstanding accepted professional customs to the contrary. Exactly where that tipping point occurs, however, involves a matter of judgment on the part of courts.

⁴⁴ On this point, there is no current, good empirical evidence to quantify what physicians' beliefs are regarding their liability risks connected with new technology. For a discussion detailing empirical evidence quantifying physicians' beliefs surrounding the liability risks connected with new technology, see David Dranove & Anne Gron, *Effects of the Malpractice Crisis on Access to and Incidence of High-Risk Procedures: Evidence from Florida*, 24 HEALTH AFF. 802 (2005), Yasmin S. Cypel, Jonathan H. Sunshine & Paul H. Ellenbogen, *The Current Medical Liability Insurance Crisis: Detailed Findings from Two ACR Surveys in 2003 and 2004*, 2 J. AM. C. RADIOLOGY 595 (2005), Pamela; Robinson et al., *The Impact of Medical Legal Risk on Obstetrician-Gynecologist Supply*, 105 OBSTETRICS & GYNECOLOGY 1296, 1300 (2005), and Michelle M. Mello, David M. Studdert,

even if we restrict our consideration of costs and benefits just to those that accrue directly to providers and their patients. If we further recognize that new technology sometimes brings positive externalities and broader enhancements to social welfare, there is an even stronger concern regarding the potential for perverse incentives associated with malpractice doctrine.⁴⁵

Drawing on this logic, there is a basic balance between policy interests that malpractice law needs to accommodate. In other words, the underlying question is: What is the ideal set of incentives that we would want to establish concerning the adoption and use of new technologies by medical providers? Presumably, the answer is that we would want providers to scrutinize new technologies carefully to protect their patients against new and incremental clinical risks, and to apply any new technology with prudence and skill. Beyond the foregoing, we would also want providers to actively consider adopting new technology where these criteria are met, and where the technology is cost-effective for providers to implement. In some instances, we might even want to promote new technology that is not cost-effective for providers to implement on their own, particularly if we believe that the technology offers broader social benefits beyond those that accrue directly to providers or their patients. Obviously, the latter aims are already implicit in existing federal laws and regulatory schemes unrelated to malpractice, notably including the FDA's regulation of new devices and pharmaceuticals (designed to produce information about clinical risks and benefits that would otherwise be unavailable), the Department of Health and Human Services' financial support connected with new technology development and dissemination, and state licensing laws regulating the profession of medicine.

Strikingly, though, much of this policy calculus concerning new technology adoption has not been incorporated into malpractice doctrine. Malpractice is basically concerned with ensuring that physicians use appropriate prudence and skill in the conduct of their professional activities. Clearly, that concern applies to situations involving new technology as well. But there is nothing intrinsic about malprac-

Jennifer Schumi, Troyen A. Brennan & William M. Sage, *Changes in Physician Supply and Scope of Practice During a Malpractice Crisis: Evidence from Pennsylvania*, 26 HEALTH AFF. w425, w425-35 (2007).

⁴⁵ Of course, we also need to acknowledge that new technology can sometimes bring negative externalities as well—as in the event of any device-related mass tort which results many injuries and substantial litigation. In the wake of the recent Supreme Court decision in *Riegel v. Medtronic*, No. 06-179, slip op. at 1-6, Feb. 20, 2008, however, the court affirmed the role of FDA oversight in addressing and preventing that set of risks.

tice that calls for discouraging new technology in itself—in some basic sense, malpractice ought to be indifferent to the technology that providers use, so long as they use it in a responsible and reasonable fashion. Put another way, we ideally want to protect people against negligence or recklessness committed by their physicians, but in so doing, we do not want to create broad disincentives to new technology in itself, simply because it is new and not yet widely in use. We do want physicians to consider the risks and benefits of new technology before they decide to adopt it. But we do not want the law to create a diffuse cloud of malpractice liability, such that providers have no certainty about how the legal system might judge them after the fact. The legal status quo arguably involves exactly that kind of cloud, with potential disincentives to new medical technology adoption that are neither intended nor socially desirable.

One way for judges and policymakers to ameliorate this problem under malpractice law would be by addressing it explicitly. That is, where malpractice and new technology collide, policymakers should focus on that intersection, and provide as much explicit guidance as possible to disambiguate the legal expectations and liability risks that physicians face as early adopters. As in addressing any other instance of regulatory perversity in managing risk, the aim of the law here should be to acknowledge and incorporate a broader set of policy considerations in seeking to achieve a balanced and appropriate rule (per Justice Breyer).⁴⁶ If malpractice incentives and new technology incentives are operating at cross purposes, then why not try to disentangle them under the law? In the absence of any solid empirical research quantifying physicians' perceptions about malpractice risks associated with new technology, we can only infer that there is likely to be significant fear among physicians around doing new things, and a corresponding desire to avoid liability standards that are not well-defined under the law. And absent better clarification, it seems unlikely that current malpractice doctrines strike an optimal balance between incentivizing appropriate skill and diligence in delivering medical services, and encouraging the optimal use of new technologies in the ongoing effort to improve the quality and efficiency of care.

⁴⁶ See STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 9-10 (1993) (discussing policy considerations regarding risk assessment and management).

CONCLUSION

Any time that a physician adopts and uses a major piece of new medical technology with a resulting shift in the nature or delivery of clinical care, the result is the potential for a new set of malpractice risks. Liability for medical malpractice is based on whether a physician meets a legally required standard of care. That legal standard is usually defined by medical custom, or else by what other reasonable physicians would do when confronted with similar circumstances. New medical technologies present a significant interpretive challenge for applying the malpractice standard. Because medical devices and equipment differ from traditional modalities of treatment, most practitioners are not yet using them. A narrow interpretation of the standard of care might lead to the conclusion that the use of a new device is unreasonable or not appropriate simply because most physicians have not adopted it yet. This kind of interpretation of the malpractice standard could impose significant liability risks onto doctors, as well as onto hospitals and other corporate entities that are in the business of providing health care services.

I suggest, though, that this is not the correct interpretation of the malpractice standard. Medical technology changes over time, and modern medicine is driven by innovation grounded in empirical science. Other legal doctrines in malpractice acknowledge this by imposing on physicians an obligation to "stay abreast" of new developments in the field. As applied to the adoption of new equipment and devices, a broader interpretation of the malpractice standard would address the circumstances under which reasonable physicians frequently do make use of new technologies. Where those new technologies pose ambiguous clinical risks, this will still leave physicians with significant malpractice concerns. But it also suggests some steps that physicians can take to protect themselves from device-related liability, such as by reading all of the clinical trial information on the risks and benefits of a new device, following any pertinent label instructions, and seeking relevant training where appropriate. These kinds of steps may help physicians to avoid the occurrence of preventable injuries in the first place. They also reflect the care and consideration that one might generally expect of reasonable physicians, especially in dealing with equipment or devices that reflect a departure from traditional modes of care.

Beyond physicians, the malpractice liability standard also has implications for technology manufacturers and policymakers. For manufacturers, malpractice risk represents a significant potential concern in the consumer market for new products. One way that manufacturers can respond to this concern is by undertaking rigorous

testing of those products, in order to identify any related clinical risks, and to ensure that the products are safe and effective for their intended purposes. But apart from quantifying and minimizing the objective risks associated with a new device, manufacturers may also have the opportunity to help physicians in taking steps to avoid device-related malpractice risks. Manufacturers can address physicians' malpractice concerns head-on by sharing available scientific and clinical trial information, by emphasizing labeling instructions, and by disclosing any clinical risks that physicians should consider in using a new device or piece of equipment. Depending on the complexity of the new technology, manufacturers might also consider providing formal training in its use, which could be built into the business model for new devices and equipment, together with ongoing technical support for the technology. Manufacturers may also be in a unique position to consult with appropriate medical professional societies, in order to clarify how a new technology should fit into existing clinical practice guidelines—something that individual physicians are unlikely to be able to do for themselves, but that could nevertheless be helpful to them in seeking to understand and comply with the malpractice standard.

For policymakers, the challenge presented by malpractice liability and new medical devices is to strike the right balance between competing interests. On one hand, we ideally want a set of malpractice rules that protect against medical negligence, and that compensate victims appropriately. On the other hand, we also want a set of rules that is clear in application, and that does not create broad disincentives to medical innovation and the adoption of new technology. Part of the answer lies simply in affirming the broader interpretation of the malpractice standard, and the idea that innovation and new device adoption by physicians is fully consistent with meeting their legal duties of care. Further clarification of the malpractice standard by policymakers, and of the steps that reasonable physicians should take in connection with using new medical devices and equipment, could help substantially in reducing the ambiguity around device-related malpractice risks.

