

WHEN SHOULD PHYSICIANS BE LIABLE FOR INNOVATION?

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Uncertainty pervades medicine. It is particularly acute when a physician deliberately deviates from generally accepted practices in an attempt to improve patient care. Unlike innovative drug and device manufacturers, treating physicians are not subject to mandatory ex ante public regulation. The question of how to constrain physician behavior thus largely falls to the tort system. Innovation by definition involves a departure from custom, so adherence to customary standards of care essentially requires physicians to solely bear the liability costs of innovative treatment. This regime, of course, protects patients from unnecessary risks associated with untested therapies, but may also unduly deter physicians from tailoring individualized treatment plans that address patients' particular needs and preferences.

There are several possible alternatives to regulating physician innovation, ranging from the highly paternalistic to the highly libertarian. The public regulatory regime could be revised to require that all untested medical interventions undergo formal testing before physicians are permitted to use them in the treatment setting. But turning an individual from a patient in a treatment setting into a subject in a research setting fundamentally transforms her role in the medical decisionmaking process and the goals of the intervention. At the other extreme, we could adopt a contract-based model of physician liability that allows for more robust and coherent adherence to principles of patient autonomy. But physicians' superior knowledge and patient vulnerabilities caution against treating a medical encounter as an arms-length negotiation.

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This Article proposes a fiduciary framework to regulate physician innovation under conditions of endogenous uncertainty. The proposed approach could be described as a “libertarian paternalism” model of medical decisionmaking. It mandates close scrutiny of the decisionmaking process but deference to the substance of medical decisions. Under this framework, the physician should be held liable for failing to act in the patient’s best interests, taking into account the patient’s unique clinical condition and value preferences. Within these constraints, however, patients should have the freedom to choose—and assume the associated risks and uncertainties—from among a range of clinically acceptable alternatives. Properly applied, fiduciary principles can strike a desirable balance that respects patient autonomy, deters unreasonable risks, and encourages beneficial innovation.

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INTRODUCTION

Medical malpractice law is slowly shifting away from standards of care based on professional custom toward a more free-form reasonableness test for assessing physician behavior.¹ While some have argued that this trend reflects growing distrust of the medical profession,² a better explanation for this shift may be tacit acknowledgement of medicine’s “radical uncertainty.”³ Departures from deference to custom in medical malpractice cases are compelled by rapid scientific change and growing recognition of substantial patient heterogeneity in both treatment responses and personal preferences. We now have a wide range of treatment options with complex risk-benefit tradeoffs derived from inevitably incomplete information. In many cases, even the most knowledgeable practitioner cannot confidently pick the “right” treatment course for any given patient, particularly when the patient’s unique needs and values are taken into account. Thus, black-letter law that defines medical malpractice as deviation from customary care is a quaint anachronism.

Medical uncertainty is particularly acute when a physician deliberately strays from generally accepted practices in an attempt to improve patient care. Physicians frequently innovate in the treatment setting outside of formal clinical trials.⁴ Physician innovation includes performing novel medical and surgical procedures and prescribing drugs and devices for uses with unknown safety and efficacy. Unlike medical product manufacturers, innovative physicians are not subject to mandatory regulation by the Food and Drug Administration (FDA) or other public agencies. Physicians come under the auspices of federal regulations governing human subject experimentation if they design a formal research protocol to test an innovative medical intervention.

¹ Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163 (2000).

² See, e.g., Maxwell J. Mehlman, *The Patient-Physician Relationship in an Era of Scarce Resources: Is There a Duty to Treat?*, 25 CONN. L. REV. 349, 374 n.88 (1993); Peters, *supra* note 1, at 196–99.

³ KATHRYN MONTGOMERY, *HOW DOCTORS THINK: CLINICAL JUDGMENT AND THE PRACTICE OF MEDICINE* 53 (2006).

⁴ See *infra* Part II.B.

However, a large swath of medical activity falls outside the statutory definition of research and thus avoids *ex ante* regulation.⁵

Medical malpractice law thus plays a key role in constraining physician behavior in the practice setting.⁶ Innovation by definition involves a deviation from customary practice, so adherence to custom in defining standards of care essentially requires physicians to solely bear the liability costs of novel interventions. This regime protects patients from unnecessary risks associated with untested treatments, but also may unduly deter physicians from tailoring individualized treatment plans that address patients' particular needs and preferences. *Ex post* regulation of clinical innovation via the tort system also perpetuates an *ad hoc* approach that obscures the bounds of permissible physician behavior.

There are several possible alternatives to regulating physician innovation, ranging from the highly paternalistic to the highly libertarian. On the most paternalistic side of the spectrum, the public regulatory scheme could be revised to require that all untested medical interventions undergo formal testing before physicians are permitted to use them in the practice setting. Under this regime, a potential patient candidate for a novel procedure or new use of a drug or device would be required to enroll as a subject in a formal clinical trial in order to obtain access to an innovative treatment. But individualized patient care decisions may not be suited to formal research protocols designed to generate population level data about medical interventions.⁷ Moreover, mandatory clinical trials raise significant ethical concerns. Transforming an individual from a patient into a research subject fundamentally alters her role in the medical decisionmaking process and the goals of the intervention. By enrolling in a randomized clinical trial, an individual forfeits decisional autonomy over her ultimate treatment course. And while the goal of a medical intervention in the treatment setting is to further the patient's interests, the goal in the research setting is to expand generalizable knowledge, with the individual subject's

⁵ See *infra* Part II.

⁶ Physicians are also constrained by limits on insurance reimbursement and by the rules and adjudication of medical licensing boards. For an overview of disciplinary actions by licensing boards, see BARRY R. FURROW ET AL., *HEALTH LAW* 82–91 (2d ed. 2000) (explaining that violations of professional standards must be proven by the disciplinary agency and that expert testimony and proceedings of Peer Review Organizations are generally admissible); see also BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 90–95 (7th ed. 2013) (including excerpts of cases involving disciplinary actions by state medical boards based on physicians' prescribing practices).

⁷ See Anna C. Mastroianni, *Liability, Regulation and Policy in Surgical Innovation: The Cutting Edge of Research and Therapy*, 16 *HEALTH MATRIX* 351, 370–72 (2006) (explaining that innovative surgical procedures designed to benefit individual patients may not be amenable to formal human subjects research); see also *infra* Part I.

interests acting as a side constraint.⁸ It is not desirable to compel every individual to accept these conditions in exchange for the opportunity to explore innovative therapies.

A less paternalistic regulatory option is to continue to allow physicians to innovate in the treatment setting but to implement a screening process to assess the merits of novel interventions. Special private boards of medical experts could be set up to evaluate the potential risks and benefits of innovative treatments, much like institutional review boards (IRBs) currently evaluate proposed research protocols. Expert panel approval could elevate the innovative treatment option to the status of standard of care in malpractice cases, thereby shielding physicians from liability exposure created by clinical innovation.⁹ The key problem with this approach is that it ignores the unavoidable uncertainties that plague medical decisionmaking. Even experts with complete understanding of existing medical data cannot know that which is unknowable about the relative merits of untested innovative technologies. Also, review panels assessing whether a particular intervention is beneficial to a general patient population cannot easily incorporate into their calculus the particular needs and preferences of individual patients.

On the most libertarian side of the spectrum, the law could allow individual patients to choose their own treatment course by shifting to a contractual model of physician liability.¹⁰ Medical uncertainty and patient heterogeneity challenges the law's historical rejection of the assumption of risk doctrine in medical malpractice cases and prohibitions against covenants not to sue. Although there are compelling reasons for prohibiting patients from assuming the risk that physicians will treat them in a negligent manner, a case can be made for allowing patients to assume liability costs when faced with a choice between treatment options with unknown risks and unclear benefits that requires the incorporation of individual preferences. Shifting the costs of medical uncertainty onto patients allows for more robust and coherent adherence to principles of patient autonomy. Yet strong public policy arguments counsel against a purely contractual approach to medical decisionmaking.¹¹ Physicians' superior knowledge and patient vulnerabilities make it undesirable to treat a medical encounter as an arms-length negotiation.

⁸ See *infra* Part II.

⁹ Gideon Parchomovsky and Alex Stein advocate this general approach to mitigating tort law's adverse effects on innovation. See Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285 (2008).

¹⁰ See *infra* Part III.C.

¹¹ See, e.g., *Tunkl v. Regents of the Univ. of Cal.*, 383 P.2d 441 (Cal. 1963) (invalidating as contrary to public policy an exculpatory provision whereby, in exchange for admission, a patient released a hospital from liability for future negligence).

This Article proposes an alternative fiduciary framework to manage uncertainty that could be described as a “libertarian paternalism”¹² model of medical decisionmaking. Part I outlines how tensions in existing medical malpractice doctrine parallel the contemporary debate within the medical community over the relative merits of professional consensus and individualized treatment. Part II explains why these tensions are particularly acute when physicians deliberately deviate from generally accepted practices in efforts to advance science and improve patient care. Part III explains why suggested reforms to the regulation of physician innovation insufficiently account for medical uncertainty and patient heterogeneity. Part IV outlines a proposed regime that mandates close scrutiny of the decisionmaking *process* but deference to the *substance* of medical decisions. Under this approach, a physician should be held liable for failing to act in the patient’s best interests, taking into account the patient’s unique clinical condition and value preferences. Within these constraints, however, patients should have the freedom to choose—and assume the associated risks and uncertainties—from among a range of reasonable alternatives. A brief Conclusion summarizes the Article’s main findings and recommendations.

I. TENSIONS IN SETTING STANDARDS OF CARE

A. *Medical Practice*

Modern medicine displays two fundamentally divergent trends. Evidence-based medicine (EBM) initiatives aim to generate population level data on the safety and efficacy of medical interventions in order to produce generalizable knowledge with which to guide clinical decisionmaking.¹³ At the same time, growing recognition of patient variation and “preference-sensitive” care is spurring efforts to incorporate individual patients’ unique needs and characteristics into treatment decisions.¹⁴ These conflicting medical trends mirror health

¹² Cass R. Sunstein & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1167, 1201 (2003) (explaining that, under libertarian paternalism, “the general presumption should be in favor of freedom of choice, and that presumption should be rebutted only when individual choice is demonstrably inconsistent with individual welfare”).

¹³ John M. Eisenberg, *What Does Evidence Mean? Can the Law and Medicine Be Reconciled*, 26 J. HEALTH POL. POL’Y & L. 369, 370 (2001) (pointing to a shift in the culture of medical education toward more science-based practice); Rose Hatala & Gordon Guyatt, *Evaluating the Teaching of Evidence-Based Medicine*, 288 JAMA 1110, 1110 (2002) (noting that an increasing number of medical schools and residency programs teach EBM).

¹⁴ John E. Wennberg & Philip G. Peters, *Unwarranted Variations in the Quality of Health Care: Can the Law Help Medicine Provide a Remedy/Remedies?*, 37 WAKE FOREST L. REV. 925, 928–29 (2002).

law and policy debates between prioritizing individual interests and maximizing collective welfare.¹⁵ The fundamental source of these tensions is patient heterogeneity across several dimensions: treatment responses, value preferences, appetite for risk, and willingness and ability to pay for health services.¹⁶

All medical interventions encompass a mix of probabilistic benefits and risks, as well as irreducible “Knightian” uncertainty¹⁷ about unknown effects whose probabilities cannot be ascertained. Pervasive uncertainty in clinical practice belies lay perceptions of medicine as a precise, context-independent science involving clear choices and predictable results.¹⁸ Physicians must grapple with incomplete information about the safety and efficacy of therapeutic options, and take into account patients’ idiosyncratic characteristics and risk preferences. For example, the decision to use anticoagulants as prophylaxis against stroke in patients with atrial fibrillation requires examination of statistical outcomes data, determination of the patient’s age and history of bleeding, and an inquiry into the patient’s willingness to accept the risk of hemorrhage in exchange for a reduction in stroke risk.¹⁹

The Hippocratic Oath²⁰ retains powerful rhetorical force, but it offers scant practical guidance to the harried 21st century physician struggling to treat her patients in the face of dizzying technological complexity. The American Medical Association (AMA) Code of Medical Ethics unequivocally states that a physician must prioritize the

¹⁵ See William M. Sage, *Relational Duties, Regulatory Duties, and the Widening Gap Between Individual Health Law and Collective Health Policy*, 96 GEO. L.J. 497 (2008).

¹⁶ See Sidney T. Bogardus et al., *Perils, Pitfalls, and Possibilities in Talking about Medical Risk*, 281 JAMA 1037, 1039 (1999) (explaining that patient preferences regarding information disclosure, risk-taking, quality of life outcomes, and tolerance of side effects vary widely).

¹⁷ FRANK H. KNIGHT, *RISK, UNCERTAINTY AND PROFIT* 224–26 (Econ. Classics reprint ed. 1964) (1921) (making important distinctions between *a priori* probability, statistical probability, and estimates, and observing that “[t]here are all gradations from a perfectly homogeneous group of . . . hazards at one extreme to an absolutely unique exercise of judgment at the other”).

¹⁸ Frances Griffiths, Eileen Green & Maria Tsouroufli, *The Nature of Medical Evidence and Its Inherent Uncertainty for the Clinical Consultation: Qualitative Study*, BMJ: BRIT. MED. J. (March 3, 2005), <http://www.bmj.com/content/330/7490/511> (cautioning health care providers to avoid “creating a myth of certainty” around inherently uncertain medical evidence, as this reinforces patients’ false understanding “of medicine as a precise science independent of context and people with the ability to predict the outcome”).

¹⁹ R. Brian Haynes, P.J. Devereaux & Gordon H. Guyatt, *Physicians’ and Patients’ Choices in Evidence Based Practice*, 324 BMJ: BRIT. MED. J., 1350, 1350 (2002) (using this example to explain why an evidence-based decision involves not only considerations of the safety and efficacy of therapeutic options, but also individual clinical circumstances and patient preferences).

²⁰ Modern medical ethics directly descend from the oath famously articulated by the medical philosopher Hippocrates in the fourth century B.C.: “I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous.” Hippocrates, *The Oath of Hippocrates*, reprinted in THE HARVARD CLASSICS VOLUME 38: SCIENTIFIC PAPERS (PHYSIOLOGY, MEDICINE, SURGERY, GEOLOGY) 11 (2006).

patient's well-being over her own self-interests.²¹ But how do physicians determine patients' best interests under conditions of medical uncertainty? Physicians must balance obligations to both respect patients' wishes and protect patients' health. In the past few decades, medical ethics has moved from a paternalistic model of decisionmaking in which the physician chooses what is best for the patient, to an autonomy-based ideal whereby the physician communicates material information that the patient needs to make welfare-maximizing choices.²² Physician Jay Katz observes that acknowledging medical uncertainty creates formidable challenges for the physician-patient relationship:

For sharing uncertainties requires a willingness to admit ignorance about benefits and risks; to profess to the existence of alternatives, each with its own known and unknown consequences; to eschew one single authoritative recommendation; to consider carefully how to present uncertainties so that patients will not become overwhelmed by the information they are required to know; and to explore the crucial question of how much uncertainty physicians themselves can tolerate without compromising their effectiveness as healers.²³

1. Evidence-Based Medicine

Historically, medical standards of care have emerged through a dynamic interplay of professional communications, meetings, and published literature.²⁴ Proponents of EBM seek to shift the basis of clinical decisionmaking from personal experience and opinion to high-grade scientific evidence generated from randomized controlled trials and observational studies.²⁵ The EBM movement has fueled efforts to develop evidence-based clinical practice guidelines (CPGs) that articulate and disseminate professional consensus on best practices.²⁶

²¹ *Opinion 8.03—Conflicts of Interest: Guidelines*, AM. MED. ASS'N (June 1994), <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion803.page?> (stating that it is unethical for a physician to provide unnecessary care, and that “[i]f a conflict develops between the physician’s financial interest and the physician’s responsibilities to the patient, the conflict must be resolved to the patient’s benefit”).

²² RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 59 (1986) (“Until recently . . . the justification of practices of disclosure and consent-seeking were strictly governed by what we shall call a *benevolence model* rather than an *autonomy model* of the physician’s responsibility for the patient.”).

²³ Jay Katz, *Epilogue: Physician-Patient Encounters “On a Darkling Plain,”* 9 W. NEW ENGL. L. REV. 207, 209 (1987).

²⁴ BARRY FURROW ET AL., *HEALTH LAW*, *supra* note 6, at 266.

²⁵ Sandra J. Tanenbaum, *Evidence and Expertise: The Challenge of the Outcomes Movement to Medical Professionalism*, 74 ACAD. MED. 757 (1999).

²⁶ BARRY FURROW ET AL., *HEALTH LAW*, *supra* note 6, at 267–68.

But developing systematic, scientifically supported rules for clinical practice remains an elusive goal.²⁷

CPG initiatives have foundered on intractable problems of scientific and moral ambiguity. EBM advocates face several challenges. Paradoxically, the practical utility of clinical data varies inversely with its scientific rigor and validity.²⁸ This is because the more tightly controlled the research protocol, the greater the biological and contextual differences between subjects in the clinical study and patients in the treatment setting.²⁹ In addition, real-world patients might prioritize treatment outcomes other than those measured in a clinical trial. For example, a trial that finds a small but statistically significant difference in survival times between two cancer treatments is of little value to a patient primarily concerned about quality of life.³⁰

While some members of the medical community strongly support the development and use of CPGs,³¹ others fear that they undermine clinical judgment and threaten professional autonomy.³² EBM skeptics note the implicit normative content embedded in probabilistic research and the impossibility of purging uncertainty from clinical decisionmaking.³³ The evolving definition of EBM reflects this debate. David Sackett, a pioneer of EBM, initially defined it as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”³⁴ In response to criticism that this definition failed to recognize the importance of

²⁷ See M. Gregg Bloche, *The Invention of Health Law*, 91 CALIF. L. REV. 247, 268 (2003) (“At least since the eighteenth century, clinical idealists have aspired to recast medicine as a systematic compilation of evidence-based rules of practice, centrally administered and enforced. That this recurring hope remains unfulfilled invites at least a suspicion that intractable problems stand in the way.” (footnote omitted)); Maxwell J. Mehlman, *Professional Power and the Standard of Care in Medicine*, 44 ARIZ. ST. L.J. 1165, 1213–15 (2012) (citing a 2009 Institutes of Medicine report finding that less than half of all delivered treatments are supported by scientific evidence).

²⁸ Bloche, *supra* note 27, at 269 (“[T]here is a roughly inverse relationship between the quality of clinical trials as science and the scope of their real-world relevance.”).

²⁹ Anna B. Laakmann, *Collapsing the Distinction Between Experimentation and Treatment in the Regulation of New Drugs*, 62 ALA. L. REV. 305, 327 (2011).

³⁰ Bloche, *supra* note 27, at 269.

³¹ Lucian L. Leape et al., *What Practices Will Most Improve Safety?*, 288 JAMA 501, 501 (2002) (“Advocates of evidence-based medicine . . . argue that medical decisions should be based, as much as possible, on a firm foundation of high-grade scientific evidence, rather than on experience or opinion.”).

³² INST. OF MED., *GUIDELINES FOR CLINICAL PRACTICE: FROM DEVELOPMENT TO USE* 24 (Marilyn J. Field & Kathleen N. Lohr eds., 1992) (“[M]any physicians, especially those longer in practice, see guidelines as a challenge to clinical judgment and resist them as a threat to the most fundamental element of professional autonomy.”).

³³ Tanenbaum, *supra* note 25, at 759–61 (noting that statistical significance levels for clinical trials incorporate normative judgments about the relative importance of false negatives and false positives, and asserting that the EBM movement is motivated by a futile desire for medical certainty).

³⁴ David L. Sackett et al., *Evidence-Based Medicine: What It Is and What It Isn't*, 312 BMJ: BRIT. MED. J. 71, 71 (1996).

making clinical judgments based on individual patients' needs and preferences, Sackett and his colleagues revised the definition of EBM to be "the integration of best research evidence with clinical expertise and patient values."³⁵

2. Preference-Sensitive Care

Medical uncertainty simultaneously fuels patients' needs for professional guidance and bolsters arguments that patients should be the ultimate arbiters of clinical decisions.³⁶ Patients' desired roles in medical decisionmaking may depend upon the particular circumstances in which decisions are made, including the patient's physical state, the closeness of their relationship with their physician, and the technical complexity involved.³⁷ While patients might willingly delegate to physicians decisions such as which particular medication to take for a routine ailment, they may wish to actively participate in major decisions involving serious consequences and subjective factors.³⁸ Patients display marked differences in the weights that they place on adverse quality of life outcomes such as incontinence, loss of a body part, or physical discomfort.³⁹ Patient input is thus frequently required in order to ensure that the patient receives a medical intervention that advances his individual interests.

Recent research from the Dartmouth Atlas Project⁴⁰ suggests that a substantial portion of medical decisions should depend heavily on individual patient values and preferences.⁴¹ Medical treatments can be

³⁵ DAVID L. SACKETT ET AL., EVIDENCE-BASED MEDICINE: HOW TO PRACTICE AND TEACH EBM 1 (2d ed. 2000) ("By *clinical expertise* we mean the ability to use our clinical skills and past experience to rapidly identify each patient's unique health state and diagnosis, their individual risks and benefits of potential interventions, and their personal values and expectations. [And that] [b]y *patient values* we mean the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient.").

³⁶ Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 222 (1985) ("[M]edical uncertainty accentuates the need for professional advice, but it also strengthens the case for ultimate decision by the person whose life is directly involved.").

³⁷ Carl E. Schneider, *Bioethics with a Human Face*, 69 IND. L. J. 1075, 1097 (1994) ("It will surely matter how sick or healthy the patient is, how well the doctor and patient know each other, how trivial or consequential the decision is, how technical the issues raised, and so on.").

³⁸ Susan M. Wolf, *Doctor and Patient: An Unfinished Revolution*, 6 YALE J. HEALTH POL'Y L. & ETHICS 487, 496 (2006) ("[L]umping together these decisional scenarios confuses the picture.").

³⁹ Dominick L. Frosch & Robert M. Kaplan, *Shared Decision-Making in Clinical Medicine: Past Research and Future Directions*, 17 AM. J. PREVENTIVE MED. 285, 287 (1999).

⁴⁰ DARTMOUTH ATLAS HEALTH CARE, <http://www.dartmouthatlas.org> (last visited Jan. 10, 2015).

⁴¹ *A Dartmouth Atlas Project Topic Brief: Preference-Sensitive Care*, DARTMOUTH ATLAS HEALTH CARE (Jan. 15, 2007) [hereinafter PREFERENCE-SENSITIVE CARE], available at http://www.dartmouthatlas.org/downloads/reports/preference_sensitive.pdf.

characterized as either “effective care” or “preference-sensitive care.”⁴² Effective care includes “services whose use is supported by well-articulated medical theories and by strong evidence of efficacy in the forms of randomized clinical trials or large cohort studies” and is amenable to a universal standard of care applicable to all patients.⁴³ Examples include mammography screening for breast cancer, sugar and lipid monitoring for diabetics, and beta-blockers and ACE inhibitors following a heart attack. Treatment of hip fracture is another example of effective care. In virtually all cases the condition can be accurately diagnosed, and surgical repair is the universally accepted approach.⁴⁴

By contrast, preference-sensitive care involves conditions for which two or more treatment alternatives exist, and either the options comprise different known risk-benefit tradeoffs, or their risk-benefit profiles are scientifically uncertain.⁴⁵ The treatment of early stage breast cancer is an example of preference-sensitive care.⁴⁶ Clinical trials show that the survival outcomes with mastectomy (complete removal of the breast) and lumpectomy (“breast sparing surgery,” a local excision of the tumor) are about the same. However, the two treatment options significantly differ with respect to other important outcomes. Women choosing mastectomy suffer disfigurement and must confront decisions about cosmetic surgery, while those electing lumpectomy may require radiation and/or chemotherapy and must live with the risk of local recurrence, which would require further surgery.⁴⁷ Other examples of preference-sensitive care include the choice between invasive treatment or more conservative medical management for chest pain due to coronary artery disease, and the choice between surgery and conservative management for patients with back pain due to disc disease.⁴⁸

Most medical interventions more closely resemble preference-sensitive breast surgery than preference-insensitive hip repair.⁴⁹ The Affordable Care Act of 2011 highlights the need for patient input in cases involving preference-sensitive care, and introduces a program to create “patient decision aids” designed to facilitate decisionmaking.⁵⁰ Clinical trials show that patients who use decision aids make more

⁴² Wennberg & Peters, *supra* note 14, at 925.

⁴³ *Id.* at 927 (footnote omitted).

⁴⁴ PREFERENCE-SENSITIVE CARE, *supra* note 41, at 2.

⁴⁵ Wennberg & Peters, *supra* note 14, at 928–29.

⁴⁶ PREFERENCE-SENSITIVE CARE, *supra* note 41, at 1.

⁴⁷ *Id.* (“Which treatment a woman chooses should depend on her own, rather than her physician’s, opinion about these outcomes.”).

⁴⁸ *Id.* at 2.

⁴⁹ *Id.* at 5 (showing a table of preference-sensitive versus preference-insensitive medical interventions).

⁵⁰ 42 U.S.C. § 299b-36 (2012).

informed decisions that better reflect their own personal values.⁵¹ Notably, these trials show a marked decrease in demand for costly invasive treatments when decision aids are used.⁵²

B. *Legal Doctrine*

The dilemma in medical practice between relying on generalized data to make clinical decisions and prioritizing patients' unique characteristics parallels the struggle to formulate medical malpractice doctrine that both enforces standards of professional competence and incorporates patient autonomy principles.

1. Customary Standards and Exceptions

Legal standards of care traditionally have been set by reference to professional custom.⁵³ This is a descriptive inquiry that asks what physicians *in fact* do, rather than a normative inquiry into what physicians *should* do under the circumstances.⁵⁴ Custom-based standards help to constrain lay expectations within realistic bounds.⁵⁵ But empirical and moral uncertainties about correct medical practices raise concerns about adhering to professional custom to set legal standards of care.⁵⁶

The shift from legal standards based on local custom to standards based on national custom has exposed a stark truth that there is little

⁵¹ PREFERENCE-SENSITIVE CARE, *supra* note 41, at 2.

⁵² *Id.*

⁵³ PATRICIA M. DANZON, MEDICAL MALPRACTICE: THEORY, EVIDENCE, AND PUBLIC POLICY 16, 139–40 (1985) (noting that deviation from reliance on customary standards is “rare”); W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 32, at 189 (5th ed. 1984) (stating that tort law “gives the medical profession . . . the privilege, which is usually emphatically denied to other groups, of setting their own legal standards of conduct, merely by adopting their own practices” (footnote omitted)); James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace?*, 11 ANNALS HEALTH L. 125, 130 (2002) (stating that in medical malpractice actions “conventional doctrine relies on the customary practices of the medical profession as the benchmark of acceptable behavior” (quoting James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1384 (1994) (internal quotations marks omitted))).

⁵⁴ *Osborn v. Irwin Mem'l Blood Bank*, 7 Cal. Rptr. 2d 101, 128 (Ct. App. 1992) (“[P]rofessional prudence is defined by actual or accepted practice within the profession, rather than theories about what ‘should’ have been done.”); Peters, *supra* note 1, at 165.

⁵⁵ Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 492 (2002) (“[A] reasonable physician standard invites juries to impose their possibly unrealistic notions of what doctors should be able to accomplish, whereas a custom-based standard attempts to keep juries within the realistic bounds of actual medical practice.”).

⁵⁶ Bloche, *supra* note 27, at 290.

professional consensus on best medical practices.⁵⁷ In addition, there is growing recognition of the need to incorporate patients' idiosyncratic needs and preferences into legal standards of care.⁵⁸ These observations have coincided with gradual doctrinal evolution away from adherence to professional custom and toward more flexible assessments of physician behavior.⁵⁹ "Subjective ripples" traverse medical malpractice doctrine, highlighting the inadequacies of uniform, strictly objective legal standards of care.⁶⁰

Several jurisdictions have relaxed the custom-based standard by recognizing "two schools of thought" or "respectable minority" rules, which preclude liability if the defendant can show that physicians are divided over the appropriate treatment course and the defendant picked one of the acceptable options.⁶¹ Some courts require the plaintiff to show that a "considerable number" of physicians have adopted the defendant's choice, while others simply require that those in the minority be regarded as "respectable" by their peers; still others mandate both requirements.⁶² Other jurisdictions reject the "respectable minority" defense, reasoning that the propriety of taking a particular approach cannot be ascertained by determining whether other physicians follow that practice.⁶³

Courts sometimes allow "honest error in judgment" jury instructions, explaining that physicians who make reasonable treatment

⁵⁷ E. Haavi Morreim, *Medicine Meets Resource Limits: Restructuring the Legal Standard of Care*, 59 U. PITT. L. REV. 1, 18 (1997) ("Prevailing practice has been replaced by near chaos; what is customary depends on who is asked.").

⁵⁸ Jamie S. King & Benjamin Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 456 (2006) ("This evidence of regional treatment variations refutes both the legal assumption that all physicians *should* abide by a single standard of care, and the legal assumption that they *do*.").

⁵⁹ Peters, *supra* note 1, at 186–87 ("[V]ariability in patients, illnesses, and possible therapeutic response often will make the notion of an established custom a quaint fairy tale."); *see also* Mehlman, *supra* note 27, at 1230 (arguing that the medical profession is no longer entitled to the self-regulation that it enjoyed when courts routinely deferred to physician consensus to ascertain medical standards of care).

⁶⁰ *See* Joseph H. King, Jr., *Reconciling the Exercise of Judgment and the Objective Standard of Care in Medical Malpractice*, 52 OKLA. L. REV. 49, 50 (1999).

⁶¹ *See, e.g.,* DiFilippo v. Preston, 173 A.2d 333, 337 (Del. 1961) (finding that defendant's choice of one of two acceptable techniques was not negligence); Downer v. Veilleux, 322 A.2d 82, 87 (Me. 1974) ("[A] physician does not incur liability merely by electing to pursue one of several recognized courses of treatment."); Haase v. Garfinkel, 418 S.W.2d 108, 114 (Mo. 1967) (stating that there can be difference of opinion among competent physicians); Furey v. Thomas Jefferson Univ. Hosp., 472 A.2d 1083, 1089 (Pa. Super. Ct. 1984) ("[W]here competent medical authority is divided, a physician will not be liable if in the exercise of his judgment he followed a course of treatment supported by reputable, respectable, and reasonable medical experts."). *But see* Hood v. Phillips, 554 S.W.2d 160, 165 (Tex. 1977) (rejecting the "respectable minority" rule).

⁶² Morreim, *supra* note 57, at 22; *see also* Mastroianni, *supra* note 7, at 383 ("Just how many physicians or surgeons qualify as a respectable minority? The number is not specified, and jurisdictions vary in their standards.").

⁶³ *See, e.g.,* State Bd. of Med. Exam'rs v. McCroskey, 880 P.2d 1188, 1194–95 (Colo. 1994).

decisions should not be held liable for bad outcomes.⁶⁴ Some jurisdictions allow the honest error in judgment instruction only where more than one treatment choice meets the objective standard of care.⁶⁵ Other courts have decided that the simplest way to avoid introducing subjective considerations into ostensibly objective negligence criteria is to eliminate the error in judgment terminology altogether.⁶⁶ These courts reason that the instruction merely restates the need to prove negligence and might confuse the jury into wrongly believing that physicians are immune if they can show any good faith judgment.⁶⁷

In *Helling v. Carey*,⁶⁸ the Washington Supreme Court replaced a custom-based standard with a looser inquiry into what a reasonable physician would do under the circumstances.⁶⁹ While several courts have rejected *Helling*,⁷⁰ some jurisdictions have agreed with the *Helling* court's more flexible approach.⁷¹ Few state statutes explicitly define the standard of care by reference to professional custom, and a number of statutes describe it as that of reasonable members of the defendant's specialty. Even in states that purportedly endorse a customary standard of care, courts generally do not require quantitative proof of prevailing practices and instead allow qualitative expert testimony about appropriate care.⁷²

Some courts allow jury instructions stating that the physician must use her "best judgment" by relying on any superior knowledge or skill that she possesses, which might dictate a higher standard of care than

⁶⁴ See, e.g., *Capolino v. N.Y.C. Health & Hosps. Corp.*, 605 N.Y.S.2d 87, 88 (App. Div. 1993) (ordering new trial because "error in judgment" instructions were not given); see also *King*, *supra* note 60, at 59 (noting that variations of this instruction include qualifying phrases such as "mere," "honest," "good faith," or "bona fide").

⁶⁵ See, e.g., *Toth v. Cmty. Hosp. at Glen Cove*, 239 N.E.2d 368, 373 n.2 (N.Y. 1968); *Spadaccini v. Dolan*, 407 N.Y.S.2d 840, 845-46 (App. Div. 1978); *Christenson v. Munsen*, 867 P.2d 626, 634 (Wash. 1994) (en banc).

⁶⁶ *Currie v. United States*, 644 F. Supp. 1074 (M.D.N.C. 1986), *aff'd*, 836 F.2d 209 (4th Cir. 1987).

⁶⁷ See, e.g., *Shumaker v. Johnson*, 571 So. 2d 991, 994 (Ala. 1990); *Ouellette v. Subak*, 391 N.W.2d 810, 815 (Minn. 1986); *Wall v. Stout*, 311 S.E.2d 571, 577 (N.C. 1984); *Shamburger v. Behrens*, 380 N.W.2d 659, 663 (S.D. 1986).

⁶⁸ 519 P.2d 981 (Wash. 1974).

⁶⁹ *Id.* at 982-83 (reversing a jury verdict for the defendant and holding that defendant ophthalmologist's failure to test for glaucoma was negligent as a matter of law, despite complying with customary practice); see also *Harris v. Groth*, 663 P.2d 113, 116-18 (Wash. 1983) (stating that subsequent legislation codified the *Helling* court's reasonableness standard).

⁷⁰ RICHARD A. EPSTEIN, *TORTS*, § 6.2, at 141 (1999) (concluding that the consensus in favor of custom intensified after *Helling*).

⁷¹ *Peters*, *supra* note 1, at 171-72; see, e.g., *Nowatske v. Osterloh*, 543 N.W.2d 265, 271 (Wis. 1996) ("If what passes for customary or usual care lags behind developments in medical science, such care might be negligent, despite its customary nature.").

⁷² *Mehlman*, *supra* note 59, at 1184 ("No one conducts surveys or polls to use as evidence in malpractice cases, and expert witnesses who testify about what is customary are not required to, and do not, introduce such empirical evidence."); *Peters*, *supra* note 1, at 185.

that of the average reasonable practitioner.⁷³ Long before the advent of EBM, courts recognized the physician's duty to stay abreast of advances in medical practice.⁷⁴ More recent cases modify customary standards by requiring physicians to take into account scientific developments.⁷⁵ A few courts have expressly found physicians negligent for failing to keep up with the latest scientific findings. For example, in *Burton v. Brooklyn Doctors Hospital*,⁷⁶ the court found the defendant physician and hospital liable for liberally administering oxygen to a premature newborn in accordance with prevailing custom because several studies had found that high oxygen levels were unnecessary and dangerous.⁷⁷

Recognized exceptions to custom-based legal standards highlight fundamental problems with existing medical malpractice doctrine. The law begins with the premise that the physician should act according to prevailing practices, but courts hit a stumbling block when they acknowledge that medical knowledge rapidly advances over time. It logically follows that the law should require the reasonable physician to incorporate newly acquired information into her decisionmaking. But courts must grapple with the fact that deviations from prior practice introduce new risk-benefit tradeoffs, and that it takes time for outcomes data on new innovations to accumulate.⁷⁸ The decisional calculus becomes even more complex when patient heterogeneity is taken into account. Rigid, objective liability standards might compel physicians to avoid high-risk patients and eschew potentially beneficial new treatments that have yet to gain general acceptance within the medical community.⁷⁹

⁷³ King, *supra* note 60, at 54–55.

⁷⁴ See, e.g., *McCandless v. McWha*, 22 Pa. 261, 268 (1853) (“The standard of ordinary skill is on the advance; and he who would not be found wanting, must apply himself with all diligence to the most accredited sources of knowledge.”).

⁷⁵ Carter L. Williams, Note, *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) (offering examples of cases that articulate standards of care using this type of qualifying language).

⁷⁶ 452 N.Y.S.2d 875 (App. Div. 1982).

⁷⁷ *Id.* at 879–80.

⁷⁸ Amy Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine*, 23 J. LEGAL MED. 449, 485 (2002) (“Acceptance of new practice approaches engendered by new technology takes time . . .”); see also *Charell v. Gonzalez*, 660 N.Y.S.2d 665, 668 (Sup. Ct. 1997) (recognizing that “nonconventional” physician practices “may well necessitate a finding that the doctor who practices such medicine deviates from ‘accepted’ medical standards,” and adding, in dicta, that this problem perhaps could be solved “by having the patient execute a comprehensive consent containing appropriate information as to the risks involved”); *Hood v. Phillips*, 554 S.W.2d 160, 165 (Tex. 1977) (adopting a standard of care based on what a “reasonable . . . member of the medical profession would undertake under . . . similar circumstances,” and recognizing that physicians should be given appropriate latitude so that “medical science can provide greater benefits for humankind”).

⁷⁹ Jeffrey O’Connell & Andrew S. Boutros, *Treating Medical Malpractice Claims Under a Variant of the Business Judgment Rule*, 77 NOTRE DAME L. REV. 373, 394 (2002).

In the early 1990s, medical organizations aggressively lobbied to implement clinical practice guidelines that would create “safe harbors” from liability if physicians complied with the guidelines. John Wennberg and his colleagues at Dartmouth Medical School engaged in efforts to develop evidence-based CPGs to set legal standards of care, revealing wide variations in health services utilization rates across different geographic regions in the United States.⁸⁰ Policymakers attributed these variations to physicians’ uncertainty about appropriate treatments for particular conditions.⁸¹ Notably, the AMA refused to endorse the 1990s’ safe harbors initiative, citing concerns that encouraging strict adherence to CPGs would stifle innovation.⁸² Despite initial enthusiasm, the campaign failed miserably at both the state and national level and legal standards of care based on CPGs were never promulgated.⁸³

The Obama administration recently revived the CPG initiative, emboldened by the notion that an improved, more scientifically rigorous approach will overcome the problems that doomed earlier efforts.⁸⁴ The Patient Protection and Affordable Care Act⁸⁵ created the Center for Quality Improvement and Patient Safety, and requires the Secretary of Health and Human Services to identify and generate clinical

⁸⁰ See Clark C. Havighurst, *I’ve Seen Enough! My Life and Times in Health Care Law and Policy*, 14 HEALTH MATRIX 107, 121 (2004) (noting that the Dartmouth research team’s findings prompted “a campaign by organized medicine to reestablish its credibility and maintain its authority over medical practice by producing ‘clinical practice guidelines’”); John E. Wennberg, *The Paradox of Appropriate Care*, 258 JAMA 2568, 2569 (1987) (“The problem [of geographic variations in health care delivery rates] must be centered in the diversity of accepted opinion on the need and value of alternative treatments. If the clinicians in these academic strongholds do not know the scientifically correct way of practicing medicine, who else could know?”).

⁸¹ Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 649 (2001).

⁸² Edward B. Hirshfeld, *Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886, 2889 (1991) (noting that the AMA’s general counsel stated that “[p]hysicians might disagree with a legally adopted standard, or they might have an idea about a new way to handle a problem, but would not feel free to test their beliefs with research or in their practices. . . . That sense of restraint could make it more difficult for new ideas to emerge, be tested, and be accepted or rejected”).

⁸³ Mehlman, *supra* note 27, at 1167–68.

⁸⁴ *Id.* at 1168 (predicting that this most recent attempt to create and use clinical practice guidelines to set legal standards is likewise destined to fail). In 2010, the Agency for Healthcare Research and Quality (AHRQ) granted the Office for Oregon Health Policy and Research (OHPR) nearly \$300,000 to “develop and implement a method for setting priorities for developing evidence-based practice guidelines, craft a broadly supported safe harbor legislative proposal that will define the legal standard of care, and develop a plan to evaluate the effectiveness of the legislative proposal, if enacted.” *Medical Liability Reform and Patient Safety: Planning Grants*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/liability/planninggrants.html> (last reviewed June 2010).

⁸⁵ Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 26 and 42 U.S.C.).

guidelines and best practices.⁸⁶ But the goal of deriving comprehensive legal standards from exacting science is illusory.⁸⁷ Skeptics of these efforts note that the sheer number of CPGs is enormous,⁸⁸ CPGs often conflict with each other and with patients' expectations,⁸⁹ many CPGs lack scientific support⁹⁰ and are tainted by conflicts of interest,⁹¹ and those that are scientifically valid are based on generalities that provide limited guidance for the treatment of individual patients.⁹² Guidelines quickly become obsolete as evidence accumulates over time,⁹³ and risk discourages clinical innovation by ossifying standards of care.⁹⁴ Crucially, clinical trials that form the evidence base for CPGs inevitably depart from real-world conditions and cannot fully account for patient heterogeneity in treatment response and individuals' differing attitudes about risk.⁹⁵ Caveats to CPGs that enable physicians to customize treatment plans according to particular patients' needs and preferences

⁸⁶ Barry R. Furrow, *Regulating Patient Safety: The Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1727, 1740–42 (2011).

⁸⁷ Mehlman, *supra* note 27, at 1216 (“Even if there were general agreement on what counted as a valid evidentiary basis for guidelines, it is not clear that the clinical trials from which the evidence is supposed to be extracted are capable of providing the necessary knowledge.”).

⁸⁸ Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 418 (2002) (noting that more than 2000 guidelines exist).

⁸⁹ Morreim, *supra* note 57, at 6.

⁹⁰ E. Haavi Morreim, *From the Clinics to the Courts: The Role Evidence Should Play in Litigating Medical Care*, 26 J. HEALTH POL. POL’Y & L. 409, 422 (2001) (“CPGs abound, many of them with dubious scientific credentials.”).

⁹¹ Noah, *supra* note 88, at 422–24 (noting that CPGs may be tainted by the same conflicts of interest that permeate the underlying biomedical research literature).

⁹² Morreim, *supra* note 90, at 422 (stating that “even the best CPGs cannot possibly dictate each patient’s course of care” because “[t]hey are based on generalities that hold true on average, but have only limited room to accommodate the natural variations among individuals in any population”); see also Peter D. Jacobson, *Medical Liability and the Culture of Technology*, in *MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM* 123 (William M. Sage & Rogan Kersh eds., 2006) (“Given the physician judgment inherent in any clinical situation, the potential multiplicity of competing and conflicting guidelines, the usual lack of certainty inherent in the guidelines development process, and direct physician testimony, it is improbable that any guideline will suffice to set the standard of care.”).

⁹³ Mehlman, *supra* note 27, at 1219 (describing guidelines on the appropriateness of percutaneous coronary intervention (PCI) as an illustration of the staleness problem).

⁹⁴ Noah, *supra* note 88, at 425 (“[CPGs] may have the effect of freezing the standard of care, thereby discouraging further research and innovation in areas about which the experts have reached a consensus.”).

⁹⁵ John R. Hampton, *Guidelines—For the Obedience of Fools and the Guidance of Wise Men?*, 3 CLINICAL MED. 279 (2003) (“[G]uidelines inappropriately applied are the antithesis of the concept that a patient should be treated as an individual.”); Terrence M. Shaneyfelt, Michael F. Mayo-Smith & Johann Rothwangl, *Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature*, 281 JAMA 1900, 1904 (1999) (“Few guidelines (21.5%) . . . discussed the role of patient preferences in choosing among the various health care options. Given the increasing appreciation of the importance of patient values in many clinical decisions, we believe this factor has not been adequately addressed in guidelines to date.”).

undermine CPGs' capacity to set standards of care in medical malpractice cases.⁹⁶

2. Informed Consent Obligations

In addition to the duty to treat her patient with due care, a physician owes a separate duty to disclose to the patient material information about proposed medical interventions. Informed consent law is steeped in the rhetoric of patient autonomy, but the doctrine's practical application belies the concept of individualized choice. An informed consent doctrine truly grounded in autonomy would require a subjective disclosure standard that asks what the actual patient needs to know in order to make a medical decision. Yet physicians' disclosure obligations are generally set according to what either the "reasonable physician" or the "reasonable patient" would consider material.⁹⁷ All but two states apply an objective test of decision causation, which asks whether the hypothetical prudent patient would have made a different treatment decision had the patient been informed of an undisclosed material risk.⁹⁸ The prevailing objective tests for establishing liability for breach of disclosure duties run counter to principles of patient self-determination. By asking what an abstract reasonable patient would have done had the undisclosed information been revealed, the law robs the actual patient of the right to make an "unreasonable" decision.⁹⁹

⁹⁶ Mehlman, *supra* note 27, at 1218 ("Frequently, guidelines include loopholes in order to enable clinicians to practice individualized medicine, and... this makes adherence to the guideline essentially useless as a defense to malpractice.").

⁹⁷ About half of the states use a "reasonable physician" standard and about half use a "reasonable patient" standard. King & Moulton, *supra* note 58, at 430, 493 & app. A; see also Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOY. U. CHI. L.J. 557, 579-80 (2000) (arguing that informed consent doctrine should be expanded to take into account individual patients' subjective treatment goals).

⁹⁸ Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 918-19 (1994). In *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979), the Oklahoma Supreme Court adopted a subjective patient-based disclosure standard that asks what the actual patient would want to know before making a medical decision. Two years later, the Oklahoma Supreme Court reined in the *Bradford* decision by applying a subjective patient-based standard but showing considerable deference to physician judgment. See *Masquat v. Maguire*, 638 P.2d 1105, 1106-07 (Okla. 1981). Similarly, while Oregon has adopted a subjective disclosure standard, courts applying that standard do so in a way that protects physicians from post-hoc patient bitterness and recriminations. See, e.g., *Arena v. Gingrich*, 733 P.2d 75, 79 (Or. Ct. App. 1987) ("[T]hat the test is subjective does not mean . . . that the only permissible determinants are the plaintiff's testimony and other evidence that pertains directly to the plaintiff's subjective choice.").

⁹⁹ Roger B. Dworkin, *Medical Law and Ethics in the Post-Autonomy Age*, 68 IND. L.J. 727, 729-30 (1993) ("The loss of dignity, autonomy, free choice, and bodily integrity that is so exalted in the rhetoric of informed consent is worth nothing at judgment time."); Schuck, *supra* note 98, at 957-58 ("The existing [informed consent] doctrine, then, suffers from an ironic, if endemic, vice: it deprives patients of choice in the name of choice."); see also Gatter, *supra* note 97, at 579-

While physicians may have *ethical* duties to tailor disclosure to the particular needs and desires of individuals, the tort liability regime does not impose individually tailored *legal* disclosure obligations.¹⁰⁰

Empirical studies reveal that objective disclosure standards ignore significant patient variation in decisionmaking preferences. Most patients wish to be informed about their clinical situations, but patients differ in their desire for decisional authority. Some patients prefer to defer to their physician's best judgment while others prefer to take a more active role.¹⁰¹ For example, a Canadian study of newly diagnosed cancer patients showed that 63% of them preferred that the physician take primary responsibility for decisionmaking, 27% preferred to share decisionmaking authority with the physician, and 10% of the patients felt they should have primary decisionmaking responsibility.¹⁰²

Patient autonomy concerns intensify when the optimal treatment option is uncertain and implicates personal values and preferences.¹⁰³ Commentators have suggested that informed consent requirements be adapted to fit different decisionmaking scenarios.¹⁰⁴ They advocate a sliding-scale approach that takes into account the magnitude of the clinical decision and the degree of uncertainty about risks and benefits. For example, it has been suggested that informed consent be eliminated altogether for relatively minor decisions involving conditions with known safe and effective treatments, such as the common cold. On the other hand, conditions such as cancer, which involve dire prognoses and treatments with serious side effects, might require an extensive informed consent process.¹⁰⁵

A physician generally does not have a duty to disclose an unknown material risk if she is reasonably unaware of its existence.¹⁰⁶ But compliance with disclosure obligations does not immunize a physician from tort liability.¹⁰⁷ Adequately informed patients retain the right to

80 (arguing that informed consent doctrine should be expanded to take into account individual patients' subjective treatment goals).

¹⁰⁰ Dworkin, *supra* note 99, at 741 & n.69 (concluding that an individualized standard is unworkable for establishing physicians' legal—as opposed to ethical—obligations, and suggesting that the tort of failure to obtain informed consent be abolished altogether).

¹⁰¹ Schneider, *supra* note 37, at 1090–103 (summarizing empirical studies of patient preferences).

¹⁰² *Id.* at 1095.

¹⁰³ Shultz, *supra* note 36, at 257, 272 (using the term “heightened electiveness” to describe medical activities that should be guided by patient preferences, and concluding that “uncertainty and diversity of medical opinion necessarily turn much of medical decision-making into an exercise in electiveness”).

¹⁰⁴ See, e.g., Schuck, *supra* note 98, at 955 (arguing, for example, that the law should more readily impute informed consent in the case of mass vaccination than in the case of elective cosmetic surgery).

¹⁰⁵ Katz, *supra* note 23, at 221–23.

¹⁰⁶ E.g., *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 360 (Iowa 1987).

¹⁰⁷ Dworkin, *supra* note 99, at 729.

claim that the physician's judgment and clinical performance failed to meet professional standards of care.¹⁰⁸ For example, a surgeon who satisfies her disclosure duty to inform her patient about the known risks of a surgical procedure can still be found negligent for her decision to perform the surgery or in the actual performance of the procedure.¹⁰⁹ Conversely, an informed consent claim can succeed even if the defendant follows the standard of care in delivering treatment.¹¹⁰

In an editorial in the *Journal of the American Medical Association*, a physician offered his personal account as a defendant in a malpractice case to illustrate the impossible dilemmas that this legal scheme creates.¹¹¹ The physician testified at trial that, after explaining to his patient the risks and benefits of the prostate specific antigen (PSA) test, his patient declined the test.¹¹² The patient later visited another doctor, who performed the PSA test without discussing with the patient the decision to screen for cancer.¹¹³ When the patient learned that he had an elevated PSA caused by advanced-stage prostate cancer, he sued and won his case against the author's residency program, aided by expert testimony that the standard of care is to perform the PSA test without consulting the patient.¹¹⁴ The jury verdict greatly surprised the defendant physician, given the fact that practice guidelines established by the American Academy of Family Physicians, the American Urological Association, and the American Cancer Society all recommended that physicians discuss the risks and benefits of PSA screening with patients.¹¹⁵

Courts generally resist physicians' and patients' efforts to avoid these problems by contracting around default tort standards.¹¹⁶ Citing public policy concerns about patient vulnerability and diminished

¹⁰⁸ Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 370 (2002) ("Informed consent generally does not, however, amount to an express waiver of the right to sue for medical malpractice. Full disclosure by physicians only satisfies their duty to warn and does not extinguish their separate obligation to provide care of a type and in a manner that accords with the standards of the profession." (footnote omitted)).

¹⁰⁹ Mastroianni, *supra* note 7, at 393; *see, e.g.*, *Burnet v. Spokane Ambulance*, 772 P.2d 1027, 1030 (Wash. Ct. App. 1989) (noting that informed consent claims and claims alleging failure to meet the standard of care are alternative bases of liability).

¹¹⁰ *See, e.g.*, *Backlund v. Univ. of Wash.*, 975 P.2d 950, 950 (Wash. 1999) (en banc) (holding that a jury's finding that the physician followed the standard of care does not preclude liability under the informed consent statute).

¹¹¹ Daniel Merenstein, *Winners and Losers*, 291 JAMA 15, 15-16 (2004).

¹¹² *Id.* at 15.

¹¹³ *Id.*

¹¹⁴ *Id.* at 15-16.

¹¹⁵ *Id.*

¹¹⁶ *See* Parchomovsky & Stein, *supra* note 9, at 302-03 ("In theory, then, in the context of medical malpractice, custom constitutes a default rule around which the parties can contract. . . . In practice, however, overcoming custom is a much more difficult and costly task than it initially appears.").

capacity, courts typically strike down patients' express waivers of health care providers' liability, even where the patient makes a conscious choice to accept the risk of known dangers.¹¹⁷ They tend to be even more hostile to the defense of implied assumption of risk, where defendants argue that the plaintiff's consent to risk is implicit in the parties' consensual interactions.¹¹⁸ This practice subtly undermines the rationale behind the informed consent doctrine, as it implies that patients are summarily incapable of making rational choices about uncertain treatments.

In recent years, a group of medical and legal scholars have advocated revising informed consent practices to incorporate shared medical decisionmaking. Under a shared decisionmaking model, the physician shares with the patient relevant risks and benefits of alternative treatments, the patient shares with the physician relevant personal information that may make one alternative preferable over another, and both parties come to a mutual decision.¹¹⁹ Critics of shared medical decisionmaking argue that this collaborative model is prohibitively costly and time-consuming, and that patients cannot and wish not to actively participate in clinical decisions.¹²⁰ Empirical studies suggest that physicians are reluctant to incorporate shared decisionmaking into their practices.¹²¹

¹¹⁷ See, e.g., *Tunkl v. Regents of the Univ. of Cal.*, 383 P.2d 441, 447–48 (Cal. 1963) (invalidating a waiver clause in a hospital admission form because, *inter alia*, the form was an adhesion contract that did not permit patients to elect to pay more for greater risk protection, and the hospital could control the risk of patient harm); *Emory Univ. v. Porubiansky*, 282 S.E.2d 903 (Ga. 1981) (holding that a liability waiver did not relieve a dental clinic of the duty of reasonable care); *Cudnik v. William Beaumont Hosp.*, 525 N.W.2d 891, 896 (Mich. Ct. App. 1994); *Ash v. N.Y. Univ. Dental Ctr.*, 564 N.Y.S.2d 308 (App. Div. 1990) (invalidating an agreement whereby a dental patient agreed to waive tort claims in exchange for care provided by dental students at half price); *Olson v. Molzen*, 558 S.W.2d 429, 432 (Tenn. 1977); *Sosa v. Paulos*, 924 P.2d 357, 363 (Utah 1996).

¹¹⁸ The modern trend is to merge the doctrines of implied assumption of risk and comparative fault so that any recognized consent to risk would merely reduce the plaintiff's damages rather than completely immunize the defendant. Schuck, *supra* note 98, at 911–12; see, e.g., *Brown v. Dibbell*, 595 N.W.2d 358, 367–68 (Wis. 1999) (stating that a patient's contributory negligence can, under some circumstances, be a defense to an informed consent claim, but underscoring that “the very patient-doctor relation assumes trust and confidence on the part of the patient and that it would require an unusual set of facts to render a patient guilty of contributory negligence when the patient relies on the doctor”).

¹¹⁹ King & Moulton, *supra* note 58, at 431; see also Robert M. Kaplan, *Shared Medical Decision-Making: A New Tool for Preventative Medicine*, 26 AM. J. PREVENTIVE MED. 81, 81 (2003).

¹²⁰ King & Moulton, *supra* note 58, at 431 (“[Critics assert] that shared decision-making will take too much time in today’s rushed medical practice, that implementation will place unbearable financial strain on the already overburdened medical system, that physicians do not have the support and resources to provide all the evidence, and that patients do not understand or want the information.”).

¹²¹ See Andrew S. Dunn et al., *Physician-Patient Discussions of Controversial Cancer Screening Tests*, 20 AM. J. PREVENTIVE MED. 130, 133 (2001) (finding that many physicians decide whether or not to screen their patients for breast and prostate cancer without involving patients in the decision); Steven H. Woolf & Alex Krist, *The Liability of Giving Patients a Choice: Shared*

Real world consent procedures fall well short of informed consent law “in books.”¹²² Physician-patient interactions tend to involve cursory assertions of physician control rather than the collaborative discussions envisioned by proponents of shared decisionmaking.¹²³ State legislatures’ repeated attempts to mandate statutory informed consent requirements suggest that the existing legal regime is ineffective. For example, fourteen states have passed laws specifically requiring physicians to disclose to patients the risk-benefit tradeoffs of mastectomy versus lumpectomy. The fact that lawmakers perceived a need to compel such disclosure indicates that prevailing legal standards fail to ensure that patients receive the information that they need to make decisions about preference-sensitive care.¹²⁴

These observations do not prove medical malpractice law’s inability to influence physicians’ behavior. Rather, they demonstrate physicians’ rational response to the existing legal regime. In sum, current doctrine holds that physicians have disclosure duties, but sets objective standards for assessing liability that discourage physicians from tailoring informed consent to individual patients’ needs and preferences. Additionally, while physicians may be held liable for failing to disclose material risks, most courts decline to shield physicians from liability even where patients are fully informed about a medical intervention’s risks and benefits. Physicians understandably respond to this legal scheme by viewing informed consent as a practically meaningless bureaucratic chore.

II. BLURRED LINES BETWEEN MEDICAL EXPERIMENTATION, CLINICAL INNOVATION, AND STANDARD TREATMENT

A. *Research vs. Practice*

The problem of regulating decisionmaking in a manner that both promotes patient welfare and respects patient autonomy is particularly acute when physicians deliberately depart from generally accepted practices in efforts to advance medical progress. Such efforts exacerbate uncertainty and raise legal questions about when physician behavior

Decision-Making and Prostate Cancer, 71 AM. FAM. PHYSICIAN 1871, 1871 (2005) (stating that shared decisionmaking rarely occurs in practice despite consensus among medical organizations on the benefits of this approach).

¹²² Schuck, *supra* note 98, at 932–34.

¹²³ *Id.* (“(1) most physician-patient discussions appear to be rather perfunctory and reinforce physician control; (2) the treatment context discourages patients from exploiting that information that physicians do provide; and (3) the nature of the tort system makes it difficult to establish an effective legal claim.”).

¹²⁴ King & Moulton, *supra* note 58, at 460–61.

crosses the line from practice into research. The highly influential Belmont Report published by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979 sought to draw clear distinctions between the two activities. The Belmont Report defines medical practice as activities designed to benefit a specific patient and having a reasonable probability of success. It further defines research as systematic protocols designed to test a scientific hypothesis in order to produce generalizable knowledge.¹²⁵ Differing objectives thus mark the line between practice and research. The goal of medical practice is to further individual patients' best interests, while the goal of research is to increase social welfare by generating scientific data.¹²⁶

This distinction is crucial, because medical research is highly regulated while medical practice is subject to comparatively little regulation. The Common Rule is the umbrella term for the set of federal regulations that governs most clinical research conducted in the United States.¹²⁷ With few exceptions, all new research protocols must be screened by an IRB, which evaluates both the informed consent process and the protocol's substantive risks and benefits.¹²⁸ By contrast, physicians who treat patients using innovative techniques face scant regulation of their activities.¹²⁹ While manufacturers of new drugs and devices must extensively test their products to generate safety and efficacy data and obtain FDA approval prior to bringing them to market, physicians typically face no such regulatory barriers.¹³⁰ FDA

¹²⁵ T.L. Beauchamp, *The Mis(Use) of Informed Consent in Medical Research*, 269 J. INTERNAL MED. 383, 383–84 (2011).

¹²⁶ See, e.g., *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875 (App. Div. 1982) (affirming a judgment for medical malpractice and failure to secure informed consent and stressing the fact that the physician researcher overrode the attending physician's customized treatment plan and failed to individually monitor the patient's clinical course).

¹²⁷ The Common Rule was published in the Federal Register. See 56 Fed. Reg. 28,012 (June 18, 1991) (codified at 45 C.F.R. § 46 (2014) (Department of Health and Human Services regulations) and 21 C.F.R. §§ 50, 56 (2014) (FDA regulations)); see also FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS, *supra* note 6, at 1576 (noting the Common Rule applies to research funded by, conducted by, or otherwise regulated by various federal agencies).

¹²⁸ Barbara A. Noah, *Bioethical Malpractice: Risk and Responsibility in Human Research*, 7 J. HEALTH CARE L. & POL'Y 175, 184–87 (2004).

¹²⁹ See Michael J. Strauss, *The Political History of the Artificial Heart*, 310 NEW ENG. J. MED. 332, 335–36 (1984); Mark R. Tonelli et al., *Clinical Experimentation: Lessons from Lung Volume Reduction Surgery*, 110 CHEST 230, 232–37 (1996); see also Mastroianni, *supra* note 7, at 366 (“The formal, systematic, highly regulated environment surrounding the testing of new drugs for safety and efficacy before they are ever prescribed to patients stands in stark contrast to the highly unregulated environment and variable approaches to establishing safety and efficacy in surgical innovation.”).

¹³⁰ See Thomas Necheles, *Standards of Medical Care: How Does an Innovative Medical Procedure Become Accepted?*, 10 LAW MED. & HEALTH CARE 15, 17 (1982) (“The FDA has long been accepted as the arbiter of the safety and effectiveness of drugs. No such arbiter exists in the field of innovative medical procedures.”). Occasionally, and controversially, the FDA has asserted

regulations reflect Congress's clear position that the FDA lacks regulatory authority to interfere with the practice of medicine.¹³¹

A significant amount of medical activity does not comfortably fit into either of the two categories delineated in the Belmont Report. Clinical care may satisfy the first element of the "practice" definition, but fail to satisfy the criterion that the intervention have a reasonable probability of success. At the same time, it may not meet the strict definition of medical research, because a physician who merely aims to draw general conclusions from her experiences treating patients does not perform medical research as defined by federal regulations.¹³² The National Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended "that significant innovations in therapy should be incorporated into a research project *in order to establish their safety and efficacy while retaining the therapeutic objectives.*"¹³³ Perhaps tacitly recognizing the difficulties of meeting these twin goals, federal and state policymakers never acted to fill this regulatory gap.

The line between research and practice can be quite thin. For example, repeated use of an innovative procedure followed by retrospective review of clinical outcomes using that procedure, while not technically research under federal guidelines, encompasses many of the features of a formal clinical trial.¹³⁴ Studies show that even IRBs and scientific experts have difficulty distinguishing between experimentation and clinical innovation.¹³⁵ Patients, referring physicians, IRBs, and researchers often fall prey to the "therapeutic misconception" that clinical research offers a reasonable potential for direct benefit to subjects.¹³⁶ Physicians have even been sued for malpractice for failing to

jurisdiction over certain types of medical procedures. See, e.g., Rick Weiss, *FDA to Regulate Certain Fertilization Procedures*, WASH. POST, July 11, 2001, at A2.

¹³¹ See 21 C.F.R. § 312.2(d) (2014) (explaining that the FDA's investigational new drug requirements "do[] not apply to the use in the practice of medicine for an unlabeled indication of [an approved] new drug"); Legal Status of Approved Labeling of Prescription Drugs, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972) ("[I]t is clear that Congress did not intend the [FDA] to regulate or interfere with the practice of medicine . . .").

¹³² 45 C.F.R. § 46.101(b)(4) (2014).

¹³³ See ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 4 (2d ed. 1988) (emphasis added) (quoting R.J. Levine, *The Impact on Fetal Research of the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 22 VILL. L. REV. 367, 380 (1977)).

¹³⁴ E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1, 62 (2003).

¹³⁵ Johane Patenaude et al., *Evaluation of Clinical Innovation: A Gray Zone in the Ethics of Modern Clinical Practice?*, 23 J. GEN. INTERNAL MED. 27, 28-30 (2008) (describing the results of a study showing substantial variation among IRBs and laboratory medicine specialists over the categorization of new medical procedures).

¹³⁶ Nancy M.P. King, *Defining and Describing Benefit Appropriately in Clinical Trials*, 28 J.L. MED. & ETHICS 332, 332 (2000).

prescribe an investigational drug not yet approved by the FDA.¹³⁷ Conversely, physicians have described the trial-and-error process of adjusting patients' therapies to fit their individual conditions as a randomized controlled trial with a sample size (N) of one.¹³⁸

The advent of laparoscopic cholecystectomy¹³⁹ in the 1980s and 1990s exemplifies the ambiguities between research and practice. The procedure initially evaded IRB review because it did not meet the definition of research under federal regulations.¹⁴⁰ Surgeons and insurers did not view the procedure as experimental, despite its untested status, because it was offered outside the context of a formal trial in order to benefit individual patients.¹⁴¹ Randomized controlled trials (RCTs) eventually were performed, but they failed to detect critical injuries, and study results were not reported until several years after the procedure had become a common surgical practice.¹⁴²

*Ancheff v. Hartford Hospital*¹⁴³ illustrates the blurred line between research and practice that courts confront when assessing the bounds of healthcare providers' legal disclosure obligations. The plaintiff alleged that the hospital had failed to inform him that he was a participant in a clinical trial and that his treatment course with the drug gentamicin was experimental in nature.¹⁴⁴ The plaintiff produced evidence show that, in 1993, Hartford Hospital was the only hospital in the country that provided a level dose of seven milligrams per kilogram of body weight rather than the conventional FDA-approved dose of three milligrams per kilogram.¹⁴⁵ Additionally, the hospital had instituted a protocol mandating that pharmacists change all gentamicin prescriptions written by treating physicians to the seven-milligrams/kilogram dosage, and it

¹³⁷ See *Bridges v. Shelby Women's Clinic*, 323 S.E.2d 372, 374–76 (N.C. Ct. App. 1984) (alleging malpractice for failure to prescribe the unapproved drug terbutaline); see also *Bell v. Maricopa Med. Ctr.*, 755 P.2d 1180 (Ariz. Ct. App. 1988) (same).

¹³⁸ See Gordan Guyatt et al., *Determining Optimal Therapy—Randomized Trials in Individual Patients*, 314 NEW ENG. J. MED. 889 (1986); Gordan H. Guyatt et al., *The n-of-1 Randomized Controlled Trial: Clinical Usefulness*, 112 ANNALS INTERNAL MED. 293, 297–98 (1990); Les Irwig et al., *Ethics of n-of-1 Trials*, 345 LANCET 469 (1995) (arguing that n-of-1 trials do not need regulatory approval). Some physicians volunteer themselves to be test subjects for new therapeutic interventions. DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING 26 (1991) (describing a tradition among physicians of first testing new therapies on themselves).

¹³⁹ Laparoscopic cholecystectomy is a less invasive alternative to open gallbladder surgery, which involves a large surgical cut.

¹⁴⁰ 45 C.F.R. § 46.101(b)(4) (2014).

¹⁴¹ Mastroianni, *supra* note 7, at 423–33.

¹⁴² *Id.* (reviewing medical malpractice cases involving surgeons' use of the procedure and concluding that "this review does not reveal any guidance on how to properly address the very early development of a surgical technique, and how to ensure that patients are properly protected and informed of their participation in the development of a surgical innovation").

¹⁴³ 799 A.2d 1067 (Conn. 2002).

¹⁴⁴ *Id.* at 1069.

¹⁴⁵ *Id.* at 1070–71.

routinely collected data on each patient.¹⁴⁶ The Connecticut Supreme Court ultimately reserved to the jury the determination of whether the gentamicin program constituted research, concluding that the Belmont Report offered insufficient guidance.¹⁴⁷

B. *Standard vs. Innovative Care*

Just as the line between research and practice is blurred, so too is the line between standard and innovative care. A physician provides standard treatment when she uses routine methods to treat patients, and she provides innovative treatment when she deliberately deviates from established practices in an attempt to improve patient outcomes.¹⁴⁸ Some commentators describe clinical innovation as an intermediate category between research and routine practice.¹⁴⁹ But the boundaries between these categories of medical activity are increasingly difficult to discern. Clinical interventions occur on a continuum of medical uncertainty and cannot be neatly fit into discrete categories.

Regulatory status does not provide a clear line between standard and innovative uses of medical products.¹⁵⁰ Questions about the safety and efficacy of FDA-approved uses of medical products persist long after their entry onto the market.¹⁵¹ Moreover, the FDA has explicitly endorsed physicians' "off-label" uses of medical products to treat patients in ways that the agency has not reviewed and approved.¹⁵² For example, physicians may select a different route of administration than that listed in the label, prescribe a drug for a patient who differs from the subject population used to test its safety and efficacy, or modify

¹⁴⁶ *Id.* at 1071.

¹⁴⁷ *Id.* at 1079–80 (upholding the trial court's exclusion of the Belmont Report because it was more prejudicial than probative).

¹⁴⁸ Morreim, *supra* note 134, at 14–15.

¹⁴⁹ See Dale H. Cowan & Eva Bertsch, *Innovative Therapy: The Responsibility of Hospitals*, 5 J. LEGAL MED. 219, 251 ("Innovative therapies or non-validated practices occupy a gray zone of medical activities between standard medical practices and activities that are properly defined as research."); Stanley Joel Reiser, *Criteria for Standard Versus Experimental Therapy*, 13 HEALTH AFF. 127, 127 (1994) (describing the oscillation between research and treatment, and proposing "crossover therapy" as an intermediate category); see also Nancy M.P. King, *The Line Between Clinical Innovation and Human Experimentation*, 32 SETON HALL L. REV. 573 (2002).

¹⁵⁰ Noah, *supra* note 108, at 394 ("One common misconception is that FDA approval of a medical technology represents the point at which it crosses the line from experimental to standard therapy. . . . The issuance of a product license does not magically transform an investigational medical technology into one that has matured fully and requires no additional scrutiny." (footnote omitted)).

¹⁵¹ Laakmann, *supra* note 29, at 328–29.

¹⁵² *Use of Approved Drugs for Unlabeled Indications*, FDA DRUG BULL. 4–5 (1982) ("Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovation . . .").

dosage amounts or schedules.¹⁵³ Perhaps most importantly, a physician may prescribe a drug to treat a disease or condition for which it has not been tested for safety and efficacy.¹⁵⁴ Off-label prescribing is a widespread, generally accepted clinical practice.¹⁵⁵ Although it is particularly prevalent in the fields of oncology and pediatrics,¹⁵⁶ off-label use is frequent across a broad range of medical specialties.¹⁵⁷ In some cases, off-label use constitutes the standard of care.¹⁵⁸

C. Hazy Tort Liability Rules for Innovative Physicians

1. Limited “Clinical Innovation” Defense

Absent clear regulatory guidance, the task of policing physician innovation has largely fallen to the tort system. Through the early 20th century, courts viewed any deviation from generally accepted practices as grounds for a malpractice claim.¹⁵⁹ In 1935, the Michigan Supreme Court departed from this strict approach in holding that clinical innovation was proper so long as procedural and substantive requirements were met:

We recognize the fact that, if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments *must be done with the knowledge and consent of the patient or those responsible for him,*

¹⁵³ Noah, *supra* note 108, at 397–98.

¹⁵⁴ *Id.* at 398.

¹⁵⁵ See James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 76 nn.55–56 (1998) (citing several cases and statutes recognizing the propriety of off-label use in various contexts).

¹⁵⁶ See Michael Soares, “Off-Label” *Indications for Oncology Drug Use and Drug Compendia: History and Current Status*, 1 J. ONCOLOGY PRAC. 102, 104 (2005); see also Am. Acad. of Pediatrics Comm. on Drugs, *Uses of Drugs Not Described in the Package Insert (Off-Label Uses)*, 110 PEDIATRICS 181, 181 (2002).

¹⁵⁷ David C. Radley et al., *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1025 (2006) (estimating that twenty-one percent of all prescriptions are for off-label uses); Fran Kritz, *FDA Seeks to Add Drugs’ New Uses to Labels*, WASH. POST, Mar. 29, 1994, at Z11 (citing an AMA official’s estimate that off-label uses comprise 40–60% of all prescriptions written annually); see also Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 193 (1999).

¹⁵⁸ See, e.g., *Gajewsky v. Ning*, 997 So. 2d 567, 570–71 (La. Ct. App. 2008) (affirming defense verdict in medical malpractice case based on testimony that off-label use was the standard of care), *writ denied*, 998 So. 2d 723 (La. 2009).

¹⁵⁹ See, e.g., *Carpenter v. Blake*, 60 Barb. 488, 491 (N.Y. Gen. Term. 1871) (“[W]hen the case is one as to which a system of treatment has been followed for a long time, there should be no departure from it, unless the surgeon who does it is prepared to take the risk of establishing, by his success, the propriety and safety of his experiment.”).

and *must not vary too radically from the accepted method of procedure*.¹⁶⁰

Since this landmark ruling, courts and legislators have struggled to define the boundaries of legally permissible innovative care.

Some courts have recognized a limited “clinical innovation” defense to malpractice claims alleging failures to adhere to prevailing practices.¹⁶¹ Innovative physicians may avoid liability if the patient is suffering from a life-threatening condition, no alternative therapy is available, and the patient understands that the offered treatment is unproven and the risks are unknown. For example, in *Karp v. Cooley*,¹⁶² the defendant physician was found not liable for injuries stemming from the first-ever use of a mechanical heart implant.¹⁶³ Conversely, in *Pernia v. Trail*,¹⁶⁴ a Louisiana court rejected the plaintiff’s claim that the law required that the physician innovate rather than use the “textbook” approach to treating the patient’s condition.¹⁶⁵

2. Heightened Disclosure Duties

Physicians who recommend innovative care are subject to heightened disclosure duties.¹⁶⁶ Courts have held that the novel or investigational nature of a medical intervention is a material fact that physicians must disclose, even if used outside the context of a formal clinical trial.¹⁶⁷ However, a physician generally is not required to discuss experimental or innovative alternatives that are not selected or recommended.¹⁶⁸ A few courts have held that the absence of FDA

¹⁶⁰ Fortner v. Koch, 261 N.W. 762, 765 (Mich. 1935) (emphasis added).

¹⁶¹ See, e.g., Brook v. St. John’s Hickey Mem’l Hosp., 380 N.E.2d 72, 75–76 (Ind. 1978) (“A physician is presumed to have the knowledge and skill necessary to use some innovation to fit the peculiar circumstances of each case.”); see also Fiorentino v. Wenger, 227 N.E.2d 296, 300–01 (N.Y. 1967) (declining to hold a hospital liable for an independent physician’s failure to secure informed consent for radical spinal surgery, and reasoning that to rule otherwise might discourage the performance of novel procedures).

¹⁶² 493 F.2d 408 (5th Cir. 1974).

¹⁶³ *Id.* at 411, 419–26 (affirming the district court’s holding that, *inter alia*, the evidence did not warrant submission to the jury on issues of negligence in the performance of the procedure, negligence based on human experimentation, or lack of informed consent).

¹⁶⁴ 519 So. 2d 231, 233–35 (La. Ct. App. 1988).

¹⁶⁵ *Id.* at 233–35 (rejecting the plaintiff’s claim that the defendant surgeon negligently failed to perform an experimental horizontal incision during the plaintiff’s operation).

¹⁶⁶ See Noah, *supra* note 108, at 361 (arguing that the blurred line between experimentation and treatment challenges the conventional wisdom that disclosure rules should differ in the research and practice settings).

¹⁶⁷ See, e.g., Estrada v. Jaques, 321 S.E.2d 240, 254 (N.C. Ct. App. 1984) (holding that the experimental nature of a novel surgical procedure must be disclosed during the informed consent process); Morreim, *supra* note 134, at 61 & n.290.

¹⁶⁸ See, e.g., Moore v. Baker, 989 F.2d 1129, 1133 (11th Cir. 1993) (holding that a physician does not have a duty to inform a patient about chelation therapy as an alternative to carotid

approval for an off-label use might itself be material information that a physician is obligated to disclose to a patient.¹⁶⁹ Other courts and commentators reject the notion physicians' disclosure duties extend to revealing a medical product's regulatory status.¹⁷⁰

Courts are divided on the extent to which physicians must disclose to patients their own lack of knowledge of the risks and benefits of innovative interventions. In *Estrada v. Jaques*,¹⁷¹ a North Carolina court held that physicians have a duty to disclose both "known risks for established procedures" and "uncertainty regarding the risks associated with experimental procedures."¹⁷² The Ninth Circuit, in *Goodman v. United States*,¹⁷³ adopted a different stance. In that case, the plaintiff sued the United States under the Federal Tort Claims Act (FTCA) after his wife allegedly died from a toxic reaction to a product used in an investigational surgical procedure performed at the National Institutes of Health (NIH).¹⁷⁴ Applying Maryland law on informed consent, the court held that the NIH physicians were not obligated to warn the patient of "an unperceived risk of which they reasonably were not aware."¹⁷⁵ The court further held that the NIH was not obligated to supplement its informed consent form to disclose that three previous patients had experienced complications when they underwent the same procedure, reasoning that such an obligation would be unduly onerous.¹⁷⁶

A few courts have departed from prevailing informed consent doctrine to legally enforce patients' actual choices in cases involving preference-sensitive care. In *Zalazar v. Vercimak*,¹⁷⁷ an Illinois appellate court refused to apply an objective, "reasonable [patient]" disclosure standard in a case involving elective cosmetic surgery, reasoning that the

endarterectomy surgery, where evidence showed that the medical community did not recognize chelation therapy as a practical alternative).

¹⁶⁹ See, e.g., *Corrigan v. Methodist Hosp.*, 869 F. Supp. 1202, 1207 (E.D. Pa. 1994) (adding that punitive damages might be available); *Retkwa v. Orentreich*, 584 N.Y.S.2d 710, 712-13 (Sup. Ct. 1992); *Shadrick v. Coker*, 963 S.W.2d 726, 729-37 (Tenn. 1998) (reversing summary judgment granted to a physician who allegedly failed to inform the patient that the FDA had not approved the use of pedicle screws in spinal surgery).

¹⁷⁰ See, e.g., *Klein v. Biscup*, 673 N.E.2d 225, 231 (Ohio Ct. App. 1996) ("Off-label use of a medical device is not a material risk inherently involved in a proposed therapy which a physician should disclose to a patient prior to therapy."); Beck & Azari, *supra* note 155, at 72 (arguing that physicians should have no legal or ethical obligations to disclose medical products' regulatory status).

¹⁷¹ 321 S.E.2d 240 (N.C. Ct. App. 1984).

¹⁷² *Id.* at 254.

¹⁷³ 298 F.3d 1048 (9th Cir. 2002).

¹⁷⁴ *Id.* at 1050-51.

¹⁷⁵ *Id.* at 1058.

¹⁷⁶ *Id.* ("To hold that the signed consent form was inadequate would require the NIH to update its already detailed [informed] consent form every time a patient experiences any sort of complication from an experimental procedure.").

¹⁷⁷ 633 N.E.2d 1223 (Ill. App. Ct. 1993).

choice to undergo the procedure was a highly personal one that only the patient could make.¹⁷⁸ The Wisconsin Supreme Court similarly rejected an objective causation standard in *Schreiber v. Physicians Insurance Co. of Wisconsin*,¹⁷⁹ a case in which the patient made an express choice to have a cesarean section rather than deliver vaginally.¹⁸⁰ The court concluded, “[a]pplying the objective test to a case such as this would result in the evisceration of [the patient’s] actually expressed and understood choice of treatment in favor of what the hypothetical reasonable person would have chosen.”¹⁸¹

Arguably, the same reasoning should compel courts to recognize an assumption of risk defense where a fully informed patient consents to innovative care. Yet unequal bargaining power and information asymmetries between patients and physicians raise concerns about immunizing physicians from liability so long as they meet disclosure obligations. Most courts have rejected assumption of risk as a defense in cases involving deviations from customary care.¹⁸² Two notable exceptions involve separate actions against the same physician defendant, where the Second Circuit applied New York law to recognize assumption of risk as a valid defense to liability for alleged harm resulting from the decision to pursue unconventional cancer treatment.¹⁸³ The court stressed that the patient had signed a consent form disclosing that the FDA had not approved the treatment she would receive.¹⁸⁴ Additionally, the patient repeatedly rejected the physician’s recommendations that she have her tumor surgically removed after it became apparent that the physician’s unorthodox treatment was not working.¹⁸⁵

In *Dennis v. Jones*,¹⁸⁶ the Court of Appeals of the District of Columbia noted that, “[b]ecause of the disparity in knowledge between

¹⁷⁸ *Id.* at 1224 (“We believe no expert or other third party could possibly assert how a reasonable person in the plaintiff’s position would have weighed the risks and complications of the surgery, and whether such individual would have decided against or gone ahead with the four-lid blepharoplasty had the proper disclosures been made . . .”).

¹⁷⁹ 588 N.W.2d 26 (Wis. 1999).

¹⁸⁰ *Id.* at 34 (“It can lead to absurd results when the known and concrete choice of the actual person may well be ignored if it does not comport to what the hypothetical reasonable person would have chosen.”).

¹⁸¹ *Id.*

¹⁸² See, e.g., *Spar v. Cha*, 907 N.E.2d 974, 982 (Ind. 2009) (concluding that assumption of risk “has little legitimate application in the medical malpractice context”).

¹⁸³ *Boyle v. Revici*, 961 F.2d 1060, 1063 (2d Cir. 1992) (concluding that a patient may expressly “dissolve the physician’s duty to treat a patient according to the medical community’s accepted standards”); *Schneider v. Revici*, 817 F.2d 987, 995–96 (2d Cir. 1987) (“[There is] no reason why a patient should not be allowed to make an informed decision to go outside currently approved medical methods in search of an unconventional treatment.”).

¹⁸⁴ *Schneider*, 817 F.2d at 989 n.1.

¹⁸⁵ *Id.* at 990.

¹⁸⁶ 928 A.2d 672 (D.C. 2007).

a doctor and his patient, the defense of assumption of risk is rarely available in medical malpractice cases,” adding that the defense might be sustained where the patient consciously disregards a doctor’s warning about a specific risk.¹⁸⁷ But courts have said little about the feasibility of an assumption of *uncertainty* defense in cases involving untested treatments with unknown benefits and risks. Current doctrine thus fails to delineate the permissible bounds of physician behavior where both the patient and the physician lack information about the safety and efficacy of new medical interventions.

III. MANAGING RISK AND UNCERTAINTY: REGULATION, TORT, OR CONTRACT?

A. Problems with Mandatory Clinical Trials

It has been argued that physician innovation should be subject to stronger ex ante public regulation. Some commentators suggest that off-label uses of medical products that are not supported by high-quality evidence of safety and efficacy should be either banned or significantly restricted.¹⁸⁸ Others argue that new surgical procedures should be tested in formal clinical trials before being introduced into the clinic. Opponents of mandatory clinical trials counter that the status quo should prevail and new techniques should remain part of therapeutic medical practice.¹⁸⁹ They assert that excessive regulation of new techniques could cause collective harm by stifling medical progress, because clinical trials implemented too early in a procedure’s development might lead to the rejection of effective procedures.¹⁹⁰ Indeed, many of the most important surgical breakthroughs of the twentieth century—such as the first operations for mitral stenosis and

¹⁸⁷ *Id.* at 677; see also *Morrison v. MacNamara*, 407 A.2d 555, 567 (D.C. 1979) (“In the context of medical malpractice, the superior knowledge of the doctor with his expertise in medical matters and the generally limited ability of the patient to ascertain the existence of certain risks and dangers that inhere in certain medical treatments, negates the critical elements of the defense, [i.e., knowledge and appreciation of the risk.]”).

¹⁸⁸ See Philip M. Rosoff & Doriane Lambelet Coleman, *The Case for Legal Regulation of Physicians’ Off-Label Prescribing*, 86 NOTRE DAME L. REV. 649, 681–82 (2011) (calling for a ban on “unjustified” off-label uses and restrictions on off-label uses “justified by the need or desire to innovate”).

¹⁸⁹ Mastroianni, *supra* note 7, at 354–55 (noting that surgical and bioethics literature reveals sharp disagreement about whether surgical innovation should be subjected to regulatory review before being introduced into the treatment setting).

¹⁹⁰ Barnaby Reeves, *Health-Technology Assessment in Surgery*, 353 LANCET 3–4 (Supp. I 1999); Steven M. Strasberg & Philip A. Ludbrook, *Who Oversees Innovative Practice? Is There a Structure that Meets the Monitoring Needs of New Techniques?*, 196 J. AM. C. SURGEONS 938, 943 (2003) (“Innovation can be impaired by overly zealous regulation . . .”).

portacaval shunts, or the first series of total hip replacements—probably would not withstand modern regulatory review.¹⁹¹

Problems with mandatory clinical trials extend beyond concerns about impeding medical progress in the name of patient safety. There are several practical impediments to this approach: the administrative costs may be prohibitive, there may not be any clinical studies underway in a particular patient's geographic area, and even if there are ongoing nearby trials the patient may not meet eligibility criteria. Moreover, ethical constraints limit the use of mandatory RCTs to reduce uncertainties about innovative treatments. The "clinical equipoise" requirement dictates that a trial should not be performed unless at least a minority of reasonable researchers believes that the investigational treatment is as good as or better than the treatment in the control arm.¹⁹² There may be insufficient evidence to support clinical equipoise where an innovative treatment is untested and thus lacks data on its safety and efficacy.

Even if a reasonable researcher would be ambivalent about the superior treatment for the subject population as a whole, there might be reasons to believe that one option is preferable over another for a particular patient. But the objectives of a clinical trial fundamentally differ from the goals of patient care. When an individual moves from the treatment setting into a research protocol, the focus of medical intervention shifts from advancing the patient's interests to expanding general knowledge by proving or disproving a research hypothesis.¹⁹³ In this sense, the individual subject is "sacrificed" for the good of the trial.¹⁹⁴ Federal regulations do not require clinical studies to offer

¹⁹¹ J.P. Bunker, D. Hinkley & W.V. McDermott, *Surgical Innovation and Its Evaluation*, 200 SCIENCE 937, 940 (1978) (speculating that contemporary review committees would not have condoned the high failure rates associated with the first series of these procedures).

¹⁹² Protection of Human Subjects; Informed Consent, 60 Fed. Reg. 49,086, 49,095 (Sept. 21, 1995); Benjamin Freedman, *Equipoise and the Ethics of Clinical Research*, 317 NEW ENG. J. MED. 141, 143–44 (1987) (distinguishing this concept from therapeutic equipoise, which would require that the individual physician-researcher be ambivalent).

¹⁹³ Samuel Hellman & Deborah S. Hellman, *Of Mice but Not Men: Problems of the Randomized Clinical Trial*, 324 NEW ENG. J. MED. 1585, 1585 (1991); Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 15–16 (1993) (noting that in clinical trials "[i]ndividual patient-centered therapy gives way to a collective patient-centered endeavor in which the abstraction of the research question tends to objectify the person-patient"); King, *supra* note 136, at 339 ("A research protocol is not treatment, no matter how much all parties wish it so."); *see also* Dale H. Cowan, *Innovative Therapy Versus Experimentation*, 21 TORT & INS. L.J. 619, 623 (1986) ("Although the use of innovative therapies may lead to the development of new knowledge, this consequence is secondary to their primary purpose of benefiting patients.").

¹⁹⁴ Charles Fried, *Medical Experimentation: Personal Integrity and Social Policy*, in 5 CLINICAL STUDIES 53 (A.G. Bearn et al. eds., 1974) ("One might say that the individual patient has perhaps not been sacrificed in the crude sense that the best available treatment has been withheld from him, but he has been sacrificed in that for the sake of the experimental design his interest in having his particular circumstances investigated has been sacrificed. But this amounts to the same thing.").

expected benefits to research subjects.¹⁹⁵ The absence of a reasonable chance of direct benefit does not preclude fully informed patients from enrolling in clinical trials for altruistic reasons, collateral benefits such as free medical care, or to take a long shot at direct benefit where no better treatment options exist.¹⁹⁶ But research designed to generate information that will lead to better treatments for *future* patients does not necessarily offer the best care for *current* subjects participating in clinical trials.¹⁹⁷

Individual patients may be exposed to greater risk in the context of a formal research trial than in a treatment setting. While investigators must not expose research subjects to unnecessary harm,¹⁹⁸ the interests of individual subjects are a side constraint rather than the primary focus of clinical research.¹⁹⁹ As a condition of enrolling in a trial, patients may be required to undergo a “washout” period during which they must forego beneficial medications.²⁰⁰ Additionally, research subjects typically do not enjoy the type of individualized care that they receive in the treatment setting. For example, research protocol parameters usually prohibit dosage adjustments or changes in therapeutic modalities in response to individual treatment outcomes.²⁰¹

IRBs typically spend considerable time evaluating the details of proposed research studies’ informed consent protocols.²⁰² Yet informed consent may be of limited value to research subjects where investigators have scant information to impart about experimental therapies.²⁰³ This

¹⁹⁵ King, *supra* note 136, at 332 (emphasizing that the Common Rule requires that “risks to subjects are reasonable in relation to anticipated benefits, *if any*, to subjects, and the importance of the knowledge that may reasonably be expected to result” (internal quotation marks omitted)).

¹⁹⁶ *Id.* at 337; see also Michelle N. Meyer, *Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem*, 65 ADMIN. L. REV. 237 (2013).

¹⁹⁷ King, *supra* note 136, at 337 (“[E]quipoise is a reasonable difference of opinion about what *will be* the better *treatment* for future patients—not about what *is* better for current subjects.”).

¹⁹⁸ 21 C.F.R. § 56.111(a)(1) (2014) (requiring that “[r]isks to subjects be minimized”).

¹⁹⁹ E. Haavi Morreim, *Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities*, 32 J.L. MED. & ETHICS 474 (2004).

²⁰⁰ *Id.* at 476.

²⁰¹ LEVINE, *supra* note 133, at 10 (“[T]he individualized dosage adjustments and changes in therapeutic modalities are less likely to occur in the context of a clinical trial than they are in the practice of medicine. . . [and this reveals] one of the burdens imposed on the patient-subject in a clinical trial.” (citation omitted)).

²⁰² See Robert D. Truog et al., *Is Informed Consent Always Necessary for Randomized, Controlled Trials?*, 340 NEW ENG. J. MED. 804, 806 (1999) (arguing that the preoccupation with informed consent is misguided and asserting that “[b]oards that approve questionable studies on the assumption that the informed-consent process will protect research subjects against abuse abrogate their responsibility . . .”).

²⁰³ See Laurence R. Tancredi, *Informed Consent: The Dilemma*, in BIOMEDICAL INNOVATION 301, 304 (Edward B. Roberts et al. eds., 1981) (stating that information about some treatments “is so insubstantial that, even though the patient may have been apprised of all information available and may have voluntarily and competently agreed to the experiment, any informed consent is precluded”); Guido Calabresi, *Reflections on Medical Experimentation in Humans*, 98 DAEDALUS 387, 391 (1969) (questioning the value of informed consent requirements in research).

begs the question: would more rigorous substantive IRB review of proposed medical interventions' risks and benefits better protect subjects? Since even medical experts know little about untested new treatments, definitive risk-benefit assessments are impossible. Hence individual patients cannot expect to gain greater protection by participating in research trials than they would by receiving innovative care in the treatment setting.

The clinical debate over the use of post-operative radiation for women with Stage 2 breast cancer illustrates ethical problems that would be created by mandating clinical trials to regulate uncertain medical practices. There is no universally accepted treatment course for some early stage breast cancer patients because the long-term benefits of radiation are not clearly established.²⁰⁴ Nonetheless, individual patients may have valid reasons to prefer one option to another. Radiation might increase the chance of remission, but it also causes permanent swelling in the arm, limits the choices women have for reconstructive surgery, and may increase the long-term risk of dying from cardiovascular or lung diseases.²⁰⁵ In these types of cases, it would be deeply troubling to require all patients to enroll in trials and forfeit decisional authority over their treatment course.²⁰⁶ At the very least, the patient should be informed of the possibility that she will be randomized into a treatment protocol that she would reject if given the choice. Fully informed patients may be understandably reluctant to enroll in clinical trials rather than select a medical intervention in the treatment setting.²⁰⁷ In fact, a large randomized study of the effectiveness of post-operative radiation for women with Stage 2 breast cancer was attempted in the United States, but it ended after it failed to attract a sufficient number of subjects.²⁰⁸

Formal clinical trials are an undeniably useful means to generate safety and efficacy information about new medical interventions, but they cannot be exclusively relied on to reduce medical uncertainty. RCTs yield statistical data that may provide insufficient guidance for the

²⁰⁴ See Laurie Tarkan, *A Debate on Radiation in Breast Cancer*, N.Y. TIMES, Feb. 24, 2004, at F1 (noting that Harvard's three affiliated hospitals each take different approaches); see also Ellen L. Jones et al., *Adjuvant Therapy of Breast Cancer in Women 70 Years of Age and Older: Tough Decisions, High Stakes*, 26 ONCOLOGY 793 (2012).

²⁰⁵ See Tarkan, *supra* note 204.

²⁰⁶ See Don Marquis, *How to Resolve an Ethical Dilemma Concerning Randomized Controlled Trials*, 341 NEW ENG. J. MED. 691, 692 (1999) (concluding that "because respect for informed consent entails offering a patient the reasonable alternatives to the recommended treatment, and because enrollment in an appropriate randomized clinical trial is often a reasonable therapeutic option," an ambivalent physician should leave it to the patient to decide whether or not to enroll in a trial).

²⁰⁷ See Jerry Menikoff, *The Hidden Alternative: Getting Investigational Treatments Off-Study*, 361 LANCET 63, 65 (2003) (noting that physicians have broad discretion to offer an unproven treatment to their patients outside of a formal trial).

²⁰⁸ See Tarkan, *supra* note 204.

treatment of particular patients and conditions.²⁰⁹ In some cases, the individual costs of mandating clinical trials in exchange for access to innovative care are simply too great. It is nonetheless essential to obtain robust data about the clinical outcomes of innovative treatments through the creation of registries and databases that track patient responses.²¹⁰ Such registries could be used in conjunction with RCTs to generate comprehensive data sets about the safety and efficacy of medical therapies in different patient populations. However, although registries can provide useful *ex post* information about new medical interventions, they cannot resolve legal and ethical issues that arise when an innovation is first introduced, such as patient selection, informed consent obligations, and substantive assessment of benefits, risks, and uncertainties.

B. *Limitations of Tort-Based Reforms*

An alternative to public regulation is to modify the ways in which the existing tort regime governs physician innovation. Advocates of tort reforms note that malpractice standards based on generally accepted practices can harm patients by penalizing physicians for implementing beneficial changes to prevailing norms.²¹¹ For example, suppose that the customary way of treating trauma patients with neck injuries carries with it a five percent chance of permanent spinal damage, while a novel technique carries with it a two percent chance of this injury. Although it would be socially beneficial for physicians to adopt the innovative technique, customary standards of care may dissuade them from doing so.²¹²

Two proposals have been offered to mitigate the tort system's welfare-reducing distortionary effects. Cost-benefit analysis could replace existing standards for assessing liability.²¹³ Alternatively, the law could retain customary standards, but elevate certain innovations to the status of custom if special boards of industry experts approve them *ex ante*.²¹⁴ The latter approach would resemble tort rules for the manufacturers of medical products, who are entitled to protections from state tort claims if the FDA previously assessed the products' safety and

²⁰⁹ See *supra* Part II.A.

²¹⁰ See, e.g., Mastroianni, *supra* note 7, at 434; Rosoff & Coleman, *supra* note 188, at 686–87; see also Laakmann, *supra* note 29, at 341 (advocating for the creation of a centralized database to track the effects of newly approved drugs).

²¹¹ Parchomovsky & Stein, *supra* note 9, at 286 (theorizing that courts' reliance on customary standards of tort liability can impede and distort the path of innovation).

²¹² *Id.* at 287–88.

²¹³ *Id.* at 289.

²¹⁴ *Id.* at 289–90.

efficacy.²¹⁵ It also would resemble the partial liability shield created by IRB review of formal clinical trials.²¹⁶

While these tort-based reforms are theoretically appealing, they insufficiently address real world problems of medical uncertainty. Cost-benefit analysis requires a reliable data set with which to make unbiased calculations. In practice, medical experts generally lack the probabilistic data to confidently conclude that an innovative technique has a superior risk-benefit profile compared to a standard method. Even the most knowledgeable expert cannot assess the relative safety and efficacy of an untested medical intervention. And, even if there are preliminary probabilistic data about a clinical innovation, such data may not address the particular needs and preferences of individual patients.

C. Policy Concerns Raised by Contractual Liability Proposals

Libertarian theorists argue instead that contract law should replace tort law to govern physician behavior.²¹⁷ Advocates of contractual liability note that medical malpractice law's negligence regime is an awkward means to govern the physician-patient encounter. Tort law generally regulates interactions between parties who have had no advance opportunity to allocate liability for adverse events, yet physicians and patients typically have a preexisting contractual relationship.²¹⁸ Additionally, tort law's objective reasonableness

²¹⁵ FDA approval preempts state tort liability to the extent that tort claims conflict with the FDA's safety and efficacy determinations. See *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011) ("Where state and federal law 'directly conflict,' state law must give way." (citing *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring))).

²¹⁶ See, e.g., *Heinrich v. Sweet*, 308 F.3d 48, 69 (1st Cir. 2002) (finding that physicians who used experimental boron neutron capture (BNCT) to treat patients' terminal brain cancer in the 1960s did not breach the standard of care applicable to a researcher and citing as "very compelling evidence" the prior approval of the research by four committees). *But cf.* *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 813–17 (Md. 2001) (finding that IRB approval of nontherapeutic research did not shield researchers and research institution from negligence actions).

²¹⁷ See, e.g., Richard A. Epstein, *Contractual Principle Versus Legislative Fixes: Coming to Closure on the Unending Travails of Medical Malpractice*, 54 DEPAUL L. REV. 503, 505 (2005) [hereinafter *Contractual Principle Versus Legislative Fixes*] ("[T]he key error is to treat [medical malpractice] as a tort problem when designing a governance regime calls for a contractual response." (emphasis added)); Richard A. Epstein, *Medical Malpractice, Imperfect Information, and the Contractual Foundation for Medical Services*, 49 L. & CONTEMP. PROBS. 201 (1986) [hereinafter *Medical Malpractice—Imperfect Information*]; Richard A. Epstein, *Medical Malpractice: The Case for Contract*, 1 AM. B. FOUND. RES. J. 87 (1976); Clark C. Havighurst, *Private Reform of Tort-Law Dogma: Market Opportunities and Legal Obstacles*, 49 L. & CONTEMP. PROBS. 143, 149 (1986).

²¹⁸ Morreim, *supra* note 134, at 33 (labeling tort regulation of contractual physician-patient relationships as a "contorts' approach"); Epstein, *Contractual Principle Versus Legislative Fixes*, *supra* note 217, at 506–07 (arguing that it does not make sense to regulate the physician-patient relationship under an objective negligence standard, because the parties are not strangers to one another); Shultz, *supra* note 36, at 223–24 (noting that, although the physician-patient

standards limit physicians' ability to effectuate value-laden treatment decisions that comport with particular patients' goals and preferences.²¹⁹ Objective reasonableness emphasizes the effect of the defendant's behavior on overall social welfare, not on the individual plaintiff's well-being.²²⁰

Contractarians frame the physician-patient interaction as a consensual transaction whereby the patient offers his body and capital in exchange for the physician's services.²²¹ This argument has intuitive force: consent is both a cornerstone of medical malpractice law and "the master concept that defines the law of contracts in the United States."²²² Contract law enforces individuals' idiosyncratic needs and desires.²²³ To the extent that the current tort regime deprives patients of care that they would rationally agree to *ex ante*, a contractual approach to medical decisionmaking would increase patient welfare by allowing patients to assume the uncertainties of potentially beneficial untested therapies.²²⁴

Yet strong public policy arguments counsel against treating the physician-patient relationship as an arms-length transaction. Skeptics of contract-based reforms contend that information disparities and patients' vulnerabilities rule out a voluntary market for health care.²²⁵ A seriously ill patient contemplating a medical intervention might significantly differ from the person he was at the time he entered into a contract with his physician. Additionally, the physician's professional

relationship typically arises through contract, the physician's performance is governed under tort law).

²¹⁹ See King, *supra* note 60, at 49 (explaining that physician liability typically is assessed by reference to objective criteria); see also *supra* Part I.

²²⁰ Medical malpractice doctrine, although grounded in negligence principles, tacitly acknowledges the undesirability of a strictly utilitarian assessment of physician behavior. See Maxwell J. Mehlman, *Dishonest Medical Mistakes*, 59 VAND. L. REV. 1137, 1157 n.80 (2006) (noting that a physician is not permitted to deprive a seriously ill patient of a costly but beneficial treatment even if this would increase net social welfare by lowering health care costs for other patients).

²²¹ Epstein, *Medical Malpractice—Imperfect Information*, *supra* note 217, at 202 (asserting that patients and physicians "can work together to organize an exchange on mutually acceptable terms, so that each obtains something more valuable than he surrenders. . . . In short, one might contend, the usual arguments for voluntary markets prevail.").

²²² Schuck, *supra* note 98, at 900; see also, MARGARET JANE RADIN, *BOILERPLATE: THE FINE PRINT, VANISHING RIGHTS, AND THE RULE OF LAW* 3 (2013).

²²³ Morreim, *supra* note 57, at 42–44 ("Contract law provides the best vehicle for providing citizens with the freedom to decide what level of health care resources to purchase, and how to prioritize health care against other things they value.").

²²⁴ See Epstein, *Contractual Principle Versus Legislative Fixes*, *supra* note 217, at 508 (arguing that rational patients should be willing to assume virtually all the risks associated with medical therapies where there is a high risk of failure irrespective of the treatment choice).

²²⁵ See, e.g., P.S. Atiyah, *Medical Malpractice and the Contract/Tort Boundary*, 49 L. & CONTEMP. PROBS. 287, 287 (1986).

duty to act in the patient's best interests might supersede existing contractual obligations.²²⁶

It has been suggested that contract law should govern resource control issues, and that physician attentiveness, judgment, and skill should remain governed under negligence-based tort principles.²²⁷ But it is often difficult to distinguish between decisions involving rationing of resources and decisions based on diligence and expertise.²²⁸ For example, if a physician decides to use a cheaper drug off-label rather than a more expensive drug for an approved use, is this a clinical judgment or a resource control decision? There is no clear answer in many cases because clinicians lack the evidence to confidently identify the medically optimal choice for a particular patient.

Advocates of contractual liability argue that allowing patients to contract over legal standards of care will enable individual patients to choose how much they are willing to pay for safety.²²⁹ Critics counter that individualized variations in standards of care will create negative externalities and lower the overall quality of healthcare delivery.²³⁰ They argue that the state is best able to weigh the benefits of tailored standards of care with the social costs of permitting such variations in legal standards.²³¹ But there is a crucial difference between unequivocally substandard care and deliberate departures from customary standards using innovative techniques. While there are convincing policy reasons for why the former type of conduct should remain governed under a state-imposed tort regime, the latter fits poorly under the existing scheme, particularly when preference-sensitive treatment decisions are involved.

The central focus of the tort versus contract debate has been on whether the law should allow patients to voluntarily choose suboptimal care in exchange for lower costs. This Article raises a distinctly different

²²⁶ See Tamar Frankel, *Fiduciary Law*, 71 CALIF. L. REV. 795, 799–800 (1983) (noting that, under contract law, “[n]o party to a contract has a general obligation to take care of the other, and neither has the right to be taken care of”).

²²⁷ See, e.g., CLARK C. HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* 287–93 (1995); E. HAAVI MORREIM, *HOLDING HEALTH CARE ACCOUNTABLE: LAW AND THE NEW MEDICAL MARKETPLACE* 92–93, 96 (2001); Morreim, *supra* note 57, at 29–44.

²²⁸ The Supreme Court in *Pegram v. Herdrich* highlighted this difficulty in holding that “mixed” treatment decisions by HMO physicians should be evaluated under a single negligence standard. 530 U.S. 211, 237 (2000).

²²⁹ See Epstein, *Contractual Principle Versus Legislative Fixes*, *supra* note 217, at 509 (describing the bargaining that would take place if patients and physicians could contract over the standard of care).

²³⁰ Jennifer Arlen, *Contracting Over Liability: Medical Malpractice and the Cost of Choice*, 158 U. PA. L. REV. 957 (2010) (arguing that four inefficiencies make contractual liability a more costly form of liability than tort liability: collective goods problems, time inconsistency, adverse selection, and network externalities).

²³¹ *Id.* at 1018.

question: to what extent should patients be permitted to choose potentially superior care that involves a deliberate deviation from prevailing practices? In this case, it is unknown whether the standard or innovative approach is better. Cost is also a wild card—in some cases the innovative alternative is more costly, and in some cases it is less costly. The key issue is whether the law should allow patients to voluntarily assume uncertainty about the quality of untested treatments in exchange for greater access to clinical innovation. Proper resolution of this issue requires moving beyond the “tort versus contract” dichotomy. Part IV proposes a fiduciary framework that loosely resembles corporate law’s regulation of officers and directors. The proposed scheme would identify the range of reasonable options for individual patients, compel physicians to fully inform patients of the costs, benefits, risks, and uncertainties associated with each reasonable option, and legally enforce patients’ rational choices.

IV. PROPOSED FIDUCIARY FRAMEWORK

A. *Distinguishing Between Disclosure, Decision, and Execution*

In bioethics and health law commentary, patients’ rights rhetoric is gradually giving way to a more nuanced discussion that stresses the importance of relational behavior.²³² This trend reflects renewed interest in trust and increasing skepticism about the capacity of narrow autonomy principles to resolve patient care dilemmas.²³³ Trust, unlike confidence or reliance, does not connote the expectation of a good outcome. Rather, the core feature of trust is one’s belief that another person is acting in their best interests.²³⁴ Although some observers perceive that patients’ trust in physicians is diminishing,²³⁵ careful examination of empirical evidence reveals a more complicated picture. Patients report greater distrust of the medical profession as a whole, yet retain remarkably high levels of trust in specific, known individual

²³² See, e.g., Hall, *supra* note 55; Sage, *supra* note 15 (exploring the delicate balance between physicians’ duties to individual patients and their duties to patient populations).

²³³ Hall, *supra* note 55, at 469 (“We are now witnessing a robust revival of trust as a topic in discussions of medical ethics and professionalism.”); see also M. Gregg Bloche, *Beyond Autonomy: Coercion and Morality in Clinical Relationships*, 6 HEALTH MATRIX 229 (1996); Dworkin, *supra* note 99; Schneider, *supra* note 37.

²³⁴ Hall, *supra* note 55, at 474.

²³⁵ Mehlman, *supra* note 2, at 374 & n.88; Peters, *supra* note 1, at 196–99; Schuck, *supra* note 98, at 926 (arguing that the increasingly bureaucratic health care system discourages physician-patient relationships based on intimacy and trust).

physicians.²³⁶ The time is ripe to reformulate medical malpractice law to capture these complex relational dynamics.

An analogy to products liability helps to distinguish between those clinical activities that are appropriately governed under the current medical malpractice regime and those that are not. The Third Restatement of Torts breaks down products liability claims into three distinct categories: warning defects, design defects, and manufacturing defects.²³⁷ Warning defects are failures to adequately inform consumers about products' risks, design defects are deliberate decisions to manufacture products that embody impermissible risk/benefit tradeoffs, and manufacturing defects are inadvertent mistakes that expose consumers to unintended risks.²³⁸ For medical products that are "unavoidably unsafe," design defect liability hinges on the adequacy of the manufacturer's warning.²³⁹ Medical malpractice claims can be analogously categorized as "disclosure" claims, "decision" claims, or "execution" claims. For example, a malpractice action involving a surgeon's use of an innovative procedure may involve three distinct claims: (1) the defendant breached his disclosure duties by failing to adequately *inform* the patient about the surgical procedure,²⁴⁰ (2) the defendant failed to meet the standard of care in *selecting* the surgical procedure,²⁴¹ or (3) the defendant negligently *performed* the surgery.²⁴² The first claim constitutes a disclosure claim, the second a decision claim, and the third an execution claim.

Admittedly, the distinction between decision and execution is not always sharp—physicians may make a series of clinical judgments when executing a treatment plan. For example, a surgeon who decides to perform a procedure must elect which tools to use. Nonetheless, this classification scheme can help to discern those aspects of the physician-patient encounter that are particularly ill served by an objective negligence standard. Execution claims alleging that the physician carried out an activity in a careless manner are adequately governed under current medical tort law. These claims involve assertions that a physician failed to demonstrate the degree of skill of the reasonable

²³⁶ Hall, *supra* note 55, at 487–88.

²³⁷ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998).

²³⁸ LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 490 (3d ed. 2012).

²³⁹ RESTATEMENT (THIRD) OF TORTS, § 6 (1998); RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1965); see James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151 (2001).

²⁴⁰ See, e.g., *Culbertson v. Mernitz*, 602 N.E.2d 98 (Ind. 1992) (plaintiff alleged that the defendant failed to inform her about risks associated with the procedure).

²⁴¹ See, e.g., *Jones v. Chidester*, 610 A.2d 964 (Pa. 1992) (plaintiff alleged negligence based on the method selected during surgery).

²⁴² See, e.g., *Locke v. Pachtman*, 521 N.W.2d 786 (Mich. 1994) (plaintiff claimed that defendants were negligent in failing to remove a broken needle fragment from the patient's body).

practitioner and can be assessed according to objective criteria without the need to ascertain the particular patient's needs or preferences. But the existing negligence regime poorly governs disclosure and decision claims. Like medical product manufacturers, physicians deliver "unavoidably unsafe" care to patients, and the reasonability of such conduct crucially depends on the adequacy of the physician's disclosure. However, unlike manufacturers' conduct, a physician's actions cannot be properly evaluated without consideration of the patient's individual characteristics and circumstances. This Part proposes that the law assess the "disclosure" and "decision" aspects of physician behavior together under a comprehensive fiduciary framework.²⁴³

B. *A More Expansive Conception of Physicians' Fiduciary Duties*

Fiduciary law governs a variety of relationships to protect those who are dependent upon the judgment of an expert decision-maker and lack the means to effectively monitor and control the expert's choices.²⁴⁴ Fiduciary relationships vary in scope and intensity.²⁴⁵ But the core feature that distinguishes fiduciary relationships from arms-length arrangements is the fiduciary's obligation to act on behalf of the entrustor²⁴⁶ by fulfilling duties of care and loyalty.²⁴⁷ A key attribute of

²⁴³ In recent litigation involving the pharmaceutical company Amgen, courts rejected claims that Amgen owed a fiduciary duty to subjects to continue providing a potentially beneficial investigational drug after it halted clinical trials due to unfavorable study results. *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006); *Suthers v. Amgen, Inc.*, 441 F. Supp. 2d 478 (S.D.N.Y. 2006) (ruling on motion to dismiss); *Suthers v. Amgen, Inc.*, 372 F. Supp. 2d 416 (S.D.N.Y. 2005) (preliminary injunction ruling). The courts reasoned that the drug manufacturer was too far removed from the subjects to have formed a fiduciary relationship with them. *Abney*, 443 F.3d at 550–51; *Suthers*, 372 F. Supp. 2d at 426–29 & n.9.

²⁴⁴ Elizabeth S. Scott & Robert E. Scott, *Parents as Fiduciaries*, 81 VA. L. REV. 2401, 2420 (1995) ("In general, the law characterizes as fiduciary those agency relationships in which the principal is particularly vulnerable and unable fully to protect and assert his own interests, thus providing the agent a peculiar opportunity and incentive to either shirk or cheat.").

²⁴⁵ Tamar Frankel, *Fiduciary Duties*, in THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 127, 127 (Peter Newman ed., 1998) ("[T]he variety of fiduciary relationships and the flexibility of fiduciary law. . . [which] varies with different classes of fiduciaries."); D. Gordon Smith, *The Critical Resource Theory of Fiduciary Duty*, 55 VAND. L. REV. 1399, 1483–84 (2002) (explaining that courts can vary the intensity of fiduciary duties along three dimensions: scope (which actions are reviewed), scrutiny (degree of deference accorded), and substance (whether or not the fiduciary must act solely for the benefit of the entrustor)).

²⁴⁶ Tamar Frankel coined the term "entrustor" to refer to the other party in any fiduciary relation. Frankel, *supra* note 226, at 800 n.17.

²⁴⁷ See D. Gordon Smith & Jordan C. Lee, *Fiduciary Discretion*, 75 OHIO ST. L.J. 609, 621–22 (2014) (explaining that many commentators view the duty of loyalty as the only distinctly fiduciary duty, although courts typically recognize both the duty of care and the duty of loyalty as fiduciary duties); see also *In re Walt Disney Co. Derivative Litig.*, 906 A.2d 27, 67 (Del. 2006) (holding that a director breaches a duty of good faith when he consciously disregards his fiduciary duties); Kelli A. Alces, *Debunking the Corporate Fiduciary Myth*, 35 J. CORP. L. 239, 257–58 (2009) (summarizing the three main theories of fiduciary duty: (1) reliance theory, which posits that

fiduciary duties compared to other legal constraints is that they are loosely defined and thus able to govern disparate situations.²⁴⁸ Yet the highly context-dependent nature of fiduciary law renders fiduciary duties meaningless without clearly articulated statements about how they apply in specific circumstances.²⁴⁹

Numerous commentators have classified physicians as fiduciaries with attendant legal obligations.²⁵⁰ Courts, too, routinely characterize the physician-patient relationship as a fiduciary one.²⁵¹ In *Moore v. Regents of the University of California*,²⁵² the California Supreme Court held that physicians have a fiduciary duty to disclose to patients economic and research conflicts of interest that might interfere with their clinical judgment.²⁵³ Other courts have invoked fiduciary principles to enforce physicians' informed consent obligations²⁵⁴ and to prohibit physicians from revealing confidential patient information.²⁵⁵

fiduciaries are morally obligated to act in a trustworthy manner; (2) agency theory, which views fiduciary duties as means to reduce agency costs; and (3) contractarian theory, which contends that fiduciary duties encompass what the parties would have agreed to if they were able to negotiate every contingency in advance); Smith, *supra* note 245.

²⁴⁸ See Alces, *supra* note 247, at 255 (arguing that attempts to make fiduciary duties predictable "rob[s] them of their greatest potential strength").

²⁴⁹ See SEC v. Chenery Corp., 318 U.S. 80, 85-86 (1943) ("[T]o say that a [person] is a fiduciary only begins analysis; it gives direction to further inquiry. To whom is he a fiduciary? What obligations does he owe as a fiduciary? . . . And what are the consequences of his deviation from duty?"); Smith, *supra* note 245, at 1400 (noting that the prevailing view is that fiduciary law is "elusive").

²⁵⁰ See, e.g., MARC A. RODWIN, *MEDICINE, MONEY AND MORALS: PHYSICIANS' CONFLICT OF INTEREST* 179-211 (1993); Peter D. Jacobson & Michael T. Cahill, *Applying Fiduciary Responsibilities in the Managed Care Context*, 26 AM. J.L. & MED. 155 (2000); Maxwell J. Mehlman, *Fiduciary Contracting Limitations on Bargaining Between Patients and Health Care Providers*, 51 U. PITT. L. REV. 365, 388-416 (1990); E. Haavi Morreim, *Economic Disclosure and Economic Advocacy: New Duties in the Medical Standard of Care*, 12 J. LEGAL MED. 275, 296-301 (1996).

²⁵¹ See, e.g., *Lockett v. Goodill*, 430 P.2d 589, 591 (Wash. 1967) ("The relationship of patient and physician is a fiduciary one of the highest degree. It involves every element of trust, confidence and good faith."). Alabama is the only jurisdiction that has rejected the notion that the physician-patient relationship is based on trust and confidence, obligating physicians to abide by fiduciary standards. See *Gunter v. Huddle*, 724 So. 2d 544, 546 (Ala. Civ. App. 1998) ("Alabama caselaw holds that a physician-patient relationship is *not* a fiduciary relationship as a matter of law.").

²⁵² 793 P.2d 479, 483 (Cal. 1990) (en banc).

²⁵³ *Id.*

²⁵⁴ See, e.g., *Nardone v. Reynolds*, 538 F.2d 1131, 1136 (5th Cir. 1976) (holding that a doctor breaches a fiduciary duty when he fails to disclose a known condition, that the duty does not terminate when the consensual-contractual relationship ends, and that a fiduciary relationship exists even if the patient is not aware that a physician is treating him); *Hales v. Pittman*, 576 P.2d 493 (Ariz. 1978) (en banc) ("[B]ecause of the fiduciary relationship between physician and patient, the scope of the disclosure required can be expanded by the patient's instructions to the physician."); *Demers v. Gerety*, 515 P.2d 645, 648, 650 (N.M. Ct. App. 1973) (approving a jury instruction on the fiduciary relationship in an action where the patient claimed that an operation had been performed without consent).

²⁵⁵ See, e.g., *Morris v. Consolidation Coal Co.*, 446 S.E.2d 648, 657 (W. Va. 1994) (holding that a patient has a cause of action against a physician for breach of the duty of confidentiality and

Courts closely scrutinize financial transactions between patients and physicians,²⁵⁶ and most courts hold that a physician breaches fiduciary obligations when he enters into a sexual relationship with a patient.²⁵⁷ Additionally, courts have cited fiduciary duties of good faith and fair dealing to prohibit physician kickbacks,²⁵⁸ unnecessary care,²⁵⁹ and improper self-referrals.²⁶⁰

Yet, despite frequent incantations of fiduciary principles, courts have enforced physicians' fiduciary duties in a haphazard, ad hoc manner.²⁶¹ While medical ethical codes and case law routinely pronounce physicians as fiduciaries, the legal substance behind this label remains elusive.²⁶² Courts' vague characterization of physicians' fiduciary duties offers woefully little guidance on the legally permissible

against an employer for inducing the physician to breach his fiduciary duty by disclosing confidential information); *see also* State *ex rel.* Dean v. Cunningham, 182 S.W.3d 561, 566 (Mo. 2006) (holding that the fiduciary duty of confidentiality comprises the foundation of the doctor-patient evidentiary privilege); Sorensen v. Barbuto, 177 P.3d 614, 619–20 (Utah 2008) (holding that a fiduciary duty of confidentiality prohibits ex parte communication between a tort plaintiff's treating physician and defense counsel).

²⁵⁶ *See, e.g.*, Mattingly v. Sisler, 175 P.2d 796, 799 (Okla. 1946) (accepting the contentions that "the relation of physician and patient constitutes a confidential relationship" and that a transaction outside the treatment context "is presumed to be void and the burden of proof is upon the party who seeks to support it to show by clear proof that he has taken no advantage over the other party and that the transaction is fair, free from fraud and is conscientious").

²⁵⁷ *See, e.g.*, Hoopes v. Hammargren, 725 P.2d 238, 242 (Nev. 1986) (stating that a physician who takes sexual advantage of a vulnerable patient "would fall below the acceptable standard for a fiduciary"). *But cf.* Korper v. Weinstein, 783 N.E.2d 877, 881–82 (Mass. App. Ct. 2003) (finding that a physician did not breach a fiduciary duty to his patient by engaging in a consensual sexual relationship with her).

²⁵⁸ *See, e.g.*, Forziati v. Bd. of Registration in Med., 128 N.E.2d 789, 791–92 (Mass. 1955). Additionally, the federal Medicare and Medicaid anti-kickback statute criminalizes any intentional solicitation or receipt of remuneration in return for a referral for goods or services reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b(b) (2012).

²⁵⁹ *See, e.g.*, Garcia v. Coffman, 946 P.2d 216, 218, 223 (N.M. Ct. App. 1997) (affirming that a physician breached a fiduciary duty where a treatment protocol included "unnecessary computerized muscle testing" performed by "incompetent personnel," on grounds that there was not "full and fair disclosure").

²⁶⁰ *See, e.g.*, Agency for Health Care Admin. v. Wingo, 697 So. 2d 1231, 1232–33 (Fla. Dist. Ct. App. 1997). Additionally, the federal "Stark" legislation prohibits physicians from making referrals for the provision of certain Medicare and Medicaid services by persons or entities with whom the referring physician has a financial relationship. 42 U.S.C. § 1395nn (2012).

²⁶¹ Bloche, *supra* note 27, at 312 ("The law has been peculiarly slow to impose on clinical caretakers the same fiduciary obligations it insists upon for lawyers, financial advisors, and other professionals."); Dayna Bowen Matthew, *Implementing American Health Care Reform: The Fiduciary Imperative*, 59 BUFF. L. REV. 715, 719 (2011).

²⁶² Morreim, *supra* note 134, at 42 & n.229 (noting that courts are reluctant to impose a comprehensive set of fiduciary duties upon physicians and citing several cases in which courts declined claims of breach of fiduciary duty); Marc A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 AM. J.L. & MED. 241, 242 (1995) ("[A]lthough doctors perform fiduciary-like roles and hold themselves out as fiduciaries in their ethical codes, the law holds doctors accountable as fiduciaries only in restricted situations.").

bounds of physician behavior under conditions of endogenous uncertainty.

Current doctrine views physicians' fiduciary obligations as separate and distinct from their duties to act non-negligently. The conventional view is that medical malpractice occurs when a physician breaches a professionally defined standard of care, while breach of fiduciary duty occurs when a physician violates a patient's trust.²⁶³ This legal separation between tort duties and fiduciary duties perpetuates the fallacy that assessment of physicians' delivery of treatment is a strictly objective inquiry that can be divorced from consideration of physicians' personal obligations to individual patients.²⁶⁴ The doctrinal framework is strained by clinical realities of preference-sensitive care and patient heterogeneity.²⁶⁵

Physicians' general disclosure and decisionmaking responsibilities should be reframed as fiduciary obligations owed to their patients. Like tort law, fiduciary law imposes involuntary, state-mandated duties;²⁶⁶ but, a fiduciary model of medical decisionmaking would align physicians' duties and patients' interests more precisely than the existing negligence regime. Agency best describes the physician-patient relationship: the physician owes a duty to act on behalf of the patient, subject to the patient's input and direction.²⁶⁷ Agency principles underscore the notion that disclosure duties should not be unidirectional; rather, physicians and patients have reciprocal obligations to share information with each other.²⁶⁸ Physicians must disclose to patients material information about treatment options' benefits, risks, and uncertainties, while patients should be obligated to provide physicians with the personalized information that providers require to assist patients in making rational choices. Of course, if a patient fails to communicate personal preferences to his physician the physician should not have *carte blanche* to disregard the patient's best interests. However, the physician's conduct should be judged on the basis of the information made available to her at the time that a medical decision is made.

²⁶³ Matthew, *supra* note 261, at 732; *see also* Mehlman, *supra* note 220, at 1138 (distinguishing between "honest" medical mistakes stemming from carelessness and "dishonest" medical mistakes involving physicians' deliberate decisions to sacrifice their patients' best interests in order to benefit themselves).

²⁶⁴ *See* Rodwin, *supra* note 262, at 249 ("Malpractice law—which holds physicians responsible for their negligence—only adumbrates fiduciary standards.").

²⁶⁵ *See supra* Part I.

²⁶⁶ Frankel, *supra* note 226, at 820–21 ("[U]nlike a party to a contract, a person may find himself in a fiduciary relation without ever having intended to assume fiduciary obligations.").

²⁶⁷ Matthew, *supra* note 261, at 753–59 (explaining why agency is the fiduciary form that best characterizes the physician-patient relationship).

²⁶⁸ *Id.* at 798.

It has been argued that doctors' divided loyalties under managed care weaken the case that physicians stand in a fiduciary relationship with their patients,²⁶⁹ but this argument rests on too narrow a view of fiduciary law. A fiduciary must refrain from self-interested behavior that harms the entrustor, but is not obligated to act selflessly.²⁷⁰ Conflicts of interest do not preclude a fiduciary relationship. In the corporate context, for example, directors and officers owe fiduciary duties to shareholders while simultaneously taking into account the interests of other constituents, such as creditors, employees, and customers.²⁷¹ Moreover, a physician's goal to provide cost-effective care need not be diametrically opposed to her duty to act in her patient's best interests.²⁷² Ideally, coverage schemes should be structured in a way that compels patients to internalize costs so that individual patients are able to reach decisions that fit their particular circumstances.²⁷³ Empirical evidence indicates that patients would demand substantially less costly care than is currently provided if shared decisionmaking were routinely used in practice.²⁷⁴ This observation suggests that adopting more subjective patient-centered legal standards of care may comport with efficiency objectives.

In corporate law, courts emphasize the decisionmaking *process* over directors' and officers' *substantive* decisions when assessing compliance with fiduciary duties.²⁷⁵ Medical malpractice law should

²⁶⁹ Rodwin, *supra* note 262, at 254–55 (arguing that the fact that doctors and medical organizations must act in the interests of the populations they serve as well as in the interests of individual patients “strains the fiduciary metaphor”).

²⁷⁰ Smith, *supra* note 245, at 1410.

²⁷¹ See Alces, *supra* note 247, at 245 (noting that corporate scholars disagree over whether officers and directors owe fiduciary duties to shareholders, or to the corporation itself).

²⁷² See Frances H. Miller, *Secondary Income from Recommended Treatment: Should Fiduciary Principles Constrain Physician Behavior?*, in *THE NEW HEALTH CARE FOR PROFIT: DOCTORS AND HOSPITALS IN A COMPETITIVE ENVIRONMENT* 159 (Bradford H. Gray ed., 1983) (arguing that physicians' fiduciary responsibilities include eschewing unnecessary care and protecting patients' financial resources by providing cost-effective treatment).

²⁷³ See Morreim, *supra* note 57, at 25–26 (“The growing urgency about costs reveals the major value choices underlying what are ostensibly medical decisions. An intervention is not ‘necessary’ or ‘unnecessary’ per se, as it is useful to one degree or another toward some particular [patient’s] goal.”).

²⁷⁴ See PREFERENCE-SENSITIVE CARE, *supra* note 41, at 2 (stating that empirical studies demonstrate that patients who participate in shared decisionmaking show a marked decrease in demand for costly invasive treatment).

²⁷⁵ See, e.g., *In re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959, 967 (Del. Ch. 1996) (“[W]hether a judge or jury considering the matter after the fact, believes a decision substantively wrong . . . provides no ground for director liability, so long as the court determines that the process employed was either rational or employed in a *good faith* effort to advance corporate interests.”); see also ROBERT W. HAMILTON, *CASES AND MATERIALS ON CORPORATIONS: INCLUDING PARTNERSHIPS AND LIMITED LIABILITY COMPANIES* 762 (7th ed. 2001) (stating that courts assess “the process by which the directors ‘become informed’ in connection with making the decision”); Charles Hansen, *The ALI Corporate Governance Project: Of the Duty of Due Care and the Business Judgment Rule, A Commentary*, 41 *BUS. LAW* 1237, 1241 (1986) (“[T]he due care standard in corporate law is applied to the decision-making process and not to its result.”). In

take a similar approach to clinical decisionmaking. Physicians should be compelled to take into account both generalized data and specific patient characteristics to identify reasonable treatment options. The focus should be on whether the physician reviewed relevant guidelines and other data to ascertain their applicability to the particular patient, sought out advice from colleagues or specialty organizations when appropriate, discussed known material information with the patient, and acted in good faith to advance the patient's interests. Healthcare institutions should be structured to encourage and support a thoughtful and deliberate decisionmaking process.²⁷⁶

Skeptics of comparisons to corporate fiduciary law may argue that patients, unlike shareholders, are incapable of evaluating medical decisions because they lack sufficient expertise.²⁷⁷ Robust fiduciary disclosure obligations, however, can help to reduce knowledge disparities by requiring the physician to communicate to the patient the information she needs to make welfare-maximizing choices.²⁷⁸ Physicians should be compelled to disclose their own ignorance about the safety and efficacy of untested therapies. Although patients frequently encounter physicians in vulnerable emotional, mental and physical states, the law should recognize their capacity to communicate their unique needs and desires. This includes both wishes to actively participate in medical decisionmaking, as well as expressed preferences to delegate decisional authority to physicians.

Legally recognizing the physician-patient relationship as a collaborative partnership rather than a contractual transaction can help to inculcate patient trust and physician trustworthiness. Medical trust in the form of emotionally based faith does not necessarily promote effective healthcare delivery.²⁷⁹ However, a fiduciary scheme can advance trust's instrumental function in producing and preserving mutually beneficial behavior. Experimental data from social dilemma games show that most people are capable of acting selfishly in some contexts and other-regarding in other contexts, and that social

2009, the Delaware Supreme Court held that corporate officers have the same fiduciary duties as directors. *Gantler v. Stephens*, 965 A.2d 695 (Del. 2009).

²⁷⁶ See Barry R. Furrow, *Patient Safety and the Fiduciary Hospital: Sharpening Judicial Remedies*, 1 DREXEL L. REV. 439, 439 (2009) (arguing that hospitals have fiduciary responsibilities to ensure patient safety).

²⁷⁷ See, e.g., Andrew Fichter, *The Law of Doctoring: A Study of the Codification of Medical Professionalism*, 19 HEALTH MATRIX 317, 332–33 (2009).

²⁷⁸ See Mehlman, *supra* note 250, at 390 (“The protections of fiduciary law are intended to permit patients to take advantage of the providers’ superior information and expertise with the expectation that the provider will use this information in the patient’s best interests.” (footnote omitted)).

²⁷⁹ Robert Gatter, *Faith, Confidence, and Health Care: Fostering Trust in Medicine Through Law*, 39 WAKE FOREST L. REV. 395, 405 (2004) (distinguishing between “trust-as-faith” and “trust-as-confidence” and arguing that the latter is sufficient to achieve health benefits).

“framing” dictates which personality type emerges.²⁸⁰ Research subjects “are remarkably sensitive to the signals they receive from the experimenter” when deciding whether to act selfishly or cooperatively.²⁸¹ These data have profound legal implications. Describing a relationship as an arms-length arrangement may encourage self-interested behavior.²⁸² Conversely, invoking fiduciary duties can reinforce trust relationships by articulating a social expectation that fiduciaries will meet a high standard of conduct.²⁸³ In the medical context, a doctrinal regime firmly grounded in fiduciary principles could help to reinforce norm-shaping ethical codes. Legal signals would encourage physicians to internalize trustworthiness, which in turn can spawn internalized trust within patients.²⁸⁴

C. Establishing Bounds of Clinical Discretion

Replacing objective standards with more robust disclosure obligations would compel physicians to tailor their communications to individual patients’ particular needs and preferences.²⁸⁵ But reforming informed consent would do little to encourage beneficial innovation without concomitant modifications to legal review of physicians’ substantive decisions. Doctors cannot be expected to share decisionmaking authority with patients until the law gives them meaningful incentives to do so. Physicians and patients may net benefit from a scheme that simultaneously mandates more comprehensive, individualized disclosure and shields physicians from liability for injuries stemming from fully informed, rational medical decisions.

Courts have been reluctant to allow breach of fiduciary duty claims in medical malpractice cases out of concern that recognizing additional claims will expose physicians to excessive liability risk.²⁸⁶ Physicians fear that imposing fiduciary duties will saddle them with higher costs and interfere with therapeutic objectives.²⁸⁷ But such concerns need not arise

²⁸⁰ Margaret M. Blair & Lynn A. Stout, *Trust, Trustworthiness, and the Behavioral Foundations of Corporate Law*, 149 U. PA. L. REV. 1735, 1742–43 (2001).

²⁸¹ *Id.* at 1797.

²⁸² *Id.* at 1784 (“Describing a relationship as a contract both assumes *and legitim[izes]* the adoption of a purely self-interested preference function by both parties.” (emphasis added)).

²⁸³ *Id.* at 1744 (“By articulating a social expectation that directors will exercise due care, judicial opinions on the duty of due care may influence directors’ behavior not so much by changing their external incentives as by changing their internal *preferences*.” (emphasis added)).

²⁸⁴ *Id.* at 1750 (“If Ann believes that Beth’s desire to behave trustworthily is strong enough to deter Beth from taking advantage of Ann, Ann may conclude it is safe to make herself vulnerable to Beth—that is, to trust Beth.”).

²⁸⁵ Matthew, *supra* note 261, at 796–97.

²⁸⁶ Morreim, *supra* note 199, at 477.

²⁸⁷ See Charity Scott, *Doctors as Advocates, Lawyers as Healers*, 29 HAMLIN J. PUB. L. & POL’Y 331, 331 (2008) (recounting her experience at a 2007 conference of mediation, health care, and

under a fiduciary framework that protects physicians against hindsight bias. Fiduciary law can provide physicians with the discretion to treat patients as individuals that they lack under the existing negligence regime.

Fiduciary law enforces the boundaries of permissible discretion by placing limits on fiduciaries' behavior rather than mandating specific actions.²⁸⁸ The range of lawful actions falling within the bounds of fiduciary discretion is often set by reference to entrustors' reasonable expectations. This standard incorporates both industry norms and the parties' individualized circumstances.²⁸⁹ Consideration of industry customs and norms ensures that fiduciary obligations adapt to social change. Sometimes social changes will curtail fiduciary duties, while other times social changes will give rise to new fiduciary obligations.²⁹⁰ In the health care context, the use of contextual benchmarks would ensure that fiduciary obligations capture evolving norms surrounding informed consent and shared decisionmaking, as well as advances in personalized medicine. Customary practices and CPGs could help to ascertain the limits of physicians' discretion, but should not be used to define a singular standard of care with respect to a particular medical decision. Consideration of relevant scientific data would obligate physicians to update their practices to incorporate new medical knowledge and clinical developments.

D. *Incorporating a "Medical Judgment" Rule*

When applying corporate law, courts invoke fiduciary principles to reinforce high expectations of performance for officers and directors, but simultaneously avoid unfairly penalizing managers for bad outcomes by shielding them with the business judgment rule.²⁹¹ The

legal professionals during which her statement that physicians owe fiduciary duties to their patients was met with angry responses from audience members, including: "You have to stop burdening doctors with more duties," and "The doctor-patient relationship is therapeutic . . . It's a disservice to suggest otherwise").

²⁸⁸ Deborah A. DeMott, *Beyond Metaphor: An Analysis of Fiduciary Obligation*, 1988 DUKE L.J. 879, 915 ("Described instrumentally, the fiduciary obligation is a device that enables the law to respond to a range of situations in which, for a variety of reasons, one person's discretion ought to be controlled because of the characteristics of that person's relationship with another."); Smith & Lee, *supra* note 247, at 25 (asserting that fiduciary law should be construed as a means for "boundary enforcement").

²⁸⁹ Smith & Lee, *supra* note 247, at 28–29.

²⁹⁰ See Melvin A. Eisenberg, *The Duty of Good Faith in Corporate Law*, 31 DEL. J. CORP. L. 1, 30–31 (2006) (noting that sometimes social changes indicate that a fiduciary obligation should be scaled back, while "[o]ther times, social changes indicate that a new specific fiduciary obligation should be articulated because a type of conduct that was once regarded as proper is no longer so regarded").

²⁹¹ See generally Blair & Stout, *supra* note 280, at 1735.

business judgment rule is a term with several different, and conflicting, meanings.²⁹² But all variations embody the rationale that the law should protect corporate fiduciaries from hindsight bias because managers must make risky decisions with uncertain outcomes.²⁹³ A similar rationale favors deferential review of physicians' decisions.²⁹⁴ The medical literature shows that even clinical experts are susceptible to hindsight bias and the related phenomenon outcome bias.²⁹⁵

The business judgment rule instructs courts to defer to directors' business decisions so long as they are made "on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the company."²⁹⁶ In cases that do not involve conflicts of interest, "good faith" and "honest belief" are generally presumed. Thus, absent conflicts of interest, director liability normally turns on whether the board's decision was informed.²⁹⁷ The American Law Institute's *Principles of Corporate Governance* articulate the business judgment rule to draw a distinction between legal review of the process and substance of corporate decisionmaking. The Principles state that a director must be "informed with respect to the subject of the business judgment to the extent the director . . . reasonably believes to be appropriate under the circumstances," and the director must "rationally believe[] that the

²⁹² See FRANKLIN A. GEVURTZ, CORPORATION LAW § 4.1, at 287–97 (2d ed. 2010) (delineating several possible meanings for the business judgment rule).

²⁹³ *Id.* at 298–99 (explaining that, without the protection of the business judgment rule, "directors have an incentive to avoid potentially more desirable higher risk activities in favor of less profitable but more sure fire undertakings").

²⁹⁴ *Id.* at 300 ("To the extent this sort of intuitive 'knowing in action' does not lend itself to an accurate after-the-fact judicial assessment of reasonableness, then perhaps there is a need to rethink the standards of malpractice generally."). Judicial deference to physicians' professional judgment appears limited to a few cases involving psychiatric care. See *Currie v. United States*, 644 F. Supp. 1074 (M.D.N.C. 1986), *aff'd*, 836 F.2d 209 (4th Cir. 1987) (holding that psychotherapists should be granted broad discretion to make commitment decisions); *Littleton v. Good Samaritan Hosp. & Health Ctr.*, 529 N.E.2d 449 (Ohio 1988) (holding that courts should not second-guess a psychiatrist's professional judgment, but stating that psychiatrists must conform to professional standards where such standards exist).

²⁹⁵ Hindsight bias is the phenomenon whereby individuals overestimate the probability that a poor outcome could have been anticipated. Outcome bias is the observation that evaluators make systematically unfair judgments about the quality of the decision if they know about a poor outcome beforehand. See, e.g., Hal R. Arkes et al., *Hindsight Bias Among Physicians Weighing the Likelihood of Diagnoses*, 66 J. APPLIED PSYCHOL. 252 (1981); Robert A. Caplan et al., *Effect of Outcome on Physician Judgments of Appropriateness of Care*, 265 JAMA 1957, 1957–60 (1991) (showing that physicians' ratings of the appropriateness of care were influenced by the severity of the adverse outcome, even though the care was identical); Neal V. Dawson et al., *Hindsight Bias: An Impediment to Accurate Probability Estimation in Clinicopathologic Conferences*, 8 MED. DECISION MAKING 259 (1988) (demonstrating hindsight bias among a group of physicians attending a case conference).

²⁹⁶ *Aronson v. Lewis*, 473 A.2d 805, 812 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 742 A.2d 244 (Del. 2000).

²⁹⁷ Blair & Stout, *supra* note 280, at 1790.

business judgment is in the best interests of the corporation.”²⁹⁸ This approach instructs courts to review directors’ decisionmaking process under an ordinary negligence standard, but to apply a more deferential standard (akin to gross negligence) to the substance of the board’s decision.²⁹⁹ If the decisionmaking process is proper, the business judgment rule shields directors from ex post judicial second-guessing.³⁰⁰

The law should take an analogous approach to medical malpractice liability. It should require physicians to diligently attend to the patient’s needs and preferences, but incorporate a “medical judgment” rule that shields them from liability for poor patient outcomes.³⁰¹ Such deference to clinical discretion manifests a supportive stance toward trust³⁰² that would enable physicians to deliver beneficial care to patients.³⁰³ However, a “medical judgment” rule must take into account significant differences between business and medical decisionmaking. Patients do not delegate decisional authority to physicians in the same way that shareholders delegate authority to corporate officers and directors. While shareholders vote on major transactions, such as mergers and large acquisitions,³⁰⁴ corporate fiduciaries do not have physicians’ informed consent obligations.

The “honest error in judgment” jury instruction that courts sometimes allow in medical malpractice cases resembles the version of the business judgment rule that stresses that directors are not negligent

²⁹⁸ 1 AM. LAW INST., PRINCIPLES OF CORPORATE GOVERNANCE: ANALYSIS AND RECOMMENDATIONS § 4.01(c) (1994) (emphasis added).

²⁹⁹ GEVURTZ, *supra* note 292, at 295.

³⁰⁰ *Id.*

³⁰¹ It has been argued that a business judgment-type rule is inappropriate in medical malpractice cases. See Hal R. Arkes & Cindy A. Schipani, *Medical Malpractice v. the Business Judgment Rule: Differences in Hindsight Bias*, 73 OR. L. REV. 587, 590–91 (1994) (favoring instead a bifurcated trial in which negligence is determined in the first phase and, if negligence is found, damages are assessed in a separate second phase). This argument is based on assertions that risk-taking is explicitly encouraged in business, but not in medicine, and that medical decisions, unlike business decisions, can be evaluated by reference to generally accepted professional practices. *Id.* at 622–30. Jeffrey O’Connell and Andrew Boutros debunk these assertions. See Jeffrey O’Connell & Andrew S. Boutros, *Treating Medical Malpractice Claims Under a Variant of the Business Judgment Rule*, 77 NOTRE DAME L. REV. 373, 391–92, 400–22 (2002) (advocating an “early offers” plan for medical malpractice cases that would enable physicians to avoid liability for noneconomic damages and which they describe as a variant of the business judgment rule).

³⁰² Hall, *supra* note 55, at 486 (explaining that a supportive stance toward trust aims to use the law to produce or sustain trust); see also Smith & Lee, *supra* note 247, at 23–24 (“After the terms of the contract, fiduciary duties, and social norms have all played their boundary enforcement roles, any remaining discretion is left to trust.”).

³⁰³ EDMUND D. PELLEGRINO & DAVID C. THOMASMA, THE VIRTUES IN MEDICAL PRACTICE 69 (1993) (“The more discretionary latitude we permit our professionals, the more vulnerable we become. Yet to limit that latitude is to limit the capacity for good as much as it may limit the capacity for harm.”).

³⁰⁴ DEL. CODE ANN. tit. 8, §§ 251(c), 271(a) (West 2006).

if they make a decision about which reasonable minds disagree.³⁰⁵ Yet the “error in judgment” instruction neglects the importance of informed consent and shared medical decisionmaking. Good faith alone should not shield physicians from liability for patient injuries. Physicians must inform both themselves and their patients about the benefits, risks, and uncertainties of treatment options. If the physician fulfills her fiduciary disclosure obligations and the parties stand in informational parity, they should have the discretion to make choices that they rationally believe serve the patients’ best interests. Informed, consensual medical decisions should be entitled to substantial deference.

E. *Enhanced Scrutiny Where Conflicts of Interest Exist*

In *Pegram v. Herdrich*,³⁰⁶ the U.S. Supreme Court held that a breach of fiduciary duty claim against an HMO physician involving a “mixed decision” about the patient’s eligibility for treatment reimbursement and the appropriate clinical course for the patient needlessly duplicates an ordinary malpractice claim.³⁰⁷ In rejecting the argument that fiduciary law should replace tort law vis-à-vis substantive review of the physician’s decision, the Court implicitly concluded that objective negligence standards effectively govern any treatment decision, regardless of the particular context in which the decision is made.³⁰⁸ The Court left open the possibility that fiduciary duties attach to the decisionmaking process when it stated in dicta that there might be a fiduciary requirement to disclose managed care incentives.³⁰⁹

However, mandatory disclosure of financial conflicts may not adequately protect patients from self-interested physician behavior. Patients cannot reasonably be expected to perform the difficult task of discerning whether or not a physician’s disclosed conflict has materially influenced his clinical judgment.³¹⁰ Instead, conflicts of interest should

³⁰⁵ GEVURTZ, *supra* note 292, at 289; *see also* Smith & Lee, *supra* note 247, at 38 (stating that most courts applying fiduciary law seem to understand “that they should not substitute their own judgments for the judgments of fiduciaries, unless the fiduciaries are not to be trusted because they are acting inappropriately in a self-interested manner. . . . *The nature of discretion is that reasonable people might come to different conclusions*” (emphasis added)).

³⁰⁶ 530 U.S. 211 (2000).

³⁰⁷ *Id.* at 235.

³⁰⁸ *Id.* at 231, 236–37.

³⁰⁹ *See id.* at 228 n.8; *see also* Shea v. Esensten, 107 F.3d 625, 628–29 (8th Cir. 1997) (recognizing a breach of fiduciary duty claim based on an HMO’s failure to disclose physician payment methods). *But cf.* Neade v. Portes, 739 N.E.2d 496, 505–06 (Ill. 2000) (“[D]eclin[ing] to recognize a new cause of action for breach of fiduciary duty against a physician for the physician’s failure to disclose HMO incentives . . .”).

³¹⁰ Mehlman, *supra* note 220, at 1150 (“Given that seriously ill patients typically have few options and inferior bargaining power, disclosure [of physician conflicts of interest] is not likely to be an adequate form of protection.”).

trigger heightened substantive scrutiny of medical decisions. Under Delaware law, corporate fiduciaries' self-interested transactions are upheld only if they satisfy both procedural requirements of full disclosure and informed consent, and substantive requirements of objective fairness. Delaware courts assess corporate fiduciaries' duty of loyalty using an "entire fairness" standard that considers both "fair dealing" and "fair price."³¹¹ Importantly, fair price is "not a point on a line, but a range of reasonable values."³¹² A similar approach should be taken to assess clinical decisions where the physician has a significant financial or research conflict of interest. Physicians should be obligated to deal fairly with patients by fully disclosing such conflicts, and courts should scrutinize the substance of treatment decisions to determine whether they fall within the range of options that reasonably could be expected to advance the patients' interests. Just as a favorable shareholder vote cannot save a directors' action that amounts to "waste"—because no reasonable person would conclude that the corporation could expect a net benefit³¹³—fully informed consent should not save a manifestly unreasonable medical decision that does not serve the patient's interests. While punitive damages generally should be unavailable in medical malpractice actions, they should be reserved for egregious abuses of physician power.³¹⁴

In sum, review of a physician's treatment decision should first assess whether or not a conflict of interest exists. If there are no significant conflicts, the focus of the inquiry should be on whether the physician adequately informed both herself and her patient about relevant risks, benefits, and uncertainties associated with available treatment options. If these procedures are met, adjudicators should deferentially review patients' and physicians' substantive decisions. If a significant conflict of interest exists, the physician's decision should be subject to heightened scrutiny analogous to corporate law's "entire fairness" test. This approach to medical decisionmaking could be described as a form of libertarian paternalism, in that it respects individual choice while also incorporating procedural and substantive constraints to block choices that are manifestly inconsistent with patient welfare.³¹⁵ Procedural constraints include disclosure requirements to inform patients of relevant costs, benefits, risks and uncertainties.

³¹¹ Smith & Lee, *supra* note 247, at 29–30.

³¹² Cede & Co. v. Technicolor, Inc., No. Civ.A. 7129, 2003 WL 23700218, at *2 (Del. Ch. Dec. 31, 2003), *aff'd in part, rev'd in part on other grounds*, 884 A.2d 26 (Del. 2005).

³¹³ GEVURTZ, *supra* note 292, at 296 (noting that most waste claims involve conflict-of-interest transactions).

³¹⁴ Though not invariably a feature of fiduciary law, punitive damages are sometimes awarded to plaintiffs who successfully litigate breach of fiduciary duty claims. See Morreim, *supra* note 57, at 71.

³¹⁵ Sunstein & Thaler, *supra* note 12.

Substantive constraints include requirements that treatment choices are reasonable and rationally expected to advance the patient's interests.

F. *Rethinking Assumption of Risk and Covenants Not to Sue*

Viewing physician innovation through a fiduciary lens invites judicious recognition of express assumption of risk and enforcement of covenants not to sue. Rather than treat all such agreements as violations of public policy, medical malpractice law should distinguish between non-negotiable fiduciary duties and duties that may be contractually modified by the parties.³¹⁶ While agents and principals are generally permitted to contract around the agent's default duties,³¹⁷ a fiduciary may not contract out of the duty of loyalty.³¹⁸ Properly applied, fiduciary law should give the patient the legal protection she needs—and which she does not enjoy under an arms-length contractual relationship³¹⁹—to negotiate a fair bargain over the parties' liability allocations.³²⁰ Allowing patients to assume liability for harms resulting from reasonable choices to receive innovative care would offer them greater access to potentially beneficial new therapies.³²¹

Cass Sunstein and Richard Thaler, the founders of libertarian paternalism, have advocated permitting patients to waive the right to sue their physicians.³²² Yet fiduciary principles dictate more nuanced treatment of liability waivers. Patients should be prohibited from waiving the right to sue for injuries caused by negligent clinical execution, because in this case there is a significant risk that the patient

³¹⁶ See Alces, *supra* note 247, at 241 (arguing that fiduciary law should apply only where contract and market forces cannot adequately constrain managerial behavior).

³¹⁷ RESTATEMENT (THIRD) OF AGENCY § 8.12 (2006) (“An agent has a duty, *subject to any agreement with the principal*.” (emphasis added)); Matthew, *supra* note 261, at 755; Smith, *supra* note 245, at 1492 (noting that, in most fiduciary relationships, parties may contractually modify fiduciary obligations).

³¹⁸ See DEL. CODE ANN. tit. 8, § 102(b)(7)(2006); Alces, *supra* note 247, at 251.

³¹⁹ Smith, *supra* note 245, at 1410 (“[C]ontracting parties may act in a self-interested manner even where the other party is injured, as long as such actions are reasonably contemplated by the contact [sic].”).

³²⁰ See Frankel, *supra* note 226, at 834 (“[F]iduciary law will protect the entrustor by ascertaining the costs of regulating the fiduciary, and also achieve fairness for both parties by allowing them to bargain freely over the allocation of the costs of regulation.”).

³²¹ See Michelle M. Mello et al., *Compact Versus Contract—Industry Sponsors' Obligations to Their Research Subjects*, 356 NEW ENG. J. MED. 2737, 2742 (2007) (noting the link between increased access to medicines and greater demands for exculpatory provisions in clinical research).

³²² RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE*, at ch. 14 (2008) (arguing that negligence liability is probably a “losing deal” for most patients); see also Tom Baker & Timothy D. Lytton, *Allowing Patients To Waive the Right To Sue For Medical Malpractice: A Response to Thaler and Sunstein*, 104 NW. U. L. REV. 233, 250 (2010) (asserting that Thaler and Sunstein's argument that patients should be able to waive the right to sue is classical libertarianism, not a more moderate libertarian paternalism).

will make a bargain that is manifestly against his own interests.³²³ However, physicians and patients should be allowed to contractually enforce discretionary decisions to deviate from prevailing practices so long as the patient's choice is informed and rational. Such an approach better embodies libertarian paternalism's core tenets.

Colton v. New York Hospital,³²⁴ a notable exception to general judicial reluctance to enforce liability waivers in the healthcare context, illustrates how covenants not to sue should be treated under a fiduciary framework. The New York court held that a covenant not to sue barred a malpractice claim arising out of an experimental kidney transplant operation.³²⁵ Importantly, the waiver of liability was only partial, in that it only absolved the health care provider of liability for the *decision* to perform the procedure and not for negligence in the *manner* in which the procedure was performed.³²⁶ The court reasoned that benefits derived from medical experimentation might be foregone if patients cannot waive liability in exchange for access to innovative techniques.³²⁷

G. Preliminary Thoughts About Implementation

This Article's proposals could be implemented through a combination of statutory revisions to standards of care, screening of malpractice claims by medical review panels,³²⁸ and self-regulation by health care systems. At some medical centers, the infrastructure for institutional oversight of physician innovation is already in place. For example, in 2001, the Boston Children's Hospital introduced a voluntary program of "review and oversight for innovative surgery that (1) 'represents a significant increase in risk, above the alternative approaches [that [sic]] could have been offered,' or (2) 'when the procedure is so novel that the risks and benefits are unknown.'"³²⁹ When the risks and benefits of an untested procedure are unknown, a definitive risk-benefit analysis is not possible. In these cases, the focus of review must be on the information gathering process and ensuring that patients and their surrogates are fully informed and capable of making rational choices about potentially beneficial new treatments.

³²³ See Baker & Lytton, *supra* note 322, at 238.

³²⁴ 414 N.Y.S.2d 866 (Sup. Ct. 1979).

³²⁵ *Id.* at 875-86.

³²⁶ *Id.* at 875.

³²⁷ *Id.* ("A patient's opportunity to be aided by innovative technology presupposes the availability of willing physicians unafraid to use it.")

³²⁸ Medical review panels have already been established in many states to screen medical malpractice claims. See, e.g., IND. CODE ANN. § 34-18-8-4 (West 2011).

³²⁹ Mastroianni, *supra* note 7, at 440 (alterations in original).

Fiduciary principles could be adapted to govern researcher-subject relationships in the context of formal medical experimentation. It has been argued that researchers do not owe fiduciary duties to subjects, because researchers' first priority is to the research protocol.³³⁰ But the thin and ambiguous line between research and practice argues against drawing a sharp distinction on when fiduciary relationships form.³³¹ As with clinical innovation in the treatment setting, oversight of medical research should emphasize enforcing procedural safeguards (i.e., ensuring fully informed consent to cede decisional autonomy), combined with a deferential substantive inquiry that takes a broad view of subjects' best interests. In addition to subjects' direct benefits from participating in a clinical trial, the substantive inquiry should consider collateral benefits, as well as individual risk preferences and altruistic motives. Fully informed subjects should be free to enroll in research trials so long as the choice falls within a broad range of reasonableness based on an expansive definition of subjects' best interests. Investigators should be shielded from liability for harm that results from non-negligent execution of the research protocol.

CONCLUSION

Medical malpractice doctrine has been criticized for both failing to actualize principles of patient autonomy and insufficiently protecting patients from harm. At the same time, it has been argued that current law unfairly exposes physicians to hindsight bias and stifles medical progress. This Article lays the groundwork to address these concerns by proposing a comprehensive fiduciary framework to regulate medical decisionmaking under conditions of endogenous uncertainty. Properly applied, fiduciary law has the potential to both promote patient welfare and to bolster clinical discretion.

³³⁰ Morreim, *supra* note 57, at 477 (arguing that investigators and subjects do not have a fiduciary relationship, but noting that her view clashes with those of other commentators).

³³¹ See Richard S. Saver, *Medical Research Oversight from the Corporate Governance Perspective: Comparing Institutional Review Boards and Corporate Boards*, 46 WM. & MARY L. REV. 619, 647-48 (2004) (contending that the governance of corporate boards can offer insight into improving IRBs' oversight of human subjects research, and arguing that IRBs can be viewed as subjects' quasi-agents).

Under the proposed model, patients should be able to choose from among a range of options with a reasonable mix of benefits, risks, and uncertainties. Physicians should be shielded from liability where they satisfactorily discharge their fiduciary disclosure duties and pursue a non-customary treatment course that rationally advances their patient's interests. This approach strikes a desirable balance that respects patient self-determination, minimizes unnecessary risk, and encourages beneficial innovation.