

CAN HEALTH LAW TRULY BECOME PATIENT CENTERED?

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INTRODUCTION

Close to a decade ago, the Institute of Medicine (“IOM”) report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, identified “patient-centeredness” as a core health care aim for the new century, “focus[ing] on the patient’s experience of illness and health care and on the systems that work or fail to work to meet individual patients’ needs.”¹ To many observers, the IOM’s statement seemed unnecessary and self-evident: what aim could *any* health care system have but to serve the needs of its patients, the *sine qua non* of medicine? Yet the report was replete with references to patients’ widespread “frustration with their inability to participate in decision making, to obtain information they need, to be heard, and to participate in systems of care that are responsive to their needs.”² While initially focused on problems in clinical encounters, the patient-centered care movement has now grown to encompass systems-level structural concerns as well. As conceptualized more broadly, a patient-centered approach to health care makes “serving the practical health care needs of patients (1) the focal point of the health care system, (2) the paramount responsibility of health professionals, and (3) the primary role of private and public financing [of] health care.”³ That transformation is not possible without close attention not only to the norms of medical practice, but also to the legal structures and rules that govern the provision of health care in the United States.

Now, as the debate over patient-centered care moves from the bioethics and health policy spheres to the legal arena, a central question emerges: can our system of health *law*, as distinct from our

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1. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 48 (2001).

2. *Id.* at 48–49.

3. Laura D. Hermer & William J. Winslade, *Access to Health Care in Texas: A Patient-Centered Perspective*, 35 TEX. TECH L. REV. 33, 34 (2004).

standards of medical ethics, truly become patient centered? Certainly, there is reason for skepticism. The sad truth is that health law has not, historically, been particularly good at being patient centered. Many of our efforts to protect patient interests—be those interests physical, psychological, or financial—have fallen far short of the goal. The complexities of the legal system offer a highly imperfect mechanism for achieving ethical ideals. Law by necessity relies on practical rules of general applicability—rules that themselves may become barriers to reaching the very goals they are designed to achieve. Experience has shown us that ethical precepts tend to translate into limited legal rules that at best protect only a small subset of patients, and at worst co-opt the language of patient-centeredness for other agendas entirely. This does not mean, of course, that we should not expect—and even demand—that health law do more. But we must be mindful of these problems, lest our renewed efforts to achieve patient-centeredness suffer a similar fate.

I. PATIENT-CENTERED FAILURES OF LAW

Examples of the failure to achieve true patient-centeredness exist throughout the myriad of topics that comprise the field of health law;⁴ I will mention only two. One example is the doctrine of informed consent, the prototypical legal tool for protecting patients' medical choices. The second example, falling within the ambit of regulatory and transactional health law rather than bioethics, concerns explicitly patient-centered efforts in recent health care fraud and abuse enforcement.

Some will no doubt object that, despite their differences, both of these topics share a litigation-oriented focus: informed consent provides a cause of action for patients whose physicians have not satisfied their duty to disclose relevant treatment information; health care fraud and abuse is subject to severe civil and criminal sanctions, not to mention high-dollar private fraud and contract lawsuits. This is a valid concern. The legal system is richly intertwined with the medical system in so many ways beyond litigation, from hospital and medical licensure to the regulation of private and public health insurance to the policy analysis and legislative negotiations that resulted in the recently enacted Patient Protection and Affordable Care Act ("PPACA"),⁵ just to name a few. Yet virtually every regulatory, transactional, and policy initiative ultimately defaults to *litigation*, in some guise, to ensure that its mandates are carried out. To the extent a lawsuit may be the option

4. See generally Mark A. Hall, Carl E. Schneider & Lois Shepherd, *Rethinking Health Law: Introduction*, 41 WAKE FOREST L. REV. 341 (2006) (discussing aspects of health law).

5. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

of last resort for individuals injured by the health care system (most of whom happen to be patients), litigation remains linked to the heart of patient-centered care. If a litigation process that purports to protect patients cannot be structured to meet this goal, some deeper reflection is in order before we can expect the concept of patient-centered care to transform other aspects of health law.

A. *The Unfulfilled Promise of Informed Consent*

Informed consent law manages to stand, simultaneously, as both the clearest hope for a truly patient-centered legal doctrine and the clearest example of its shortcomings. At its core, this right of medical self-determination is designed to ensure that physicians disclose the information necessary for patients to make informed choices about their medical care and to provide a cause of action when physicians fail to carry out this duty.⁶ Despite decades of case law, statutes, and commentary, however, there is scant evidence that the legal rules mandating informed consent actually work. Yet the bedrock doctrine persists, both as an ethical ideal and as a litigation threat.

While this legal-ethical duality may be one of the hallmarks of informed consent, it makes it difficult to assess how well the doctrine has met its patient-centered goals. Informed consent is very much a product of the legal system, but its effects have been far broader than merely creating a cause of action. The development of the doctrine in mid-twentieth-century case law corresponded with, and in turn reinforced, a cultural shift in our attitudes toward the patient's role in medical care: from a paternalistic system in which medical decisions were made by physicians for their patients—albeit with the patients' "best interests" in mind—to a system that stressed patients' rights (and perhaps responsibilities) to participate in the decision-making process.⁷ To many the shift was nothing short of seismic. As Professor George Annas has explained, "Informed consent, more accurately termed informed choice, is the most important legal doctrine in the doctor-patient relationship and in health care facilities. Information is power, and because information sharing inevitably results in decision sharing, the doctrine of informed consent has helped transform the doctor-

6. Note that informed consent to participation in medical *research*—abuses of which led to the genesis of the doctrine—has followed a different model, dominated by federal government regulation and oversight by institutional review boards rather than by state statutes and case law.

7. For a brief history of this shift, see RUTH R. FADEN & TOM L. BEAUCHAMP WITH NANCY M.P. KING, A HISTORY AND THEORY OF INFORMED CONSENT 53–101 (1986); JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 1–29 (1984). For an analysis of whether the modern emphasis on autonomy has gone too far for some patients, see CARL E. SCHNEIDER, THE PRACTICE OF AUTONOMY: PATIENTS, DOCTORS, AND MEDICAL DECISIONS (1998).

patient relationship.”⁸ Participants in the Wake Forest symposium and workshop agreed that informed consent has, for better or worse, changed patient expectations of the role they should play in their own medical care.

Yet to say that the *principle* of informed consent, or perhaps the ethical ideal, has had a transformative effect on the doctor-patient relationship is very different from saying that the *legal rules* governing informed consent have been able to achieve their patient-centered aims. From the start, critics argued that the norms of the medical profession were at best an ill fit for, and at worst antithetical to, the legal doctrine of informed consent.⁹ In this view, the doctrine’s vision of shared decision-making is an illusion—or in the immortal words of Professor Jay Katz, a “fairy tale”—and the legal system is powerless to mandate the types of professional and social changes necessary to enable that vision to come to fruition.¹⁰ In this view, “informed consent has done nothing to *change* historical medical practice because informed consent has never really *arrived* in medicine, never really taken hold. . . . Katz seems right in his thesis that informed consent has not changed the fundamental character of the physician-patient relationship.”¹¹

Both empirical evidence and anecdotes support these criticisms. As experienced by patients, informed consent seems less a shared decisional process than a *transaction*, one in which the legally required quantum of information is packaged into discrete nuggets and presented on standardized forms for the patient’s signature—not unlike the forms required to obtain a home mortgage. Physicians refer to the task of “consenting” patients, not to “informing” them.¹² This failure rests squarely on the legal system:

[A]s the doctrine has developed during the last several decades, it has failed consistently to work as it was intended to work. This failure is a consequence of actual practice, which often differs from the ideal, and it is a consequence of lawmakers having elaborated the parameters of the doctrine. . . . [O]ften, in practice, the presumptively autonomous patient does little more than opt for or against a

8. GEORGE J. ANNAS, THE RIGHTS OF PATIENTS 113 (3d ed. 2004) (emphasis omitted).

9. See FADEN ET AL., *supra* note 7, at 57.

10. See generally Jay Katz, *Informed Consent—A Fairy Tale? Law’s Vision*, 39 U. Pitt. L. Rev. 137 (1977) [hereinafter Katz, *Law’s Vision*]; Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL’Y 69 (1994). As Katz noted, “[W]hat passes today for disclosure and consent in physician-patient interactions is largely an unwitting attempt by physicians to shape the disclosure process so that patients will comply with their recommendations.” KATZ, *supra* note 7, at 26.

11. FADEN ET AL., *supra* note 7, at 100.

12. See JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 188 (2d ed. 2001).

proposed course of treatment. Critics argue that the doctrine has facilitated the move from a trust-centered model of the doctor-patient relationship to one based around legal rules.¹³

Not surprisingly, the heavy reliance on forms does little to convey important information to patients. A recent commentary in *The Journal of the American Medical Association*, for example, concluded that “current efforts to inform patients are inadequate,” the information distributed to patients “ha[s] limited educational value,” and many patients do not read the disclosure forms and “misunderstand the benefits and risks” of their treatments.¹⁴ Indeed, the ones who benefit most from the form-heavy process appear to be medical professionals, who can point to the signatures as proof that legally sufficient consent was obtained.

Informed consent thus remains something of an enigma. The legal mandate does little to ensure that patients either comprehend relevant information or feel empowered to act on the information they do receive, while at the same time shielding medical professionals who merely get the paperwork done. Yet for all its failings, the law has had what Professor Nancy King and others describe as a “paradoxically richer effect” on both patient expectations and the field of bioethics more generally.¹⁵

At the same time that nothing has changed in medicine, everything has changed. Every day, in hospitals and clinics all over the United States, patients are giving their “informed consents” to surgery, diagnostic procedures, anesthesia, and the like. True, these may be less than substantially autonomous exercises of decisional authority; nevertheless, the practice of medicine has been changed, at least on the surface. Physicians must, at the very least, pay lip service to the rights of their patients to be informed and to consent; they (or the nurses) must introduce the subject and get the forms signed. Moreover, we suspect that many health care professionals pay more than lip service.¹⁶

Whether informed consent has succeeded as a patient-centered mechanism, then, depends very much on whether the focus is on the individual or systemic level.

The theme of this symposium, however, is not just “Patient-Centered Ethics,” but rather “Patient-Centered Law and Ethics.” To be considered a success under this paradigm, the *law* of informed consent, not merely the ethical ideals it represents, must be capable

13. Janet L. Dolgin, *The Legal Development of the Informed Consent Doctrine: Past and Present*, 19 CAMBRIDGE Q. HEALTHCARE ETHICS 97, 102 (2010) (Eng.) (footnotes omitted).

14. Harlan M. Krumholz, *Informed Consent To Promote Patient-Centered Care*, 303 JAMA 1190, 1190 (2010).

15. This phrase was used by participants in the symposium discussion.

16. FADEN ET AL., *supra* note 7, at 100.

of making medical care more patient centered, or at the very least not leaving patients worse off—as they may be when they hurriedly sign forms after receiving a barrage of medical information they do not fully comprehend and will be unable to recall. That informed consent law has had *symbolic* patient-centered effects is unequivocally a positive thing, but it is not sufficient to deem the legal doctrine itself a patient-centered success.

B. Patient-Centered Fraud Enforcement: An Uneasy Alliance

On perhaps the other end of the health law spectrum, a similar story can be told with regard to patient-centered efforts in health care fraud and abuse enforcement. As I have discussed extensively elsewhere, despite the fact that health care fraud harms patients—and the fact that the protection of beneficiaries is often a key reason offered to justify expansive new anti-fraud initiatives—compensating patients does not play a significant role in resolving most health care fraud disputes.¹⁷ The funds recovered through health care fraud enforcement are distributed to the Medicare Trust Fund, to the federal agencies that investigate and prosecute health care fraud, and to the private parties (known as “relators”) who file suit on the government’s behalf under the *qui tam* provisions of the civil False Claims Act¹⁸—but rarely, if ever, to the patients who were harmed by the fraud. While returning funds to the treasury helps assure that the federal health care programs remain solvent and provide care to the aggregate beneficiary population, the practice offers little remedy for injured individuals.

As a preliminary matter, one might ask why individual patients should be expected to benefit at all from fraud settlements in which wrongdoers are forced to repay money that was taken from health care payers, such as Medicare, Medicaid, or private insurers. The answer begins with the fact that health care fraud harms patients in a number of serious ways. Patients may suffer *financial* harm by fraud, such as by being charged an excessive copayment for a drug with an artificially inflated price; patients may suffer *physical* harm, including injuries both from substandard or useless treatments and from legitimate but unnecessary medical interventions; and patients may suffer *intangible* harms, such as when their medical information is misused by a third party to submit fraudulent claims for payment.¹⁹ Drawing on these examples, prosecutors and policy-makers have invoked what I call the “rhetoric of patient protection,”

17. See generally Joan H. Krause, *Health Care Fraud and Quality of Care: A Patient-Centered Approach*, 37 J. HEALTH L. 161 (2004) [hereinafter Krause, *Health Care Fraud and Quality of Care*]; Joan H. Krause, *A Patient-Centered Approach to Health Care Fraud Recovery*, 96 J. CRIM. L. & CRIMINOLOGY 579 (2006) [hereinafter Krause, *A Patient-Centered Approach*].

18. See 31 U.S.C. §§ 3729–3733 (2006).

19. See Krause, *A Patient-Centered Approach*, *supra* note 17, at 587–95.

advancing the goal of protecting patients as a key motivation for aggressive fraud enforcement. In the words of then-Associate U.S. Attorney James Sheehan (now the New York Medicaid Inspector General), “[T]he bigger issues going forward are not the issues of billing for services not rendered; the bigger issues are what is happening to the patients . . . That’s what the jury is going to focus on, that’s what the fraud statutes are basically designed to protect, the victims of the fraud.”²⁰

Despite this rhetoric, very little of the money recovered in these cases is returned in any measurable fashion to these “victims.” In a *qui tam* case, for example, roughly fifteen to twenty-five percent of the proceeds will be awarded to the relator who initiated the suit.²¹ In accordance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), most of the remaining funds, as well as civil penalties and health care related criminal fines and forfeitures, must be deposited into the financially troubled Medicare Part A Trust Fund.²² From there, those funds are available for appropriation to the Health Care Fraud and Abuse Control Account, a special expenditure account jointly available to the Secretary of Health and Human Services and the Attorney General to fund those agencies’ ongoing anti-fraud efforts.²³ As a result, the money recovered in fraud cases is available to the Medicare program, to

20. James Sheehan, Assoc. U.S. Att'y, Biotech Fraud: Reality or Fantasy?, Address at the Houston Journal of Health Law & Policy Biotechnology Symposium, in 2 Hous. J. HEALTH L. & POL'Y 11, 20, 26 (2002); *see also* Krause, *Health Care Fraud and Quality of Care*, *supra* note 17, at 173–75 (discussing rhetoric). Note that this rhetoric was more prominent during the Clinton and George W. Bush administrations. While mindful of the harm to individuals, the Obama administration’s strong anti-fraud agenda has focused more on the financial consequences of fraud, primarily the diversion of money away from paying for legitimate health care services. *See, e.g.*, HEAT Task Force, *Success: Health Care Fraud Prevention and Enforcement Action Team*, STOPMEDICAREFRAUD.GOV, <http://www.stopmedicarefraud.gov/heatsuccess/index.html> (last visited Nov. 1, 2010) (“Health care fraud perpetrators are stealing billions of dollars from the federal government, American taxpayers[,] and some of our most vulnerable citizens. This not only drives up costs for everyone in the health care system, it hurts the long term solvency of Medicare and Medicaid, two programs upon which millions of Americans depend.”).

21. *See* 31 U.S.C. § 3730(d) (2006) (discussing range of awards for *qui tam* plaintiffs).

22. Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. § 1395i(k)(2)(C)(iv) (2006) (authorizing the transfer of penalties and damages obtained in health care cases to the Trust Fund, with the exception of funds awarded to a relator, funds designated for restitution, or as otherwise authorized by law); *see also* MEDICARE PAYMENT ADVISORY COMM'N, A DATA BOOK: HEALTHCARE SPENDING AND THE MEDICARE PROGRAM 13 (2010), <http://www.medpac.gov/documents/Jun10DataBookEntireReport.pdf> (projecting that the Medicare Trust Fund could be exhausted between 2014 and 2028).

23. *See* 42 U.S.C. § 1395i(k)(3) (2006) (describing appropriations to the Health Care Fraud and Abuse Control Account).

whistleblowers, and to the investigating and prosecuting agencies themselves, but not to compensate the patient-victims on whose behalf the enforcement was supposedly undertaken. While the rhetoric of health care fraud enforcement is explicitly patient centered, the reality of fraud recovery turns out to be anything but.

II. UNDERSTANDING THE FAILURE: WHO IS THE “PATIENT” AT THE CENTER OF PATIENT-CENTERED CARE?

In the search for a reasoned explanation for the weakness of patient-centered legal protections, we must remember that health law is only one aspect of the overall legal system. Doctrines such as informed consent seek to protect the interests of individual patients, but they do so within a larger legal framework that must balance individual protection against such concerns as basic fairness, judicial economy and efficiency, optimal deterrence, the collateral economic effects of large damages awards, and the need for binding case law precedent. Once an ethical precept such as patient-centeredness is put through what euphemistically might be termed the “jurisprudential meat grinder,” the result tends to be a preference for bright-line rules that can streamline disputes into a standard, easily replicated resolution model.²⁴ At some point, if the system is to remain even remotely functional, the preferences of individual patients may have to yield to common rules.

These factors may help to explain the lack of direct compensation to patients in the health care fraud context. In many cases, the harm to patients from large-scale fraud schemes is so diffuse as to make individual compensation nearly impossible.²⁵

24. One long-studied problem in both informed consent and broader tort law, for example, is the failure to provide meaningful compensation to patients whose injuries are “dignitary” rather than physical or financial in nature. See Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 320–22, 364–68 (1999) (reviewing the problem and potential solutions). See generally Alan Meisel, *A “Dignitary Tort” as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 L. MED. & HEALTH CARE 210 (1988); Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941 (2006). These restrictions can be viewed not only as further proof of the doctrine’s failure to meet its patient-centered goals, but also through the lens of judicial efficiency: in the absence of observable, verifiable physical harm, it is difficult to determine whether (let alone how much) compensation is due.

25. See Krause, *A Patient-Centered Approach*, *supra* note 17, at 610–19. For example, many drug companies have been accused of marketing their products “off-label” for conditions for which the drugs have not been approved by the Food and Drug Administration (and sometimes for which approval explicitly has been denied). See, e.g., Sentencing Memorandum of the United States at 10, 13–26, United States v. Warner-Lambert Co., Criminal No. 04-10150 RGS (D. Mass. June 2, 2004) (documenting the decision to engage in off-label marketing of the drug Neurontin, as well as the failed attempt to gain

Moreover, health care fraud implicates not only the government's role as a *protector* of its citizenry, but first and foremost as a responsible steward of the funds set aside to pay for the federal health care programs. When those programs are defrauded, the primary goal is to remedy the government's *own* financial harm.²⁶ Recovered funds are directed to the Medicare Trust Fund because it is the Trust Fund that improperly paid for these services; sharing the recovery with individual patients, while laudable, would have the effect of siphoning scarce resources away from these programs. Without that money, the programs might be unable to provide health care to the beneficiary population—a population that, lest we forget, usually includes the victims themselves.

In health law, the tensions inherent in the legal system often coalesce around a common question: who is the "patient" to whom these protections should flow? The issue may arise, for example, in a malpractice case in which an injured individual seeks compensation from a physician who spoke informally with the treating physician. In that context, the legal rules governing the establishment of the doctor-patient relationship place somewhat arbitrary limits on which individuals, within the larger universe of

drug approval as a solo therapy for epilepsy). But because the off-label restrictions limit only the manufacturer's *promotion* of the drug, rather than a physician's *use* of the drug, physicians are generally free to prescribe an approved drug for off-label purposes. *Id.* at 10. As a result, identifying the victims of an off-label promotional scheme is quite difficult: it requires not only identifying all patients who received the drug, but specifically those patients who were prescribed the drug for an off-label use (which in turn requires review of individual medical records), as well as consideration of the perhaps unanswerable question of whether each prescribing physician was influenced by the manufacturer's marketing efforts or would have prescribed the drug anyway in accordance with her medical judgment.

26. At the symposium, Professor Lois Shepherd asked me whether I believed fraud enforcement *should* always be patient-centered; I answered in the negative. Let me explain. In the absence of an explicit commitment to protecting patients through a particular initiative, which must be satisfied through a mechanism that benefits those patients, I recognize that in many of these cases the government is the primary victim and may have interests that diverge from those of beneficiaries. True, the federal health care programs exist in order to benefit patients; but those programs exist only because a decision was made to expend government funds for that purpose. In an unprecedented financial crisis, for example, a decision to suspend or reduce Medicare and Medicaid benefits might well be defensible if the programs' funds were needed to keep the government solvent and able to provide even more basic services to the U.S. population—as, by analogy, the decision was made to temporarily switch many of the Federal Bureau of Investigation health care fraud agents to antiterrorism efforts in the wake of September 11. Thus, I believe the government's primary duty is to be *citizen-centered* rather than *patient-centered*, or perhaps that the latter is but one subset of the former.

those who have been harmed, are able to recover damages.²⁷

Health care fraud cases often invoke one aspect of this patient identity problem, the question of individual versus aggregate victims and beneficiaries. Individual patients *are* in fact helped by general fraud recoveries, both in terms of the quality and the security of their health care benefits. When nursing homes or hospitals settle quality-related fraud allegations, for example, the settlements often include measures directly related to quality improvement, such as requiring specialized staff training or external quality monitoring.²⁸ This does not directly compensate a patient who has been harmed, but it may well improve the quality of care for similar patients in the future. Health care fraud recoveries also play a role in extending the solvency of the Medicare Trust Fund. By reclaiming diverted funds, fraud enforcement increases the likelihood that Medicare will be able to provide care for its ever-growing beneficiary population. While protecting patients in the aggregate clearly differs from compensating individuals personally harmed by fraud, it does assure that the victims continue to have access to health care services—small comfort, perhaps, until one considers the alternative. State attorneys general, who are not bound by HIPAA's federal recovery allocation rules, also have been quite creative in using *cy pres* mechanisms to devote money from fraud settlements to benefit similar (if not identical) patient populations.²⁹

A more complicated iteration of the patient identity problem occurs in informed consent, most notably in relation to the legal standards used to assess the elements of disclosure and causation (i.e., whether the patient would have undergone the treatment even if apprised of the omitted information). Rejecting a professional disclosure standard focused on the information that a reasonable or prudent physician would have disclosed, the court in *Canterbury v. Spence* found that “[r]espect for the patient’s right of self-determination . . . demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves,” and held that the scope of the disclosure “must be measured by the patient’s need, and that need is the information

27. See, e.g., *Reynolds v. Decatur Mem'l Hosp.*, 660 N.E.2d 235, 236 (Ill. App. Ct. 1996) (finding that no physician-patient relationship was created when a treating pediatrician called the defendant physician at home for informal advice).

28. See, e.g., Consent Order at 3, *United States v. Tucker House II, Inc.*, Civil Action No. 96-1271 (E.D. Pa. Mar. 6, 1996), available at <http://www.justice.gov/usao/pae/nursing/tucker.pdf>.

29. See Krause, *A Patient-Centered Approach*, *supra* note 17, at 610–19 (describing examples of state fraud settlements mandating that funds be used to benefit patient populations, as well as state consent orders negotiated in parallel to recent federal settlements).

material to the decision.”³⁰ However, the patient-centered nature of this standard was quickly undercut by the court’s instruction that such need would be determined by reference to what a *reasonable patient* would consider material, rather than the particular patient-plaintiff.³¹

The situation is even bleaker with regard to causation. The *Canterbury* court bluntly rejected a subjective patient-centered standard:

In our view, [the subjective] method of dealing with the issue on causation comes in second-best. It places the physician in jeopardy of the patient’s hindsight and bitterness. It places the factfinder in the position of deciding whether a speculative answer to a hypothetical question is to be credited. It calls for a subjective determination solely on testimony of a patient-witness shadowed by the occurrence of the undisclosed risk.

Better it is, we believe, to resolve the causality issue on an objective basis³²

It is difficult to imagine a more scathing rejection of a truly patient-centered legal standard. For an individual patient, the result may be devastating. As one of the few courts to adopt a subjective causation standard has acknowledged, “To the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient’s right of self-determination is *irrevocably lost*.”³³ The point was made even more starkly by Professor Jay Katz, who noted that “the very right at issue in cases of informed consent, the right of individual choice, may be precisely the right to prefer a course of treatment that a majority of patients would not choose.”³⁴ If being patient centered means anything at all, it would seem to require protection of patients not when their preferences mirror the norm, but precisely when they seek to make *atypical* choices.

And that is precisely the crux of my concern: that when the ethical precept of patient-centered care is translated into standardized legal rules, courts and legislatures will find it nearly impossible to vindicate the preferences of individual, rather than prototypical, patients. In my view, nothing less than the identity of patient-centered care is at stake. In short, do we want health law to

30. *Canterbury v. Spence*, 464 F.2d 772, 784, 786 (D.C. Cir. 1972) (emphasis added) (footnotes omitted); *accord* Krause, *supra* note 24, at 308–22 (describing problematic elements of the law).

31. *Canterbury*, 464 F.2d at 787.

32. *Id.* at 790–91 (footnotes omitted).

33. *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979).

34. Katz, *Law’s Vision*, *supra* note 10, at 164.

be *patient* centered, or *Patient* centered—focused on the individual patient or on the illusory Patient writ large? Put another way, is the model of patient-centeredness to be a centrifugal one in which all obligations flow outwards from the individual patient, or a centripetal one in which layers of obligation are sequentially filtered as they flow down to individuals? The IOM clearly envisioned the former, noting that “[t]he goal of patient-centeredness is to customize care to the specific needs and circumstances of each individual, that is, to modify the care to respond to the person, not the person to the care.”³⁵ But it is far from clear that all patient-centered advocates share this vision.

A corollary question, one far too complex to explore in this brief Essay, is *who decides* whether a particular decision is patient- (or Patient-) centered and on what basis? Must the choice be one that a strict majority of patients would make, or will we protect a plurality or minority view as well?³⁶ Will we require statistical evidence of what the Patient would choose, or will anecdote and experience suffice? In the medical context, will we rely on physicians and hospitals—the very decision-makers whose unbridled paternalism the doctrine was created to limit—to decide what choices are patient centered? At the broader policy level, as in health care fraud enforcement, will assessments of patient-centeredness be made by bureaucrats with no patient contact, whose sole responsibility is to protect the financial interests of the government? Will patient-centered care require that health care decisions protect the *wishes and choices* of patients or simply that such decisions meet patients’ *needs*—which are not always the same thing?³⁷

While the debate over the identity of the patient/Patient may

35. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *supra* note 1, at 51.

36. The legal system deals with these issues for physicians, for example, in the context of the “two schools of thought” defense to malpractice. See, e.g., *Jones v. Chidester*, 610 A.2d 964, 969 (Pa. 1992) (requiring “a considerable number of physicians, recognized and respected in their field,” to recommend an alternative treatment in order to establish a second “school of thought”).

37. The complexity of these concepts can be seen in the long-standing debate over whether surrogate decision-makers should be expected to act in accordance with a best-interests or a substituted-judgment standard. It has proven difficult to establish a standard that effectively removes the surrogate’s *own* views from the decision about what is appropriate for the patient. See, e.g., Thomas G. Gutheil & Paul S. Appelbaum, *Substituted Judgment: Best Interests in Disguise*, 13 HASTINGS CENTER REP. 8, 10 (1983) (noting that substituted judgment “in most cases represents a complicated form of guesswork, suffused by the decision maker’s biases”); Marshall B. Kapp, *Medical Decision-Making for Incapacitated Elders: A ‘Therapeutic Interests’ Standard*, 33 INT’L J.L. & PSYCHIATRY (forthcoming 2010) (noting that “[t]he focus of the best interests test is satisfaction of the patient’s needs, *as those needs are perceived by others*” (emphasis added)).

seem unnecessarily abstract to some, it has particular salience for populations already disadvantaged by their divergence from the norm. Female patients and patients of color, in particular, have long had reason to distrust physicians, bioethicists, and health lawyers on this score: disparities in access to care, research, treatment, and health care professionals' attitudes have been well-documented.³⁸ As one critique bluntly notes:

[F]eminist scholarship has exposed the assumptions regarding women and their health which have permeated the medical profession and coloured that profession's attitudes towards women, their access to health care and subsequent treatment. What has been revealed is the presence of deep-rooted prejudice against women whether they are the recipients or providers of health care.³⁹

Rebuilding the core of health law around the concept of patient-centeredness may not be a welcome development from the perspective of those who are, incontrovertibly, anything but the typical patient. A patient-centered approach that further subordinates the individual to the group, the real to the ideal, the patient to the Patient, may be little improvement over the current state of affairs and quite possibly may be worse.

CONCLUSION

While patient-centered care promises both a theoretically and practically appealing antidote to many of the shortcomings of the U.S. health care system, it remains unclear how well the legal system can advance that agenda. Indeed, several contributors to this Symposium raise compelling arguments against the notion that health law can or even should cede such a role to individual patients. Professors Bill Sage and Ted Ruger, for example, note the tensions between an individualistic concept of patient-centered care and a collective one. Sage argues for a collective vision of health

38. For an introduction to the voluminous literature on this topic, see Rebecca Dresser, *What Bioethics Can Learn from the Women's Health Movement*, in FEMINISM & BIOETHICS: BEYOND REPRODUCTION 144, 146 (Susan M. Wolf ed., 1996) (observing that "bioethics has been unresponsive to many of the women's health movement's paramount concerns"); Lisa C. Ikemoto, *In the Shadow of Race: Women of Color in Health Care Disparities Policy*, 39 U.C. DAVIS L. REV. 1023, 1025 (2006) (noting that "[w]omen of color . . . have not figured significantly on the federal health agenda").

39. Susan M. Nott & Anne Morris, *All in the Mind: Feminism and Health Care*, in WELL WOMEN: THE GENDERED NATURE OF HEALTH CARE PROVISION 1, 1 (Anne Morris & Susan Nott eds., 2002) (footnotes omitted). Similar arguments can be made with regard to the experiences of women with disabilities. See generally, e.g., Elizabeth Pendo, *Disability, Equipment Barriers, and Women's Health: Using the ADA To Provide Meaningful Access*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 15 (2008).

care that reinvigorates community-based preventive public health efforts rather than focusing exclusively on ill individuals; Ruger explores whether it would be possible to incorporate collective values at the institutional level while still permitting medicine itself to remain individualistic.⁴⁰ Similarly, Professor Nan Hunter considers the concept of “health care citizenship,” in which a patient’s rights must be coupled with responsibility “for prevention, wellness, and maintenance.”⁴¹ It is not clear that we actually *want* health law to be patient centered in the way the IOM envisioned, nor that we are close to agreeing on an alternative vision.

For my part, I remain far more concerned about the lack of *transparency and honesty* in patient-centered care than the lack of a unified vision. As my fellow participants have so cogently argued, some aspects of health care appear inextricably linked to the individual patient, while others demand a communal or population-based approach. Informed consent seems to me an example of the former; health care fraud may be an example of the latter, at least until the point when regulators or prosecutors promise that a particular anti-fraud initiative will remedy the harm suffered by individual victims. A concept of patient-centered care that is not broad enough to encompass these and other health law objectives has little chance of succeeding over the long term.

But if patient-centered care has a broader meaning than the phrase might at first imply, it is incumbent on us to make that clear. If informed consent rests on the concept of the reasonable patient, then during the consent process it must be made clear to patients that their rights are protected only insofar as their wishes correspond to what that hypothetical patient would choose. If the goal of health care fraud enforcement is to assure the continued viability of the federal health care programs, then individual patient-victims of fraud schemes (not to mention the members of Congress and the American public) must be told that such harm will be compensated only by assuring continued access to health care benefits and wise use of our collective tax dollars. Permitting the legal system to adopt individualized patient-centered rhetoric, while pursuing more standardized goals, is both hypocritical and ultimately untenable.

Can health law truly become patient centered? Perhaps, although there is ample reason for skepticism. In the end, perhaps the answer does not matter. Perhaps simply by asking the question, by contemplating what it might mean to be truly “patient centered,”

40. See generally Theodore W. Ruger, *Can a Patient-Centered Ethos Be Other-Regarding? Ought It Be?*, 45 WAKE FOREST L. REV. 1513 (2010); William M. Sage, *Should the Patient Conquer?*, 45 WAKE FOREST L. REV. 1505 (2010).

41. Nan D. Hunter, *Rights Talk and Patient Subjectivity: The Role of Autonomy, Equality, and Participation Norms*, 45 WAKE FOREST L. REV. 1525, 1526 (2010).

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we can begin to question our assumptions about how the health care system operates. Perhaps the goal, even if elusive, will free us to contemplate new models for providing and receiving health care in ways that both satisfy societal needs and respect individual dignity. Perhaps.