TEST-DRIVING "PATIENT-CENTERED HEALTH LAW"

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INTRODUCTION

"Patient-centeredness" accommodates itself to a wide range of often contradictory perspectives about the nature of the good in health care.[1] Earlier reconstructions of health law,[2] in the 1970s and 1980s, for example, could qualify as patient centered as each of these shifted the focus of law away from the dominant paradigm of professionalism and toward the well-being of patients. They did so in radically different ways, however.

The health-law reform movement of the 1970s asserted the primacy of the individual patient's moral agency, autonomy, and choice. This priority is apparent in legal norms of informed consent; choice at the end of life, including living wills; participation of lay members on medical licensure boards; as well as other developments. This reform movement was patient centered in that it elevated the power and status of the individual patient in the physician-patient relationship and revealed that the relevant norms in decision making about medical treatment were not owned by medicine alone, but rather were social and individual moral questions.

The subsequent reforms of the 1980s incorporated the notion of the autonomous patient but reconceived as a consumer.[3] Much of the effort of that decade, however, was focused on limiting consumer choice at the point of service, relying on arguments that patients were ill-positioned to decide whether medical interventions recommended by their physicians were necessary or beneficial.

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1. *See generally* Lois Shepherd, *Different Ways To Understand Patient-Centered Health Law*, 45 WAKE FOREST L. REV. 1469 (2010).

2. In this Essay, I am addressing health law as an area of practice rather than as an academic discipline. *Cf.* Mark A. Hall, Carl E. Schneider & Lois Shepherd, *Rethinking Health Law: Introduction*, 41 WAKE FOREST L. REV. 341, 341–45 (2006) (discussing health law as an academic discipline).

3. *See* Mark Hall, *Musings on Patient-Centered Law and Ethics*, 45 WAKE FOREST L. REV. 1461, 1463 (2010).

These reforms of the 1980s, like those of the 1970s, also could be viewed as patient centered. Their goal was to improve the well-being of patients by enhancing quality, expanding access to necessary medical services by decreasing cost, and avoiding harm suffered at the hands of unnecessary medical care stimulated by perverse financial incentives.

Thus, the legal reforms of both the 1970s and the 1980s could fairly be considered patient centered—one on an individual basis and the other on a population basis—even though they adopted contrary notions of the capacity of patients and potentially contrary measures of success. This illustrates the threshold challenge that must be confronted by designers of a more patient-centered health law.

This Essay makes three points. First, it illustrates that notions of the good in health law are often competing and that a goal of patient-centeredness, standing alone, will not resolve those conflicts. Second, it briefly discusses the sometimes perverse interaction between law and medicine and argues that a focus on the outcomes of law should be an essential component of a more patient-centered health law. Finally, it addresses claims that the current health-law framework relies on false notions of the patient and of medical professionalism and thus is not patient centered. The current framework, according to this claim, misses the mark by failing to recognize how illness limits the capacity of patients and by excessively discounting the skill base, expertise, and moral authority provided by medical professionalism.[4] This Essay argues that recovering older notions of the roles of patient and doctor does not adequately capture the physician-patient relationship and that, instead, a strong model of mutuality better explains physician behaviors that law seeks to influence.[5]

Treatment for patients in pain provides the context for this discussion. Pain treatment is a good test run for patient-centered health law for several reasons. First, pain permeates health care delivery—it is a highly prevalent reason for seeking health care[6]

4. *See id.* at 1462–63.

5. This Essay assumes that a patient-centered health law would aim to influence physician behavior. Health law has aimed to change physician behaviors in relation to patients and in collegial and business relationships. *See, e.g.*, PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 388–89 (1982) (discussing the influence of rights-based movements); James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459, 1459–60 (1994) (arguing that extension of legal norms regarding antitrust drove a paradigm shift in notions of professionalism); Clark C. Havighurst, *I've Seen Enough! My Life and Times in Health Care Law and Policy*, 14 HEALTH MATRIX 107, 118 (2004) (describing the shift of legal norms from professional control to the market as a "revolutionary cause").

6. For example, pain is the reason given for the vast majority of visits to the emergency department. William H. Cordell et al., *The High Prevalence of*

and is a cause of poor outcomes in medical care.[7] It is also quite costly in terms of medical treatment and lost productivity.[8] Second, pain management is one of the more highly regulated areas of medical practice because of the central role of medications that are controlled substances.[9] It, therefore, provides a relatively detailed illustration of the interplay between health law and medical practice, revealing some fundamental characteristics of law and its impact on physician behavior. Third, the experience of pain is highly variable. Severe pain exists even in the absence of an observable physical cause,[10] and different patients react differently to painful stimuli and to pain medications. While subjectivity is inherent in medical practice,[11] the level of subjectivity and variability in treatment for pain, especially chronic pain, is recognized as a particular challenge in both medicine and law.[12] Finally, responses to individuals reporting pain, including responses from physicians, are socially constructed. These characteristics also present an opportunity to explore the extent to which the physician-patient relationship is defined by both physicians' and patients' experience of vulnerability, fear, and inadequate knowledge.

I. COMPETING GOALS FOR PATIENT-CENTEREDNESS

In the Introduction, this Essay illustrated that "patient centered" lacks definition and that both individualized and

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Pain in Emergency Medical Care, 20 AM. J. EMERGENCY MED. 165, 167 (2002); *see also* Knox H. Todd, *Chronic Pain and Aberrant Drug-Related Behavior in the Emergency Department*, 33 J.L. MED. & ETHICS 761, 762 (2005).

7. *See* James Ducharme, *Acute Pain and Pain Control: State of the Art*, 35 ANNALS EMERGENCY MED. 592, 596 (2000) (noting that acute pain that is inadequately treated may establish a chronic pain syndrome).

8. Overall economic costs are estimated to range between $100–$150 billion in the U.S. annually. *See, e.g.*, THE MAYDAY FUND, A CALL TO REVOLUTIONIZE CHRONIC PAIN CARE IN AMERICA 2 (2009) (estimating annual costs for chronic pain alone at over $100 billion); W.F. Stewart et al., *Lost Productive Time and Cost Due to Common Pain Conditions in the U.S. Workforce*, 290 JAMA 2443, 2449 (2003) (estimating the annual cost of lost productivity at $60 billion).

9. *See generally* Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55 (2003); Douglas J. Pisano, *Controlled Substances and Pain Management: Regulatory Oversight, Formularies, and Cost Decisions*, 24 J.L. MED. & ETHICS 310 (1996).

10. Int'l Assoc. for the Study of Pain, Task Force on Taxonomy, *Pain Terms, A Current List with Definitions and Notes on Usage*, *in* CLASSIFICATION OF CHRONIC PAIN 208, 210 (Harold Merskey & Nikolai Bogduk eds., 1994).

11. *See generally* Eric J. Cassell, *Uses of the Subjective in Medical Practice*, *in* CHANGING VALUES IN MEDICINE 151, 151–66 (Eric J. Cassell & Mark Siegler eds., 1979).

12. *See* Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701, 736–37 (2009); Sandra H. Johnson, *The Social, Professional, and Legal Framework for the Problem of Pain Management in Emergency Medicine*, 33 J.L. MED. & ETHICS 741, 745–46 (2005).

population-based methods for improving patients' well-being can be viewed as meeting that standard even though their approaches may differ radically in design, operation, and outcome. This Part is concerned with the challenges and trade-offs confronted in public policy in identifying patient-centered goals. It highlights how empathy influences public policy priorities regarding regulation of prescription of pain medication in a way that results in segmenting the universe of patients, advantaging some over others, and producing legal norms that can cause harm.[13] The three mini-narratives that follow help to illustrate these points.

A. *"I am a forty-six-year-old registered nurse who specializes in oncology care and education. I am also a patient who suffers from chronic nonmalignant pain, and this malady has been the most frightening, the most humiliating, and the most difficult ordeal of my life. . . . I found myself begging [for treatment], as though I were a criminal. . . . Now, when I see unnecessary suffering caused by intractable, 'mismanaged' chronic pain, I am disgusted. As a health care provider, I am ashamed."*[14]

We know the data about unnecessary suffering from neglected pain—it is persistent; it crosses all populations but hits the most vulnerable in even higher numbers.[15] We probably know the stories of patients in pain, some in our own families. We may know a friend in sickle cell crisis who is in agony in the emergency department ("ED") because his knowledge of his own disease coupled with his audacity to identify the medication that has worked in the past triggers suspicions that he is an addict.[16] Perhaps we have known a friend, young or old, who never achieves adequate function from a knee replacement because inadequate pain control limited movement and allowed the formation of confining scar tissue.[17] If we are old enough, we remember the screaming of a family member with cancer who is waiting for the next too-small dose of morphine permitted by the doctor-prescribed schedule.[18]

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13. For a discussion of the role of empathy in the legislative process concerning a different health policy issue, see Katherine Beckett & Bruce Hoffman, *Challenging Medicine: Law, Resistance, and the Cultural Politics of Childbirth*, 39 LAW & SOC'Y REV. 125, 158, 162–63 (2005).

14. Cynthia A. Snyder, *An Open Letter to Physicians Who Have Patients with Chronic Nonmalignant Pain*, 22 J.L. MED. & ETHICS 204, 204–05 (1994).

15. *See* Johnson, *supra* note 12, at 745–46.

16. *See generally* Vence L. Bonham, *Race, Ethnicity, and Pain Treatment: Striving To Understand the Causes and Solutions to the Disparities in Pain Treatment*, 29 J.L. MED. & ETHICS 52 (2001).

17. *See generally* Xavier Capdevila et al., *Effects of Perioperative Analgesic Technique on the Surgical Outcome and Duration of Rehabilitation After Major Knee Surgery*, 91 ANESTHESIOLOGY 8 (1999).

18. *See generally* June L. Dahl & David E. Joranson, *The Wisconsin Cancer Pain Initiative*, *in* 16 ADVANCES IN PAIN RES. & THERAPY 499 (1990).

Relieving suffering, including pain, is a core value in medicine. In all but quite unusual cases, the tools for pain management are accessible and relatively inexpensive. So, when I think about what patient-centered health care would look like, I believe that I know: it would make pain relief the very top priority in the physician-patient relationship. As a correlative, patient-centered health law in this circumstance would be that which would help assure that pain patients receive effective treatment. As a matter of public policy and law, my experience tells me that law and public policy should land firmly on the side of patients in pain. If laws stigmatize pain patients by intimidating doctors with threats of investigation, discipline, or criminal prosecution, these laws are not patient centered.[19]

B. *"It just drains the carpe right out of your diem to start the day off in a series of ugly little dogfights over drugs with people whom, to put it charitably, you have concerns about the validity of their reported pain."*[20]

Effective treatment for pain begins with recognizing that the patient is in pain. In all circumstances, this requires trust in the physician-patient relationship because it requires the physician to trust the patient's report of the existence and severity of pain.[21] Nearly every doctor in practice, however, even the most expert pain management specialist, has been tricked by a patient who is lying to get drugs for nontherapeutic purposes. Even if this experience occurred only during her student rotation in the ED, she remembers it for the rest of her career and that common experience among doctors is magnified as the stories are told and retold. No doctor wants to be the puppet that provides drugs under false pretenses because that is not practicing good medicine, and it makes the doctor feel like a fool.[22]

An essential component of advocacy for effective pain relief is the assertion that patients' reports of pain must be trusted.[23] Pain-relief advocates allow for rejection of patient reports in some cases in which deception is proven but also argue that deception is often a

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19. *See generally* Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231 (2008).

20. Shadowfax, *Drug Seekers and Pain Complaints in the ER: How To Know What's Real*, BETTER HEALTH (Feb. 23, 2010), http://getbetterhealth.com/drug-seekers-and-pain-complaints-in-the-er-how-to-know-whats-real/2010.02.23.

21. Hellman, *supra* note 12, at 733–44.

22. Michael W. Kahn, *Occupational Hazard: Playing the Fool*, N.Y. TIMES, June 8, 2010, at D5.

23. *See* Nessa Coyle, *Opioids, Cancer Pain, Quality of Life, and Quality of Death: Patient Narratives and a Clinician's Comment*, *in* OPIOIDS AND PAIN RELIEF: A HISTORICAL PERSPECTIVE 175, 177 (Marcia L. Meldrum ed., 2003).

survival strategy to which patients in pain resort in the face of poor pain management.[24] No one argues that a doctor should provide medication to a patient who claims pain falsely to get drugs for nontherapeutic purposes, but the subjectivity and variability in pain treatment at times make the distinction between dishonest and honest patients difficult. What is often overlooked is that deep-seated stereotypes and biases have a significant influence on how doctors hear and interpret complaints of pain—a form of subjectivity that also confounds the ability to distinguish between genuine and disingenuous complaints.[25]

What the debate between deceived doctors and earnest pain-management advocates also often misses is the emotional burden that deception exerts on physicians and the behaviors that these emotion-laden circumstances produce.[26] Absent recognition of the emotional state of mind of physicians in practice, however, it is unlikely that persistent calls for more trust between patient and physician will achieve the desired outcome.[27]

C. *"[E]ven just one physician who uses his/her DEA registration for criminal purposes can cause enormous harm. In the words of one commenter: 'It takes only a few untrained or unscrupulous physicians to create large pockets of addicts.'"*[28]

One should certainly include addicted individuals, whether currently receiving medical care or not, as part of our population of patients about whom patient-centered health law must be concerned. Patient-centeredness, unless more specifically defined, would seem to demand that attention be paid to all patients and to all suffering, not just to select categories.

On a pragmatic level, however, public policy and law will reflect

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24. *See* Todd, *supra* note 6, at 763 (discussing "pseudoaddiction" and arguing that "[e]ven such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief").

25. One study of emergency physicians, for example, showed that the physicians interpreted patients' reports of pain in a way that supported the doctors' assessments of the underlying circumstances so that identical reports of pain were interpreted as either evidence of pain or evidence of drug seeking. *See* Joshua H. Tamayo-Sarver et al., *Variability in Emergency Physician Decisionmaking About Prescribing Opioid Analgesics*, 43 ANNALS EMERGENCY MED. 483, 492 (2004). Studies show that stereotypes about particular patient populations have a significant impact on pain assessment and treatment. *See generally* Bonham, *supra* note 16; Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29 J.L. MED. & ETHICS 13 (2001).

26. *See* David A. Ruben, *Doctor Cops and the Black Art of Medicine*, PAIN MEDICINE NEWS (Apr. 2010), http://www.painmedicinenews.com/index.asp?section_id=83&show=dept&issue_id=621&article_id=15038.

27. For a discussion of the impact of legal process on decision making, see *infra* Part II.

28. *See* Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716–52,723 (Sept. 6, 2006).

the participation and influence of stakeholders with competing worldviews. In the case of regulations governing the prescription of controlled substances, those advocates from the world of addiction and substance abuse and those individuals from the world of chronic pain and pain management each brings different experiences and a resultant empathy that underlies their competing assessments of the relative interests of patients and the public.

Pain-relief advocates are most concerned that patients in pain receive good care, which will very often include the prescription of controlled substances. From this perspective, statistics showing an increase or decrease in the prescription of controlled substances for pain relief are viewed as an indicator of adequate or inadequate access to medical care. Advocates concerned with drug control and the suffering of addiction will view decreases in the prescription of pain medications that are controlled substances as an indicator of success and increases in prescriptions as a threat to public health.[29]

While the goals of promoting pain relief and of preventing addiction and diversion are not entirely mutually exclusive, efforts to improve one will often have adverse effects on the achievement of the other.[30] Law cannot be effective if the goals are unclear, contradictory, or based on inappropriate values or bad science.[31]

What is currently sought in law regarding competing concerns over drug addiction and pain management is regulatory balance, assuring that legal norms and processes prevent substandard behaviors that encourage addiction and diversion while not

29. The data indicating increases in prescribing of pain medications are clear. What is missing is reliable data linking these increases to abuse and diversion. *See* David B. Brushwood, *Maximizing the Value of Electronic Prescription Monitoring Programs*, 31 J.L. MED. & ETHICS 41, 42 (2003) [hereinafter Brushwood, *Maximizing*]; Bridget A. Martell et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146 ANNALS INTERNAL MED. 116, 123–25 (2007) (describing the poor quality of studies reporting the prevalence of substance use disorders among patients receiving opioid medication for chronic back pain); David B. Brushwood, *Drug Control out of Balance*, PAIN & L. (Sept. 4, 2003), http://www.painandthelaw.org/mayday/brushwood_090403.php. *See generally* David E. Joranson & Aaron M. Gilson, *Wanted: A Public Health Approach to Prescription Opioid Abuse and Diversion*, 15 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 632 (2006) (describing deficiencies in major databases used to estimate the abuse and diversion of opioid analgesics and highlighting the need to account for nonmedical sources of diversion).

30. A classic illustration of conflicting policies and outcomes is the use of triplicate prescription-monitoring systems that depressed the prescription of controlled substances for pain management, an outcome that was viewed either positively, as a method for controlling drug use, or negatively, as a barrier to effective pain management. *See infra* notes 32–37 and accompanying text.

31. The experience with changing practice regarding physical restraints in nursing homes illustrates these prerequisites. *See* Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 1003–04 (2009).

impeding access to medications required for pain relief.[32] For example, Drug Enforcement Agency ("DEA") statistics prove that the Agency investigates and prosecutes only a microscopic number of physicians for their prescribing of controlled substances. The DEA asserts that doctors who are practicing good medicine have nothing to fear.[33] Medical boards have adopted guidelines that proclaim that the boards understand there is a duty to treat patients in pain and that following particular practice-management guidelines will guarantee that the doctor will not run afoul of disciplinary processes.[34] No state retains the triplicate prescription-monitoring system that depressed prescribing, instead replacing that system with a relatively invisible electronic monitoring system.[35] Several states allow doctors to access that system to check on patients' prescriptions to assure that they are not doctor shopping and getting too many prescriptions.[36] On the other hand, the FDA is imposing particular restrictions on controlled-substance pain medications meant to restrict their use for non-therapeutic purposes. Furthermore, criminal prosecutions of even a few physicians have an impact larger than their numbers would indicate.[37]

Is regulatory balance an instance of patient-centered health law? It depends. If balanced regulations encourage physicians to give pain patients the best care, which includes taking steps to assure that pain medication is given in doses that are effective and to monitor whether the patient is receiving relief, then the balance captured in drug-control regulation benefits all patients. If instead the balance restricts care to patients in pain because it stigmatizes these patients and this medical condition or because it establishes barriers of procedure or training or reporting that do not contribute to quality of patients' care, the balance is not patient centered.

This brief query raises the question of the role of public health concerns in patient-centered health law. In the area of pain management, the worry about generalized public health goals regarding addiction and diversion includes concerns that the data

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32. *See* PAIN & POL'Y STUD. GROUP, ACHIEVING BALANCE IN FEDERAL AND STATE POLICY § 3 (5th ed. 2008), http://www.painpolicy.wisc.edu/Achieving_Balance/EG2008.pdf.

33. News Release, U.S. DEA, The Myth of the "Chilling Effect": Doctors Operating Within Bounds of Accepted Medical Practice Have Nothing To Fear from DEA (Oct. 30, 2003), *available at* http://www.usdoj.gov/dea/pubs/pressrel/pr103003.html.

34. *See* Fed'n of State Med. Bds. of the U.S., Inc., *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (May 2004), http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf.

35. *See* Scott M. Fishman, *Repeal of Triplicate Prescribing and the New Security Paper Prescription Requirement in California*, 53 CAL. SOC'Y ANESTHESIOLOGISTS BULL. 1, 2–3 (2004).

36. *See* Brushwood, *Maximizing*, *supra* note 29, at 42.

37. *See* Hoffmann, *supra* note 19, at 293, 295, 309.

continue to show a miniscule risk of addiction for a pain patient without a history of prior substance abuse, that there is no data indicating that doctors' offices are a significant source of drugs that show up in illicit trade, and that they raise the economic and reputational costs for physicians treating patients in pain and especially chronic pain. Public health concerns that are data-driven and that address substantial risks to patients in pain can improve care of pain patients, but at some point it is likely that trade-offs will occur between individuals in pain and individuals suffering from addiction caused by the illicit use of prescription medications.

The goal of regulatory balance seeks to free doctors from legal concerns, allowing doctors to treat their pain patients effectively while avoiding harm from addiction and diversion. Doctors still claim, however, that fear of legal penalties, from the DEA or the medical boards or hospital credentialing agencies, still causes them to under-treat patients in pain.[38] If one is concerned about patient-centered health law, how should these claims of perverse effects of law be interpreted?

II. "BAD LAW" CLAIMS AND PATIENT-CENTERED OUTCOMES

One frequently hears doctors claim that laws designed to improve patient care actually cause harm to patients. The claim is often frustrating to those who have attempted to establish legal norms that benefit patients, even as the frequency of such complaints makes them entirely predictable.

These "bad law" claims on the part of doctors should not be dismissed, however. They should be taken seriously, although not at face value, as a source of important information about the impact of law on patient care. The evaluation of health law should measure the impact of law on physician behavior as a tool in assessing whether a particular set of legal standards or processes is actually patient centered. A generalized inquiry into some "bad law" claims reveals relevant characteristics of the relationship of law and medicine that will influence any effort to transform the physician-patient relationship through law, including efforts to make law more patient centered.

First, doctors may blame law for actions they are taking for other reasons.[39] This is largely the case in treatment for pain. Doctors' distrust and under-treatment of patients in pain, in fact, are grounded more in reputational or other social network concerns: powerful stereotypes about particular patients, aversion to suffering and to patients who are different from the physician, the emotional burden of past or anticipated victimization through patients'

38. *See* Sandra H. Johnson, *Legal and Ethical Perspectives on Pain Management*, 105 ANESTHESIA & ANALGESIA 5, 6 (2007).

39. *See* Johnson, *supra* note 31, at 993.

deception, and customary nonevidence-based medical practices that support harmful practices that allow treatable, severe pain to persist.[40] These motivations are embedded in the medical culture rather than developing as a response to legal concerns, and "bad law" claims in this instance scapegoat the law.

Second, doctors' learning patterns tend to value clinical experience,[41] and so they are likely to learn about legal norms and processes by word of mouth among colleagues, a process that flattens out legal nuance and complexity. Their distrust of the legal system amplifies resistance to legal processes. Doctors are more influenced by the horror story (the one doctor investigated or prosecuted or sued) than they are by the bigger picture—the details of individual cases or the system-wide data.[42] The grapevine is likely to promulgate perceptions of the content of legal norms that present higher legal risks than those that actually exist, which in turn leads to more risk-sensitive—and at least for pain patients—less effective, medical treatment.

Third, studies show that doctors are likely to be more influenced in their practice by institutional norms than by legal norms.[43] Private governance can reaffirm legal standards and can be a tool for incorporating public goals and norms into private health care practice.[44] The adoption of pain assessment requirements by the Joint Commission, for example, may have done more to improve pain relief for hospital patients (although the evidence is mixed) than have the intractable pain statutes.[45] Health care institutions, however, have incentives to avoid legal risk by establishing standards or processes that are more standardized and probably more restrictive than the law actually requires. Institutions may also levy penalties in excess of those provided for in disciplinary or other legal processes. An organization's overcompliance is a problem if it produces poor care.[46]

Fourth, any rational person fears becoming entangled in legal process, unless she initiates that process herself, and that fear may be even more acute in the case of physicians. The "penalties of the process" (reporting, monitoring, inquiry, investigation, and

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40. *See id.*

41. *See* Finlay A. McAlister et al., *Evidence-Based Medicine and the Practicing Clinician*, 14 J. GEN. INTERNAL MED. 236, 238–40, 240 fig.1 (1999).

42. *See generally* CHARLES L. BOSK, FORGIVE AND REMEMBER: MANAGING MEDICAL FAILURE (2d ed. 2003).

43. *See, e.g.*, Carol A. Heimer, *Competing Institutions: Law, Medicine, and Family in Neonatal Intensive Care*, 33 LAW & SOC'Y REV. 17, 49–50 (1999).

44. *See* Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 594–625 (2000).

45. *See, e.g.*, Ben A. Rich, *The Politics of Pain: Rhetoric or Reform?*, 8 DEPAUL J. HEALTH CARE L. 519, 528, 537 (2005) (comparing pain treatment during the era of intractable pain statutes to pain treatment after adoption of the Joint Commission standards).

46. *See* Johnson, *supra* note 31, at 996–97.

adjudication) exert their own deterrent effect and produce avoidance behaviors that can actually undermine the goals of the formal legal requirements. This has been a particular problem for achieving regulatory balance in regard to the prescription of controlled substances for pain relief.[47] Empirical research also indicates that reporting requirements, standing alone, can be an effective tool for changing physician behavior with less intrusion and less expense than other means.[48] Visible prescription-monitoring systems, standing alone, reduce the amount of drugs prescribed, for example. Whether this is a positive outcome depends largely on whether one believes that the reduction is harming patients in pain and, if so, whether there is an offsetting benefit in preventing addiction.[49]

The most common responses to unintended consequences in the application of law to medicine illustrate some central limitations in the capacity of law to respond to undesirable physician behavior motivated by fear of legal risk.[50] For example, educational efforts to improve physician understanding of the law instead may heighten risk-averse behavior. There are few simple yes/no answers in law, especially when law is designed to be fact-sensitive or is changing or when lawyers must advise clients based on one or two judicial opinions in related, though not identical, circumstances. We also cannot reassure doctors by telling them that an appellate case or a final agency determination eventually upheld standards of good medicine, as they see the adjudication process itself as extremely harmful. Furthermore, law does not speak with one voice. Lawyers assume specific roles in the health care environment, and their perspective and advice can depend on that role. Messages from even one agency can be mixed when the explicit norms move in one direction, but the enforcement processes are perceived as moving in another.[51] Legislative and administrative fixes such as immunity

47. For example, medical boards believe that their duties to protect patients require that they inquire of physicians who seem to be in substantial violation of standards of care, but doctors call such an inquiry the $10,000 letter. *Heart-to-Heart Radio Series Program I: Beyond Pain* (Public Radio International Radio Broadcast Jan. 1, 2004) (transcript available at http://www.prx.org/pieces/5305/transcripts/5305). In a survey of medical board personnel, one board member commented that "[d]octors like to cry foul anytime we inquire about anything" but that the board's obligation to protect patients justified inquiries. Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. MED. & ETHICS 21, 32 (2003).

48. *See* Johnson, *supra* note 31, at 1003–05 (discussing the effect of reporting requirements on physician behavior).

49. *See supra* notes 17–21, 29–32 and accompanying text.

50. *See* Johnson, *supra* note 31, at 1009–16.

51. For example, medical board policy statements regarding treatment for pain with controlled substances may be quite positive toward the practice, but their publishing lists of doctors disciplined for prescription abuse may evidence a different standard. *See id.* at 1012–13.

statutes and safe-harbor rules also may fail to change physician behavior. Immunity statutes tend to incorporate indeterminate standards, such as good faith or reasonableness, that shred the shield they offer because they are fact-sensitive and litigable. Safe-harbor rules protect specified practices from legal scrutiny but tend to leave a range of acceptable and perhaps necessary treatment decisions outside the safe harbor in order to preserve prosecutorial discretion. If doctors stay within the "safe zone," beneficial treatment modalities that lie outside the narrow range will be forgone to the detriment of patients.[52]

This argument asserts that patient-centeredness must be concerned with outcomes at least as much as with norms in law. It argues for an empirical approach to assessing the performance of law in relation to physician behavior that produces health outcomes for patients. It also argues for a population-based analysis rather than the more episodic approach common in assessing whether individual cases, for example, recognize appropriate standards. The unresolved issue, of course, is the identification of outcomes that are patient centered, particularly in circumstances in which goals are in conflict.[53]

III. PATIENT-CENTERED HEALTH LAW AND THE NATURE OF THE PHYSICIAN-PATIENT RELATIONSHIP

Arguments that health law currently rests on an inadequate understanding of the nature of the physician-patient relationship and that this inadequacy results in law that is not patient centered are appealing. Health law often reflects dominant social views of the patient-physician relationship, and the allocation of legal rights and responsibilities among the parties often rests on assessments of the nature of each party, including concern for relative power and vulnerability.

The traditional notion of patients and physicians tends to view them as opposites. Patients are dependent, are emotionally burdened by illness, and have limited capacity to understand relevant information and make decisions, while physicians have superior powers of analysis, knowledge, and detached decision-making capacity. This conceptualization supports doctor-dominated decision making.

More contemporary views of patients and physicians elevate patients' capacity and moral agency in relation to doctors, but at times persist in placing doctors and patients in opposition to each other. Early living will statutes, for example, fundamentally misunderstood the nature of the physician-patient relationship and treatment decision making. Living wills, as originally conceived, set

52. *See id.* at 1015–17, 1021–22.
53. *See, e.g., id.* at 1030.

up a pattern of "sequential domination," with the doctor viewed as the source of specialized and otherwise inaccessible information, the patient as the independent decision maker, and then the doctor as the executor of the patient's treatment directions.[54] The same argument extends to legislation establishing a pain patient's "bill of rights,"[55] which is symbolic but generally futile.

We tend to view these opposing conceptualizations of the nature of the physician-patient relationship as products of their times. The picture of the dominant, paternalistic doctor and the dependent, needy patient is located in pre–civil rights/individual rights eras. The vision of the autonomous patient and the collaborative, or compliant, doctor arose within the later equality and rights movements[56] and appears most clearly in informed consent generally and in end-of-life decision making in particular.

Current public policy and law, however, wavers between the two frames, at times adopting the vulnerable patient-superior physician dyad and at other times the autonomous patient and directed physician.[57] The vacillation reflects the inadequacy of any generalizations as they are applied to particular situations, but it also reflects the inherent inadequacy of both of these approaches. Most discussions seem to move along the line that is bounded on each end by these archetypes.

Instead, health law and policy may become more patient centered by relying on a model of mutuality rather than a dependency-superiority model. A model of mutuality would see both patient and doctor as vulnerable and emotional, and as knowledgeable and skilled. There is a rich literature, especially in narrative form, that attests to the fact that doctors are quite vulnerable to emotions such as fear, anger, and sadness in working with patients and in confronting illness.[58] This emotional context certainly has an impact on care.

There is also substantial evidence that physicians' knowledge base is often quite limited or actually mistaken.[59] In such cases, patients may, in fact, have superior knowledge.

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54. *See generally* Sandra H. Johnson, *Sequential Domination, Autonomy, and the Living Will*, 9 W. NEW ENG. L. REV. 113 (1987).

55. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 124960–124961 (West 2006); HAW. REV. STAT. ANN. § 327H-1 (LexisNexis 2010).

56. STARR, *supra* note 5, at 388–90.

57. Examples include the federal regulation of research, which claims a strong autonomy as choice theory but at the same time prevents individuals from consenting to particular categories of research. *See, e.g.*, Richard A. Epstein, *Defanging IRBs: Replacing Coercion with Information*, 101 NW. U. L. REV. 735, 738 (2007).

58. *See, e.g.*, KATE SCANNELL, DEATH OF THE GOOD DOCTOR (1999).

59. In the treatment of acute abdominal pain, for example, physicians as late as 1998 continued to withhold pain medication from patients for fear of interfering with diagnoses, relying on a medical opinion from the 1920s despite a total absence of evidentiary support. Johnson, *supra* note 12, at 744–45.

At its best, the physician-patient relationship when the patient is in pain offers the opportunity for exercising what is best in medicine—mutual trust and respect between doctor and patient cooperating in treatment with the result that pain and suffering are relieved. The physician-patient relationship around pain relief, however, still often does not meet this ideal. It often operates out of the doctor's fears—fear of the patient in pain, fear of failure in the face of persistent pain, fear of being lied to, and fear of subjectivity. It often relies on antiscientific beliefs frequently shared by physicians and patients alike—the belief that the risk of addiction is large, that particular patient populations are at higher risk for diversion, that treating pain impedes diagnosis, and that a doctor can be a lie detector.

CONCLUSION

Current efforts to create a more patient-centered health law suffer from a lack of definitional clarity. Patient-centeredness in health law can be represented in a normative framework (as in the case of the 1970s adoption of informed consent) or in outcomes relating to the well-being of patients (as was intended in the market reform of the 1980s that limited consumer choice to improve cost, quality, and access). Whether focused on norms or outcomes, however, competing notions of what ought to be done will persist and general slogans of patient-centeredness standing alone will not resolve those conflicts.

At a minimum, one would expect that patient-centered health law would be concerned with its actual impact on physician behavior. This Essay has identified categories of physicians' response to legal risk and lawyers' responses to "bad law" claims that may illuminate certain patterns. The evaluation of the impact of law in particular circumstances, however, is essentially an empirical inquiry. If notions of patient-centeredness are to progress beyond the identification of particular norms and into outcomes across populations, engagement in empirical assessment of impact is required.

An important factor in explaining the "why" of instances in which law fails to alter physician practice is the psychological or emotional content of medical practice. Neither the paternalist model nor the autonomy model of the physician-patient relationship accounts for this, and a patient-centered health law that relies on either one of these models will struggle with their inadequacy.