

## REGULATING PHYSICIAN BEHAVIOR: TAKING DOCTORS' "BAD LAW" CLAIMS SERIOUSLY

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### INTRODUCTION

Physicians are the nerve center of the health care beast. This is so even after the developments of the past two or three decades in which the hospital has emerged as a mature organization with interests that it pursues apart from its medical staff, and health care payers have established extensive bureaucracies to control physician-driven costs. Physician behavior remains a key target of government regulation that is intended to improve the efficiency, quality, and accessibility of health care. In fact, one might say that the core of the health law enterprise,<sup>1</sup> both public and private,<sup>2</sup> has been focused on

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1. An entertaining debate is raging as to whether health law has a "core" and, in fact, whether the field exists at all. *See, e.g.*, M. Gregg Bloche, *The Invention of Health Law*, 91 CAL. L. REV. 247 (2003) (considering current models of health law and presenting an alternative model to guide the development of health law); Symposium, *Rethinking Health Law*, 41 WAKE FOREST L. REV. 341 (2006); Theodore W. Ruger, *Health Law's Coherence Anxiety*, 96 GEO. L.J. 625 (2008).

2. This paper places legislation, litigation, and administrative regulation under the single umbrella of legal efforts to "regulate" physician behavior. There are significant differences in the operation and behavior of each of these legal regimes; those differences have been explored elsewhere. *See, e.g.*, William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387 (2003). While this paper uses the term regulation to signify governmental efforts to regulate physician behavior, that term has been used frequently to include private efforts to determine behavior. This paper does not ignore those

incentivizing, deterring, and directing physician behavior<sup>3</sup> across a wide range of activities,<sup>4</sup> including essential components of the doctor-patient relationship.

More than simply detecting and punishing the maverick doctor, legal efforts to control physician behavior over the past several decades have aimed at transforming the practice of medicine. This effort intended to work fundamental change in both the physician-patient relationship and the relation of medicine to the market.<sup>5</sup>

Doctors<sup>6</sup> frequently claim that the very law intended to improve the lot of their patients is instead making the doctors provide poor care.<sup>7</sup> These “bad law” claims are levied against malpractice litigation that makes doctors practice “defensive medicine”;<sup>8</sup> against patients’ rights that make doctors

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private efforts, *see infra* Part II.C, but instead addresses them as distinct from public regulation of physician behavior.

3. “The historical evolution of the field of health law starts with this central focus on the physician-patient relationship.” Barry R. Furrow, *From the Doctor to the System: The New Demands of Health Law*, 14 HEALTH MATRIX 67, 69 (2004) (describing the expanding scope of the health law field); *see also* Elliot S. Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. W-44 (2006), <http://content.healthaffairs.org/webexclusives/index.dtl?year=2006> (criticizing the “fragmented system” of care experienced by patients when regulatory and quality control measures place too much accountability on individual doctors); Nicolas P. Terry, *A Medical Ghost in the E-Health Machine*, 14 HEALTH MATRIX 225, 227 (2004) (identifying the continuing physician-centrism of health law as a significant weakness).

4. Of course, hospitals are highly regulated as well: “[F]ew entities have been subjected to more extensive regulatory controls from all governmental levels than the acute care hospital.” John D. Blum, *Feng Shui and the Restructuring of the Hospital Corporation: A Call for Change in the Face of the Medical Error Epidemic*, 14 HEALTH MATRIX 5, 12 (2004).

5. *See discussion infra* Part I.

6. For a discussion of the problem of over-generalizing the profession by lumping all doctors together, *see infra* note 31.

7. Medicine is not entirely hostile to the operation of law within medical practice and, in fact, medicine often uses law as a tool. For example, medical licensure provided a nascent allopathic medical profession with both a high degree of legitimacy and the ability to control the practice of outsiders, including practitioners of other schools of medicine. Restrictive scope of practice regulation that limits the practice of non-physician health care providers is one continuing example of the use of law as a shield. *See, e.g., Scope of Practice: Allied Health Professionals Form Coalition to Oppose Efforts to Restrict Their Practices*, 15 Health L. Rep. (BNA) 711 (June 15, 2006) (discussing the American Medical Association’s (AMA) Scope of Practice Partnership (SOPP), an advocacy group formed to influence state regulation).

8. *See e.g.,* William M. Sage, *Malpractice Reform as a Health Policy Problem*, 12 WIDENER L. REV. 107, 112–15 (2005) (defining “defensive medicine” as medical care that is motivated by the avoidance of liability rather than by benefit to patients); *see also* David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2612 (2005) (reporting that 93% of physicians surveyed in Pennsylvania “sometimes or often” engage in at least one form of defensive medicine due to the threat of malpractice liability).

provide futile care;<sup>9</sup> against controlled substances laws that require them to neglect their patients in pain<sup>10</sup> or to deny their patients the sterile injection tools that would prevent the spread of disease;<sup>11</sup> against antitrust laws that prevent doctors from organizing themselves in ways that would produce more cost-effective and accessible care;<sup>12</sup> and against regulations that impede important medical research.<sup>13</sup> These "bad law" claims assert that the law's effort to promote patient health and well-being has actually caused significant harm.

These "bad law" claims have often fallen on ears deafened by the reform effort itself. Changes intended to move the physician-patient relationship to a more egalitarian or consumer-oriented model, whether through the legal obligation of informed consent or through the removal of legal barriers impeding operation of the market, required that traditional claims of professionalism be weakened or rejected. Legal and policy efforts over the last several decades thus deconstructed the traditional claims of medical professionalism about the right relationship of law to medicine. Medicine's complaints about defective law came to be characterized as the work of a self-serving guild, rather than a profession motivated by altruism and armed with expertise, or at least as the work of the recalcitrant "bad apples" who continued to resist improvements that the more enlightened among them embraced.<sup>14</sup> These narratives marginalized physicians' "bad law" claims and diminished them as a source of legitimate information about the effectiveness of reform efforts.

This paper argues that physicians' "bad law" claims should be taken seriously and treated as sentinel events that warrant closer consideration. "Sentinel events," as the term is currently used in health care quality improvement, describe incidents that cause injury or present a risk of serious

9. See, e.g., Judith F. Daar, *Medical Futility and Implications for Physician Autonomy*, 21 AM. J.L. & MED. 221 (1995); Seth Rivera et al., *Motivating Factors in Futile Clinical Interventions*, 119 CHEST 1944, 1946 (2001).

10. See discussion *infra* Part II.D–E.

11. See Scott Burris et al., *Harm Reduction in the Health Care System: The Legality of Prescribing and Dispensing Syringes to Drug Users*, 11 HEALTH MATRIX 5 (2001).

12. See Thomas L. Greaney, *When Politics and Law Collide: Why Health Care Reform Does Not Need Antitrust 'Reform,'* 39 ST. LOUIS U. L.J. 135 (1994).

13. See Symposium, *Censorship and Institutional Review Boards*, 101 NW. U. L. REV. 399 (2007); see also Kathleen Dracup & Christopher W. Bryan-Brown, *The Law of Unintended Consequences*, 13 AM. J. CRITICAL CARE 97, 99 (2004); Jennifer Kulynych & David Korn, *The Effect of the New Federal Medical-Privacy Rule on Research*, 346 NEW ENG. J. MED. 201 (2002); Beverly Woodward, *Challenges to Human Subject Protections in US Medical Research*, 282 JAMA 1947 (1999).

14. See discussion *infra* Part I.

injury.<sup>15</sup> These events are sentinel “because they signal the need for . . . investigation and response.”<sup>16</sup> Doctors’ “bad law” complaints signal that there may be a risk of harm to patients caused by the effect of law on medical decisionmaking in particular circumstances.

Again in the parlance of current quality efforts, these signaling events trigger an obligation to engage in a root cause analysis<sup>17</sup> which requires that one examine sentinel events from the perspective of an entire system rather than as the failing of individuals.<sup>18</sup> It focuses on the performance and outcomes of the system rather than on attaching fault to individual actors. Root cause analysis looks at the operation of a system upon the human beings that work within it rather than simply asking whether the individuals involved conformed themselves appropriately to the system.<sup>19</sup> Importantly for the arguments in this paper, root cause analysis identifies system changes that accommodate observed and predictable behavior patterns rather than expecting these patterns to accommodate themselves to the system.<sup>20</sup> Systemic change in response to the root cause analysis of sentinel events is intended to avoid harm in the future.<sup>21</sup> Its accommodation of the system to established behavior patterns does not sacrifice quality or patient protection but rather uses these patterns strategically to better achieve quality and patient safety goals.<sup>22</sup> Neither the self-serving guild nor the “few bad apples” narrative of physicians’ “bad law” claims meets the expectations of root cause analysis and system change.

As the discussion below will show, however, taking “bad law” claims seriously does not mean that they must be accepted at face value. In fact, serious testing of such claims should provide the groundwork both for adjusting legal standards and processes when the complaints are valid and for rejecting the wholesale abandonment of useful standards and processes when complaints are not valid. Far from arguing that reformers should retreat from challenging the medical profession’s claims of bad law, this paper argues that

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15. THE JOINT COMMISSION, SENTINEL EVENTS POLICY AND PROCEDURES (July 2007), available at <http://www.jointcommission.org/SentinelEvents/PolicyandProcedures> (follow “Sentinel Events Policy and Procedures”).

16. *Id.* The Joint Commission requires that accredited hospitals set up systems to detect sentinel events; particular sentinel events must be reported to the Commission. *Id.*

17. Root cause analysis was borrowed from other high risk industries and now is embedded in hospital quality efforts due to the Joint Commission’s requirements. Despite its common use, the effectiveness of root cause analysis in reducing error and injury has been documented only anecdotally. See, e.g., Albert W. Wu et al., *Effectiveness and Efficiency of Root Cause Analysis in Medicine*, 299 JAMA 685 (2008).

18. THE JOINT COMMISSION, *supra* note 15.

19. *Id.*; Wu, *supra* note 17, at 686.

20. THE JOINT COMMISSION, *supra* note 15.

21. Wu, *supra* note 17, at 687.

22. See discussion *infra* Part IV.

there is significant work to be done to test whether these claims are, in fact, dishonest and strategic, mistaken or misinformed, or valid and revealing. Absent this work, doctors' bad law claims are likely to have either too much power or too little power.<sup>23</sup> Only by mere accident will the formal response to these claims further the goals of health policy reformers.

Using specific examples, this paper offers an instrumental analysis of "bad law" claims as a lens through which it explores the application and translation of law into medical practice. Each of the "bad law" claims chosen for discussion involves a claim by doctors that a law intended to produce better health care is in fact causing them to treat their patients poorly.

There is surprisingly little empirical research devoted to finding out whether or how doctors alter their behavior in response to legal risk.<sup>24</sup> Empirically grounded theories of human behavior contribute significantly to our understanding of how people make decisions and react to certain forms of communication, external constraints, and risks; these theories are increasingly migrating to analysis of law.<sup>25</sup> Those behavioral theories may be extrapolated

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23. See, e.g., Clark C. Havighurst, *Starr on the Corporatization and Commodification of Health Care: The Sequel*, 29 J. HEALTH POL. POL'Y & L. 947, 956 (2004) ("My own diagnosis of why the health care 'revolution' failed to topple medicine as a 'sovereign' profession . . . [is] that the American political system is far too committed to compromise and half-measures . . ."). For further discussion of the influence of such claims, see *infra* Part III.

24. Most frequently, the best evidence available as to the influence of law is the ubiquitous attitude survey in which doctors identify legal requirements as the cause of their self-reported suboptimal behavior. See, e.g., Flora Johnson Skelly, *Fear of Sanctions Limits Prescribing of Pain Drugs*, AM. MED. NEWS, Aug. 15, 1994, at 13 (reporting that 69% of doctors surveyed said that the risk of disciplinary action made them more conservative in prescribing opioids for pain, and that of this group, one-third said their patients thus suffered from untreated pain); HARRIS INTERACTIVE INC., COMMON GOOD, FEAR OF LITIGATION STUDY: THE IMPACT ON MEDICINE 8 (2002), <http://commongood.org/assets/attachments/57.pdf> (reporting that 76% of doctors surveyed stated that concerns about malpractice litigation hurt their ability to provide quality care, and 79% that they themselves—and 91% have noticed that other physicians—ordered more tests than necessary due to concerns about malpractice). Attitude surveys of this type are notoriously unreliable as indicators of either actual behaviors or actual motivations, and some believe that they may even be used strategically by doctors to achieve certain political goals. See MARSHALL B. KAPP, OUR HANDS ARE TIED: LEGAL TENSIONS AND MEDICAL ETHICS 29 (1998) (calling such studies "'feels bad' surveys").

25. Behavioral law and economics, for example, revises the law-and-economics analysis of the impact of law with a more empirically based understanding of human decisionmaking. See, e.g., Cass R. Sunstein, *Behavioral Analysis of Law*, 64 U. CHI. L. REV. 1175 (1997). Cognitive theory generally is applied to a number of areas of law to anticipate and explain how people make decisions in legally significant contexts. For an inventory of heuristics developed through cognitive psychology as applied to quality assessment, see Jason Ross Penzer, Note, *Grading the Report Card: Lessons from Cognitive Psychology, Marketing, and the Law of Information Disclosure for Quality Assessment in Health Care Reform*, 12 YALE J. ON REG. 207 (1995). See also Thomas L. Greaney, *Economic Regulation of Physicians: A Behavioral Economics*

further to physicians and could provide a useful framework for hypothesizing about physician behavior in reaction to fear of legal entanglement. There is a rather substantial body of research, however, that identifies apparently unique experiences, motivations, and reactions on the part of physicians. Research examining the training of physicians, for example, reveals heightened sensitivity to shame associated with errors, a refined notion of the centrality of character, and the attachment of serious moral content to breaches of particular, but not all, standards of behavior.<sup>26</sup> In addition, significant distrust on the part of physicians toward the legal system may influence them to react differently to *legal* risks and incentives as compared to other risks and incentives.<sup>27</sup> This research provides some basis for arguing that physicians are different from the general population and perhaps even from other professionals. Of course, there are good reasons to believe that doctors are not unique but are quite like lawyers, and so the potential for borrowing from empirical research on lawyers to predict the behavior of doctors may be substantial.<sup>28</sup> In regard to legal risk, however, one would expect that the

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*Perspective*, 53 ST. LOUIS U. L.J. 1189 (2009) (using behavioral economics to explain why the law's use of financial incentives and financial regulation of physicians is and is not successful).

26. See, e.g., CHARLES L. BOSK, FORGIVE AND REMEMBER: MANAGING MEDICAL FAILURE (2d ed. 2003) (the classic study of physician residency training in the late 1970s).

27. Trust has assumed a central position in discussions of efforts to regulate physician behavior. Most of the literature addressing the difficult issue of the extent to which society, and patients in particular, generally trusts physicians, explains patterns in the regulation of medical practice or can be used as a guide for choices in regulatory form. See, e.g., Mark A. Peterson, *From Trust to Political Power: Interest Groups, Public Choice, and Health Care* 26 J. HEALTH POL. POL'Y & L. 1145, 1155–56 (2001). Another trust, or confidence, issue that exists in this regulatory effort, however, is the trust or distrust that physicians carry for the law. See, e.g., William M. Sage, *Why Are Demonstrations of Comprehensive Malpractice Reform So (At All) Controversial?*, 37 U. MEM. L. REV. 513, 515 (2007) (“[P]hysicians are demanding reform because of their own emotions rather than documented fact—that for over a generation they have been scared of lawyers and that their fear leads them to practice worse medicine.”); see also ROBERT A. BURT, *DEATH IS THAT MAN TAKING NAMES: INTERSECTIONS OF AMERICAN MEDICINE, LAW, AND CULTURE* 69 (2002) (“A 1973 report by a federal commission . . . conveys the professional paranoia of the time in its opening observation: . . . ‘As one member of the Commission put it, “As a physician, I live in an aura of fear—fear of suit . . . . It may be hard to believe but we are a frightened profession . . . . [The doctor] really doesn’t want to believe the hostility he feels.”’”); Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1606 (2002) (arguing that defensive medicine often occurs “solely (or mostly) to reduce the probability of litigation”); sources cited *infra* notes 209, 221–223 (immunity statutes).

28. See, e.g., Diane E. Hoffmann, *Are Health Care Conflicts All That Different? A Contrarian View*, 29 HAMLINE J. PUB. L. & POL'Y 235 (2008) (arguing that conflicts involving doctors and patients are more like conflicts involving lawyers and clients than not).

reactions may be quite distinct due to differing levels of familiarity.<sup>29</sup> On the other hand, studies of physician behavior in relation to financial incentives tend to show that doctors change their behavior in response to payment and profit in ways expected of the rest of humankind.<sup>30</sup>

Furthermore, this paper refers to "doctors" as a single population. Of course, this device suffers from the weakness of all generalizations: what one gains in simplicity of reference, one loses in complexity.<sup>31</sup> In the face of the very thin relevant research on the issues addressed in this paper, however, the generalization is unavoidable. Finally, even if we had a better understanding of how doctors generally react to legal risk, it would not resolve the question of how doctors respond to particular legal requirements or legal risks.<sup>32</sup> This paper proceeds despite, or because of, the significant gaps in relevant empirical

29. J. Douglas Peters et al., *An Empirical Analysis of the Medical and Legal Professions' Experiences and Perceptions of Medical and Legal Malpractice*, 19 U. MICH. J.L. REFORM 601, 625–29 (1986).

30. See, e.g., Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252, 252 (2003) (reporting that prescribing patterns respond to even small financial rewards). But see Paul H. Rubin, *An Uncertain Diagnosis*, REGULATION, Summer 2005, at 34, 37–38 (noting that the data does not support conclusions that the prescriptions were not medically appropriate). Studies on the influence of gifting on physician practice also do not account for the impact of the pedagogical interventions proven to be effective in altering physician behavior that accompany these gifts. See Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J. L. SCI. & TECH. 61, 78–79 (2008); discussion *infra* Part III.A.

31. Janet Dolgin argues, for example, that the medical profession is experiencing an ideological division over the appropriate relationship between medicine and profit. Janet L. Dolgin, *Debating Conflicts: Medicine, Commerce and Contrasting Ethical Orders*, 35 HOFSTRA L. REV. 705, 718–19 (2006). Based on her review of the rhetoric of the debate within medicine, Dolgin concludes that the more traditional segment of the profession views the relationship between medicine and the market as one which threatens the focus on healing. *Id.* at 721–22. The other segment of the profession assumes that medicine can achieve more good things with the support of industry than without it. *Id.* at 722–25; see also M. Gregg Bloche, *The Market for Medical Ethics*, 26 J. HEALTH POL. POL'Y & L. 1099, 1106 (2001) ("The [medical] profession has become a complex mix of overlapping subgroups with both shared and competing interests."); John Harley Warner, *Grand Narrative and Its Discontents: Medical History and the Social Transformation of American Medicine*, 29 J. HEALTH POL. POL'Y & L. 757, 769 (2004) (recognizing that "the medical profession" as a category of analysis is an overgeneralization).

32. Substantial studies of physician reaction to the malpractice system conclude that physicians generally view it as haphazard, unpredictable, and unfair. See, e.g., Michelle M. Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375, 388 (2005) ("One concern [of using tort law to regulate patient safety] is that there is scant evidence that physicians process the deterrent signal sent by malpractice litigation in a constructive way."). It is not known whether the same is true of other legal signals.

research on physicians' reactions to legal requirements because there is no other choice at this point.<sup>33</sup>

Part I of this paper further explains the context for the sections that follow. It briefly describes the reform agenda of health law and its relationship to understandings of claims based on traditional professionalism. This section also acknowledges significant critiques of evaluating law based solely on its consequences; and thus, it sets limits on expectations for empirical work.

Part II analyzes "bad law" claims made by physicians in specific contexts. After acknowledging that some "bad law" claims make a scapegoat of legal requirements in the service of doctors' self-interest, this section examines how common learning and decisionmaking patterns in medicine may lead doctors to misunderstand specific legal requirements and legal risk. The section then moves on to consider two situations in which analysis of formal legal requirements and processes fails to produce any evidence of the bad law that the doctors claim exists. In each of these two situations, a shadow system may be operating to confound the expressed intent and purpose of the law. Finally, the section addresses situations in which scapegoating, misunderstanding, and shadow systems have each been ruled out as a root cause of the specific "bad law" claim, leaving one to conclude that the rules simply are wrong.

While often marginalized and misinterpreted, doctors' "bad law" claims are not entirely ignored. Part III examines several of the most common responses to "bad law" claims. Educational efforts to disabuse doctors of their misunderstanding of the law and overestimation of legal risk are often the frontline response, and this section begins with an analysis of these efforts. This section then addresses immunity statutes as a common legislative response to doctors' claims that legal risk forces them to behave inappropriately, and safe harbors as a regulatory effort to create a safe space for particular activities by restraining prosecutorial discretion. Finally, this section discusses the legal response to situations in which legal risk is unbalanced, fails to reflect policy goals, and inappropriately falls on only one side of a treatment choice. In using these specific examples, this section explains why "bad law" claims persist despite remedies that would be expected to be effective.

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33. Calls for more empirical research on the impact of law currently permeate legal scholarship. See, e.g., Carl E. Schneider & Lee E. Teitelbaum, *Life's Golden Tree: Empirical Scholarship and American Law*, 2006 UTAH L. REV. 53, 59–60. Health law scholarship has begun to respond to this call, albeit in some areas more than others. See Michelle M. Mello & Kathryn Zeiler, *Empirical Health Law Scholarship: The State of the Field*, 96 GEO. L.J. 649 (2008); see also Blum, *supra* note 4, at 20 (noting that "law is often cast as a tool to positively address some of the causes of medical errors," but that the literature on medical error has not considered "the role of law as a causative element" of medical error in its impact on hospital structure and behavior).



Part IV makes recommendations on two fronts. First, it calls for a different framework for evaluating the impact of law on medicine. It argues that the evaluation of the law as applied should be reframed to examine population-based effects on the behavior of physicians. Second, Part IV addresses circumstances in which policy-level decisions relating to enforcement strategies operate to highjack the formal legal standards that have been put in place to govern physician practice. In this latter effort, the paper recommends that regulators audit the performance of the monitoring and investigation stages of the regulatory process to reduce negative spillover effects. Specifically, this section argues that regulators should adjust monitoring systems, by choosing between visible and invisible systems, to accommodate physician sensitivity to oversight without abandoning the regulatory goal that the monitoring system seeks to obtain. It also offers a critique of "catch-and-release" investigation practices, which subject a significantly larger number of doctors to governmental inquiries with the intention of moving to sanctions on only a few.

These recommendations do not require reducing the commitment to the underlying legal requirements. Nor are they another iteration of the familiar debates over whether regulatory enforcement systems should provide individual inspectors with discretion and flexibility rather than requiring a stricter and more rule-oriented process.<sup>34</sup> The recommendations do, however, assume that knowledge of the way that physicians alter their behavior in the face of legal risk can provide a legitimate tool for the design of regulatory systems.<sup>35</sup> These discrete recommendations also acknowledge that "bad law" complaints can have substantial political power in the absence of serious examination and may indeed result in formal responses that undermine the publicly adopted goals of the regulatory system.

## I. THE REFORM EFFORT

### A. *Reforming Law to Reform Medicine*

To the extent that law imposes standards external to the medical profession, it departs from the traditional model of professionalism in which standards of practice emerge from and are enforced by the profession itself.<sup>36</sup>

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34. See, e.g., EUGENE BARDACH & ROBERT A. KAGAN, GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS 34–35 (1982) (describing the "rule versus discretion" dilemma in regulatory enforcement as "ancient").

35. See discussion *infra* Part IV.

36. Of course, medical malpractice law still formally rests primarily on the notion that the standard of care against which an individual physician's behavior is to be measured for liability purposes is that which is evident in contemporary medical practice. See BARRY F. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 336–39 (6th ed. 2008). Informed

The duty of informed consent, for example, one of the fundamental building blocks of the modern physician-patient relationship, can accurately be viewed as a creature of the law.<sup>37</sup> There is debate about whether the practice of informed consent grounded as an ethical obligation would have emerged from within the medical profession itself at a later time without the interference of judicial opinions.<sup>38</sup> Neither the practice of informed consent nor strong support for the concept, however, had developed within medicine prior to judicial intervention. Although calls for informed consent to be recognized as an ethical foundation for medical treatment predated the landmark *Canterbury v. Spence*,<sup>39</sup> the case law at least accelerated its development if it did not actually create the concept out of whole cloth. Certainly, for better or worse, and probably for worse, subsequent legal developments—including statutory presumptions attached to the execution of the consent form<sup>40</sup>—contributed significantly to the current practice of “consenting” patients.<sup>41</sup> Similarly, court

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consent and the relative authority of doctors and family in decisionmaking at the end of life, both of which developed at least in part through malpractice litigation and which are discussed in this paper, are examples of departures from standard practice. See also *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875, 880 (N.Y. App. Div. 1982) (regarding provision of oxygen to neonates), and *Helling v. Carey*, 519 P.2d 981 (Wash. 1974) (regarding testing for glaucoma), for instances in which courts imposed standards of care that exceeded customary practice.

37. See Alan Meisel, *Canterbury v. Spence: The Inadvertent Landmark Case*, in *HEALTH LAW AND BIOETHICS: CASES IN CONTEXT* 9, 33 (Sandra Johnson et al. eds., 2009) (discussing the significance and context of the case).

38. See JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 52 (1984).

39. *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) (holding that doctors’ overall obligation to a patient includes a duty of reasonable disclosure of therapy choices and corresponding risks); see, e.g., Jon R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 Nw. U. L. Rev. 628, 637–44, 644 n.63 (1969).

40. See, e.g., GA. CODE ANN. § 31-9-6(d) (2006) (providing that a written and signed consent that “discloses in general terms the treatment or course of treatment . . . shall be conclusively presumed to be a valid consent in the absence of fraudulent misrepresentations of material facts”); see also FLA. STAT. ANN. § 766.103(4)(a) (West 2005) (providing that a written and signed consent creates a “rebuttable presumption” of informed consent); IND. CODE ANN. § 34-18-12-2 (LexisNexis 1998) (providing that written consent can create a “rebuttable presumption” of informed consent); IOWA CODE ANN. § 147.137 (West 2005) (providing that written consent can create “a presumption” of informed consent).

41. The presumption statutes gut the requirement of informed consent in its broader sense of patient-centered decisionmaking as an enforceable legal standard, and they can be viewed as an abandonment of the aspirations for empowerment of patients embedded within that principle. See Alan Meisel & Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407, 416–17, 467–77 (1980); see also Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 932–38 (1994). These statutes may illustrate collusion between medicine and law, and the capture of state legislatures by the medical profession. Meisel & Kabnick, *supra*, at 469. On the other hand, they may simply be a rational restraint on lawsuits that should leave the normative and signaling effect of the legal requirement in place. See *id.* at 415 & n.18, 467–68; Schuck, *supra*, at 939–47 (advocating for a cost-

opinions concerning refusal of treatment at the end of life, beginning with *Quinlan*, established that the right to make those decisions belonged to the patient rather than to the physician alone.<sup>42</sup> Again, arguments to that effect already existed in the literature in ethics<sup>43</sup> and moral theology,<sup>44</sup> but *Quinlan* elevated patient choice in the face of significant resistance among the medical profession.<sup>45</sup> Although some would argue that *Quinlan* preserved a controlling role for physicians,<sup>46</sup> the decades of legislation and court cases after *Quinlan* assumed the primacy of patient choice and tested the boundaries of that choice as against social norms and practical and conceptual challenges in surrogate decisionmaking.

These legislative and judicial efforts intended from the start to be more than routine policing actions. They did not merely strengthen or take over the enforcement aspect of medical self-regulation; they aimed instead at transforming customary medical practice. For this reason, health law has been called a reform movement.<sup>47</sup>

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effectiveness analysis of informed consent to determine if it helps to keep health care costs down). A similar backing away from the initial goals and principles of antitrust law has also been observed. See, e.g., Thomas (Tim) Greaney, *Thirty Years of Solicitude: Antitrust Law and Physician Cartels*, 7 HOUS. J. HEALTH L. & POL'Y 189 (2007).

42. *In re Quinlan*, 355 A.2d 647, 663 (N.J. 1976).

43. See, e.g., LEON R. KASS, *LIFE, LIBERTY AND THE DEFENSE OF DIGNITY: THE CHALLENGE FOR BIOETHICS* 201–29 (2002).

44. Pope Pius XII, *The Prolongation of Life*, Address Before an International Congress of Anesthesiologists (Nov. 24, 1957), in 4 THE POPE SPEAKS 393, 397 (1958) (stating that the doctor's right to continue ventilator support relies on consent from the family or the patient). See Stanley J. Reiser, *View the Third*, HASTINGS CENTER REP., Nov.–Dec. 1993, at S13, S14, discussing Pope Pius XII's address: "[T]he moment when both the physician and the Pope acknowledged that a problem was beyond them is perhaps as good a time as any to take as the beginning of the modern biomedical ethics movement." See also Brief for New Jersey Catholic Conference as Amicus Curiae, *Quinlan*, 355 A.2d 647 (No. A-116), in 2 IN THE MATTER OF KAREN QUINLAN: THE COMPLETE BRIEFS, ORAL ARGUMENTS, AND OPINION IN THE NEW JERSEY SUPREME COURT 197 (1976) (supporting the Quinlan family's decision to withdraw treatment).

45. See BURT, *supra* note 27, at 67–70 (discussing the case law that dismantled physician authority and noting that the case law reflected changing social attitudes toward physicians); see also Sandra H. Johnson, *Quinlan and Cruzan: Beyond the Symbols*, in HEALTH LAW AND BIOETHICS, *supra* note 37, at 53, 68 (discussing the *Quinlan* decision in light of the negative reactions it elicited from various members of the medical community).

46. See, e.g., M.L. Tina Stevens, *The Quinlan Case Revisited: A History of the Cultural Politics of Medicine and the Law*, 21 J. HEALTH POL. POL'Y & L. 347, 362–63 (1996).

47. See, e.g., Clark C. Havighurst, *I've Seen Enough! My Life and Times in Health Care Law and Policy*, 14 HEALTH MATRIX 107 (2004) (regarding health care antitrust law); Carl E. Schneider, *After Autonomy*, 41 WAKE FOREST L. REV. 411 (2006) (regarding bioethics). Reform of the physician-patient relationship occurred contemporaneously with the broader civil rights movements that emphasized individual rights. Paul Starr observed that "[m]edical care figured prominently in this generalization of rights, particularly as a concern of the women's movement

The reform aspect of health law is especially pronounced in the context of bioethics. Many histories of bioethics, in fact, attribute its origins to legal interventions. For some, the *Quinlan* case gave birth to the field.<sup>48</sup> Others identify the Nuremberg Trials concerning the Nazi experiments as the beginning of bioethics,<sup>49</sup> and still others, the events that set the stage for the familiar scandal-reform call and response common in health care regulation generally.<sup>50</sup>

The building blocks of bioethics bear law's imprint—the emphasis on individual rights, the primacy of autonomy, and the default to procedure and evidentiary rules rather than substance for the resolution of conflict.<sup>51</sup> Legal tools became the instruments both of radical change and of moderation in bioethics.<sup>52</sup> This is not to say that law was the only player in the generation of bioethics, but law was at the table in even the earliest efforts.<sup>53</sup>

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and in the new movements specifically for patients' rights and for the rights of the handicapped, the mentally ill, the retarded, and the subjects of medical research." PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 388–89 (1982). Others note the current effect of increased commercialization, the emergence of evidence-based medicine in response to variations in medical practice, and the expanded management prerogatives stimulated by financing changes. See, e.g., BOSK, *supra* note 26, at xiv; Bloche, *supra* note 31, at 1108–09; Dolgin, *supra* note 31, at 712–14.

48. Albert R. Jonsen, *The Birth of Bioethics*, HASTINGS CENTER REP., Nov.–Dec. 1993, at S1, S3 (identifying the *Quinlan* case, revelations of abuse in medical research, and the allocation of dialysis machines by a citizen committee in Seattle as potential birthdates for the field).

49. See, e.g., BURT, *supra* note 27, at 80 (stating that the influence of the Nuremberg Code is the key to understanding the current emphasis on the "self-determination principle" in medical treatment contexts).

50. See Arthur L. Caplan, *What Bioethics Brought to the Public*, HASTINGS CENTER REP., Nov.–Dec. 1993, at S14, S14 (noting that the media was attracted to covering bioethics issues because they arose in scandals).

51. "Law sides with patients to oppose the arbitrary use of power whether by physicians or the government; the rubric is patient rights. This is why American law, not philosophy or medicine, is primarily responsible for the agenda, development and current state of American bioethics." GEORGE J. ANNAS, *STANDARD OF CARE: THE LAW OF AMERICAN BIOETHICS* 3 (1993). But see Daniel Callahan, *Why America Accepted Bioethics*, HASTINGS CENTER REP., Nov.–Dec. 1993, at S8, S8 (identifying American liberalism as the source of bioethics' emphasis on patients' rights); Robert M. Veatch, *From Forgoing Life Support to Aid-in-Dying*, HASTINGS CENTER REP., Nov.–Dec. 1993, at S7, S7 (attributing the emphasis to the social movements of the 1960s).

52. Callahan, *supra* note 51, at S8, notes that bioethics took a middle course between extreme positions: "That middle course is regulation . . . . On the one hand you avoid the extremes of simple prohibition of things, while on the other hand you show that you are serious and willing to be cautious."

53. DAVID J. ROTHMAN, *STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING* 3–4 (1991) (identifying bioethics as an interdisciplinary effort); K. Danner Clouser, *Bioethics and Philosophy*, HASTINGS CENTER REP., Nov.–Dec. 1993, at S10, S10.

Recommendations emerging from the works of the first multidisciplinary groups to approach bioethics problems were rather quickly translated into legal standards.<sup>54</sup> The influence of the law in developing this new field as something distinct from "medical ethics" is undeniable.<sup>55</sup>

The reform agenda of health law does not stop at bioethics. Change in the law applicable to physicians' financial and business dealings intended, in part, to deter collusion and cartel behavior among doctors and to realign their financial interests to better serve those of the payment systems and efficiency concerns.<sup>56</sup> Changing the legal environment for physicians' financial relationships, including extending the restrictions of antitrust law to the medical profession, was a "revolutionary cause,"<sup>57</sup> intended to encourage doctors to change their behaviors—to be more entrepreneurial, to be more market-oriented than tradition allowed, but not too much so.<sup>58</sup> Regulation of physicians' behavior to strike the appropriate balance between the ideal of a free market and the reality of market failure—for example in the context of billing, payment to medical researchers, joint ventures, or receipt of financial support from vendors—represents a significant reform movement as well.<sup>59</sup>

54. See, e.g., The Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, *A Definition of Irreversible Coma*, 205 JAMA 85 (1968) [hereinafter Ad Hoc Committee] (defining determination of death). See generally *In re Quinlan*, 355 A.2d 647, 656 (N.J. 1976) (accepting the Ad Hoc Committee's standards); Eun-Kyoung Choi et al., *Brain Death Revisited: The Case for a National Standard*, 36 J.L. MED. & ETHICS 824, 825 (2008) (recounting that state legislatures began to write the concept of brain death into law following the Ad Hoc Committee's report).

55. Callahan, *supra* note 51, at S8 ("[R]egulation [is] the way we in the United States typically deal with controversial issues."); Veatch, *supra* note 51, at S7 ("The development of rights approaches is totally alien to the traditional Hippocratic medical ethics."). But see Roger B. Dworkin, *Bioethics? The Law and Biomedical Advance*, 14 HEALTH MATRIX 43, 44 (2004), for the argument that "lawyers have nothing special to say about any of these [bioethics] matters" and that philosophy is "best equipped to evaluate bio-social questions."

56. See, e.g., Greaney, *supra* note 41, at 189–90; Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 532–33 (1988).

57. Havighurst, *supra* note 47, at 118 (describing the developments that shifted legal norms away from professional control and toward the market, including the extension of antitrust laws to health care); see also James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459 (1994) (arguing that application to, and enforcement of antitrust principles in the U.S. health care market have driven a paradigm shift).

58. See, e.g., James F. Blumstein & Frank A. Sloan, *Redefining Government's Role in Health Care: Is a Dose of Competition What the Doctor Should Order?*, 34 VAND. L. REV. 849, 924–26 (1981) (concluding that neither competition nor regulation alone provides an adequate and appropriate tool for controlling physician behavior and that the choice between regulatory and market approaches needs to be made on other than an abstract level).

59. Concerns about market-responsive behaviors, such as self-referrals and conflicts of interest, illustrate the continuing discomfort with market models for medical practice. See

### B. Reform and Professionalism

According to health law and policy scholars,<sup>60</sup> Paul Starr's Pulitzer-prize-winning book, *The Social Transformation of American Medicine*,<sup>61</sup> is one of the most influential texts ever written about the medical profession and the health care system. Its effect on legal scholarship is impressive: as of 2003, it had been cited more than 1400 times in 433 law review articles.<sup>62</sup> In addition, Starr's book appealed across ideological lines as it "redefined how lawyers think about medicine";<sup>63</sup> providing support to those who sought to strengthen market forces as well as to those who sought to enhance justice concerns.<sup>64</sup>

In his book, Paul Starr narrates the history of medicine through a lens that deconstructs the notion of profession, demonstrating that the medical

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generally MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST* (1993) (discussing physicians' conflicts of interest and the incentives that cause them to increase or decrease services); Dolgin, *supra* note 31 (contrasting attitudes of physicians regarding the parameters of medicine as related to market incentives provided by the pharmaceutical industry); Benjamin P. Falit, *Ancillary Service and Self-Referral Arrangements in the Medical and Legal Professions: Do Current Ethical, Legislative, and Regulatory Policies Adequately Serve the Interests of Patients and Clients?*, 58 S.C. L. REV. 371 (2006) (comparing self-referral regulations pertaining to doctors and lawyers respectively); William M. Sage, *Some Principles Require Principals: Why Banning "Conflicts of Interest" Won't Solve Incentive Problems in Biomedical Research*, 85 TEX. L. REV. 1413 (2007) (addressing regulation of financial relationships in the field of medical research).

60. See Special Issue, *Transforming American Medicine: A Twenty-Year Retrospective on The Social Transformation of American Medicine*, 29 J. HEALTH POL. POL'Y & L. 557 (2004). In addition to the Pulitzer Prize, Starr's book won several prizes from academic and professional organizations, including the American College of Healthcare Executives, and was reviewed on the front page of the *New York Times*. Joel D. Howell, *What the Doctors Read*, 29 J. HEALTH POL. POL'Y & L. 781, 781–82 (2004).

61. STARR, *supra* note 47.

62. Timothy Stoltzfus Jost, *The Uses of The Social Transformation of American Medicine: The Case of Law*, 29 J. HEALTH POL. POL'Y & L. 799, 799 (2004). Jost observes that the effect of the book on health law as a practice, rather than as a field of study, is less clear, *id.* at 809, although it seems to have been especially influential in the application of antitrust law to the profession, *id.* at 811. See also Howell, *supra* note 60, at 783 n.3 (noting that the Science Citation Index reported over 2000 citations to the book as of July 2003).

63. Jost, *supra* note 62, at 808 (quoting Sara Rosenbaum during an interview with Jost) (internal quotation marks omitted).

64. Jost notes that "[l]egal scholars from a wide range of perspectives found in the book an elegant, accessible, and comprehensive history of physician dominance of health care, which supported their own vision of how the health care system had to change." *Id.* at 807. The book was viewed by free market advocates as refuting the view that professional power was a response to market failure, *contra* Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 *passim* (1963), rather than conscious and deliberate self-serving behavior; while it was viewed by the "left wing in health law scholarship" as providing an important framework for thinking about diverse problems of justice and rights, Jost, *supra* note 62, at 808.

profession quite frequently—or perhaps inherently—advocates for its own self-interest in the guise of concerns over quality and with a claim of special expertise and professional virtue.<sup>65</sup> The debunking of the myth of the profession by Starr and others<sup>66</sup> laid the intellectual groundwork for the rejection of deference to professional self-regulation and self-governance.

Medicine's claims of altruism and special expertise as the best guardians of patient welfare have been used to justify paternalism in the physician-patient relationship and to insulate medicine from the discipline of the market.<sup>67</sup> As this paternalism and insulation were peeled away, the deference traditionally accorded to the profession and its views of its right relationship to law were removed as well.<sup>68</sup> This new understanding—that the traditional deference accorded the profession had been manipulated to subject law to its service—certainly influenced how reformers heard physicians' claims that the new legal order for medicine harmed rather than helped patients.<sup>69</sup> Rather than the deep

65. STARR, *supra* note 47, at 15–16. Although a key event in intellectual history, Starr's book reflected social movements of its time in attacking professional hegemony, just as the ascendancy of physician dominance was supported by social movements of its era. See Bernice A. Pescosolido & Jack K. Martin, *Cultural Authority and the Sovereignty of American Medicine: The Role of Networks, Class, and Community*, 29 J. HEALTH POL. POL'Y & L. 735, 737–38 (2004) (distinguishing physician dominance and physician sovereignty in light of Starr's book). Starr also recognizes the role of social movements in establishing and maintaining the status (whether high or low) of the medical profession over time. STARR, *supra* note 47, at 144.

66. See, e.g., ELIOT FREIDSON, *PROFESSIONAL DOMINANCE: THE SOCIAL STRUCTURE OF MEDICAL CARE*, at xi (1970); MAGALI SARFATTI LARSON, *THE RISE OF PROFESSIONALISM*, at xi–xviii (1977); Walter Gellhorn, *The Abuse of Occupational Licensing*, 44 U. CHI. L. REV. 6, 9–10 (1976). Starr acknowledges that the view of medicine as a cartel was expressed in much of the literature of the time. STARR, *supra* note 47, at 15–17. In fact, the Supreme Court's 1975 decision applying antitrust law to the legal profession made a significant contribution to dismantling the legal deference traditionally accorded the “learned professions.” *Goldfarb v. Va. State Bar*, 421 U.S. 773, 787 (1975).

67. William M. Sage, *Relational Duties, Regulatory Duties, and the Widening Gap Between Individual Health Law and Collective Health Policy*, 96 GEO. L.J. 497, 498–99 (2008) (“Professional (that is, physician) control over health care has a long, checkered history of both public-mindedness and protectionism.”).

68. See Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155, 155–56 (2004) (discussing the movement from deference to the profession, through “modestly egalitarian” models, and finally to reliance on market forces).

69. See, e.g., David A. Hyman, *When and Why Lawyers Are the Problem*, 57 DEPAUL L. REV. 267, 268–69 (2008) (“[O]ne should view complaints by professionals about how competition will adversely affect consumers with considerable skepticism, because self-interest has a distinct tendency to skew such assessments.”). Hyman notes that innovations in health care delivery attract “a heated response from the usual suspects making the usual arguments.” *Id.* at 271. Hyman compares medicine and law, finding similar self-interest, although noting that the legal profession has been more successful in protecting itself. *Id.* at 268; see also Clark C. Havighurst & Nancy M. P. King, *Private Credentialing of Health Care Personnel: An Antitrust Perspective* (pt. 2), 9 AM. J.L. & MED. 263, 291–92 (1983) (“Under the banners of ‘medical

insights of a venerable profession, such claims came to be viewed as the work of a self-serving guild that sought to protect itself.<sup>70</sup> A great range of complaints—that informed consent was unworkable; that living wills were impractical; that licensure boards for medicine and for other health professions had to be controlled by doctors; that cost controls would dangerously confine treatment decisionmaking—could each be interpreted through the “self-serving guild” narrative in which medicine struggles to maintain physician control of treatment decisions through paternalism in the physician-patient relationship and through exemption from the workings of competitive markets. These claims could then be marginalized as merely self-interested and dismissed as an effort to grasp at the remnants of the gilded age of professional hegemony wherever possible.<sup>71</sup>

Public regulation of physicians did not operate from a notion that all doctors were bad or that all medicine was bad, of course. In fact, regulation generally justifies and orients itself around the few bad apples model of the profession.<sup>72</sup> Its rules and enforcement efforts are targeted at finding, punishing, and deterring bad behavior on the part of a minority of the physician population.<sup>73</sup> This model, too, influences how physician complaints about legal requirements are heard. With the few bad apples in mind,

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science,’ ‘quality of care,’ and ‘professional prerogative,’ the medical profession was able to repel most attacks along its borders . . .”). Kenneth J. Arrow offers an opposing view of the significance of claims of professionalism in light of market failure in his classic article, *Uncertainty and the Welfare Economics of Medical Care*, *supra* note 64. Arrow argues that professionalism overcomes market failures in the medical context and thus, its claims are socially beneficial. *See id.* at 947, 967. Arrow’s analysis of market failure has had significant influence on health policy, “eclipsing in influence [his] case for the social welfare benefits of anticompetitive professional norms.” Bloche, *supra* note 31, at 1104.

70. *See, for example*, Bloche, *supra* note 31, at 1099–1100, for the argument that the “guild ideology,” as constructed by Richard Posner and others, understands claims of professionalism as serving the self-interest of guild members and “deceiv[ing] both its own adherents and the public concerning members’ furtherance of their own interests at society’s expense” and thus, does not deserve “law’s deference.” *See also* Harold C. Sox, Editorial, *Medical Professionalism and the Parable of the Craft Guilds*, 147 ANNALS INTERNAL MED. 809 (2007) (using the illustration of medieval guilds to explain medicine’s current subjection to government control).

71. Regulatory collusion in the effort to retain status and power is recognized in critiques of administrative agency behavior based on regulatory capture. *See, e.g.*, Richard A. Epstein, *Living Dangerously: A Defense of Mortal Peril*, U. ILL. L. REV. 909, 927–28 (1998).

72. *See, e.g.*, BARDACH & KAGAN, *supra* note 34, at 65–66 (discussing the extension of the “bad apple” metaphor in health and occupational safety regulation); Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825, 839 (1995).

73. *See* BARDACH & KAGAN, *supra* note 34, at 65 (arguing that the proportion of bad apples in most regulatory programs is overestimated despite suggestions to the contrary from commentators and from demonstrated regulatory practice).



resistance to efforts to punish and deter bad behavior can easily be interpreted as the squealing of these outliers or their empathetic allies.

Dismissing "bad law" claims out of hand blocks efforts to seriously assess the operation and impact of the regulatory system at issue.<sup>74</sup> The deconstruction of the traditional notions of professionalism and the construction of the guild and the few bad apples archetypes created a bias in the way that doctors' "bad law" claims often have been received. This selective hearing impedes the learning that closer examination of physician reports of defective legal standards and controls can yield.<sup>75</sup> Furthermore, deference to medicine's professionalism claims is not entirely extinct,<sup>76</sup> and dependency on medicine's superior knowledge can afford doctors' "bad law" claims disproportionate authority. Neither dismissiveness nor oversensitivity to doctors' claims well serves efforts to reform physician behavior toward building a better health care system or providing better care to patients.

### C. *Consequences as an Inadequate Basis for Evaluating Reform*

Concerning oneself with physicians' "bad law" claims gives priority to the consequences of the law in relation to physician behavior.<sup>77</sup> The assertion that the product of law reform should be evaluated based on its consequences does not go unchallenged, however. Measuring legal standards solely by their effect gives an inadequate accounting of the purposes of law. The symbolic and

74. See, e.g., Jesse A. Goldner, *The Unending Saga of Legal Controls over Scientific Misconduct: A Clash of Cultures Needing Resolution*, 24 AM. J.L. & MED. 293, 343 (1998) ("The historical tendency in science to view research misconduct as aberrational has undoubtedly contributed to the lack of attention paid to the very real problems that often result from both true and untrue charges.").

75. See, e.g., Thomas L. Greaney, *Chicago's Procrustean Bed: Applying Antitrust Law in Health Care*, 71 ANTITRUST L.J. 857, 858 (2004) (urging "courts and enforcers to pause" before applying rules to the health care marketplace).

76. See, e.g., Eric G. Campbell et al., *Professionalism in Medicine: Results of a National Survey of Physicians*, 147 ANNALS INTERNAL MED. 795, 795-96 (2007) (surveying physicians on the meaning of professionalism, and noting adoption of professionalism claims on the part of national medical organizations); Fred Hafferty, *Finding Soul in a "Medical Profession of One,"* 28 J. HEALTH POL. POL'Y & L. 133, 136 (2003) (reviewing ELIOT FREIDSON, PROFESSIONALISM: THE THIRD LOGIC (2001)) ("[O]rganized medicine has sought respite and redemption [from contemporary challenges] by embracing the ideology of professionalism with an almost religious fervor."); Clark C. Havighurst, *How the Health Care Revolution Fell Short*, 65 LAW & CONTEMP. PROBS. 55, 72-73 (2002); Rosenblatt, *supra* note 68, at 156.

77. The concern about the consequences of law originated with legal realism, predating and giving rise to theories of law and social norms, law and economics, critical legal studies, and more recently, cognitive theory and law. See, e.g., Oliver Wendell Holmes, Justice of the Supreme Judicial Court of Massachusetts, *The Path of the Law*, Address Delivered at the Dedication of the New Hall of the Boston University School of Law (Jan. 8, 1897), in 110 HARV. L. REV. 991, 1001 (1997) (arguing that the law should be designed so that its actual effects take precedence over arguments based solely on morality or history or philosophy).

normative effect of law, for example, is significant even if it has little or no effect on behavior.<sup>78</sup>

Legal norms in health care, in fact, quite explicitly rest on religious and ethical principles. The opinion in *Quinlan*, for example, relied extensively on Catholic moral theology.<sup>79</sup> Federal regulation of research rests on the normative framework of the Belmont Report.<sup>80</sup> Arguments about physician payment regulation often speak in terms of physicians' moral or ethical duties to their patients.<sup>81</sup>

The influence of the normative content and purpose of law may be one reason that there is such a dearth of empirical research on the effect of law on physician behavior.<sup>82</sup> In some areas of health law, for example in the legal requirement of informed consent<sup>83</sup> or the implementation of living wills and

78. See generally Robert E. Scott, *The Limits of Behavioral Theories of Law and Social Norms*, 86 VA. L. REV. 1603 (2000) (exploring the effect of law on social norms).

79. The opinion in *Quinlan* incorporates nearly the complete amicus brief filed by the conference of bishops of New Jersey. For a discussion of the role of Catholic thought in this case, see Johnson, *supra* note 45, at 66–68.

80. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at <http://www.nih.training.com/ohsr/site/guidelines/belmont.html>. For the report's impact on federal regulations, see CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 52–56 (2005).

81. See, e.g., Ron Roizen, *Why I Oppose Drug Company Payment of Physician/Investigators on a Per Patient/Subject Basis*, IRB: ETHICS & HUM. RES., Jan.–Feb. 1988, at 9 (questioning whether “percapita physician payment [is] ethical” and criticizing some physicians’ “self-serving deception” of patients).

82. See Sandra H. Johnson, *End-of-Life Decision Making: What We Don't Know, We Make Up; What We Do Know, We Ignore*, 31 IND. L. REV. 13, 36 (1998) (discussing the tension between the norm-setting function of law and the demands that standards rest on substantial voluntary compliance); Mello et al., *supra* note 32, at 398–99 (attributing the lack of empirical research on cost-effectiveness of health care regulation to continuing deference to ethical norms). Another significant barrier to basing regulatory design on empirical research is the difficulty of designing effective and valid studies. Compare William M. Sage, *Judicial Opinions Involving Health Insurance Coverage: Trompe L'Oeil or Window on the World?*, 31 IND. L. REV. 49 (1998) (arguing that current empirical research on judicial decisions is useless when it does not indicate whether or not the health insurance system is accomplishing public policy goals), with Karen A. Jordan, *Empirical Studies of Judicial Decisions Serve an Important Role in the Cumulative Process of Policy Making: Comments on a Paper by Professor William Sage*, 31 IND. L. REV. 81, 87–88 (2008) (arguing that empirical studies of judicial decisions can play a more important role than Sage suggests), and Maxwell J. Mehlman, *Getting a Handle on Coverage Decisions: If Not Case Law, Then What?: Comments on a Paper by Professor William Sage*, 31 IND. L. REV. 75 (2008) (agreeing that “case law is a poor source of empirical data” but disagreeing with Sage that other good sources of data exist). See generally Mello & Zeiler, *supra* note 33, at 662–66 (identifying “significant methodological challenges” to empirical health law studies).

83. Evidence concerning informed consent indicates that neither patients nor doctors are up to the task, both in terms of desire and capacity. See Schneider, *supra* note 47, at 414.

patient determination of care at the end of life,<sup>84</sup> we have significant evidence that the legal norm has been less than effective, at least in the way in which it was intended to work.<sup>85</sup> We are unlikely to abandon informed consent as a requirement for treatment or patient choice as the touchstone for end-of-life care. The evidence of the failings of this norm just does not matter. This commitment evidences true belief both in the moral content of these legal standards specifically, and in the normative character of law generally.<sup>86</sup> An appreciation for the expressive power of law itself supports an inclination to maintain aspirational norms.<sup>87</sup>

Commitment to the normative content of such laws also breeds optimism that the gap between the ideal and the reality can be fixed using the force of law and supplementary levers, applied to physicians over enough time. Furthermore, if resistance is interpreted as a strategy in a battle over professional power or if these complaints are attributed to bad apples in the profession, they will be discounted. These expectations lead critics to dismiss the possibility that professional resistance is a serious substantive critique of the design or function of the law.<sup>88</sup> Both the normative aspirations of law reform and low expectations for doctors' responsiveness to reforms contribute to the rejection of "bad law" claims.

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84. "[T]he facts are that applying the autonomy framework in end of life decision-making has had little practical effect and much fictitious posturing. Efforts to persuade people to create and implement advance directives to protect their autonomy if they should become incompetent have essentially failed." Robert A. Burt, *The End of Autonomy*, HASTINGS CENTER REP. (SPECIAL REP.), Nov.-Dec. 2005, at S9, S9.

85. Comparing the nature of the physician-patient relationship as it existed in the 1950s as compared to the twenty-first century, however, it is difficult to say that the patient's position in the relationship has not changed considerably and that perhaps some of this change was produced by legal recognition of informed consent, at least as a normative principle or public policy. See *supra* text accompanying notes 36-46. On the other hand, the demise of the paternalistic model and the rise of the more egalitarian model may be more attributable to increasing commercialization in medicine rather than the informed consent norm. Dolgin, *supra* note 31, at 712-15.

86. Johnson, *supra* note 82, at 36.

87. Robert Gatter, *Faith, Confidence, and Health Care: Fostering Trust in Medicine Through Law*, 39 WAKE FOREST L. REV. 395, 438-45 (2004) (arguing that the law can be used as a powerful tool for increasing consumer confidence in health care).

88. Of course, some of the defense of legal standards, despite evidence of their ineffectiveness in achieving stated goals, may reflect self-interest on the part of the legal profession. See, for example, Havighurst, *supra* note 47, at 122, noting "the power of the rights-based legal paradigm and of the trial lawyers who defend [medical malpractice law]" for their own benefit.

## II. "BAD LAW" CLAIMS

Not all "bad law" claims are the same. Some are dishonest or strategic. Some result from misunderstanding or misinformation about the particular legal standard at issue. Once dishonesty and confusion are ruled out, however, the remaining claims should be considered to be valid even if an examination of formal standards and processes do not confirm them to be so. Some complaints about bad law refer not to formal legal requirements but rather to shadow systems that confound the intent and purpose of the formal legal requirements. Doctors may be pointing at requirements that are adopted and enforced by private organizations, for example, or they may be identifying informal penalties imposed by processes through which the law is enforced by government agencies. Finally, some "bad law" claims reveal that legal standards do, in fact, require bad medicine and harm, rather than improve, health care access, efficiency, or quality.

This Part discusses each of these categories of "bad law" claims. It begins with a brief discussion of dishonest claims.<sup>89</sup> It then addresses claims that arise from misunderstanding, and demonstrates how physicians' learning patterns breed misinformation about the law.<sup>90</sup> The discussion then focuses on two instances in which "bad law" claims are valid even though an examination of formal legal requirements and procedures do not support their assertion. Although distinct, each of these two instances reflects the operation of shadow systems or rogue standards that are not evident in the formal legal regime.<sup>91</sup> Finally, this section concludes with a brief discussion of situations in which the formal legal standard is, in fact, wrong.<sup>92</sup>

The taxonomy offered here<sup>93</sup> is not intended to be comprehensive.<sup>94</sup> In addition, "bad law" claims in specific contexts may actually overlap and fall within more than one of the categories. Finally, physician behavior responds to environmental influences other than law or fear of legal entanglement, including social, ethical, financial, and administrative pressures.<sup>95</sup> This

89. See discussion *infra* Part II.A.

90. See discussion *infra* Part II.B.

91. See discussion *infra* Part II.C–D.

92. See discussion *infra* Part II.E.

93. See Sandra H. Johnson, *Managed Care as Regulation: Functional Ethics for a Regulated Environment*, 23 J.L. MED. & ETHICS 266 (1995) (using an early version of this analytical framework to analyze physicians' reactions to managed care restrictions).

94. For example, some physician "bad law" claims may result from a sort of free-floating anxiety or distrust. See, e.g., David L. Ralston, *Pain Management: Texas Legislative and Regulatory Update*, 24 J.L. MED. & ETHICS 328, 330 (1996) (reporting on a survey of Texas physicians in which 68% believed that the medical board's policy influenced pain treatment, but 61% reported that they did not know the board's standards for opioid prescribing).

95. See, e.g., BOSK, *supra* note 26, *passim* (addressing the influence of social norms and social networks on physician accountability); Sandra H. Johnson, *The Social, Professional, and*

taxonomy addresses only claims relating to law, although the influence of other environmental factors is accounted for indirectly.<sup>96</sup>

#### A. Dishonest: Scapegoating the Law

Dishonest "bad law" claims disguise motivations that relate solely to the provider's own interests. A doctor, for example, may find it easier to tell a patient that the law does not allow her to prescribe particular medications rather than explaining that the doctor has concerns about the patient's living arrangements or use of alcohol or marijuana; that the doctor thinks the patient is manipulative or weak and whiny; or that the doctor is concerned about his or her reputation as easily duped or incompetent for providing this treatment to this particular patient.<sup>97</sup>

Blaming the law is a particularly powerful source of control because it diverts attention from the real decisionmaker (the physician) and from the true reason for the denial of care (worries about the patient's characteristics or social network concerns). It does so in a fashion that creates an assumption of both good will and powerlessness on the part of the patient's dear doctor.<sup>98</sup>

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*Legal Framework for the Problem of Pain Management in Emergency Medicine*, 33 J.L. MED. & ETHICS 741 (2005) (describing ethical and social influences in emergency medicine).

96. See, e.g., discussion *infra* Part III.

97. These are common concerns expressed by doctors treating chronic pain patients. See Ann M. Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J.L. MED. & ETHICS 332, 334, 336–41 (1998).

98. "Bad law" claims may also be strategic in a larger sense to forge coalitions to support change in legal standards. Legislatures apparently have been influenced by claims that doctors would not provide emergency care for fear of liability, James Fehlberg, Note, *Physicians—Civil Liability for Treatment Rendered at the Scene of an Emergency*, 1964 WIS. L. REV. 494, 497 n.20 (1964); would not treat Medicare patients if rates were reduced, William Blanchet & Wayne Phillips, *Health Care and the Election*, BOULDER DAILY CAMERA, Oct. 2, 2008, at A (arguing that Medicare fee reductions blocked by Democrats in Congress would have "forced most of the few remaining private Medicare providers to resign"); Mike King, Editorial, *Medicare Fix Only Delays Inevitable: Halting Pay Cuts to Doctors Was a Start, but a Healthy Debate Awaits Down the Road*, ATLANTA J. CONST., July 27, 2008, at B6 ("The battle [over reduction of Medicare physician fees] pitted doctors against insurance companies, and because of their relationships with patients (read: voters), doctors always have more political clout than insurance companies."); Am. Health Line, Am. Political Network, *AHL Highlights Recent Efforts by Republicans*, July 30, 2008, available at WESTLAW, 7/30/2008 APN-HE 8 (reporting that Republicans were trying to mend their relationship with "once-loyal allies" in the medical profession after supporting a reduction in Medicare fees which ultimately was blocked by Democrats); would have to endanger mothers and newborns through early discharge if "drive-through deliveries" were not outlawed, William H. Dow et al., *Differential Effectiveness in Patient Protection Laws: What Are the Causes?: An Example from the Drive-Through Delivery Laws*, 31 J. HEALTH POL. POL'Y & L. 1107, 1107–08 (2006) (noting such statutes were part of the "backlash" against managed care); David A. Hyman, *Drive-Through Deliveries: Is "Consumer Protection" Just What the Doctor Ordered?*, 78 N.C. L. REV. 5, 89 (1999); or would not continue to deliver babies if malpractice litigation were not reined in, Douglas A. Kysar et al., *Medical*

*B. Misinformed: I Heard It Through the Grapevine*

The doctor may be wrong about what the law requires or prohibits, yet the doctor's understanding of the law is honestly asserted. Non-expert individuals dealing with an extensive body of rules that govern their actions on a daily basis do not ordinarily seek legal counsel and instead rely substantially on informal, word-of-mouth sources. At a very early point, the time and expense required to secure a more authoritative description of the law simply makes the effort impractical and unbearable. Any rule-oriented system, in which the specific rules are not easily accessible to those bound by them, will experience a similar informal, underground communication network.

In their clinical decisionmaking, physicians are more likely to turn to physician colleagues for advice rather than referring to journal articles or other decision supports.<sup>99</sup> This same pattern may operate in their seeking advice as to the legal requirements for their practice, crowding out counsel from persons with more legal expertise. Intuitively as well, one has to believe that doctors trust other doctors more than they do lawyers.<sup>100</sup>

Doctors value clinical experience rather than rules and guidelines in treatment decisionmaking.<sup>101</sup> This heuristic may operate in the context of assessing legal risk and developing responsive behaviors as well. Thus, the stories told by doctors about their own or others' experiences with the law take on even more power in part because they fit the learning and evidence-gathering patterns generally familiar in medicine.<sup>102</sup> In addition, stories told within physician groups are likely to amplify extremes in terms of the rendition of the facts of the case, as well as the view that the system is offensive and unfair.<sup>103</sup>

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*Malpractice Myths and Realities: Why an Insurance Crisis Is Not a Lawsuit Crisis*, 39 LOY. L.A. L. REV. 785, 812–13 (2006) (analyzing and refuting claims that malpractice premiums were causing “provider flight” among obstetricians); Michelle M. Mello et al., *Policy Experimentation with Administrative Compensation for Medical Injury: Issues Under State Constitutional Law*, 45 HARV. J. ON LEGIS. 59, 60–61 (2008) (describing sources of pressure for malpractice reform). See also, for example, Hyman, *supra* note 69, at 272, referring to doctors’ “mobilization of pliable state agencies to do the dirty work.” Hyman levies similar charges against the legal profession. *Id.* at 273. Such politically strategic claims may fall within any of the categories discussed in this paper.

99. Johnson, *supra* note 30, at 76.

100. See *supra* note 27.

101. See Johnson, *supra* note 30, at 74–76.

102. See, e.g., BOSK, *supra* note 26, at 86–87, 104 (describing the powerful impact of the single experience and the “horror stories” shared among physicians as a part of physician learning).

103. See, e.g., Molly J. Walker Wilson, *A Behavioral Critique of Command-and-Control Environmental Regulation*, 16 FORDHAM ENVTL. L. REV. 223, 240–42 (2005) (discussing group polarity in a regulatory setting).

When the rule is miscommunicated, it will have an impact quite different from that intended, possibly to the disadvantage of the patient, the doctor, and the public. Legal standards applicable to medical practice tend to be complex or fact-sensitive and, thus, are particularly resistant to accurate mouth-to-mouth communication on the grapevine. Yet, this informal communication network is the source of choice for physicians for much of their information and learning about legal requirements that affect their practice.

*C. From the Shadows: Whose Rule Is This Anyway?*

A doctor may honestly and sincerely charge that the "law" restricts good care and may accurately understand the "rule," but may be pointing the finger at the wrong target. In fact, someone else's rule, and not the law, may be the problem. Health care organizations all have their own informal and formal structures that establish standards and procedures internal to the organization.<sup>104</sup> Common illustrations of these efforts include the work of the hospital risk manager;<sup>105</sup> the efforts of compliance officers who set requirements for billing, and thus, for physician work;<sup>106</sup> policies and consultations provided by the ethics committee;<sup>107</sup> the hospital's pharmaceuticals and therapeutics committee that determines whether specific drugs will be available for prescribing;<sup>108</sup> the credentialing process that increasingly monitors physicians' practice patterns, patient outcomes, and personal behavior;<sup>109</sup> the hospital's quality management and patient satisfaction programs that set and enforce expectations for responding

104. See, e.g., Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 594–625 (2000) (discussing how Medicare and Medicaid operate in private organizations, such as nursing homes). This analysis would also apply to the influence of the Joint Commission on the operation of hospitals and physician practices within those institutions. See *id.* at 610–15 (discussing how the Joint Commission enacts standards in tandem with the Health Care Financing Administration).

105. See Mello et al., *supra* note 32, at 409 (discussing the role of the hospital risk manager when he or she learns that an adverse event has occurred).

106. See D. Scott Jones & Paul N. Bind, Jr., *Are Compliance Officers Leading the Way When It Comes to Quality?*, J. HEALTH CARE COMPLIANCE, Sept.–Oct. 2008, at 43, 47 (discussing the work of compliance officers in the context of billing).

107. Giles R. Scofield, *What Is Medical Ethics Consultation?*, 36 J.L. MED. & ETHICS 95, 95 (2008) (describing the role and significance of ethics consultation).

108. Am. Soc'y of Hosp. Pharmacists, *ASHP Statement on the Pharmacy and Therapeutics Committee and Formulary System*, 49 AM. J. HOSP. PHARMACY 648 (1992).

109. See Joint Commission, *Behaviors that Undermine a Culture of Safety*, SENTINEL EVENT ALERT, July 9, 2008, available at [http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea\\_40.htm](http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_40.htm); Eleanor D. Kinney, *Hospital Peer Review of Physicians: Does Statutory Immunity Increase Risk of Unwarranted Professional Injury?*, 13 MICH. ST. U. J. MED. & L. 57 (2009).

positively to patients' and families' requests regarding medical care;<sup>110</sup> and so on. In this environment, it is quite possible that the law the doctor identifies as requiring inappropriate care is the *organization's* policy, rule, or procedure and not any formal legal requirement. In fact, the influence of law in medicine can be crowded out by these private organizational forces that have more direct contact with the physician's day-to-day work.<sup>111</sup>

The internal structures that influence, direct, or control physician behavior in health care, now frequently referred to as "new governance,"<sup>112</sup> are pervasive. These private players operate on a parallel track or in partnership with legal regulatory efforts<sup>113</sup> and are often hailed as a supplement to the public enforcement of legal norms. The organization's rule, however, may differ from the law.

Organizational policies, for example, are likely to be designed to put some distance between the organization and legal risk,<sup>114</sup> avoiding conflicts that may or may not bloom into legal issues.<sup>115</sup> One might think that if observance of legal standards is a good thing, then being especially observant must be just as good if not better. It is not. Just as the Sunday drivers cruising ten miles below the speed limit on a major thoroughfare actually become a safety hazard, rules that aim at bringing medical practice well within legal boundaries may be hazardous to patients. Organizational policies that influence doctors toward behaving more cautiously may restrict health care access for particular patient populations (those viewed as likely to be difficult or to raise risks of adverse outcomes or oversight). They may restrict treatments or medications (with

110. See MICHAEL E. MILAKOVICH, *IMPROVING SERVICE QUALITY* 193–97 (1995).

111. See generally Carol A. Heimer, *Competing Institutions: Law, Medicine, and Family in Neonatal Intensive Care*, 33 L. & SOC'Y REV. 17, 49–50 (1999) (arguing that unless those who monitor day-to-day activities of hospitals translate the law into hospital routines, its effect "is much more muted").

112. See Louise G. Trubek, *New Governance and Soft Law in Health Care Reform*, 3 IND. HEALTH L. REV. 139 (2006); See also Scott Burris et al., *Changes in Governance: A Cross-Disciplinary Review of Current Scholarship*, 41 AKRON L. REV. 1 (2008) (providing an in-depth analysis of governance applying to health care as well as other contexts).

113. See generally Peter D. Jacobson, *Regulating Health Care: From Self-Regulation to Self-Regulation*, 26 J. HEALTH POL. POL'Y & L. 1165, 1171–73 (2001); Jost, *supra* note 72, at 827–41 (providing a history of the concurrent development of public and private regulatory efforts).

114. "When the regulated organization cannot determine with a high degree of confidence what is required for compliance with a new regulation, several special costs are incurred. If the organization is risk averse or the penalty for noncompliance is high, organizations may overcomply." Mello et al., *supra* note 32, at 401–02.

115. The hospital's lawyers are likely to have provided legal counsel for these efforts. Actual legal standards may allow the organization more flexibility than the organization or counsel chooses to allow in the organization's policies. See discussion *infra* Part III. See also Sandra H. Johnson & Jesse A. Goldner, *Hospitals Broaden Role of In-House Counsel*, HEALTH PROGRESS, May 1987, at 68 (arguing that hospitals should press counsel on advice concerning legal risk).



doctors avoiding those that require pre-approval or the hospital eliminating those with black-box warnings).<sup>116</sup> They may encourage doctors to provide unnecessary care or testing (that which the patient or family demands prior to completing the patient satisfaction survey).<sup>117</sup>

The context of end-of-life care provides a useful parallel and illustrates the significance of the concept of "over-observance" of the law. Reconceptualizing continued medical interventions to delay dying as "overtreatment" and as much an error as "undertreatment" produced a new way of thinking about choices concerning medical treatment at the end of life. When continued ventilator support, for example, was considered as merely maintaining the status quo and not as a "decision," only discontinuation of ventilator support required that a decision be made. Only when continued ventilator support was reframed as active treatment, and in fact as *overtreatment*, did a substantial choice between two equal and competing options present itself where none had existed before.<sup>118</sup> So, too, an understanding of the costs of "overobservance" of law provides a tool for assessing the impact of private organizational activity designed to avoid legal risk.<sup>119</sup>

Coordination between public enforcement and private regimes can be mutually reinforcing in protecting patients. "Double enforcement," however, can put the public regulatory system out of balance and distort the intended relationship between penalty and offense. For example, a physician and the state medical board may agree to resolve an inquiry as to the physician's prescribing practices, without proof of actual violation of standards, by having the doctor enroll in a continuing medical education (CME) program. This may be viewed as a very light penalty, if a penalty at all, by the medical board and quite appropriate in light of the nature of the board's inquiry. On the doctor's part, the agreement to participate in CME may be a rational and practical compromise of the dispute over particular practices with the board and one that would take the "death penalty" of license revocation off the table.<sup>120</sup>

116. *Heart-to-Heart Radio Series Program I: Beyond Pain* (Claire Schoen produced Jan. 1, 2004) (transcript available at <http://www.prx.org/pieces/5305/transcripts/5305>).

117. See Liz Kowalczyk, *Doctors Don't Report Colleagues, Errors: Study Finds Practices at Odds with Beliefs*, BOSTON GLOBE, Dec. 4, 2007, at A1.

118. See, e.g., Brief for SSM Health Care System, et al. as Amici Curiae at 9, *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990) (No. 88-1503); Thomas Finucane, *Thinking About Life-Sustaining Treatment Late in the Life of a Demented Person*, 35 GA. L. REV. 691, 695 (2001) (emphasizing the importance of viewing both overtreatment and undertreatment as serious issues).

119. James Gibson, *Doctrinal Feedback and (Un)reasonable Care*, 94 VA. L. REV. 1641, 1644-45 (2008) (discussing the impact of overcompliance with formal legal standards in the context of tort law).

120. See Martino, *supra* note 97, at 340.

If, however, the hospital then revokes the doctor's staff privileges as a result of the CME agreement,<sup>121</sup> that penalty has been magnified exponentially.<sup>122</sup> While one might assume that the hospital's action supports the legal effort, it is, in fact, levying a much more serious penalty than the public agency may have believed necessary or appropriate. The heightened risks to a doctor contemplating treating particular patients (for example, chronic pain patients, pain patients with a history of substance abuse) or providing particular treatments (for example, opioids for chronic pain) may deter the doctor from those choices.<sup>123</sup>

If the doctor is deterred from providing inappropriate or harmful treatment, there is no loss and only gain when private organizations magnify the penalty levied by the governmental agency. If, however, the doctor is an early adopter<sup>124</sup> of newer and perhaps more evidence-based medical knowledge, raising the penalties through this "double enforcement" by public and private entities prevents patients from receiving effective and necessary care. In the case of pain management, for example, early adopters of new knowledge regarding the effectiveness and safety of the long-term use of opioids in higher volumes than had been customarily prescribed were frequently investigated by the state medical boards.<sup>125</sup> The CME compromise can operate as a release valve in the regulatory process to create some space for accommodating emerging standards and change in medical practice and medical knowledge. The CME compromise is not an entirely satisfactory resolution of the regulatory challenge to accommodate change, of course, but at least its effect, and its threat, is not as dire as it would be if the doctor knew that agreeing to CME would result in loss of his livelihood due to termination or limitation by the hospital or health plans on which he depended.<sup>126</sup> Thus, double enforcement by private organizations of public penalties may carry quite negative effects as well as the positive effects for which mobilization of private organizations in the service of legal standards is usually praised.

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121. Hospitals are required to consult the National Practitioner Data Bank, to which state medical boards are required to report disciplinary actions, as a part of the hospital's credentialing process. Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11131–11137 (2000); see ALISON MCCRYSTAL BARNES, HEALTH CARE LAW DESK REFERENCE 41 (2001).

122. See Martino, *supra* note 97, at 340 (reporting incidences of such actions and discussing their implications on physician prescribing behavior).

123. *Id.* at 341.

124. See, e.g., Shana Campbell Jones et al., *The Interoperable Electronic Health Record: Preserving Its Promise by Recognizing and Limiting Physician Liability*, 63 FOOD & DRUG L.J. 75, 83 (2008) (discussing liability risks of early adopters of electronic health record systems).

125. Sandra H. Johnson, *Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act*, 24 J.L. MED. & ETHICS 319, 320 (1996).

126. But see discussion *infra* Part II.D (penalties of the process).

The interests at stake in establishing private ordering within health care institutions do not necessarily represent the breadth of interests at stake in the adoption of legal standards. The enforcement of legal duties and rights carries clearly stated formal penalties. Formal penalties usually take into account the seriousness of the violations and weigh a number of competing factors, including fairness, proportionality, protection of the public, repeat offenses, the potential for rehabilitation, and conflicting substantive regulatory goals.<sup>127</sup> The severity of the punishment that follows a violation of legal standards figures substantially into the deterrent effect of the law with more severe penalties, at least theoretically, producing a greater margin of avoidance. While voluntary compliance is the essential goal of legal standards, health care organizations do not contribute to this effort when they reinterpret legal requirements in ways that alter the balance of risk and benefit and the competing policies in the original standard. More—more caution, more risk-aversion, more penalties—is not necessarily better.<sup>128</sup>

*D. From the Shadows, Too: All's Not Well that Ends Well*

The enforcement process itself also imposes significant penalties in the course of identifying violators. These penalties are distinct from formal penalties levied after a conclusive finding that a violation has occurred. These

127. See generally Michael A. Simons, *Prosecutors as Punishment Theorists: Seeking Sentencing Justice*, 16 GEO. MASON L. REV. 303 (2009) (arguing prosecutors should consider these punishment theories in assessing appropriate potential sentences for crimes charged). The question of "regulatory balance" in enforcement practices in the context of conflicting goals appears in regulatory literature generally and in health care policy in particular. See, e.g., Johnson, *supra* note 95 (describing questions of regulatory balance in enforcement efforts related to controlled substances); Brian Rubens, *Common Law Versus Regulatory Fraud: Parsing the Intent Requirement of the Felony Penalty Provision of the Food, Drug, and Cosmetic Act*, 72 U. CHI. L. REV. 1501, 1529 (2005) (arguing that the judicial requirement of specific intent upsets the regulatory balance struck in the statutory fraud provisions of the Food, Drug, and Cosmetic Act (FDCA)); Jeffrey Rudd, *Regulating the Impacts of Engineered Nanoparticles Under TCSA: Shifting Authority from Industry to Government*, 33 COLUM. J. ENVTL. L. 215 (2008) (recommending that the Environmental Protection Agency must strike the appropriate regulatory balance between safety and new product development).

128. Private organizations may amplify the penalties of the investigative process (as distinct from actual sanctions) by penalizing—formally or informally—those who are investigated but against whom ultimately no action is filed or sanction levied. See Goldner, *supra* note 74, at 342–43 (discussing federally mandated scientific misconduct investigations and procedures). Goldner describes the results of a survey of researchers accused of misconduct but where no misconduct was found, but who nonetheless suffered subsequent penalties, such as loss of employment, promotions, or salary increases; ostracism; reduction in research or support staff; and other actions. *Id.* at 342. Goldner argues that institutions need to address the issue of private penalties for persons investigated but cleared of misconduct charges. *Id.* at 343. See also discussion *infra* Part II.D (penalties of investigations).

“penalties of the process”<sup>129</sup> exert their own deterrent effect.<sup>130</sup> When substantial, they will produce avoidance behaviors on the part of those who might fall within the investigative net even though the likelihood that they will be subject to formal sanctions is nil or close to it.<sup>131</sup>

The deterrence effect of these informal penalties may produce results that actually undermine the goals of the formal legal requirements. Yet, they are all but invisible—they make no appearance in the formal description of the standards and procedures incorporated in the law. The best information available concerning the operation of this shadow system of enforcement comes from the people who experience it, those doctors who claim that there is “bad law” causing them to avoid doing the right thing.

This particular form of “bad law” claim was demonstrated dramatically in a 1996 conference focusing on the prescribing of controlled substances for pain patients.<sup>132</sup> In a small workshop for that conference, the president of the Federation of State Medical Boards (FSMB), an organization of state medical boards, presented the boards’ standards and practices relating to physicians’ prescribing opioids for their chronic pain patients. He argued that the boards’ standards and enforcement practices were not impediments to prescribing these drugs as they did not target physicians prescribing these medications legitimately. Dr. Kathleen Hoover, a doctor who had been subject to disciplinary proceedings in Florida for her prescription of controlled substances for her patients in pain, was in the audience.<sup>133</sup> Dr. Hoover asked the official how he squared his view that the standards and processes used by the boards were legitimate and did not impede good care with the fact that the Florida board had subjected her to discipline for that very practice. Noting that the Florida board’s penalty ultimately had been overturned by the Florida Court of Appeals in Dr. Hoover’s case, he responded that everything had turned out alright in the end in her case.<sup>134</sup> After two years of expensive and

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129. The classic analysis of the effect of the costs of pursuing adjudication of legal violations was studied in the context of criminal prosecutions and plea bargains. MALCOLM M. FEELEY, *THE PROCESS IS THE PUNISHMENT: HANDLING CASES IN A LOWER CRIMINAL COURT* 199–201, 235–43 (1979).

130. This section of the paper focuses on the deterrent effect of legal enforcement systems. Deterrence is a major goal and effect of regulatory systems; however, significant research and theory argues that compliance with legal norms may be stimulated by positive understandings of moral or social obligations rather than fear of penalty alone. See Peter J. May, *Compliance Motivations: Affirmative and Negative Bases*, 38 *LAW & SOC’Y REV.* 41 (2004).

131. See discussion of investigations *infra* Part IV.B.

132. Am. Soc’y of Law, Med. & Ethics, National Meeting on Legal, Ethical, and Institutional Issues in Pain Relief (Nov. 1–2, 1996).

133. See *Hoover v. Agency for Health Care Admin.*, 676 So.2d 1380 (Fla. Dist. Ct. App. 1996).

134. He did not make an argument that the disciplinary action was appropriate in her case. The Agency for Health Care Administration (Agency) submitted the Board’s recommendation for

wrenching litigation contesting the sanctions levied against her, Dr. Hoover did not exactly agree. Furthermore, physicians were quite aware of the litigation in Dr. Hoover's case as well as similar cases in several other states at the time, and it hardly altered their risk calculus that the sanctions ultimately were overturned by an appellate court.<sup>135</sup>

Doctors' fear of the actions of state medical boards relating to their caring for patients in chronic pain focused on the very threshold of disciplinary action. They feared the investigative process itself because of the heavy costs it placed on the individual physician. State medical boards viewed a letter of inquiry, asking a doctor to respond to particular issues the board detected in its surveillance of the physician's prescribing,<sup>136</sup> as a neutral and non-punitive action that doctors who were engaged in legitimate practice had no reason to fear.<sup>137</sup> Doctors, on the other hand, called that communication the "\$10,000 letter,"<sup>138</sup> solely because of the financial costs of responding: many would hire an attorney to advise them on how to respond (as they believed that their license to practice was at risk) and every doctor would take time away from

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disciplinary action to the state's administrative hearings commission for a hearing, and the hearing officer concluded that the agency had failed to meet its burden of proof. *Id.* at 1382. Despite the hearing officer's findings and conclusions, the Board disciplined Dr. Hoover, including a reprimand, a \$4000 fine, mandatory CME on prescribing abusable drugs, and two years probation. *Id.*

135. At the time of the conference, only ten states, including Florida, had statutes that addressed the prescription of controlled substances for the treatment of intractable pain, and only six of those statutes addressed the concern of disciplinary action. Chris Stern Hyman, *Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment*, 24 J.L. MED. & ETHICS 338, 340 (1996). Only twelve more states had guidelines or regulations on the subject. *Id.* at 341. In 1998, as the result of a working group that included a representative from the American Society of Law, Medicine & Ethics (ASLME) project group that developed the 1996 conference, the Federation of State Medical Boards (FSMB) adopted a set of model guidelines to encourage state medical boards to reform their standards and practices. Sandra H. Johnson, *Providing Relief to Those in Pain: A Retrospective on the Scholarship and Impact of the Mayday Project*, 31 J.L. MED. & ETHICS 15, 16 (2003); see also FED'N OF STATE MED. BDS. OF THE U.S., INC., MODEL POLICY FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN (2004) [hereinafter FSMB, MODEL POLICY], available at [http://www.fsmb.org/pdf/2004\\_grpol\\_Controlled\\_Substances.pdf](http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf). By 2002, twenty-three states had enacted legislation and more than forty states had adopted policy statements, guidelines, or regulations. Johnson, *supra*, at 22, 19 n.24.

136. See discussion *infra* Part IV.B (prescription monitoring).

137. In a survey of medical board personnel, one 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).

138. *Heart-to-Heart Radio Series Program I: Beyond Pain*, *supra* note 116.

their practice to review charts and prepare responses.<sup>139</sup> The penalties embedded in the process, including disruption of practice, damage to reputation and to necessary business relationships, and stress and shame, were so severe that it became clear that “[t]he most effective antidote to the physicians’ fear [was] ensuring that state medical boards [were] not *investigating* . . . physicians who treat pain appropriately.”<sup>140</sup>

The Ninth Circuit Court of Appeals addressed the power of the investigative process standing alone to alter physician behavior in *Conant v. Walters*.<sup>141</sup> In that case, the court considered the federal government’s policy of investigating California doctors who discussed the medical use of marijuana with their patients after the state had legalized its use for such purposes.<sup>142</sup> Patients and doctors challenged the federal government’s policy as a violation of the First Amendment and sought and received a permanent injunction prohibiting the federal government from “threatening” and investigating such physicians.<sup>143</sup> The suit did not challenge any sanctions against specific

139. See Linda Pembroke, *How to Survive a State Board Investigation*, PAIN MED. NEWS, May–June 2007, at 1, 1, 10, for a discussion between a doctor and lawyer regarding the conduct of a medical board during an inquiry into the doctor’s prescribing practices, in which ultimately all potential charges were dismissed by the board. The doctor describes the notice that gave her fourteen days to prepare and submit “certified true copies of the [requested] medical records,” a summary of those records, and a notarized affidavit. *Id.* at 10. Seven days had already passed by the time the letter was received. *Id.* Summarizing the records posed a challenge as the inquiry letter did not specify any particular concern. The doctor reports that she needed to seek counsel to answer the following questions:

[W]hat constitutes a certified true copy? Can I send copies of copies? If I sign an affidavit certifying that these are copies of copies, but I’m not sure of that fact, did I just perjure myself? Do I really have to respond within 14 days? If I write a summary of what happened, should I write a little or a lot? Should I account for what I did, what the nurses did, what the patient did? Should I point out the patient’s deficiencies? . . . And why do they want my billing records?

*Id.* The Pembroke article also notes that malpractice insurance ordinarily does not cover the costs related to medical board inquiries or disciplinary actions. *Id.* See also Martino, *supra* note 97, at 340 (“To be investigated or sanctioned by a board could result in a loss of stature, reputation, institutional privileges, or access to insurance panels.”).

140. Hyman, *supra* note 135, at 338 (emphasis added).

141. 309 F.3d 629, 638–39 (9th Cir. 2002).

142. *Id.* at 632–33.

143. *Id.* at 633–34. This lawsuit was narrowly targeted to reach only the case of physicians discussing or recommending but not prescribing or distributing marijuana in a clinical setting. *Id.* at 632, 634. In *United States v. Oakland Cannabis Buyers’ Cooperative*, 532 U.S. 483, 486 (2001), the Supreme Court upheld the Controlled Substances Act classification of marijuana as a Schedule-I drug that cannot be prescribed legally, against a claim that the Act implied a “medical necessity” defense that would allow physicians to prescribe the drug for patients in certain circumstances. In *Gonzales v. Raich*, 545 U.S. 1, 9 (2005), the Supreme Court upheld the Controlled Substances Act as within the scope of the power of the federal government under the Commerce Clause.

physicians; it merely challenged the investigative process.<sup>144</sup> The injunction issued by the District Court prohibited the federal government from "initiating any investigation solely on" the basis of "a recommendation for the use of medical marijuana based on a sincere medical judgment."<sup>145</sup> The Ninth Circuit upheld the injunction based on the impact of threatened investigation on practicing doctors.<sup>146</sup>

Reporting requirements, which generally would indicate heightened prospects for investigation, can themselves alter behavior. The case of the use of physical restraints in nursing homes illustrates this point. Rates of 25–85% of residents in restraints were not uncommon among nursing homes in the late 1980s.<sup>147</sup> No government regulation required that nursing homes physically restrain their ambulatory residents to prevent them from falling or wandering, but falls and unsupervised departures from the facility required, at a minimum, that an incident report be filed with the regulatory agency and could trigger government investigation or inquiry.<sup>148</sup> Tying a patient to a bed or a chair did not require that an incident report be filed nor would it cause any serious inquiry from the government agency. Simply doing the bad thing—restraining the resident—became the course that was not penalized by the system. Such a

144. *Conant*, 309 F.3d at 633. The federal government agreed with the plaintiffs that a doctor who merely discussed marijuana with his patients would not violate federal law (the Controlled Substances Act), and the plaintiffs agreed with the federal government that doctors who actually prescribed or dispensed the drug would be in violation of the Act. *Id.* at 633–34. In essence, the suit concerned whether a recommendation, standing alone, violated the Act and whether a policy of investigating physicians who merely discussed or recommended marijuana to their patients violated the First Amendment. *Id.* at 632.

145. *Id.* at 634 (quoting *Conant v. McCaffrey*, No. C97-00139 WHA, 2000 WL 1281174, at \*16 (N.D. Cal. Sept. 7, 2000), *aff'd sub nom.* *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002)). The appellate court's majority opinion notes that the Drug Enforcement Administration (DEA) agreed that physicians who recommended marijuana to their patients should "have a genuine fear of losing" their prescribing permit. *Id.* at 639. Judge Kozinski, in his concurring opinion, quoted the report submitted by an expert who said that "[a] physician's career can be effectively destroyed merely by the fact that a governmental body has investigated his or her practice." *Id.* at 640 n.2 (Kozinski, J., concurring).

146. *See Conant*, 309 F.3d at 638–39. *See also Sermchief v. Gonzales*, 660 S.W.2d 683, 684–85 (Mo. 1983) (en banc), where the court awarded plaintiff nurses and physicians a declaratory judgment that the medical practice act was not violated by the work of the nurse practitioners in a situation where the board had simply "threatened to order the . . . nurses and physicians" to prove that the nurses were not guilty of the unauthorized practice of medicine. The board had taken no formal action against the nurses (or against the doctors for aiding and abetting the unauthorized practice of medicine in their work with the nurses), but the doctors reasonably feared that they would be so charged and argued that they would discontinue working with the nurses if the threat persisted. *See id.* at 684 & n.1 (emphasis added).

147. Laurence Z. Rubenstein et al., *Falls in the Nursing Home*, 121 ANNALS INTERNAL MED. 442, 449 (1994).

148. *See supra* text accompanying notes 15–20.

state of affairs communicated an unmistakable message: What did the regulations require? They required restraints.<sup>149</sup> It hardly mattered that no government regulation could be found to support that commonly held belief.<sup>150</sup>

Penalties of the process are magnified when enforcement employs the accoutrements of criminal prosecution.<sup>151</sup> Law enforcement personnel understand the power of public arrest, handcuffing, seizure of property, and disruption of business to dramatize the government's power and the grievousness of the personal misconduct. The arrest ritual communicates a powerful message to potential perpetrators: be afraid of us; be very afraid. For physicians at least, the "be very afraid" message is heard by good and bad alike, and it would not be surprising if the good (as well as the bad) alter their behavior accordingly, and not in a desirable direction.

149. One of the significant changes in federal regulations to address the excessive use of restraints was the inclusion of the percentage of residents physically restrained as an element in the Minimum Data Set required to be reported to the federal government by each nursing home. See Katherine Berg et al., *Identification and Evaluation of Existing Nursing Home Quality Indicators*, HEALTH CARE FIN. REV., Summer 2002, at 19, 20–21, 32–33. The more recent Centers for Medicare & Medicaid Services, Nursing Home Quality Initiative includes the rate of restraint use as a quality indicator. See Jennifer L. Hilliard, *The Nursing Home Quality Initiative: Shift in Policy, Shift in Paradigm*, 26 J. LEGAL MED. 41, 52–53 (2005).

150. Even after federal regulations were adopted to restrict the use of physical restraints in nursing homes, the practice persisted. According to providers, concerns about liability risks were at least a partial motivation for the use of physical restraints. See, e.g., Joseph Francis, Letter to the Editor, *Using Restraints on the Elderly Because of Fear of Litigation*, 320 NEW ENG. J. MED. 870, 870 (1989) (describing a newsletter from a malpractice insurance carrier concerning malpractice claims for falls by elderly patients and addressing the use of restraints to prevent those falls). An empirical study of a claims-filed database, the incidence of claims against nursing homes generally, and court opinions addressing liability for falls and wandering, proved that the liability concerns were unfounded. Sandra H. Johnson, *The Fear of Liability and the Use of Restraints in Nursing Homes*, 18 J.L. MED. & HEALTH CARE 263, 264–65 (1990). In addition, emerging actions for injuries due to the inappropriate use of physical restraints counterbalanced the risk of liability for falls. *Id.* at 267. Eventually, rates of nursing home residents in restraints declined so that rates of no more than 5% are common, and many facilities aim at 0% restraint use. See Bruce C. Vladeck, *The Past, Present and Future of Nursing Home Quality*, 275 JAMA 425, 425 (1996) (noting the reduction in the use of restraints after the regulations were in place). Of course, the effort to reduce restraint use involved more than changing the law. See, e.g., Catherine Hawes et al., *The OBRA-87 Nursing Home Regulations and Implementation of the Resident Assessment Instrument: Effects on Process Quality*, 45 J. AM. GERIATRICS SOC'Y 977, 978, 984 (1997) (citing the overall need to reduce "[p]oor care practices," which included the use of physical restraints). The fact that the reform effort involved more than legal change does not alter the fact that claimed "bad law" was influential in perpetuating the practice.

151. See Burris et al., *supra* note 11, at 7–8 (discussing criminal sanctions associated with prescribing and dispensing sterile syringes to injection drug users); 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, 233 (2009) ("In the course of the last decade federal and state prosecutors have arrested and charged several hundred physicians with criminal violations related to their prescribing of opioid analgesics.").



The decision of what has to be reported; whom to investigate; when to make an inquiry; how to dramatize an arrest—are all powerful enforcement tools in themselves.<sup>152</sup> These mid-level policy decisions can upset the balance sought to be achieved in the formal standard-setting process, but they are usually undocumented and rarely studied. In particular, reporting requirements and investigations do more than produce raw material for oversight and sanctions. Standing alone and apart from the decision to sanction, they exert an influence on physician behavior. Thus, they create a shadow system or rogue standards that doctors experience and report in “bad law” claims that can so easily be dismissed as either insincere<sup>153</sup> or misinformed.<sup>154</sup>

#### *E. Differential Diagnosis: The Rules Are Wrong*

Sometimes physicians' claims that the legal standard is bad are correct: the rules are wrong. The doctors are not dishonest or mistaken; and the formal rule is not being perverted by a shadow system: it is just wrong.<sup>155</sup>

This certainly was the case with physician complaints that state medical boards were using the wrong standards in investigating and penalizing doctors for prescribing opioids over the long term and in larger amounts than used traditionally for patients with chronic non-cancer pain.<sup>156</sup> After an investigation that included review of all news articles over a two-year period, phone and written surveys of state medical board members concerning standards and practices, review of written board policies, and review of statutes and judicial opinions, we found that, in fact, the rules were wrong.<sup>157</sup> Medical boards did sanction doctors for prescribing opioids appropriately for this patient population.<sup>158</sup>

152. See discussion of recommended adjustments to these decisions *infra* Part IV.

153. See discussion *supra* Part II.A.

154. See discussion *supra* Part II.B.

155. Although this analysis is a differential diagnosis in that other causes for the “bad law” claim are ruled out, “bad law” claims can overlap. Some of the examples discussed in this section, for example, also appear in other sections. Because the categories in this taxonomy are intended to focus responses as well as identify problems, however, it is useful to identify each of the categories into which a particular situation may fall.

156. See, for example, *Hoover v. Agency for Health Care Administration*, 676 So.2d 1380, 1381–83 (Fla. Dist. Ct. App. 1996), in which the only evidence against the doctor who was sanctioned for her prescribing of pain medication was provided by two physicians who testified that they never cared for patients in chronic pain and who admitted that they had not reviewed her patient's medical records, but who testified based on the pharmacy printouts alone that she had prescribed “excessive, perhaps lethal amounts” of the drugs and a “tremendous number of pills.” See text accompanying notes 132–135.

157. Johnson, *supra* note 125.

158. Symposium, *Appropriate Management of Pain: Addressing the Clinical, Legal, and Regulatory Barriers*, 24 J.L. MED. & ETHICS 285 (1996).

The conclusion that the rules are wrong can rest on a number of pragmatic and normative bases. The error, for example, may be a matter of the knowledge base on which the rule relies; a matter of the ethical principles it adopts; or a matter of the perspective which the rule assumes. In each of these, good law can become bad law just as good medicine can become bad medicine.

Rules that may have been right become wrong when the knowledge base in medicine shifts.<sup>159</sup> For health care regulation, the challenges of changes in technology receive considerable attention, but advances in knowledge, especially when those advances proceed in fits and starts, present significant challenges as well.<sup>160</sup> Rules prohibiting or penalizing the prescription of opioids for chronic pain, for example, were based in part on false notions that they are highly addictive and probably lethal.<sup>161</sup> The reporting system requiring reports of falls but not of the use of restraints<sup>162</sup> relied on mistaken but commonly held knowledge that restraints made people safe when instead even apparently benign restraints like bedrails caused significant injuries.<sup>163</sup>

Underlying ethical principles that support customary practice can also come to be viewed as mistaken as applied in particular situations. For example, in the case of pain management, the customary practice of withholding effective medication was based on strongly held beliefs that the drugs were addicting. Even for terminally ill cancer patients, concerns over addicting the patient caused doctors to withhold necessary pain medicine with

159. Changes in social knowledge also may reveal how a rule is wrong. For example, a recent investigation, by the *Los Angeles Times*, of the use of presumed consent for tissue retrieval revealed that it was applied in a fashion that caused a significant race-based disparate impact, with the vast majority of “donors” coming from racial minorities. See Michele Goodwin, *Deconstructing Legislative Consent Law: Organ Taking, Racial Profiling, & Distributive Justice*, 6 VA. J.L. & TECH. 2, ¶¶ 1–7 (2001), <http://www.vjolt.net/vol6/issue1/v6i1a02-Goodwin.html>; see also Burris et al., *supra* note 11 (finding that state laws which make “physicians and pharmacists the gatekeepers to syringe access” may be wrong in light of evidence regarding benefits of needle exchanges).

160. For a discussion of this problem in relation to the regulation of off-label prescribing, see Johnson, *supra* note 30.

161. Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians’ Perspective*, 24 J.L. MED. & ETHICS 296, 296, 299–303 (1996).

162. See *supra* text accompanying notes 147–50.

163. Neville E. Strumpf & Lois K. Evans, *Physical Restraints of the Hospitalized Elderly: Perceptions of Patients and Nurses*, 37 NURSING RES. 132, 132 (1988); see also Johnson *supra* note 150, at 263 (“The risks of using restraints on elderly patients are serious and substantial. These risks include strangulation, medical ailments caused by immobility, and increased agitation . . . [and] can lead to misdiagnosis due to masking of symptoms . . . .”); *Morning Edition: Bedrails Can Cause Deaths in Frail, Elderly* (NPR radio broadcast June 29, 2006), available at <http://www.npr.org/templates/story/story.php?storyId=5519589> (discussing FDA guidelines aimed at curtailing physical entrapment of patients in bedrails used on hospital beds).

tragic results.<sup>164</sup> Eventually, that beneficence norm as applied to the terminally ill was challenged, with stronger arguments made that the relief of pain was morally superior to the avoidance of addiction in a dying person.<sup>165</sup> Once the ethic changed, doctors then began to provide the drugs in larger doses.<sup>166</sup> As more people lived with cancer over a longer time, a body of evidence regarding long-term and higher-dose use of opioids developed. This new learning indicated that the risk of addiction of patients in pain was very remote, ultimately benefiting chronic pain patients as well.<sup>167</sup> In the case of physical restraints, the normative framework for care of nursing home residents gave primacy to keeping the residents safe.<sup>168</sup> Developing a new framework, one that valued functioning and social interaction, was required to offset a generation of normative training that had encouraged nurses and doctors to engage in restraining patients despite the distress experienced by patient and caregiver alike.<sup>169</sup>

Perspective conflicts are played out in the public policy arena where stakeholders argue for competing notions of good policy. Perspective is more than rational argument about data or values; it emerges from one's experience or empathy.<sup>170</sup> For example, if one experiences or empathizes with suffering caused by unnecessary pain, one favors increasing easy access to effective pain medications and is likely to have more tolerance for the risks of addiction and diversion. If the miseries of addiction inform one's perspective, it is likely to lead to a rule with very low tolerance for the use of narcotics that can be

164. June L. Dahl & David E. Joranson, *The Wisconsin Cancer Pain Initiative*, in 16 ADVANCES IN PAIN RESEARCH AND THERAPY 499, 499 (K.M. Foley et al. eds., 1990).

165. Moral claims to aggressive pain management in end-of-life care have their parallel in law. See Robert A. Burt, *The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care*, 337 NEW ENG. J. MED. 1234, 1235–36 (1997).

166. Bridget M. Kuehn, *Opioid Prescriptions Soar: Increase in Legitimate Use as Well as Abuse*, 297 JAMA 249, 249–50 (2007). There are still significant concerns over the inadequacy of pain management at the end of life. See Kathryn L. Tucker, *The Chicken and the Egg: The Pursuit of Choice for a Human Hastened-Death as a Catalyst for Improved End-of-Life Care; Improved End-of-Life Care as a Precondition for Legalization of Assisted Dying*, 60 N.Y.U. ANN. SURV. AM. L. 355, 375 (2004) (demanding accountability for the failure to “treat pain adequately” during end-of-life care); see also Jill L. Loeb, *Pain Management in Long-Term Care*, 99 AM. J. NURSING 48 (1999) (discussing factors that contribute to the “high incidence of inadequately controlled pain” among residents in long-term-care facilities).

167. See Portenoy, *supra* note 161, at 303.

168. Rosalie A. Kane & Robert L. Kane, *Long-Term Care: Variations on a Quality Assurance Theme*, 25 INQUIRY 132, 135–36 (1988).

169. Strumpf & Evans, *supra* note 163, at 132, 136–37.

170. See, e.g., Katherine Beckett & Bruce Hoffman, *Challenging Medicine: Law, Resistance, and the Cultural Politics of Childbirth*, 39 LAW & SOC'Y REV. 125, 158, 162–63 (2005) (describing empirical studies of legislative processes concerning recognition of midwifery demonstrating that legislators' personal experience with midwives or childbirth greatly influenced their position on proposed legislation).

addictive or can be diverted. If one assumes the perspective of persons dying of preventable infectious disease, it is likely to produce a stronger claim for distribution of sterile needles to prevent transmission. If, on the other hand, one is drawn to the suffering of addiction, the distribution of sterile needles might be resisted as removing a real or symbolic obstacle to illegal drug use.<sup>171</sup> Of course, these perspectives may not present true conflict, but instead may be reconcilable given appropriate information and resources for response. In most cases, however, perspective differences do at some point remain at odds, and a value choice as to what degree or direction of error is acceptable will have to be made.<sup>172</sup>

Even government agencies may not share the same perspective. For example, as the FSMB was adjusting medical board standards and practices to accommodate greater access to pain medication, the federal Drug Enforcement Administration (DEA) was establishing stricter standards, criminalization, and aggressive prosecution.<sup>173</sup> This conflict persists because of a difference in perspective of the two agencies. The FSMB identifies its mission as promoting good medicine.<sup>174</sup> The DEA identifies its mission as preventing the abuse and diversion of drugs.<sup>175</sup> The problem is not confined to morally charged areas of law, such as drug policy, of course.<sup>176</sup> In all cases, however, when government agencies are engaged in a conflict over the appropriate standard or policy, the subjects of their regulation have to view one of the rules as wrong. In fact, one may argue that truly conflicting regulations are by definition wrong.

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171. See Burris et al., *supra* note 11.

172. Bill Sage persuasively argues that the reductionist tendency to personalize health reform issues inappropriately narrows the focus to the physician-patient dyad and excludes consideration of collective costs and benefits. Sage, *supra* note 67, at 500.

173. See, e.g., Letter from the Nat'l Ass'n of Att'y Gens. to Karen P. Tandy, Adm'r, DEA (Jan. 19, 2005) (on file with Saint Louis University Law Journal) (regarding the DEA's revocation of its posted FAQ that indicated the agency's agreement with the standards used by state medical boards and its move toward criminalizing physician prescribing, stating that "state and federal policies are diverging with respect to the relative emphasis on ensuring the availability of prescription pain medications to those who need them").

174. Fed'n of State Med. Bds., Mission Vision, Core Values and Goals, <http://www.fsmb.org/mission.html> (last visited Apr. 4, 2009).

175. U.S. Drug Enforcement Administration, *DEA Briefs & Background, Drug Policy, DEA Mission Statement*, <http://www.usdoj.gov/dea/agency/mission.htm> (last visited Apr. 4, 2009).

176. See Mello et al., *supra* note 32, at 381 ("Uncoordinated pluralistic regulation may result in overlapping and conflicting mandates.").

### III. RESPONDING TO PHYSICIANS' FEARS OF LEGAL RISK

Physicians' claims that law is compelling bad medicine often generate a response aimed at relieving their fears and reducing or managing the legal risk, real or perceived, so that doctors can freely engage in the socially desirable behaviors threatened by the operation of the putative bad law. This section examines four of the most common responses to physician complaints about bad law. The responses selected for discussion below include redoubling educational efforts to relieve doctors' concerns; enacting immunity legislation addressing the specific source of risk; establishing legal safe harbors; and eliminating asymmetry.<sup>177</sup>

Each of these responses, in theory, should work to relieve physicians of the fear of legal entanglement that they report leads them to make different medical decisions than they otherwise would and should have. These common responses, however, are relatively ineffective in achieving their intended goal. In fact, in some circumstances, the efforts to quell physicians' legal concerns may produce negative outcomes of their own. As the following sections demonstrate, however, the failure of these efforts does not in itself prove that the original complaint was dishonest or misinformed.

#### A. Education

An assessment of particular legal requirements and their implementation may provide convincing evidence that physicians' fears of the law in a particular practice context are based on misinformation or misunderstanding. The first and most common response in this situation is simply to tell the doctors that this is so, to engage in educational activities to allay their concerns and assure them that they can provide good medical care without fear. These efforts are extraordinarily common in health law. As an educator, I am hardly one to argue that they are not very effective—but they probably are not.

Elsewhere, I have written about the weak impact of didactic forms of continuing medical education upon physician practices.<sup>178</sup> Physicians absorb

177. Legislatures and regulators have adopted other responses to physicians' "bad law" claims, including the adoption of strong presumptions of legal compliance as in the context of informed consent. See *supra* text accompanying notes 36–47. Furthermore, some claims of bad law asserted by physicians are really "there ought to be a law" claims in which the doctors argue that the legislature should act to protect them and their patients from harm worked by private ordering. See generally Diane E. Hoffmann, *Physicians Who Break the Law*, 53 ST. LOUIS L.J. 1049, 1084–88 (2009). Significant examples of such claims have produced legislation regarding managed care, including state laws against "drive-through deliveries"; laws prohibiting health plans from terminating doctors for "advocating" for patients; and laws requiring health plans to pay for emergency services without prior authorization.

178. See, e.g., Johnson, *supra* note 30, at 77–81; see also Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44

the information transmitted in such programs, but do not conform their treatment decisions to this new information.<sup>179</sup> There is no reason to think that education about legal standards would fare better in changing physician legal-risk-avoidance behavior. The educational techniques that have a proven effect in altering physician behavior, (such as multiple contacts between instructor and student following a learn-work-learn sequence; information that is provided at the exact point of an expressed need to know; comparative information on the behavior of other physicians; follow up with personal phone calls; and proctoring and shadowing)<sup>180</sup> are not the ones we generally use for legal education of physicians.

Even dismissing the data about physician learning generally, one is left with the substantial problem of designing content that would actually assuage physicians' fears of the risk of legal entanglement. The task of designing such an educational effort quickly reveals characteristics within the law, including its indeterminacy and the multiple perspectives emerging from attorneys' role identification, which doctors complaining of bad law may experience as threatening rather than comforting.

First, the analysis of the content and application of legal standards to medical practice requires some skill.<sup>181</sup> There are few simple yes-or-no answers.<sup>182</sup> Where legal requirements are at all dependent on the particular facts of the case, understanding what the law requires, or rather will require,<sup>183</sup> calls for the exercise of significant professional skill and judgment. Is this case

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ARIZ. L. REV. 373 (2002) (discussing the "horizontal process" by which medical professionals learn and share information and its effects on law).

179. Dave Davis et al., *Impact of Formal Continuing Medical Education*, 282 JAMA 867, 873 (1999) (basing its conclusion that such programs "have little or no role to play" in changing physician practice on a meta-analysis of studies on the effect of didactic CME).

180. *Id.* at 870–71. These methods are used in pharmaceutical detailing. See Wayne Kondro, *Academic Drug Detailing: An Evidence-Based Alternative*, 176 CAN. MED. ASS'N J. 429, 430 (2007). They also bear similarities to ethics consultation in hospitals, which operates as both a problem-solving intervention for difficult treatment decisions and an educational opportunity for the health care professionals whose cases are subject to consultative services.

181. See Scott Burris et al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 ST. LOUIS U. L.J. 1089, 1110 & n.106 (2009).

182. Sandra H. Johnson, *Five Easy Pieces: Motifs in Health Law*, 14 HEALTH MATRIX 131, 134 (2004); Johnson & Goldner, *supra* note 115, at 68 (advising hospitals on the limitations of legal advice).

183. See Louis M. Brown & Thomas L. Shaffer, *Toward a Jurisprudence for the Law Office*, 17 AM. J. JURIS. 125, 133–34 (1972), in an early work on "preventive law," describing the relationship of law and fact and distinguishing the "fact-law" analysis used to identify rights and duties after an event has occurred and the "law-fact" analysis used to make decisions in advance of legal disputes. In the litigation context, the facts are "cold" or "hard," indicating that they can not be changed; in the law office context, the facts are "hot" or "soft," indicating that there are decisions to be made in which the law is not necessarily the determining factor. *Id.* at 134.

just like the case that the courts have already decided, or is it different in some significant way?<sup>184</sup>

Furthermore, the infrequency of written judicial opinions and authoritative case law usually presents a connect-the-dots puzzle for legal counsel in which some important dots are missing. For example, even in an area such as discontinuing treatment at the end of life,<sup>185</sup> where there are enough judicial opinions to provide the fodder for an extensive treatise,<sup>186</sup> any one state may have no more than one or two such cases. In fact, with few exceptions,<sup>187</sup> this is the reality for most states. Take, for example, the state of Missouri. Lawyers in this state have two cases,<sup>188</sup> and no substantive statutes,<sup>189</sup> on which to base their judgments as to what the law in Missouri requires of physicians in providing or withholding treatment from incompetent patients in the absence of an advance directive. The only case to have reached the state's supreme court, *Cruzan v. Harmon*,<sup>190</sup> involved a patient in persistent vegetative state where the treatment at issue was nutrition and hydration. Do the standards in that case—that clear and convincing evidence of the patient's choice is required, and is adequate for withdrawal of treatment—extend to cases where the patient is minimally conscious or suffering? To cases where the treatment is chemotherapy? To cases where the patient was never competent to make a decision? How does a significant change in the composition of the court factor into our advice? Lawyers routinely refer to the case law of other states, but deciding whether Missouri's courts will follow the courts of other states requires educated guessing.<sup>191</sup>

184. The discussion in this subsection addresses the analysis of case law only as an illustration. Of course, case analysis alone is an inadequate methodology for developing any meaningful description of what the law is. Sage, *supra* note 82, at 61. See generally Burris et al., *supra* note 181, at 1142–47.

185. Other similar issues arise with the physician's duty to warn third parties of imminent danger presented by a patient, an exception to the physician's duty of confidentiality. See 7 MICHAEL L. PERLIN, MENTAL DISABILITY LAW: CIVIL AND CRIMINAL § 7A-5 (2d. ed. 1998). Once again, the rule is extremely fact-sensitive, and written court opinions in any one state are few in number or nonexistent. *Id.*

186. ALAN MEISEL & KATHY L. CERMINARA, THE RIGHT TO DIE: THE LAW OF END-OF-LIFE DECISIONMAKING § 12.01 n.1 (3d. ed. 2008) (describing end-of-life case law among the states).

187. *Id.* California, New York, and Florida are among the exceptions.

188. *In re Warren*, 858 S.W. 2d 263 (Mo. App. 1993); *Cruzan v. Harmon*, 760 S.W.2d 408 (Mo. 1988) (en banc), *aff'd sub nom. Cruzan v. Dir.*, Mo. Dep't Health, 497 U.S. 261 (1990).

189. Cf. MO. ANN. STAT. § 459.040 (West 2007) (providing only for written designation of an agent for decisionmaking); MO. ANN. STAT. § 459.010 (providing only for a written living will). The state has no legislation providing for surrogate decisionmaking for an incompetent patient without an advance directive.

190. *Cruzan*, 760 S.W.2d. 408.

191. In fact, the Missouri Supreme Court rejected the work of the vast majority of the courts in other states in its holding in *Cruzan*. See Sandra H. Johnson, *From Medicalization to*

Deciding what the law is in such situations requires prognostication, and reasonable and competent attorneys can disagree.<sup>192</sup> Attorneys, therefore, present a calculation of risk, using terms like “highly unlikely” and “probably not.” It is hardly ever the case that lawyers can tell doctors: “I assure you that you have nothing to be concerned about from the law. It is completely on your side. You are safe.” Lawyers are trained to root out any possible risk in a planned action and generally communicate that sense of heightened risk.<sup>193</sup> So, instead, what doctors often hear lawyers say is: “Well, anyone with a filing fee can sue you, but they are not going to win.” This consolation—intended to inject humor and reality into a situation that a lawyer can see is based on fears of nearly nonexistent eventualities—has to ring hollow to anyone who has been the defendant in any suit, even one that is eventually dismissed. Instead of reassurance, one could understand that this phrase would be heard as confirmation of the unpredictability of the legal hammer.

Furthermore, law does not speak with one voice. Lawyers assume specific roles in the health care environment (e.g., defense or plaintiff malpractice litigator; prosecutor or regulator; academic; in-house counsel), and the content and tenor of educational programs depend on the role identification of the speaker. In the classic dichotomy, for example, the hospital’s or doctor’s malpractice attorney is likely to tell quite a different story about the risk of malpractice liability for particular decisions than will the law faculty member invited to give the “law talk.”<sup>194</sup> The fraud prosecutor or the attorney for the medical board is likely to want to communicate a message of reasonableness in their exercise of discretion, but maintain a strong emphasis on deterrence. Threats against the bad apples in the profession are internalized by the audience of good doctors who identify with colleagues in trouble and see a fine line between themselves and these other doctors.<sup>195</sup>

At times, the message even from a single legal voice is deeply conflicting. Medical boards, for example, typically have used their newsletters to announce new policies or issue statements to encourage physicians to provide effective

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*Legalization to Politicization: O’Connor, Cruzan, and Refusal of Treatment in the 1990s*, 21 CONN. L. REV. 685, 695–96 (1989).

192. Thaddeus Mason Pope, for example, takes issue with nearly every earlier attempt to describe the law as it applies to medical futility. Thaddeus Mason Pope, *Involuntary Passive Euthanasia in U.S. Courts: Reassessing the Judicial Treatment of Medical Futility Cases*, 9 MARQ. ELDER’S ADVISOR, 229, 238–41 (2008).

193. David Maister, *The Trouble with Lawyers*, AM. LAWYER, Apr. 2006, at 97, 100 (“Probabilities do not seem to influence the discussion, only possibilities. There is no greater condemnation in legal discourse than to describe something as risky.”).

194. See KAPP, *supra* note 24, at 18.

195. Bosk noted, for example, that “[s]urgeons are loathe to judge the technical performance of others” because of a heightened sensitivity to the essential uncertainty of the practice of medicine. BOSK, *supra* note 26, at 173.



opioid treatment to patients in pain. In the same issue of that newsletter, however, they might have a piece on their interest in looking at physicians who are not vigilant about drug diversion.<sup>196</sup> They also have published lists of physicians disciplined, many of whom were disciplined for "prescribing abuse" related to controlled substances, without any further explanation that would show that the boards actually were using their new pain policy statements.

Efforts to repeatedly assure physicians that there is little legal risk may heighten rather than reduce anxiety. To the extent that physicians form their understanding of legal requirements and legal risks from dramatizations in newspapers, in industry newsletters, or in stories told by colleagues, telling them that the information is false may not dislodge the power of the narrative.<sup>197</sup> Doctors were not relieved, for example, to read the DEA's statement, *The Myth of the Chilling Effect: Doctors Operating Within Bounds of Accepted Medical Practice Have Nothing to Fear from DEA*.<sup>198</sup> In this 2003 document, the DEA declared that they hardly ever arrested doctors, and reported statistics that showed that out of nearly one million registrants, only 557 had been investigated; only 34 physicians had been arrested by the agency; and only 441 had been sanctioned in any formal fashion during the first three quarters of that year.<sup>199</sup> At the same time, the agency was pursuing an infamous criminal prosecution seeking a twenty-five year prison sentence against Dr. William Hurwitz, whose story was well-known among physicians treating pain patients, for his prescribing of controlled substances.<sup>200</sup> The

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196. The Texas State Board of Medical Examiners had adopted a policy to encourage physicians to prescribe adequate controlled substances for the treatment of chronic pain, but its newsletter instead published an article on "Narcotic Drug Prescribing" that stated that it was "obligated by statute to . . . investigate complaints alleging that the licensee is prescribing . . . what could be excessive quantities of drugs to persons who may be addicted to the medications." Ralston, *supra* note 94, at 328 (quoting *Narcotic Drug Prescribing*, MED. BD. REP. (Tex. State Bd. of Med. Exam'rs, Austin, Tex.), Fall/Winter 1988, at 6). In a later newsletter, the Board stated on the front page that "[t]he Board does not wish to inhibit the proper treatment of pain. However, the Board will continue to be concerned about the inappropriate use of narcotics in non-malignant conditions . . . ." *Id.* (quoting *Narcotics and Pain Relief*, MED. BD. REP. (Tex. State Bd. of Med. Exam'rs, Austin, Tex.), Spring/Summer 1992, at 1). The newsletter did not mention the legislature's newly enacted intractable pain act at all. *Id.*

197. See discussion *supra* Part II.B; see also, KAPP, *supra* note 24, at 12–14 (describing the influence of these sources of information in leading doctors to vastly overestimate their risk of being sued).

198. News Release, 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>.

199. *Id.*

200. Hoffmann, *supra* note 151, at 245–50.

power of the Hurwitz narrative, carried on the back of distrust of the DEA,<sup>201</sup> displaced the potential persuasive authority of the DEA's data-driven statement.<sup>202</sup>

In the medical setting, doctors hear about legal risk from colleagues.<sup>203</sup> Counterintuitively, the more that lawyers tell doctors that what they have heard is untrue, the more the untrue stories may be viewed as accurate. Research on the persistence of false rumors indicates that refutations of untruths have a perverse effect. Persons hearing refutations of the false information actually have a higher retention rate for the false information as true than those who have heard it denied less often.<sup>204</sup> In a similar fashion, there is some evidence that a message that focuses on the bad apples and on noncompliance as justification for government action may actually induce higher levels of noncompliance.<sup>205</sup> Furthermore, reassurance from the domain of law is filtered through medicine's distrust of law. Doctors do not trust the law or the legal system to be fair, predictable, or appropriate as it applies to medical practice. This deep distrust forms a cultural norm that influences how lawyers' educational efforts about legal requirements will be interpreted and internalized or rejected in medical practice.<sup>206</sup>

#### B. Immunity

One of the more familiar legislative responses to physician-reported fears of legal risks is statutory immunity. The Good Samaritan statutes<sup>207</sup> are the classic example, but there are others as well: the intractable pain acts (governing prescribing of controlled substances),<sup>208</sup> the living will statutes

201. See discussion *supra* INTRODUCTION.

202. See discussion *infra* Part IV (statistical evaluation of regulatory processes).

203. See discussion *supra* Part II.B.

204. See, e.g., Farhad Manjoo, *Rumor's Reasons*, N.Y. TIMES MAG., Mar. 16, 2008, at 22.

205. See, e.g., STEPHEN COLEMAN, MINN. DEP'T OF REVENUE, THE MINNESOTA INCOME TAX COMPLIANCE EXPERIMENT: STATE TAX RESULTS 5–6 (1996), available at [www.taxes.state.mn.us/taxes/legal\\_policy/research\\_reports/content/complnce.pdf](http://www.taxes.state.mn.us/taxes/legal_policy/research_reports/content/complnce.pdf). The study noted that reports of income and actual taxes paid increased among taxpayers who received a letter touting a high level of compliance with state tax obligations. *Id.* at 18–19. Taxpayers who received a letter describing the adverse effect on state budgets when taxpayers failed to pay taxes did not have the same effect. *Id.* The study also reported that taxpayers from lower and middle income levels reported significantly more income and paid more taxes when they received a letter warning them of an upcoming audit, while higher income taxpayers, as a group, showed no increase in reported income or taxes paid in response to the letter. *Id.* See also Valerie Braithwaite et al., *Taxation Threat, Motivational Postures, and Responsive Regulation*, 29 L. & POL'Y 137, 138 (2007) (discussing factors that contribute to compliance and non-compliance).

206. See discussion *supra* INTRODUCTION.

207. See statutes cited *infra* note 221.

208. See statutes cited *infra* note 223.

(providing immunity for compliance with advance directives);<sup>209</sup> the anatomical gift acts (providing immunity for organ procurement);<sup>210</sup> immunity for peer-review activities;<sup>211</sup> immunity for reporting child abuse;<sup>212</sup> and so on. The immunity response would seem to be the strongest legal weapon in quelling doctors' fears of legal risk. Yet, the evidence seems to indicate otherwise.

The Good Samaritan immunity statutes were enacted precisely in response to physicians' expressed fears of liability for their efforts to rescue individuals in medical distress in environments that were unequipped for medical care.<sup>213</sup> Studies indicate, however, that these statutes may have little or no effect.<sup>214</sup> There is no demonstrable or observable difference in physician response to emergencies in states with Good Samaritan legislation as compared to those without such a statute.<sup>215</sup> If this research is reliable, why would immunity statutes have so little apparent impact when they would appear to be so powerful a shield?<sup>216</sup>

Immunity statutes are designed to communicate a reassuring message to physicians; to alleviate fears that lead them to behave in less socially useful ways. For them to operate as a communicative device, however, physicians have to be aware of the existence of the statutes.<sup>217</sup> In addition, as a communicative device these statutes may have the unexpected effect of confirming rather than relieving fears, just as refuting unfounded rumors tends to reinforce beliefs in the rumors' truthfulness.<sup>218</sup> In addition, an immunity statute may not be able to overcome distrust of the law. A physician participating in a focus group on disciplinary actions, for example, stated:

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209. See, e.g., WIS. STAT. § 155.50 (2008) (providing immunity both for complying with a durable power of attorney for health care and for not complying with it; although the latter situation requires the doctor to transfer the patient to another's care).

210. See statutes cited *infra* note 222.

211. See, e.g., Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, 100 Stat. 3784 (codified as amended at 42 U.S.C. §§ 11101-11152 (2000)).

212. See, e.g., CAL. PENAL CODE § 11172 (West 2000).

213. Fehlberg, *supra* note 98, at 497-98 & n.20.

214. Eric A. Brandt, Comment, *Good Samaritan Laws—The Legal Placebo: A Current Analysis*, 17 AKRON L. REV. 303, 306 (1983).

215. See Frank B. Mapel, III & Charles J. Weigel, II, *Good Samaritan Laws—Who Needs Them?: The Current State of Good Samaritan Protection in the United States*, 21 S. TEX. L.J. 327, 354 (1981).

216. Testing impact can be difficult. For example, intractable pain acts have not appeared frequently in case law. See, e.g., Hoover, *supra* note 133, at 1385 (holding that statute rebutted claim that public policy supported disciplinary action even if act in force at time of doctor's actions). But see note 230 and accompanying text and note 234.

217. There may be gaps in informing doctors about such legislation. See discussion *supra* note 196.

218. See discussion *supra* Part II.

Doctors are asking for reassurance, not more rules or laws. Even the best intentioned of them [laws and rules], create only more fears in the minds of doctors trying to do their best, and place more ammunition in the hands of lawyers and regulators! Doctors will avoid the treatment of pain, so as not to take the chance of “not being in compliance” with some minor detail . . . .<sup>219</sup>

The lack of direct effect on physician behavior after adoption of immunity legislation should not be interpreted as proof that doctors’ undesirable behavior is not attributable to “bad law,” but rather is motivated by concerns and incentives other than law. It certainly is true that many competing, and at times contradictory, forces influence physician behavior, and it is quite unlikely that fear of legal entanglement explains everything.<sup>220</sup> Viewing immunity legislation as a controlled experiment that holds all variables constant but for legal risk, however, does not account for limitations in the design of such statutes, at least as they apply to health care.

Immunity statutes in the health care context are rarely absolute. At a minimum, they are always qualified by requirements that the beneficiary of this protection have acted in good faith; and under some immunity statutes, the health care provider must have acted reasonably or have met the expected standard of care. The Good Samaritan statutes, for example, typically provide immunity only to physicians who have acted in “good faith” and who have not engaged in gross negligence, recklessness, or intentional misconduct.<sup>221</sup> The organ procurement immunity statutes also typically set what may be considered the lowest or most easily attainable standard for securing immunity; i.e., that the party merely have acted in “good faith.”<sup>222</sup> The intractable pain acts are even more qualified, typically providing that the prescribing physician has immunity if the prescribing meets the standards of the profession or some other third party standard.<sup>223</sup>

These qualifiers make the immunity shield considerably smaller and thinner than one might anticipate. Even if the statute adopts the good faith

219. Martino, *supra* note 97, at 333 (alteration in original).

220. See discussion *supra* Part I.

221. See, e.g., CAL. BUS. & PROF. CODE § 1627.5 (West Supp. 2009); MO. ANN. STAT. § 537.037.1(1)–(2) (West 2008); ALA. CODE § 6-5-332(e) (LexisNexis 2005); ALASKA STAT. § 09.65.090(d) (2006).

222. See, e.g., ALA. CODE § 22-19-125 (LexisNexis 2006); ARIZ. REV. STAT. ANN. § 36-856(A) (2007); MISS. CODE ANN. § 41-39-135(a) (Supp. 2008).

223. See, e.g., FLA. STAT. ANN. § 458.326(3) (West 2007) (referring to the “level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances”); NEV. REV. STAT. § 630.3066 (2007) (protecting physicians that conform to regulations adopted by the Board); see also Project on Legal Constraints on Access to Effective Pain Relief, *The Pain Relief Act*, 24 J.L. MED. & ETHICS 317, 318 (1996) (providing immunity for doctors “who can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that guideline and with the standards of practice” identified in the Act); Johnson, *supra* note 125 (discussing the Act and reviewing other state statutes).

standard for immunity, it does not prevent the filing of a lawsuit,<sup>224</sup> nor does it allow for dismissal of the plaintiff's claim.<sup>225</sup> At best, the qualified immunity statute requires that discovery proceed and that the claim be considered at the summary judgment stage, the earliest point at which the facts that relate to good faith or reasonableness can be determined. A number of cases, in fact, require that questions of good faith be submitted to the jury.<sup>226</sup> For a population that fears the litigation process, this is too little too late to provide much reassurance.<sup>227</sup>

Identifying this limitation in immunity statutes begs the question of why absolute immunity is not usually considered a workable solution in health care. In fact, doctors are not the only ones who are afraid. Policymakers are afraid that doctors completely unleashed will behave badly—or at least some of them will—and that patients will suffer without legal recourse.<sup>228</sup> Agencies responsible for policing the medical profession are under constant public pressure to do more, catch more, and be tougher.<sup>229</sup> Unfortunately, in the face of serious risk aversion one cannot both keep doctors on the leash and free them. This is not to argue that absolute immunity for physicians should be the norm, but rather that limited immunity is a rather limited response to claims that the risk of liability and prosecution is causing doctors to neglect or provide inadequate care to patients. The fact that immunity does not eliminate strategic behavior on the part of physicians seeking to avoid legal entanglement should not be surprising.

224. Litigation concerning organ procurement illustrates this point. *See, e.g.,* Ramirez v. Health Partners of S. Ariz., 972 P.2d 658, 669 (Ariz. Ct. App. 1998) (granting summary judgment to defendant); Perry v. Saint Francis Hosp., 886 F. Supp. 1551, 1465 (D. Kan. 1995) (denying summary judgment to hospital); Schembre v. Mid-Am. Transplant Ass'n, 135 S.W.3d 527, 533 (Mo. Ct. App. 2004) (denying summary judgment because good faith is a question of fact requiring trial); Sattler v. Nw. Tissue Ctr., 42 P.3d 440 (Wash. Ct. App. 2002) (reversing grant of summary judgment to defendant on the question of good faith).

225. *See, e.g.,* Hilton v. Children's Hosp., No. 02-57053, 2004 WL 1700562, at \*733 (9th Cir. July 29, 2004).

226. *See Schembre*, 135 S.W.3d at 533; *Sattler*, 42 P.3d at 445.

227. *See* discussion *supra* Part II.D (penalties of the process).

228. *See* Sage, *supra* note 67, at 499–500 (discussing the focus on compensation of the individual injured patient as an impediment to good policy in regard to medical malpractice liability).

229. Public Citizen, for example, issues an annual report on the effectiveness of each state medical board as measured by the percentage of the state's doctors who had been disciplined. SIDNEY M. WOLFE & KATE RESNEVIC, PUBLIC CITIZEN'S HEALTH RESEARCH GROUP RANKING OF THE RATE OF STATE MEDICAL BOARDS' SERIOUS DISCIPLINARY ACTIONS, 2005–2007, (2008), <http://www.citizen.org/documents/medicalboardtable.pdf>; *see* BARDACH & KAGAN, *supra* note 34, at 72–74 (discussing the impact of quantitative expectations for number of citations by inspectors).

In addition to the obvious intention to influence doctors, immunity statutes may be intended to communicate to enforcement agencies and potential plaintiffs. One would expect, for example, that prosecutors and plaintiffs might account for immunity statutes in deciding whether to prosecute or file suit at all. Immunity legislation may also be intended to communicate to regulatory agencies. For example, in the case of the intractable pain acts, the prospects of legislative action giving doctors immunity from discipline in particular situations pushed the medical boards toward changing their own policies to demonstrate to the legislatures that the statutes were not needed. In fact, the FSMB advised state medical boards to “be proactive in the promotion of pain management policy initiatives *to preclude legislative intervention*.”<sup>230</sup> From the perspective of advocates for those immunity statutes, the effect on medical boards itself furthered the achievement of the goals of the legislative effort.

### C. *Safe Harbors*

Government agencies regularly identify detailed templates for financial and management arrangements that are deemed to meet the legal requirements those agencies enforce. These “safe harbors” channel transactions toward the designs that the agency has determined are acceptable under the law. These rules are not mandates or prohibitions: safe harbors don’t prohibit providers from structuring their agreements otherwise, but they provide an official seal of approval for particular arrangements. They are a voluntary restraint on the exercise of prosecutorial discretion and make a promise of sanctuary for those favored transactions. Those doctors who are more entrepreneurial, or more well-armed with legal and financial counsel, or who have more to gain will test the waters outside of the transactional safe harbors.

There are some safe harbors in clinical areas as well. Some states have enacted legislation to create a safe harbor for physicians’ denying their patients “futile” care.<sup>231</sup> Some states have enacted legislation to protect physicians who comply with particular guidelines from malpractice liability.<sup>232</sup> In the area of prescribing, many state medical boards for some time have informed doctors

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230. FED’N OF STATE MED. BDS., POSITION OF THE FEDERATION OF STATE MEDICAL BOARDS: IN SUPPORT OF ADOPTION OF PAIN MANAGEMENT GUIDELINES 2 (1998), [http://www.fsmb.org/pdf/1998\\_grpol\\_Pain\\_Management\\_Guidelines.pdf](http://www.fsmb.org/pdf/1998_grpol_Pain_Management_Guidelines.pdf) [hereinafter FSMB, POSITION IN SUPPORT OF GUIDELINES] (emphasis added).

231. See, e.g., Thaddeus Mason Pope, *Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment*, 75 TENN. L. REV. 1 (2007) (criticizing safe harbor statutes for medical futility decisions as ineffective, with the exception of the Texas statute). The presumptions attached by statute to signed consent forms could also be viewed as a safe harbor as they typically do not provide that treatment without a signed form is a battery. They simply identify a “safest” channel for the practicing doctor. See *supra* note 41.

232. See FURROW ET AL., *supra* note 36, at 1516–24.

that they would not take any action against them for prescribing controlled substances if their patients had cancer or were terminally ill.<sup>233</sup> Further, the FSMB issued formal guidelines, adopted by many state medical boards, to assure physicians that their treatment of patients for chronic pain would not violate the boards' standards.<sup>234</sup>

Two physicians considering the potential impact of legal guidelines meant to provide a safe harbor from regulatory scrutiny speculate from their own experience that these efforts may have a perverse effect. They observe:

Our experience suggests that many physicians will briefly scan guidelines and may come away with the wrong impression . . . It is entirely possible that the promulgation of guidelines will make physicians perceive that prescribing opioids for chronic pain is under even greater scrutiny than they thought, causing them to be even less willing to prescribe opioids for any reason.<sup>235</sup>

Whether doctors behave differently in terms of pushing the boundaries of the templates set in transactional safe harbors, as compared to clinical safe harbors, is a matter of speculation.<sup>236</sup> There is some sense that doctors are willing to push the envelope on the financial side and in their business relationships and are less willing to do that, and assume avoidable legal risk, in their clinical decisions.<sup>237</sup> The importance of reputation and the shame

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233. David E. Joranson et al., *Opioids for Chronic Cancer and Non-Cancer Pain: A Survey of State Medical Board Members*, 79 J. MED. LICENSURE & DISCIPLINE 15 (1992) (reporting on attitudes of board members). See also *Hurwitz v. Bd. of Med.*, 46 Va. Cir. 119, 1998 WL 972259 (Va. Cir. Ct. Jun. 30, 1998), referring to state's intractable pain act as a "safe harbor."

234. FSMB, MODEL POLICY, *supra* note 135. This policy revises the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. The Policy requires physicians to take a medical history and perform a physical exam of the patient with some frequency; to document in the medical record the nature and intensity of the pain and current and past treatment for pain, related conditions, the effect of pain on function, any history of substance abuse, and at least one "recognized medical indication" for prescription of a controlled substance; establish a written treatment plan; secure informed consent; and seek appropriate consultation, among other items. *Id.* These guidelines have been adopted in some form by twenty-two state medical boards. *Id.* A study of medical board practices concludes that the boards actually relied on such policies in their disciplinary actions. Hoffmann & Tarzian, *supra* note 137, at 23.

235. J. David Haddox & Gerald M. Aronoff, Commentary, *The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain*, 26 J.L. MED. & ETHICS 350, 351 (1998).

236. It is not clear that transactional safe harbors and clinical safe harbors are functionally the same either. It might be reasonable to hypothesize that transactional safe harbors can be more definitive and less ambiguous than clinical safe harbors, for example, so that clinical safe harbors always bear the burden of uncertainty. This uncertainty in legal standards may produce more cautious responses. The discussion that follows assumes that the safe harbors function in essentially the same manner but that doctors react differently.

237. See *supra* note 31 (discussing the limitations of generalizations about the behavior of doctors). In particular, some have hypothesized significant differences among doctors in relation to commercial interests and incentives. See, e.g., Dolgin, *supra* note 31, at 733-34.

associated with failures of medical judgment are well-documented.<sup>238</sup> Shortcomings in the care of patients go to the very identity of the physician.<sup>239</sup> It is possible that the same shame and identity issues are not triggered when doctors get in trouble for business relationships,<sup>240</sup> and so they are quite willing to push the envelope and bear a risk of legal sanction in the commercial sphere of their activities.<sup>241</sup>

A distinction between testing the boundaries of business as compared to clinical safe harbors also may reflect a rational calculation of risk and benefit. The upside risk of going beyond the boundaries of business safe harbors is increased profit and income, a significant temptation of payoff. The upside risk of pushing the envelope of clinical safe harbors for most doctors is treating one patient instead of a fungible other who also needs medical care but may be considered undesirable because of the risk involved. In his concurring opinion in *Conant v. Walters*,<sup>242</sup> for example, Judge Kozinski notes that:

[T]he doctor's interest in giving advice about the medical use of marijuana is somewhat remote and impersonal; they will derive no direct *benefit* from giving this advice, other than the satisfaction of doing their jobs well. At the same time, the *burden* of the federal policy [of investigating physicians who recommend marijuana to their patients] . . . falls directly and personally on the doctors . . . . [T]hey may destroy their careers and lose their livelihoods.

This disparity between benefits and burdens matters because it makes doctors peculiarly vulnerable to intimidation . . . .<sup>243</sup>

238. See COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., TO ERR IS HUMAN (Linda T. Kohn & Molla S. Donaldson eds., 1999); Robert A. Burt, *Doctors vs. Lawyers: The Perils of Perfectionism*, 53 ST. LOUIS U. L.J. 1177 (2009).

239. Bosk observed that some errors were forgivable and others were not in the context of residency training. BOSK, *supra* note 26, at 168–69. Those that could be categorized as moral failings were unforgivable, but those that were errors in technique or skill were not. *Id.*; see also KAPP, *supra* note 24, at 1 (noting that doctors interpret a malpractice suit as “deeply personal and intimate, yet simultaneously an embarrassingly public affront against their very integrity and worth as professionals and as people”).

240. Of course some business relationships, such as self-referrals and other forms of conflicts of interest, bridge the business and clinical personas. As discussed earlier, however, this crossover may not be appreciated. See generally Jesse Goldner, *Regulating Conflicts of Interest in Research: The Paper Tiger Needs Real Teeth*, 53 ST. LOUIS U. L.J. 1211 (2009) (discussing the physician researchers’ conflicts of interest when conducting human subject research).

241. See, e.g., Greaney, *supra* note 41, at 189 (“[The] Department of Justice and the Federal Trade Commission . . . have confronted bands of businessmen who have steadfastly refused to pay attention to legal precedent, repeated governmental pronouncements, and administrative sanctions imposed on their colleagues[.] . . . [demonstrating] a willingness to blatantly disregard the law by repeatedly undertaking arrangements already deemed illegal by the enforcers . . . .” (referring to physicians)).

242. *Conant v. Walters*, 309 F.3d 629, 639–48 (9th Cir. 2002).

243. *Id.* at 639–40.



The development of safe harbors for clinical practice presents an additional challenge for the quality of medical care. Safe harbors typically are developed through a stakeholder process involving regulators, prosecutors, consumers/patients, and those subject to the safe harbor.<sup>244</sup> Prosecutors and regulators have strong motivation to retain a margin of discretion for themselves to be used in deciding whether or not to prosecute individual cases. In addition, those charged with enforcing legal standards are quite concerned with how the safe harbors and guidelines will influence ongoing prosecutions that they view as falling outside of the safe harbor.<sup>245</sup> With the retention of discretion and success in prosecution as primary and immediate professional and policy goals, prosecutors would be expected to argue that the safe harbor should establish boundaries that would be well within the range of what would ultimately be considered acceptable and legitimate medical practice. Thus, the clinical safe harbor creates a legally "safest" channel within the range of acceptable medical practice.

To illustrate: assume a range of interventions from 1 to 100, and that the range of appropriate treatment lies between 10 and 90. To retain a margin for prosecutorial or regulatory discretion in individual cases, the clinical safe harbor is set to cover behavior in the range of 30 to 70. This means that while doctors practicing in the range between 10 and 30 and between 70 and 90 are engaged in legitimate medical practice, they simply are not guaranteed protection from government scrutiny.

The risk-averse doctor who fears investigation and potential prosecution by enforcement agencies and the rational doctor who calculates the risks and benefits of choosing to treat one type of patient over another both stay well within the identified safe harbors. At the same time, risk-averse prosecutors are setting the boundaries of the safe harbor more narrowly than the bounds of legal, appropriate, desirable and perhaps necessary medical practice. The problem with this double risk aversion is that prosecutors' preservation of discretion and doctors' avoidance of legal risk results in a channeling effect that leaves some patients stranded in the margins. For example, the state medical board safe harbors for those physicians treating patients who have cancer or who are terminally ill<sup>246</sup> certainly may have reassured doctors and encouraged them to treat those patients with adequate analgesics; but they may have likewise driven doctors toward that safest channel and away from chronic

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244. The FSMB, for example, gathered state medical board members and investigators, DEA investigators and administrators, practicing physicians, medical researchers, and patient advocates, among others, in developing its model guidelines on the use of controlled substances in pain management. FSMB, POSITION IN SUPPORT OF GUIDELINES, *supra* note 230, at 1.

245. See Hoffmann, *supra* note 151, at 245–50, 282 (discussing the *Hurwitz* case and the DEA's withdrawal of the FAQs).

246. See discussion *supra* Part III.C.

pain patients, decreasing the availability of necessary treatment for those patients. Furthermore, the FSMB's safe harbor sets special requirements for the treatment of patients who have a "history of substance abuse" or who are at a "high risk of medication abuse" or who are "at risk of medication misuse, abuse, or diversion" without further specification.<sup>247</sup> At a threshold level, these descriptors may lead physicians to exclude patients whose general characteristics, including race, medical condition, or source of pay, are mistakenly viewed as surrogates for a risk of abuse or diversion of controlled substances.<sup>248</sup> Any patient whose characteristics, medical needs, or other circumstances place them outside of the safest channel may find it more difficult to secure appropriate and necessary care even though they fall within the scope of legitimate medical practice.

While the safe harbor process may intend only to "green light" particular practices, doctors receiving that signal in the clinical setting may think of the safe harbors in terms of the familiar green-yellow-red progression. What is not green must be red or yellow; and it can be dangerous to proceed through a yellow light, especially with massive on-coming traffic. Safe harbors and guidelines are comfortable tools for regulators, but at least as to the clinical safe harbors, some have asserted "bad law" claims; i.e., that they dissuade good doctors from providing good care. Empirical research that would reveal whether clinical safe harbors are having the negative channeling effect that results in limiting appropriate and necessary care is missing. The self-reports that do exist may be misleading, but if clinical safe harbors induce the undesired behavior as some have argued, it would be important to know that.

#### D. *Eliminating Asymmetry*

At times, legal risk is lined up entirely on one side as the doctor looks at the risks of particular decisions. For example, in the situation addressed in *Conant v. Walters*, only the doctor who discussed the potential of marijuana for control of particular symptoms or conditions faced the risk of DEA investigation and prosecution.<sup>249</sup> The doctor who remained silent faced no legal risk at all: the patient could not sue her for failing to disclose a legitimate treatment and neither the state medical board nor the DEA would make an inquiry about the adequacy of care. Similarly, when we began our work on pain management in 1995, only the doctor who prescribed opioids for his

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247. See FSMB, MODEL POLICY, *supra* note 135; see also NAT'L CTR. ON ADDICTION AND SUBSTANCE ABUSE, UNDER THE COUNTER: DIVERSION AND ABUSE OF CONTROLLED PRESCRIPTION DRUGS IN THE U.S. 31 (2005).

248. See Johnson, *supra* note 95, at 747 (discussing "red-flags," or indicators, often used mistakenly to identify patients as suspicious).

249. See discussion *supra* Part II.D.

patients in pain faced investigation, sanctions, and liability claims.<sup>250</sup> The doctor who used the less effective medications and neglected their patient's pain faced no legal risk at all.

The natural response to legal risk asymmetry is to even things up. In the pain management field, advocates of improved treatment encouraged medical boards to discipline physicians for negligent care of patients in pain as a signal to the profession that failing to prescribe adequate medications ("underprescribing") was as risky as "overprescribing."<sup>251</sup> They also increased the liability risk by bringing high-profile lawsuits in egregious cases of neglect.<sup>252</sup> Eliminating asymmetry was a primary strategy of some advocates in the case of physical restraints as well. They encouraged and participated in personal injury lawsuits on behalf of persons injured by restraints<sup>253</sup> and advocated a change in regulations that would set standards and penalties for the use of restraints. Similarly, individuals concerned that doctors rejected patients' or surrogates' decisions to withdraw consent for continued life-sustaining medical treatment, for fear of criminal prosecution, advocated recognition of a cause of action for non-compliance with the patient's or surrogate's decision.<sup>254</sup>

Not surprisingly, these efforts to eliminate asymmetry are not warmly received in medicine. Instead of viewing these developments as efforts to balance legal risks rationally, with an eye toward producing better outcomes, doctors are nihilistic about the operation of law. You're damned if you do, and damned if you don't.<sup>255</sup> What matters is whether eliminating asymmetry has the desired outcome of improving patient care.

250. See Johnson, *supra* note 125, at 320; Ben A. Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 WM. MITCHELL L. REV. 1, 49–50 (2000); Robyn S. Shapiro, *Health Care Providers' Liability Exposure for Inappropriate Pain Management*, 24 J.L. MED. & ETHICS 360, 363 (1996).

251. See Rich *supra* note 250, at 16 & nn.97–99, 69 & n.374.

252. See *id.* at 84, 90 (discussing *Bergman v. Chin*, No. H205732-1 (Cal. App. Dep't Super. Ct. Feb. 16, 1999); *Estate of Henry James v. Hillhaven Corp.*, No. 89 CVS 64 (N.C. Super. Ct. Jan. 15, 1991)); Shapiro, *supra* note 250, at 361 (discussing *Estate of Henry James*, No. 89 CVS 64)).

253. Julie A. Braun & Elizabeth A. Capezuti, *The Legal and Medical Aspects of Physical Restraints and Bed Siderails and Their Relationship to Falls and Fall-Related Injuries in Nursing Homes*, 4 DEPAUL J. HEALTH CARE L. 1, 22–25 (2000) (describing litigation involving injuries due to restraints).

254. See generally Samuel Oddi, *The Tort of Interference with the Right to Die: The Wrongful Living Cause of Action*, 75 GEO. L.J. 625 (1986) (describing such cases).

255. Matthew Yi, *Doctor Found Reckless for Not Relieving Pain*, S.F. CHRON., June 14, 2001, at A1.

## IV. REFRAMING EVALUATION AND SURVEILLANCE

This paper has argued that doctors' "bad law" claims can carry important information that is critical to the achievement of the goals of regulation. Some of these claims reveal concrete problems in the implementation of regulatory standards, including the "shadow systems" that lurk below the formal surface of the regulatory system.<sup>256</sup> Taking doctors' "bad law" claims seriously requires that we expand our notions of and methods for measuring the effectiveness of law. It also requires that enforcement policies take account of predictable risk-avoidance behavior.

A. *Defining and Measuring Effectiveness*

Empirical research on physician response to legal risk is thin, and motivations are likely to be complex. It seems entirely believable, however, that fears over the prospect of legal entanglement and potential sanctions may influence doctors to alter their practices in undesirable ways. Just as medical treatment produces iatrogenic harm, legal regimes intended to protect patients from bad doctors or doctors behaving badly can have negative spillover effects. Arguing that something is likely is not the same as having convincing proof that it is so, however. Empirical research focused specifically on the question of physician behavior in response to legal risk can contribute to the effort to align regulatory effects with regulatory goals.

Framing empirical research on the impact of law in terms of the individual case—did this case appropriately apply the standard to this particular doctor—is too narrow. Individualized case-based analysis can make a contribution to our understanding of the content and application of the law by the courts or agencies in their adjudicative function,<sup>257</sup> but it does not give us a window into the impact of that law on physician practices and, thus, the law's impact on access to and quality of care. Statistical analysis of the incidence of enforcement activities—what proportion of doctors are disciplined by the state's medical board in comparison to other states,<sup>258</sup> for example, or what amount of federal monies are recovered in fraud prosecutions<sup>259</sup>—certainly broadens the frame away from the individual case. When statistical analysis

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256. See discussion *supra* Part II.

257. Even as to this question, the study of cases is limited. See Sage, *supra* note 82, at 50.

258. See, e.g., WOLFE & RESNEVIC, *supra* note 229 (providing an annual report on the number and percentage of doctors disciplined, and evaluation of states based on those numbers).

259. See DEP'T OF HEALTH & HUMAN SERVS. & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FY 2007, at 6–8 (2008), available at <http://www.usdoj.gov/dag/pubdoc/hcfacreport2007.pdf>.

operates without a notion of what the "right" number is, however, it is not helpful<sup>260</sup> and can be harmful.<sup>261</sup>

Neither of these two concepts—defining effectiveness in terms of application to the individual case or in terms of statistical data about the incidence of enforcement actions—is adequate. Whether taken separately or together, these concepts of effectiveness do not take account of how the regulations and enforcement efforts influence the behavior of physicians who are not caught in the proceedings that produce the individual case or the statistical analysis of enforcement actions. They cannot measure changes in physician risk-avoidance behavior that may be producing lower quality or less accessible care. We want to deter bad doctors and bad behavior, but we also have to assess what impact the regulatory system is having on the good doctor and good behavior left undone. The evaluation of the law as applied should be reframed to examine the population-based effects on the behavior of physicians, adopting a public health model for the effect of law, despite the considerable challenges in doing so.<sup>262</sup>

#### B. *Accounting for Behavior Patterns*

Some features of physician behavior in reaction to legal risk should be accepted as they are. This call to take doctors' "bad law" claims seriously and to accept certain behavior patterns does not argue that regulatory standards and goals should be abandoned. Rather, an understanding of the reactive, risk-

260. The GAO, for example, issued two reports concerning the effectiveness of federal-state efforts to enforce quality standards for nursing homes. Acknowledging that the number of nursing homes cited for deficiencies decreased between 1999 and 2005, the GAO reports that the reduction in cited deficiencies does not correlate, in their view, with improvements in the quality of care but rather with less effective inspection and enforcement systems. U.S. GEN. ACCOUNTING OFFICE, NURSING HOMES: CONTINUED ATTENTION IS NEEDED TO IMPROVE THE QUALITY OF CARE IN SMALL BUT SIGNIFICANT SHARE OF HOMES (2007); U.S. GEN. ACCOUNTING OFFICE, EFFORTS TO STRENGTHEN FEDERAL ENFORCEMENT HAVE NOT DETERRED SOME HOMES FROM REPEATEDLY HARMING RESIDENTS (2007). In contrast, the Department of Health and Human Services reported that the quality of nursing homes actually has improved. *Nursing Home Quality Improves, HHS Says in Announcing Expanded Initiative*, 14 Health L. Rep. (BNA) 34 (Jan. 6, 2005).

261. See BARDACH & KAGAN, *supra* note 34, at 73–74 (discussing the impact of counting citations on surveillance behavior).

262. This argument may also be situated in a public health approach to the impact of law just as medicine is being challenged to reframe itself toward a public health methodology that looks at population-based outcomes rather than only the individual patient. See, e.g., Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data to Promote Patient Welfare*, 49 CATH. U. L. REV. 449, 450–51 (2000) ("Providers have strongly protested the allocation of health services on a population-wide basis under managed care . . . . [B]ut the collection, analysis, and dissemination of information relating to adverse drug reactions demands an emphasis on population-based outcomes and utility." (footnote omitted)).

avoidance behavior of doctors should be used strategically to enhance the effectiveness of the regulatory effort.<sup>263</sup> In particular, this understanding and accommodation should assure that policy goals are not hijacked by the enforcement process. This paper has argued at several points that mid-level decisions and policies concerning enforcement practices—what is monitored or required to be reported; who is investigated; what rituals and processes accompany the investigation—can have a profound effect on physician behavior in avoiding particular patients or practices. In particular, monitoring and investigation processes are likely to have a substantial influence on physician behavior that can lead to undesired consequences.

### 1. Monitoring

Simply watching someone, or persuading someone that they are being watched, makes the person change their behavior. Visible surveillance is a powerful tool of social control.<sup>264</sup> Regulatory monitoring, thus, should be viewed as a tool to determine behavior rather than simply a source of information.

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263. Cf. FURROW ET AL., *supra* note 36, at 163–67 (comparing nursing homes to hospitals and arguing that differences between the two explain observed differences in the nature of regulatory design for each). See generally IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* 4 (1992) (arguing that regulatory design should take account of industry structure, motivations of regulated agents, and industry conduct). Contrary to the argument in this paper that established behavior patterns should be used where possible to make regulation more effective, Jolls and Sunstein argue that the law can be used to “debias” familiar heuristics. Christine Jolls & Cass R. Sunstein, *Debiasing Through Law*, 35 J. LEGAL STUD. 199, 207–19 (2006). Critiques of the application of cognitive theory to regulation might argue that the approach recommended here manipulates human behavior. See, e.g., Wilson, *supra* note 103, at 224 (responding to claims that designing regulatory systems to respond to heuristics identified by cognitive research is exploitative).

264. This phenomenon is commonly referred to as the “Hawthorne Effect,” stemming from behavioral research at the Hawthorne Works factory outside of Chicago in the early 1900s in which researchers observed improvements in worker productivity that could be attributed only to the fact that the workers knew that they were being evaluated. See Stephen R.G. Jones, *Was There a Hawthorne Effect?*, 98 AM. J. SOC. 451, 451 (1992). The concept has been tested in a variety of settings. See, e.g., Carol L. Freund et al., *Natural Settings Trials—Improving the Introduction of Clinical Genetic Tests*, 32 J.L. MED. & ETHICS 106, 108 (2004) (discussing the ethical challenges of accounting for the Hawthorne Effect in clinical trials); Herbert Sherman, *Surveillance Effects on Community Physician Test Ordering*, 22 MED. CARE 80 (1984) (documenting effects of surveillance on physician behavior in ordering a diagnostic test); see also *infra* notes 266–72 and accompanying text (discussing prescription monitoring). Some criticism of the Hawthorne Effect as a viable methodological theory has emerged. See, e.g., Jones, *supra*, at 452; Michael C. Dorf, *After Bureaucracy*, 71 U. CHI. L. REV. 1245, 1269–70 (2004) (book review).

Doctors may be hypersensitive and culturally resistant to any external oversight of their actions.<sup>265</sup> If this position on their part is morally or politically offensive, the regulatory battle can be engaged as a matter of principle: we have a duty to make you accountable, and so shall you be. If instead, better patient care or a better health care system remains the priority, a more pragmatic approach should be adopted. If the reactive behavior change is desired, monitoring becomes an effective tool; if instead, the monitoring-stimulated behavior change is undesirable, visible monitoring becomes an impediment to achievement of the primary goal.

Prescription monitoring offers a useful example.<sup>266</sup> Every state engages in some system of monitoring to collect individualized data on doctors' prescribing of controlled substances. Until the late 1990s, many of these efforts were paper-based systems in which doctors produced three paper copies of the prescription (one for the pharmacy, one for the doctor's files, and one for the state).<sup>267</sup> Doctors could not avoid being aware of government oversight of each prescription they wrote. Both survey data about self-reported changes in prescribing<sup>268</sup> and quantitative data about volume and frequency in prescribing of particular medications<sup>269</sup> showed that these paper monitoring systems actually reduced the prescription of controlled substances. If the goal of the monitoring system was to reduce the availability of controlled substances, this effect was a success. It is a passive and inexpensive

265. See Deborah A. Savage, *Professional Sovereignty Revisited: The Network Transformation of American Medicine?*, 29 J. HEALTH POL. POL'Y & L. 661, 671, 674 (2004) (discussing network theory as a support for the primacy of peer monitoring in medicine and the rejection of managerial or other outsider monitoring); see also Bruce E. Landon et al., *Changes in Career Satisfaction Among Primary Care and Specialist Physicians, 1997–2001*, 289 JAMA 442, 447 (2003) (relating satisfaction primarily to autonomy and the ability to provide high quality care); Jin Lei, *Clinical Autonomy and the Rationalization of Clinical Practice* (Aug. 14, 2004) (unpublished manuscript), available at [http://www.allacademic.com/meta/p\\_mla\\_apa\\_research\\_citation/1/1/0/3/8/p110387\\_index.html](http://www.allacademic.com/meta/p_mla_apa_research_citation/1/1/0/3/8/p110387_index.html).

266. Mandatory reporting systems are monitoring systems, and so can operate in the same fashion. See *supra* notes 147–150 and accompanying text (discussing mandatory reporting in the context of physical restraints).

267. This particular paper-based monitoring system was called the triplicate prescription system. Another paper-based system required that physicians use state-issued sequentially numbered prescription slips for prescriptions of certain medications categorized as controlled substances.

268. David B. Brushwood, *Maximizing the Value of Electronic Prescription Monitoring Programs*, 31 J.L. MED. & ETHICS 41, 46–47 (reporting on data that shows that prescribing of pain medications increased in states that moved from paper-based prescription monitoring systems to electronic systems).

269. See, e.g., ABA COMM'N ON LEGAL PROBLEMS OF THE ELDERLY, REPORT TO THE HOUSE OF DELEGATES: PROPOSED ABA POLICY ON LEGAL OBSTACLES TO EFFECTIVE PAIN MANAGEMENT (2000), available at <http://www.abanet.org/aging/resources/docs/policyfinal.doc> (citing studies that show that paper-based monitoring “may deter legitimate prescribing”).

enforcement system because no one even has to actually review the material produced in order for the system to have its targeted effect. Reducing the prescribing of controlled substances for the treatment of pain, however, is not consistent with the goal of improving patient care.<sup>270</sup>

The switch to an electronic monitoring system,<sup>271</sup> which does not involve any action by the physician, appears not to have the same effect on the volume and frequency of prescribing.<sup>272</sup> If the goal of the system is appropriate prescribing, rather than a simple reduction in volume, an invisible system better achieves that goal without hampering oversight.

A visible monitoring system has an independent impact on physician behavior and produces an outcome that may either reinforce or undermine the goals of regulating physician prescribing. Whether the monitoring system should be visible or invisible can be resolved on an entirely pragmatic level. A pragmatic approach would accept physician sensitivity to external oversight as a given. Rather than exhorting doctors to practice good medicine without fear, advocates for better care can accommodate the monitoring system to physician behavior and better accomplish their goals.<sup>273</sup>

The choice between visible and invisible monitoring systems, however, requires clarity in the substantive goals of the particular regulation. If the desire is to reduce the prescription of narcotics, for example, a very visible monitoring system that reminds physicians daily that they are being watched should be chosen. If the concern is that reduction in the prescription of narcotics results in poor care because doctors are not prescribing necessary medication, however, one would choose an invisible monitoring system, all other things being equal.<sup>274</sup> Of course, electronic prescription monitoring

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270. David E. Joranson & Aaron M. Gilson, *Regulatory Barriers to Pain Management*, 14 ONCOLOGY NURSING 158 (1998) (reporting on the large body of research documenting adverse effects on prescribing: “although administrators of [paper-based] prescription monitoring programs assert that quality of care is not compromised, empirical evidence suggests otherwise”).

271. See, e.g., Nathaniel Katz et al., *Update on Prescription Monitoring in Clinical Practice: A Survey Study of Prescription Monitoring Program Administrators*, 9 PAIN MED. 587 (2008) (reporting on the operation of electronic monitoring programs).

272. See Brushwood, *supra* note 268, at 44–45. Brushwood notes, however, that the evidence of increase in prescribing may not be directly related to the change in monitoring, as there may have been other influences as well. *Id.* at 47. It may be that as doctors come to “see” the monitoring, its invisibility will dissipate and the monitoring effect on behavior will set in; but this does not undermine the point made here.

273. For discussion in another context, see Fazal Khan, *The Human Factor: Globalizing Ethical Standards in Drug Trials Through Market Exclusion*, 57 DEPAUL L. REV. 877, 911 (2008), suggesting that visible observation might be used to increase compliance with regulatory standards for drug trials. See also Johnson, *supra* note 93 (describing impact of monitoring of hospital length-of-stay on physician behavior).

274. This article addresses only the issue of monitoring physician prescribing and not the monitoring of patient behavior in regard to prescriptions. In addition, the electronic system will



raises its own complicated issues relating to the appropriateness and accuracy of the data collected and the use to which it is put.<sup>275</sup> Prescription monitoring, however, illustrates both the strategic accommodation to physician behavior to achieve regulatory effectiveness, and the policy issues that must be decided in evaluating the operation of the monitoring system.

## 2. Investigation

Doctors also fear being subjected to government inquiry or investigation. The costs of the inquiry or investigation include financial costs, disruption of the practice, damage to reputation, resultant ostracism or termination of necessary business relationships, stress, shame, and other losses that are quite significant.<sup>276</sup> At the same time, regulators enforcing standards want to assure that they uncover the few bad apples and so may cast a broad investigative net. This broad net would be expected to catch the small number of violators, but it would also be expected to catch a number of doctors who will not be charged with violations. The regulator who justifies casting the investigative net broadly as triggering "only" an inquiry or further investigation but not necessarily sanctions fails to appreciate the substantial penalties that are inherent in the investigation itself. The intent of the law—protection of patients—is subverted by a "catch-and-release" surveillance system.

A rational reaction to the personal costs of inquiry or investigation, which are well-understood by doctors, is to alter their practice and treatment

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produce data that is much more easily used in the enforcement process, so concerns over the quality and use of the data remain. As a monitoring device standing alone, the invisible program has the advantage of avoiding perverse effects on physician prescribing. *See* Brushwood, *supra* note 268, at 41 (arguing that such systems should be evaluated on whether they are safe (in terms of avoidance of adverse consequences such as invasions of patient privacy and interference with legitimate prescribing in the way that the data is used) and effective (in terms of reducing abuse of controlled substances)). *See also* *Whalen v. Roe*, 429 U.S. 589 (1977) (considering the constitutionality of New York's triplicate prescription monitoring system).

275. This discussion leaves open the question of whether the data collected is appropriate and accurate and whether it is used in an appropriate manner. To some extent, of course, the capacity of the electronic system itself becomes a driving source for ever-expanding use of the data. Electronic prescription monitoring systems are subject to failures in the quality and accuracy of the data collected as well as abuses in the use of the data against physicians and patients. *See, e.g.,* Katz et al., *supra* note 271, at 592–93 (describing some of these concerns as to how the electronic systems are operating in this regard). The electronic system's responsiveness to concerns over the negative influence of paper systems on physician prescribing may be offset by the effects on prescribing that the particular uses of the data may produce. Physicians may have the capacity to monitor each patient's complete prescription profile, an outcome that seems consistent with health concerns, but may then use exclusionary criteria for treatment that do not relate to medical concerns or evidence-based standards of care. *See* Brushwood, *supra* note 268, at 44–45.

276. *See* discussion *supra* Part II.D.

decisions to avoid being caught in the net at all.<sup>277</sup> “Net avoidance” can mean that doctors will avoid particular patients or particular treatments that in fact are legitimate and are quite unlikely to result in formal sanctions.<sup>278</sup> This reaction to the prospects of investigation thus can cause harm, in terms of reduced access or lower quality of care, and can undermine the ultimate goal of improving patients’ health and well-being.

For example, state medical boards and the DEA routinely mine data from the prescription monitoring systems<sup>279</sup> to identify those doctors who write the higher volumes of prescriptions for controlled substances in their geographic area. Doctors on the high side of prescribing are then subjected to further inquiry and investigation. Net avoidance would explain, then, why doctors want to stay in the middle of the pack in their prescribing. Unfortunately, however, the middle of the pack may be practicing bad medicine by failing to provide adequate treatment for their patients—denying them effective medication.<sup>280</sup> At a minimum, regulators should set the parameters for investigation and inquiry as narrowly as possible to achieve the goals that they desire, and in a fashion that does not contradict the formal legal standard. They should recognize that they have to balance the risk that some violators will not be caught if the investigative parameters are too narrow with the risk that the majority of doctors will gear their practice to avoid being investigated. In addition, they should not use indicators, such as the prescription volume, that standing alone have little to do with whether the physician is practicing good or bad medicine.

Of course, instead of adjusting their use of inquiries and investigations, regulators could maintain an aggressive investigation stance and try to educate doctors about the importance of the agency’s efforts and to reassure them that “good doctors” are safe. These efforts are quite likely to be ineffective.<sup>281</sup> This is the course that the DEA has adopted, for example.<sup>282</sup> The agency could make sure that doctors understand that their being investigated is not a finding

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277. See discussion *supra* Part III.

278. See discussion *supra* Part III.C.

279. See Brushwood, *supra* note 268, at 45–47 (discussing the use of data by the DEA and several states to determine the success of paper-based prescription monitoring systems); *supra* Part IV.B.1.

280. See discussion of early adopters, *supra* notes 124–25 and accompanying text; *supra* note 119 and accompanying text concerning overcompliance; and *supra* notes 147–50 and accompanying text concerning use of restraints.

281. See discussion *supra* Part III.A. Similarly, as used as an indicator, the percentage of nursing home residents who were physically restrained did not reflect quality of care, nor did it negate the influence of claimed “bad laws” on perpetuating the practice. See *supra* notes 147–150 and accompanying text.

281. See discussion *supra* Part III.A.

282. See News Release, *supra* note 198.

of guilt, even though there is some evidence that health care organizations of their peers may take action based on the investigation alone<sup>283</sup> and that the agency may thereafter view the doctor as suspicious.<sup>284</sup> No amount of reassurance is likely to persuade a doctor that an inquiry or investigation by the state medical board or the DEA is not threatening and damaging. Regulation that is goal-oriented will account for these reactions in selecting the parameters for triggering an investigation or inquiry.

#### CONCLUSION

Even firm supporters of regulatory efforts, including this author, must accept that well-intentioned regulatory standards and enforcement systems can have negative outcomes as physicians react, and patients suffer as a result. Taking physicians' "bad law" complaints seriously brings physician behavior to the table as a credible and legitimate factor in evaluating the performance of the law. Physicians' "bad law" claims, if treated like sentinel events that require further investigation, can provide critical and otherwise unattainable information about the operation of legal standards. In addition, physician response to a specific regulation or enforcement system, including risk-avoidance behavior that reduces the availability of appropriate care, may alter the risk-benefit calculus for particular standards. Taking "bad law" claims seriously appreciates that the behavior-inducing effects of the enforcement effort may thwart the goals of the regulation itself.

Our common responses to physicians' "bad law" complaints are not as effective as they may appear. We need new tools, and one of those tools may be a better understanding of how doctors alter their behavior in relation to legal risk. This paper has demonstrated, for example, that better understanding of physician reaction to monitoring and investigations should influence how surveillance is conducted.

Even assuming perfect information and perfect alignment of tools and goals, however, persons concerned with the impact of law on physician behavior face at least two persistent challenges. First, empirical research on the influences on physician behavior consistently reveals multiple motivations, and it is unlikely that addressing legal concerns alone will make significant change. Still, a hammer is what law reformers have, and so some responsibility for its strokes lies there. Second, some of the negative effects of regulating physician behavior are irreducible. Law is not a precision instrument, and some degree of negative consequences, at the margins at least,

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283. See Goldner, *supra* note 74, at 342–43 (detailing organizational responses to physicians cleared in investigations for scientific misconduct).

284. See BARDACH & KAGAN, *supra* note 34, at 73.

seems unavoidable. Reducing negative consequences is worthwhile however, even if zero tolerance is impractical.

A better understanding of physician behavior in the face of legal risk would allow us to improve the effectiveness of law in achieving desired goals. This better understanding begins with taking physicians' "bad law" claims seriously, neither dismissing them too easily nor taking them at face value. Still, the health law reform effort remains a normative and political exercise; and social, political, and ethical norms influence the standards we choose to set for medicine. In some circumstances, consequences will be viewed as unimportant, but better that they are known than unknown when that choice is made.