

## RESPONSIBILITY IN HEALTH CARE: SPANNING THE BOUNDARY BETWEEN LAW AND MEDICINE

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### I. INTRODUCTION

One hears considerable criticism of health law today, and it comes from many quarters. Apparently, health law is not doing what others expect it to do. If the work of law includes apportioning responsibility for socially consequential actions, helping settle disputes, and ensuring a fair and orderly distribution of social goods,<sup>1</sup> then health law should be concerned with matters such as: (a) the duties of physicians, hospitals, health insurers, and pharmaceutical companies toward their patients, especially in establishing which actions are obligatory (trying to cure, protecting confidentiality) and which ones are forbidden (the strong prohibition against harming the patient); (b) settling disputes about who will pay for health care, who can deliver care, or how to arrange for compensation when physicians or others make mistakes; and (c) fairly allocating health care under conditions of scarcity (including rules about what to do when an emergency room is full, for instance).<sup>2</sup> Health law is criticized for failing to do its job in each of

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1. See, e.g., RICHARD LEMPERT & JOSEPH SANDERS, AN INTRODUCTION TO LAW AND SOCIAL SCIENCE: DESERT, DISPUTES, AND DISTRIBUTION 4 (1986).

2. See generally M. Gregg Bloche, *The Invention of Health Law*, 91 CAL. L. REV. 247, 301-03 (2003) (discussing the future aim of health law to improve overall public health); Roger B. Dworkin, *Getting What We Should from Doctors: Rethinking Patient Autonomy and the Doctor-Patient Relationship*, 13 HEALTH MATRIX 235, 281 (2003) (describing the benefits derived from shifting health law's focus from patient autonomy to respect for all); Rand E. Rosenblatt,

these areas. For example, law is often accused of a backward-looking orientation—of concerning itself with accountability, apportioning blame after the fact. This is particularly troublesome in health law, where compensation cannot make anyone whole. Because they cannot restore health or bring back the dead, neither the compensation offered by tort law nor the punishment of criminal law are especially attractive solutions in health law. Some of these complaints seem fair; others seem unfounded because they are not really complaints about health *law per se*, but about the rest of the regulation of health care.

For most people, the line between law and other forms of regulation (“non-law”) is fuzzy, and criticisms are, therefore, to some degree aimed at the wrong target. What concerns critics is that these law-like prescriptive statements—whether they come from state or national legislatures, quasi-public regulatory bodies such as the Joint Commission on the Accreditation of Healthcare Organizations (“JCAHO”), professional associations, international bodies regulating the use of intellectual property, or even health maintenance organizations (“HMOs”)—are not working well.<sup>3</sup> As I will argue in the following Article, one of the troubles is “legal incoherence”—that rules come flying from all directions with no one taking the trouble to make them consistent.

This Article thus builds on a recognition that law is only one of several institutions that govern health care and offers a vision of a more productive partnership between law and these other quasi-legal institutions. In thinking about how to improve health law, we need to think realistically about what health law is. My contention is that health law is *not* just statutes and regulations, but includes guidelines and other kinds of “rules” that form the penumbra of law. What are, from the point of view of law, “facts” about a “case” are often the outcomes of medical guidelines, contracts of adhesion in health insurance, or distant consequences of intellectual property claims made valid by scientific panels reporting to the U.S. Food and Drug Administration (“FDA”), for example. These prescriptive, law-

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*The Four Ages of Health Law*, 14 HEALTH MATRIX 155, 187-89 (2004) (discussing the inequalities and failures of the market competition model of health care); Lois Shepherd, *Face to Face: A Call for Radical Responsibility in Place of Compassion*, 77 ST. JOHN'S L. REV. 445, 471-75 (2003) (explaining compassion as a basis of medical decisionmaking).

3. See, e.g., Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 525-26 (2002) (discussing how rules support or undermine trust); William M. Sage, *Managed Care's Crime: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597, 609-10 (2003) (discussing the framework of contractual obligations between patients, physicians, and health insurers).

like statements vary in where they originate (in legislatures, professional associations, health care organizations, regulatory bodies, and court decisions, to mention only a few), in whether they are backed up by the authority of the state, and in whether they are intended to be applied rigidly or are merely starting points for protracted negotiations or coordination. It is, of course, important that statutes, court decisions, administrative regulations, standards of accrediting bodies, clinical guidelines, organizational procedures and policies, and professional norms vary along these dimensions. Yet it is also important that many actors are confused about the origins, authority, or prescriptiveness of rules, often believing rules to be backed by the state when they are not. Indeed, one might argue that a key task of legal actors would be to clarify for others which rules are backed by the authority of the state and which are not.

For a variety of reasons, American health law has become increasingly rule-driven.<sup>4</sup> I suggest that this increased legalism has three key causes: (1) the turn toward evidence-based medicine (with its emphasis on improving health care by introducing clinical guidelines); (2) the growth of clinical research (which, even more than caregiving, requires meticulous adherence to rules applied uniformly in all of the settings in which a research project is being carried out); and (3) the widely diffused effects of anxiety about malpractice suits.<sup>5</sup> The first of these causes works through the agency of professional communities, health care organizations, and insurers, with some regulation by governmental bodies; the second through the agency of protocol committees, monitors, regulatory bodies such as the FDA, and drug companies; and the third through entities like JCAHO, legal departments of hospitals, insurers, and the like.

What this means, however, is that there is much more indigenous "law" within the medical world than there used to be. This, in turn, means there is much more for the legal system to

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4. This may be especially true in the United States, but because health care, including both research and treatment, spans national boundaries, some of what is true in the United States is necessarily also true in other countries.

5. See, e.g., Cynthia D. Mulrow & Kathleen N. Lohr, *Proof and Policy from Medical Research Evidence*, 26 J. HEALTH POL. POL'Y & L. 249, 250, 255 (2001) (listing types and methods of evidence-based medicine); Judith A. O'Brien et al., *Clinical Practice Guidelines and the Cost of Care: A Growing Alliance*, 16 INT'L J. TECH. ASSESSMENT IN HEALTH CARE 1077, 1077-78 (2000) (cataloguing the growth of clinical practice guidelines). See generally TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* 1-3, 45-67 (2005) (discussing medical malpractice insurance issues).

“double institutionalize,” to use Paul Bohanan’s phrase.<sup>6</sup> This boundary between law and rule-bound medicine seems ripe for investigation as scholars contemplate the future of health law.

## II. LAW AND THE INDIGENOUS RULES OF MEDICINE

A few years ago, most news stories about law and medical care focused either on licensure or malpractice. Professional associations have long sought the help of government bodies in limiting competition from rival professional groups.<sup>7</sup> These jurisdictional disputes continue into the present as controversies over which practitioners’ fees should be reimbursable by public and private insurance, who should be eligible to practice in hospitals, and which professions should be licensed by state boards. In the mid-1970s, news publications and professional bodies reported an astronomical rise in medical malpractice suits, although some analysts have contended that insurers misled journalists and the public in order to increase the number, size, and cost of malpractice insurance policies.<sup>8</sup> Rhetoric about liability is often used in the process of creating and enforcing rules, so there is typically more talk about suing than there are tort cases. In any case, however, the growth of quasi-legal practice, other authoritative rules, and law-like thought is larger than we might expect from concerns about liability. While licensure and liability remain important issues, the law, legal actors, and legal styles of thought have now penetrated much more deeply into the medical world. Questions about consent, carelessness, and conflicts of interest in medicine appear routinely in the news. Many health care organizations now have legal departments and, according to Robert Zussman, physicians are deeply concerned about whether their practices are legally defensible.<sup>9</sup>

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6. Paul Bohanan, *The Differing Realms of the Law*, 67 AMER. ANTHROPOLOGIST (SPECIAL ISSUE) 33, 34-36 (1965). By “double institutionalization,” Bohanan refers to the process by which a rule, initially created and backed by the resources of the sphere to which it applies, comes to be guaranteed by the resources of the legal system as well. *Id.* at 35-36. The rule or norm thus becomes the rule of two institutions, has the support of both, and is enforced by both. *Id.*

7. *See, e.g.*, ANDREW ABBOTT, *THE SYSTEM OF PROFESSIONS: AN ESSAY ON THE DIVISION OF EXPERT LABOR* 165-67 (1988); PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 128-34 (1982) (detailing the attempts of the American Medical Association (“AMA”) to control nostrum makers).

8. *See, e.g.*, BAKER, *supra* note 5, at 1-2 (exposing the error in mid-1970s reports of rising medical malpractice litigation); JETHRO K. LIEBERMAN, *THE LITIGIOUS SOCIETY* 82-85 (1981) (stating that the 1970s malpractice crisis was not caused by the legal system, but rather by “insurer malpractice”).

9. *See* ROBERT ZUSSMAN, *INTENSIVE CARE: MEDICAL ETHICS AND THE*

The news stories about health care—including, for example, stories about errors in transplantation, difficulties with implanted devices to regulate the heart, side effects of statins, and high-profile deaths of research subjects—betray some considerable public confusion about where the legal regulation of medicine begins and ends. This should not be surprising, given that even legal scholars describe health law as chaotic. “The law governing American health care,” Gregg Bloche writes, “arises from an unruly mix of state and federal agencies and from a jumble of statutes and common-law doctrines conceived, in the main, without medical care in mind.”<sup>10</sup> In medical care, rules are made not only by legislatures, but also by government regulators acting on legislative mandates (for example, the FDA or the Surgeon General), insurers, quasi-public regulatory bodies (especially JCAHO), professional associations (the AMA, the American College of Surgeons, the American Academy of Pediatrics, and countless other associations of specialists), medical schools and research institutes, and health care organizations such as hospitals and managed care organizations.<sup>11</sup> Generally, journalists do not distinguish between the actions and products of the formal legal system and the internal, indigenous “legislative” and “judicial” processes of the medical world.

Among the key elements of health care’s indigenous system of rules are clinical practice guidelines and other rules about medical care itself, rules about the conduct of research and the gathering and dissemination of data, and rules about governance and administrative matters. Although these three types of rules overlap in many empirical settings, they have somewhat separate jurisdictions and purposes and were developed on different timetables as responses to distinct pressures.

Clinical practice guidelines translate the findings of medical science into practical instructions about what medications or therapies are called for, given the patient’s symptoms, medical history, and personal characteristics. The Institute of Medicine defines clinical practice guidelines as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”<sup>12</sup>

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MEDICAL PROFESSION 183 (1992) (arguing that physicians resent the intrusion of law both because it adds legal uncertainty to the medical and social uncertainties they already face and because it constitutes a “symbolic representation of the limits of medicine’s authority”).

10. Bloche, *supra* note 2, at 249-50.

11. *E.g.*, Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: Call for Judicial Deference to Medical Practice Guidelines*, 77 CAL. L. REV. 1483, 1509-10 (1989).

12. Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts*

Clinical practice guidelines are one embodiment of evidence-based medicine; in practice, the two terms are often used interchangeably. The complex history of clinical protocols can be traced back to the fourth century B.C. and has included repeated calls for evidence-based medicine by such luminaries as Florence Nightingale and Abraham Flexner.<sup>13</sup> More recently, concern with medical effectiveness has led to the crafting of clinical practice guidelines by physician groups, private research organizations, state and federal regulatory bodies, research organizations, and even insurers.<sup>14</sup> The result has been an explosion of guideline production, with 1,700 guidelines created since 1970, over three-quarters of them after 1990.<sup>15</sup>

The conduct of research is, of course, governed strictly by scientific rules, such as how to carry out statistical tests to determine whether the observed differences between experimental and control groups are statistically significant. However, there are also deep research practice regulations such as the principles of informed consent and lesser harm, rules about how control groups should be selected, and rules specifying what kind of treatment must be given to control group members when drugs are being tested.<sup>16</sup> Until quite recently, adherence to ethical principles in medical research was enforced primarily through informal pressure from other researchers and somewhat more formal control by research sponsors.<sup>17</sup> Formalization followed revelations about abuses in Nazi medical experiments, the Tuskegee syphilis study, and research on psychoactive drugs.<sup>18</sup> The Nuremberg Code,<sup>19</sup> the

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*Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. (SPECIAL ISSUE) 327, 328 (2001).

13. See generally SYDNEY A. HALPERN, LESSER HARMS: THE MORALITY OF RISK IN MEDICAL RESEARCH 17-39 (2004) (detailing the history of rulemaking around medical interventions); MICHAEL L. MILLENSON, DEMANDING MEDICAL EXCELLENCE: DOCTORS AND ACCOUNTABILITY IN THE INFORMATION AGE 141-43 (1997) (discussing measuring patient outcomes and standardizing care); STARR, *supra* note 7, at 118-26 (elaborating on the 1910 Flexner report and subsequent response).

14. O'Brien et al., *supra* note 5, at 1078.

15. *Id.*

16. See, e.g., Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 J. AM. MED. ASS'N 2701, 2703-07 (2000); ETHICAL AND REGULATORY ASPECTS OF CLINICAL RESEARCH: READINGS AND COMMENTARY (Ezekiel Emanuel et al. eds., 2003).

17. See, e.g., HALPERN, *supra* note 13, at 3-6, 41-65 (discussing self-policing in polio vaccine research).

18. See, e.g., Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 8-9 (1993); Jonathan D. Moreno & Susan E. Lederer, *Revising the History of Cold War Research Ethics*, 6 KENNEDY INST. ETHICS J. 223, 225-26

1964 World Medical Association Declaration of Helsinki,<sup>20</sup> the Uniform Requirements for Manuscripts Submitted to Biomedical Journals,<sup>21</sup> and the 1974 National Research Service Award Act<sup>22</sup> in the United States have led to much more rigorous policing of research on human subjects, especially by the institutional review boards (“IRBs”) of universities and research organizations.<sup>23</sup> Written in developed countries, and more often by clinicians and researchers than by patients or research subjects, rules about the conduct of research often face challenges in the field.

Rules about governance say how medical and support staff may interact with patients and each other, mandating utilization reviews and adherence to medical and administrative routines as methods of controlling costs and rationalizing medical care. Especially controversial are the “gag rules” of managed care organizations, which sometimes forbid physicians from discussing cost-containment schemes, physicians’ compensation and incentive plans, and treatments not covered by the insurer.<sup>24</sup> Although challenges to these rules, such as patient bills of rights, may occur in courts and legislatures in developed countries, in developing nations with severe resource shortages, the rules may seem

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(1996) (discussing these events as impetuses for formal research guidelines).

19. 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181-82 (U.S. Gov’t Printing Office 1949) (establishing the ten basic principles now known as the Nuremberg Code), available at <http://www.hhs.gov/ohrp/references/nurcode.htm>.

20. World Medical Association [WMA], Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (Oct. 9, 2004), <http://www.wma.net/e/policy/pdf/17c.pdf>.

21. International Committee of Medical Journal Editors [ICMJE], Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (Feb. 2006), <http://www.icmje.org/icmje.pdf>.

22. Pub. L. No. 93-348, 88 Stat. 342 (1974) (codified as amended in scattered sections of 42 U.S.C.).

23. See generally, e.g., Nat’l Comm’n for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1978). On the codes governing human experimentation, see generally THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION (George J. Annas & Michael A. Grodin eds., 1992); COUNCIL FOR INT’L ORGS. OF MED. SCIS. & WORLD HEALTH ORG., ETHICS AND RESEARCH ON HUMAN SUBJECTS: INTERNATIONAL GUIDELINES (Zbigniew Bankowski & Robert J. Levine eds., 1993).

24. E.g., Carol A. Heimer et al., *Risk and Rules: The “Legalization” of Medicine*, in ORGANIZATIONAL ENCOUNTERS WITH RISK 92, 97 n.3 (Bridget Hutter & Michael Power eds., 2005); Nancy J. Picinic, *Physicians, Bound and Gagged: Federal Attempts to Combat Managed Care’s Use of Gag Clauses*, 21 SETON HALL LEGIS. J. 567, 569-72 (1997).

generous and optimistic when compared with the treatment patients normally receive.

Each of these bodies of rules is the result of a long process of cooperation and contest between patients' rights advocates, professional associations, governmental bodies, international health organizations, and other interested parties such as drug companies, insurers, HMOs, and universities. As they produce these rules, such bodies necessarily make claims about best practices: which ways of doing things are the most thoroughly researched, have the most solid scientific backing or best pedigrees, or lead to the best results as medicine moves from research phases to clinical use. It is clear that these questions of legitimacy matter to the potential adopters of rules.<sup>25</sup> The production of rules and the production of legitimacy thus go hand in hand.

The scholarly literature about medical protocols, mostly from legal scholars or medical workers, fails to give much attention to how rules are implemented, to what strategies rulemakers employ to justify the imposition of rules or to defend their legitimacy, or to how the contest varies with the mix of participants. One article, for example, worries about how gag rules will affect physicians' relationships with their patients and decrease the information available for patient decisionmaking,<sup>26</sup> but fails to ask how much physicians are actually gagged and how often managed care organizations actually fire physicians who disobey gag rules. Although gag rules undoubtedly have some chilling effect, some physicians surely resist corporate rules. The outcome of the contest undoubtedly varies depending on the mix of weak and strong participants and whether participants are professionals or lay people. It may matter, as well, whether disputes are framed as narrow disagreements about specific rules or can be deflected to a meta level where claims of technical expertise can be used to delegitimize intervention by those without professional expertise.

To some degree, then, two groups of professionals—physicians and lawyers—compete for the right to shape the laws, rules, and guidelines that will govern medical practice. Just as lawyers develop and promote model codes, physicians and other medical experts develop model medical protocols and attempt to convince others that one set of routines or protocols is superior to another. This contest over expertise and legitimacy takes place on several

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25. See, e.g., Robert Hayward et al., *Canadian Physicians' Attitudes About and Preferences Regarding Clinical Practice Guidelines*, 156 CAN. MED. ASS'N J. 1715, 1719 (1997).

26. See Gordon S. Brand et al., *The Two Faces of Gag Provisions: Patients and Physicians in a Bind*, 17 YALE L. & POL'Y REV. 249, 256, 261 (1998).

planes simultaneously: medical experts compete with legal experts, professional bodies compete with one another as well as with commercial producers of protocols, and international regulatory bodies vie with national regulators.

Sociolegal scholars have highlighted the discrepancy between law on the books and law as it is actually implemented and experienced (“law in action”).<sup>27</sup> They also have uncovered systematic biases that tend to favor the “haves” over the “have-nots” and “repeat players” over “one-shotters.”<sup>28</sup> These biases are also manifested in legal consciousness and people’s expectations about what the legal system can and should do for them, in legal institutions, and in the legal endowments passed on from one generation to the next in constitutions, legislation, and the everyday practices of the legal system.<sup>29</sup>

Although sociolegal scholars have long been interested in the fuzzy boundary of the legal sphere, a focus memorably captured in Robert Mnookin and Lewis Kornhauser’s concern with the “shadow of the law,”<sup>30</sup> in studying the legal regulation of medicine, we have not gone far enough in our investigation of these boundaries. Recent scholarship has examined how the legal system is entwined with and influenced by other parts of society. For instance, Lauren Edelman, Christopher Uggen, and Howard Erlanger argue that law cannot properly be conceived as exogenous to the social system when the practices of organizations—for example, attempts to conform to equal employment opportunity law—shape court decisions about what should be considered compliance.<sup>31</sup> Unlike Lauren Edelman,

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27. See Roscoe Pound, *Law in Books and Law in Action*, 44 AM. L. REV. 12, 15 (1910) (drawing the distinction, now widely employed by sociolegal scholars, between “law in the books” and “law in action”).

28. Marc Galanter, *Why the “Haves” Come Out Ahead: Speculations on the Limits of Legal Change*, 9 LAW & SOC’Y REV. 95, 97, 124 (1974); see also Marc Galanter, *Contract in Court; or Almost Everything You May or May Not Want to Know About Contract Litigation*, 2001 WIS. L. REV. 577, 599-600 (2001) (uncovering a systemic bias favoring organizational litigants, who are often repeat players, over individuals, who tend to be one-shotters).

29. See PATRICIA EWICK & SUSAN S. SILBEY, *THE COMMON PLACE OF LAW: STORIES FROM EVERYDAY LIFE* 34-39, 45-47 (1998) (discussing the importance of legal consciousness); LEMPERT & SANDERS, *supra* note 1, at 430-38 (arguing for the presence, importance, and mechanisms of legal endowments); SALLY ENGLE MERRY, *GETTING JUSTICE AND GETTING EVEN: LEGAL CONSCIOUSNESS AMONG WORKING-CLASS AMERICANS* 37-63 (1990) (presenting ethnographic evidence about the expectations of working class people regarding the kinds of disputes courts should handle).

30. Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L.J. 950, 969-71, 996-97 (1979).

31. Lauren B. Edelman et al., *The Endogeneity of Legal Regulation:*

whose focus is on endogeneity in the interpretation and implementation of law,<sup>32</sup> Bruce Carruthers and Terence Halliday explore endogeneity also in the *development* of law in their study of the reform of corporate bankruptcy law.<sup>33</sup> They suggest that we should be seeing law as recursive because the very legal actors who help reformulate the law are the ones who subsequently practice in the new field they have helped to create.<sup>34</sup> In medicine this means that those writing the protocols will craft them in a way to create attractive opportunities and working conditions for themselves.

In health care, clinical practice guidelines serve to protect physicians from malpractice suits by identifying the “standard practice.”<sup>35</sup> By developing and institutionalizing an internally coherent system of rules, physicians engage in meta bargaining with legal actors over which parts of medical care should be subject to external regulation and which parts are properly governed by medical actors.<sup>36</sup> Although the system of medical rules is developed and implemented in dialogue with the formal legal system, medical professionals go to great lengths to cordon off the medical world and to govern it without undue intrusion from outsiders. From the perspective of legal pluralism, the indigenous legal system of medicine is particularly interesting because its high-status professionals repeatedly insist on their autonomy both in interpreting the law and in proposing sophisticated, coherent rule systems as alternatives or supplements to the law.

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*Grievance Procedures as Rational Myth*, 105 AMER. J. SOC. 406, 445-49 (1999).

32. See Lauren B. Edelman, *Legality and the Endogeneity of Law*, in LEGALITY AND COMMUNITY: ON THE INTELLECTUAL LEGACY OF PHILIP SELZNICK ch. 11 (Robert A. Kagan et al. eds., 2002).

33. BRUCE G. CARRUTHERS & TERENCE C. HALLIDAY, *RESCUING BUSINESS: THE MAKING OF CORPORATE BANKRUPTCY LAW IN ENGLAND AND THE UNITED STATES* 50-55 (1998).

34. *Id.* at 53-62.

35. Carol A. Heimer et al., *supra* note 24, at 107-13. See generally Rosoff, *supra* note 12, at 336-41 (discussing various way courts could use clinical practice guidelines in medical malpractice litigation). Cf. Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 654 (2001) (arguing that clinical practice guidelines shape the practice of medicine toward best outcomes and cost containment and, therefore, should not be used for medical malpractice suits, which focus on the minimally acceptable quality of care).

36. See, e.g., Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 384-90 (1995) (discussing the treatment of clinical practice guidelines by courts).

### III. HEALTH LAW IN ACTION

Although rules often are made above the level of individual health care facilities by professional societies (for clinical practice guidelines)<sup>37</sup> or by university IRBs implementing national laws and international codes,<sup>38</sup> we can only know how they are used by looking at what happens in the places where health care takes place. These are the primary worksites of the legal and quasi-legal system of medicine. The story is likely to be much more complicated than the “legislators” might hope. Practice rarely conforms exactly to the rules, for the good reason that rules cannot anticipate the astonishing variability of the real world. But knowing what use people make of rules—as guidelines that will need modification, as starting points that allow workers to coordinate their activities, and as a way of establishing hierarchy—permits us to ask why some rules “work” to encourage responsibility and others do not.

In law, the objective of universality is fairness—that the law should treat people in similar circumstances alike. In many organizational settings, such as factories and universities, those who devise rules believe that they have developed a superior method for performing some task, whether it be assembling a car or compiling grades. The objective of the rule, then, is to ensure that some task is carried out “correctly.” If there are several equally good methods, choosing only one will make coordination easier, whether we are talking about standardization in construction or surgery. Written in the days before clinical practice guidelines and governance protocols were so common, Charles Bosk’s classic book on the training of surgeons nevertheless shows how seriously physicians take rules.<sup>39</sup> For instance, his discussion of “quasi-normative errors,” offenses against rules of procedure established by each head surgeon for his or her surgical team, is an excellent example of rules as coordination

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37. See, e.g., Agency for Healthcare Research and Quality, National Guideline Clearinghouse, [http://www.guideline.gov/browse/browseorgsbyLtr.aspx?Letter=\\*](http://www.guideline.gov/browse/browseorgsbyLtr.aspx?Letter=*) (last visited Mar. 30, 2006) (listing evidence-based clinical practice guidelines by organization or professional society).

38. See, e.g., Northwestern University, Office for the Protection of Research Subjects (OPRS), Institutional Review Board (IRB), <http://www.research.northwestern.edu/research/OPRS/irb/faqs> (last visited March 30, 2006) (providing information on where the IRB gets its authority and what the IRB has authority to do); Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271 (reviewing federal regulations mandating IRBs and asking whether federal regulations on IRBs violate the First Amendment).

39. See, e.g., CHARLES L. BOSK, FORGIVE AND REMEMBER: MANAGING MEDICAL FAILURE 36-70 (1979).

mechanisms.<sup>40</sup> As the least serious errors committed by surgical residents, quasi-normative errors were violations of the very local rules of procedure.<sup>41</sup> Acknowledged to be largely arbitrary, these rules nevertheless made teamwork possible in the high-pressure operating theater.<sup>42</sup>

Despite strong arguments for the value of uniformity, we have ample evidence that rules are not always followed and that outcomes are rarely uniform. Sociologists of science show that scientists rarely work the way philosophers of science have suggested they should.<sup>43</sup> The studies of law in action show the discrepancy between laws as they appear on the books and as they are implemented.<sup>44</sup> Organizational sociologists write about the consequences of nonconformity in organizations.<sup>45</sup> Neo-institutionalists show that rules adopted for ceremonial, rather than instrumental, purposes may nevertheless be taken seriously by some participants.<sup>46</sup> Anthropologists uncover the resistance that often lies behind apparent compliance.<sup>47</sup> Finally, scholars write extensively about why rules, including those intended to put limits on people in power, are so often ignored, bent, or misapplied.<sup>48</sup> Despite this, scholars rarely conclude that rules are useless.

A recent article on medical protocols illustrates how rules can be useful even when they are not precisely followed. Studying the use of both an oncology research protocol and the Cardio Pulmonary Resuscitation ("CPR") protocol, Stefan Timmermans and Marc Berg found that participants often did not follow the script.<sup>49</sup> Rather than

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40. *See id.* at 61-67.

41. *See id.*

42. *See id.* at 63.

43. *See, e.g.*, GEOFFREY C. BOWKER & SUSAN LEIGH STAR, *SORTING THINGS OUT: CLASSIFICATION AND ITS CONSEQUENCES* (1999); HARRY COLLINS, *GRAVITY'S SHADOW: THE SEARCH FOR GRAVITATIONAL WAVES* ch. 43 (2004); BRUNO LATOUR & STEVE WOOLGAR, *LABORATORY LIFE: THE SOCIAL CONSTRUCTION OF SCIENTIFIC FACTS* (1979).

44. *See, e.g.*, MICHAEL LIPSKY, *STREET-LEVEL BUREAUCRACY: DILEMMAS OF THE INDIVIDUAL IN PUBLIC SERVICES* (1980).

45. *See, e.g.*, Diane Vaughan, *The Dark Side of Organizations: Mistake, Misconduct, and Disaster*, 25 *ANN. REV. SOC.* 271, 273-83 (1999).

46. *See, e.g.*, Lauren B. Edelman & Mark C. Suchman, *The Legal Environments of Organizations*, 23 *ANN. REV. SOC.* 479, 496-97 (1997).

47. *See, e.g.*, JEAN COMAROFF & JOHN COMAROFF, *OF REVELATION AND REVOLUTION: CHRISTIANITY, COLONIALISM, AND CONSCIOUSNESS IN SOUTH AFRICA* ch. 8 (1991); JAMES C. SCOTT, *DOMINATION AND THE ARTS OF RESISTANCE: HIDDEN TRANSCRIPTS* ch. 6 (1990); JAMES C. SCOTT, *WEAPONS OF THE WEAK: EVERYDAY FORMS OF PEASANT RESISTANCE* ch. 7 (1985).

48. *See, e.g.*, Stewart Macaulay, *Popular Legal Culture: An Introduction*, 98 *YALE L.J.* 1545, 1556 (1989).

49. *See* Stefan Timmermans & Marc Berg, *Standardization in Action:*

functioning as prescriptions imposed on docile participants, protocols are instead tools by which participants remind each other what they are supposed to be doing.<sup>50</sup> Of course, this is motivated reminding that takes into account the objectives of the participants and the features of the materials with which they are working; for example, drowning victims are treated differently than those who have been hung.<sup>51</sup> Protocols are thus a crystallization, a very local universalism, produced by participants building on the local infrastructure and customs, using the materials at hand, and shaping the activity to their own purposes.<sup>52</sup> As Annemarie Mol and Marc Berg comment, “Medicine doesn’t fail to meet the standards: the standards fail to meet reality.”<sup>53</sup> However, standards and protocols still matter.

Since Stewart Macaulay’s article on why details of contracts are often ignored and why contractual partners so rarely take each other to court,<sup>54</sup> we have known that the role of contracts is anything but transparent. Even though their authors may hope to induce a more rigid structuration, such as hard and fast rules and ironclad agreements, in fact laws and contracts often become simply a defensible starting point for future bargaining. Wanting lawyers and judges kept out of dispute resolution is not the same as ignoring the contract, either in health care or in other fields. Applying Timmermans and Berg’s argument,<sup>55</sup> this means that production, interpretation, and implementation are not fully separate activities. The production of law is an ongoing activity in which both written law, including rules and protocols, and the local situation matter. The “haves” come out ahead precisely because the production of law takes place in settings where the inequalities of daily life continue to matter. The gross inequalities between rich and poor have their effects repeatedly. They enter into medical rule construction first when the “have-nots” are unrepresented in initial bargaining and then a second time as the rules are used to organize health care and research.

Adaptation of rules is inevitable, but what sort of adaptation is

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*Achieving Local Universality through Medical Protocols*, 27 SOC. STUD. SCI. 273, 288 (1997).

50. *Id.* at 296.

51. *See id.* at 291.

52. *Id.* at 275.

53. Annemarie Mol & Marc Berg, *Differences in Medicine: An Introduction*, in DIFFERENCES IN MEDICINE: UNRAVELING PRACTICES, TECHNIQUES, AND BODIES 1, 10 (Marc Berg & Annemarie Mol eds., 1998).

54. Stewart Macaulay, *Non-Contractual Relations in Business: A Preliminary Study*, 28 AMER. SOC. REV. 55, 58-59 (1963).

55. Timmermans & Berg, *supra* note 49, at 295-98.

required, what sort of resistance is encountered, where adaptation occurs, who does the adapting, and whether adaptation is acknowledged and incorporated into the “official” rules varies a good deal from one situation to another. When the infrastructural support for a routine is missing—for instance when a routine developed in a well-resourced setting is deployed in a poorer one—we can be sure that adaptations will have to be made, although the adaptation may be simply to treat the routine as a ceremony decoupled from reality. We know from other research that it is particularly hard to write routines for interactive work.<sup>56</sup> Medical treatment and research protocols govern the activities of people acting on other people, so the characteristics of individuals and their interpretations of situations will matter a great deal. Adaptation will be especially likely when protocols govern situations where participants are quite unequal and have quite divergent interests.<sup>57</sup> Patients will often be at the mercy of health care workers and researchers, willing to do nearly anything to get treatment but probably not actually willing to remold themselves into creatures with only the interests and needs of research subjects. Thus, we should expect to find an ongoing production of law, a temporary crystallization of rules to create an extremely local universalism.

How much rigidity rules bring probably depends on how fully institutionalized they are. Protocols vary in the extent to which they are “doubly institutionalized”<sup>58</sup> or, perhaps more accurately, “multiply institutionalized.” Protocols are institutionalized first through endorsement by professional associations and other drafting bodies.<sup>59</sup> They are subsequently institutionalized in

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56. See, e.g., TIMOTHY DIAMOND, MAKING GRAY GOLD: NARRATIVES OF NURSING HOME CARE 143-44 (1992) (arguing that it is difficult to construct routines for the use of nursing home staff because their residents do not respond as anticipated); ROBIN LEIDNER, FAST FOOD, FAST TALK: SERVICE WORK AND THE ROUTINIZATION OF EVERYDAY LIFE *passim* (1993) (developing contrast between interactive service work and standardization in manufacturing using evidence from fast-food restaurants and life insurance sales); Carol A. Heimer & Mitchell L. Stevens, *Caring for the Organization: Social Workers as Frontline Risk Managers in Neonatal Intensive Care Units*, 24 WORK & OCCUPATIONS 133, 135-36 (1997) (arguing that social workers in hospital neonatal intensive care units manage the uncertainties of interactive service work on behalf of other professionals).

57. See Carol A. Heimer, *Your Baby's Fine, Just Fine: Certification Procedures, Meetings, and the Supply of Information in Neonatal Intensive Care Units*, in ORGANIZATIONS, UNCERTAINTIES, AND RISK 161, 186-87 (James F. Short, Jr., & Lee Clarke eds., 1992) (discussing difficulties of parents in participating in meetings with large versus small numbers of health care staff).

58. See *supra* note 6 and accompanying text.

59. See, e.g., Press Release, Am. Coll. of Obstetricians and Gynecologists,

practice by functioning organizations, such as hospitals, and regulatory bodies, such as JCAHO.<sup>60</sup> Only some of them are then reinstitutionalized as enforceable laws by legislatures, court decisions, legal “facts” about whether a given treatment is malpractice, contracts, or other legal devices.<sup>61</sup> We might expect, nevertheless, that rules that are multiply institutionalized would be even more powerful as orientation points than those not so fully institutionalized. Moreover, keeping in mind the research of the neoinstitutionalists, we should add a caveat to Timmermans and Berg’s argument about the crystallization of protocols: negotiations will be sensitive to symbolic as well as instrumental concerns, to legitimacy as well as the need to get the work done. The necessity of getting the work done is one multiply institutionalized rule. On the ground, it has to compete with the others. For example, it is basic to science that the work is never done for all time to come; a conclusion is only a temporary resting place in a research program.

In addition to these theoretical considerations about the nature of rules and standardization, we should also watch for contextual effects. Some research receives more government scrutiny than other research. Health workers are more sensitive to rules around the time of an accreditation review than in the intervening periods.<sup>62</sup> Rules that have been tested in court may be treated differently than rules that have not. Health care workers may have different reactions to clinical practice guidelines in states where they can be used in court as “shields” for defendants than in states where they can only be used as “swords” by plaintiffs.<sup>63</sup> In fact, clinical practice guidelines were cited in only thirty-seven cases between 1980 and 1994.<sup>64</sup> This surely understates their importance, since clinical practice guidelines likely have “prelitigation effects,” such as in decisions about whether to go to trial and what settlement is appropriate. Arnold Rosoff also believes that clinical practice

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ACOG Endorses JCAHO’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery (Dec. 2, 2003), [http://www.acog.org/from\\_home/publications/press\\_releases/nr12-02-03.cfm](http://www.acog.org/from_home/publications/press_releases/nr12-02-03.cfm).

60. See, e.g., Joint Comm’n on Accreditation of Healthcare Orgs., Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery (2003), [http://www.jcaho.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal\\_protocol.pdf](http://www.jcaho.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf).

61. See, e.g., GA. CODE ANN. § 43-34-26.1 (2005) (establishing legal protocol limiting a doctor’s delegation of authority to a nurse or physician’s assistant).

62. See, e.g., Martin Gottlieb & Dean Baquet, *Questions of Ethics Confront Hospitals Facing Inspections*, N.Y. TIMES, Mar. 12, 1992, at A1 (discussing how some hospitals rush to rewrite quality assurance meeting minutes on the eve of inspections so as to conform to rules for taking such minutes).

63. See, e.g., Rosoff, *supra* note 12, at 342-43.

64. *Id.* at 341.

guidelines have typically been more helpful for plaintiffs than for defendants.<sup>65</sup>

Finally, we need to ask how standards affect the quality of people's performances. Eugene Bardach and Robert Kagan argued that the American legal system encourages accountability—abiding by the letter of the law and avoiding blame—rather than responsibility—doing what the spirit of the law requires.<sup>66</sup> There is substantial variability in rules, however, and we might expect some medical rules to encourage responsibility even though others lead people to concentrate on accountability. Whatever the script says, some of those who crystallize the protocol in any given situation may care more about responsibility than accountability. Patients' families, for instance, will care more about getting good care than about whether they can sue the physician who makes a mistake.<sup>67</sup> That is, they are more concerned with responsibility than accountability. Clinical practice guidelines do have some features of rules that encourage responsibility, however, such as being updated regularly to take account of new knowledge.<sup>68</sup> What is distinctive here is that the discussion about medical rules as a moral opportunity is occurring at the level of corporations, pharmaceutical companies whose prices are too high for poor countries, and governments, which might give aid to support prevention and treatment in poorer countries, rather than being confined to the offices of individual care providers.

Whether they are drafted by legislatures or by groups of

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65. *Id.*; see also Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & L. 289, 292 (1996) (analyzing lawyers' awareness of clinical practice guidelines when deciding to take cases).

66. EUGENE BARDACH & ROBERT A. KAGAN, GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS 323 (1982).

67. See, e.g., CAROL A. HEIMER & LISA R. STAFFEN, FOR THE SAKE OF THE CHILDREN: THE SOCIAL ORGANIZATION OF RESPONSIBILITY IN THE HOSPITAL AND THE HOME 226-78 (1998).

68. See, e.g., National Guideline Clearinghouse, About NGC, <http://www.guideline.gov/about/about.aspx> (last visited Mar. 30, 2006); National Guidelines Clearinghouse, Guideline Index, [http://www.guideline.gov/browse/guideline\\_index.aspx](http://www.guideline.gov/browse/guideline_index.aspx) (last visited Mar. 30, 2006) (stating that NGC currently contains 1849 individual summaries); National Guidelines Clearinghouse, Updated NGC Summaries, <http://www.guideline.gov/browse/gaupdated.aspx> (last visited Mar. 30, 2006) (stating that NGC currently contains 1,110 guidelines that have been superseded); National Guidelines Clearinghouse, Guidelines in Progress, <http://www.guideline.gov/browse/workqueue.aspx> (last visited Mar. 30, 2006) (stating that the NGC currently contains 146 guidelines in progress); National Guidelines Clearinghouse, Withdrawn NGC Summaries, <http://www.guideline.gov/browse/gawithdrawn.aspx> (last visited Mar. 30, 2006) (stating that the NGC currently contains 731 guidelines in the withdrawn archive).

physicians, the creation and adoption of rules are just the first parts of a production process that continues as rules are used as coordination points, as bids for legitimacy, and as moral opportunities.

#### IV. ELEMENTS OF A RECONFIGURED HEALTH LAW

Thus far, I have shown that the world of health care differs from the universe that health law *imagines* that it governs in several important respects. Physicians have tried valiantly to protect their own autonomy as professionals and to keep the physician/patient encounter focused on the welfare of the individual patient. Despite these efforts, physician autonomy has been eroded, and physicians now often work as employees of health care organizations, subject to the rules of those organizations.<sup>69</sup> Moreover, those organizations are larger and more likely to be embedded in large multi-institution entities, with at least some uniformity in policies and procedures.<sup>70</sup> Decisions about what is best for the patient are not and never have been made in a vacuum, though almost certainly concerns about payment, the rules of a variety of third-party payers, and worries about malpractice suits play a larger role now than they have in the past. Although the rhetoric continues to emphasize what is best for the individual patient, many organizational policies seem oriented instead to balancing the budget by creating artificial shortages or rationing care by making people wait in queues. If care is rationed, however, and it is, the collective concern that justifies this rationing is the financial health of the health care organization rather than widely diffused and equitable access to basic health care. Often, these rules also aim to raise the bar of medical practice by insisting that physicians follow professional guidelines unless they have good reason to deviate, and, in some instances, only if they are willing to

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69. *E.g.*, Phillip R. Kletke et al., *Current Trends in Physicians' Practice Arrangements: From Owners to Employees*, 276 JAMA 555, 555 (1996) (reporting that from 1983 to 1994 the percentage of patient care physicians practicing as employees rose from approximately twenty-four to forty-two percent, the percentage of those self-employed in solo practices fell from approximately forty to twenty-nine percent, and the percentage of those self-employed in group practices fell from approximately thirty-five to twenty-eight percent).

70. *See generally* W. RICHARD SCOTT et al., INSTITUTIONAL CHANGE AND HEALTHCARE ORGANIZATIONS 265-95 (2000) (explaining the vertical structure of health care organizations); STARR, *supra* note 7, at 428-36 (showing the growth of for-profit hospital chains, transition toward for-profit activities in not-for-profit hospitals, and the decline of stand-alone hospitals starting in the early 1980s).

offer their justifications in writing for others to review. But if the bar is raised by making guidelines more prescriptive, adding the force of organizational procedures to the suasion of professional guidelines, it may come at the expense of flexibly incorporating the newest scientific knowledge. In some areas, medical innovation occurs quickly,<sup>71</sup> and rules and formal law need to keep abreast of these changes or at least not get in the way of practitioners who are willing and able to take account of the latest research results.

Turning now to how law might be reshaped, I suggest five aspirations for a reconfigured health law. These aspirations are responses to deficiencies in health law in its current form. First, a perennial challenge for law is to adapt to changing circumstances. Often, law does this awkwardly with analogies and fictions. In a field such as medicine, where we hope to encourage updating of rules to incorporate the latest scientific discoveries, the rigidity of law serves us particularly poorly. Rather than taking formal law as a model, then, we should instead take clinical guidelines as a model and consider how to add the backing of the legal system to what medical practitioners are already doing well. This, then, is an aspiration about the content of law and how best to keep it current and current, ideally, with the best medical practice.

A second aspiration concerns how rules are applied. The vaunted universalism of law serves us better in some arenas than others. Again, medicine perhaps provides a lesson that law should take to heart. In medicine, it is clear that often little is gained and much is lost by a completely uniform application of rules. Just as it seems advisable to give up some of the continuity and permanence of law to get rapid incorporation of medical innovation, it also seems that in health law we should aspire to have more particularism and

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71. Patients and caregivers sometimes think it is not fast enough; for example, there is often pressure from patients to fast-track AIDS drugs. See generally, e.g., Martha Rosengarten et al., *After the Euphoria: HIV Medical Technologies from the Perspective of Their Prescribers*, 26 SOC. HEALTH & ILLNESS 575 (2004) (arguing that HIV treatment is not as settled as treatment of other diseases); Scott A. Wolfe, *IAPAC, HIVMA Collaborate on U.S. HIV Specialization*, 9 INT'L ASS'N OF PHYSICIANS IN AIDS CARE 281 (2003) (arguing that HIV care providers need to keep up with changes in standard of care via continuing medical education and clinical experience with HIV); Patrick G. Yeni et al., *Treatment for Adult HIV Infection: 2004 Recommendations of the International AIDS Society-USA Panel*, 292 JAMA 251, 262-63 (2004) (claiming that HIV medicine is a constantly evolving field that practitioners must keep up with); see also COMM. ON THE ELIMINATION OF TUBERCULOSIS IN THE U.S., DIV. OF HEALTH PROMOTION & DISEASE PREVENTION, INST. OF MED., ENDING NEGLECT: THE ELIMINATION OF TUBERCULOSIS IN THE UNITED STATES 33-48 (2000) (discussing tuberculosis research showing that the slow pace of change in drug research and treatment complicates elimination of the disease).

less universalism. However effective the drug may be in treating some condition, the clinical guideline specifying the use of that particular drug should not be followed if a patient is known to be allergic to the drug.

A third point of dissatisfaction and, therefore, a third aspiration, concerns those who apply the rules. In medicine, this aspiration pertains especially to doctors and other health care professionals, since it is they who apply the rules. Because others lack the specialized training and experience necessary to assess their work, the argument goes, professionals should largely regulate themselves, rather than being subject to regulation by untrained outsiders.<sup>72</sup> Legal systems have been particularly weak here, as often bolstering as challenging medical professionals' claims that they should be permitted to regulate themselves. High error rates suggest that licensure and state regulation of professionals do not have a good record for weeding out incompetents or broadcasting information about dangers.<sup>73</sup> Rather than protecting the public, they often give the appearance of circling the wagons to protect their professional peers. Although claims about specialized professional knowledge are certainly valid, if professionals are to police themselves, we should aspire to have in place some mechanism to make professionals collectively accountable to the rest of us. This third aspiration, then, is for moral competence.

In its current instantiation, health law also suffers from a fourth problem, a constricted sense of who it is that needs to be protected and how those protections should be offered. Focused on protecting the sanctity of the doctor/patient relationship, health law seems to envision health as a good belonging to individuals rather than to families, communities, and societies. Often, then, health law focuses on the wrong subjects, because it imagines that it is individuals who must be protected when, instead, it is a family or community whose health must be secured.

A final difficulty arises not from having the wrong subject but from failing to understand that subject. Assumptions that we are all alike—failing to take sufficient account of difference—often is associated with failures to think about a wide range of solutions, because we assume that others would want just what we want. I refer to this as a problem of bounded imagination.

Taken together, these aspirations break down the artificial boundary between law and non-law and simultaneously focus on

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72. See generally, e.g., ABBOTT, *supra* note 7, at 33-58; STARR, *supra* note 7, at 21-29; THE INTERNATIONAL ENCYCLOPEDIA OF THE SOCIAL SCIENCES 536-47 (1968).

73. See, e.g., BAKER, *supra* note 5, at 22-44.

responsibility, rather than accountability. After discussing these five aspirations, I turn, in the conclusion, to the special contribution law might make in achieving these aspirations.

A. *The Empirical Basis of Rules: Laws, Guidelines, and the Incorporation of New Knowledge*

Rules and laws cannot hope to produce desirable outcomes if they are based on incorrect or outdated understandings of the world they are attempting to govern. Rules can be related to knowledge in at least four ways.

First, a rule can have a very direct relationship to knowledge about the world if the rule says: under circumstance A, take action B, with the assumption that action B will produce result C. In this case, the rule is a recipe that is based on a belief that the action will produce, hopefully with some high probability, the anticipated result. The rule prescribing the action is based on knowledge about the empirical world, for example, that action B leads to result C. A secondary rule might doubly institutionalize the knowledge-based recipe, giving it additional force. This is the case, for instance, when practitioners are required by payers, health care organizations, or even by statute (which is rare) to follow clinical guidelines, which are directly based on scientific studies.

In the example above, if newly available information tells us something different about causal relations, then we would usually wish people to modify their behavior, for instance, distinguishing between circumstances A' and A" and taking action B only for the subgroup for which it had been shown to be effective and taking some other action, or no action, for the other subgroup. For instance, when some strains of HIV are found to be resistant to a particular drug regimen, we would want physicians to continue to give the original drug regimen only to patients infected with non-resistant strains and to give some modified regimen to those infected with resistant strains.<sup>74</sup> In situations in which prescriptive statements are strongly based on an evolving body of knowledge, then, we want primary rules—the guidelines—to adapt quickly and we want secondary rules—requiring people to follow the guidelines—to be written so that they encourage such adaptation.

Many of the indigenous rules of health care are related to

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74. See generally Victoria A. Johnson et al., *Update of the Drug Resistance Mutations in HIV-1: Fall 2005*, 13 TOPICS IN HIV MED. 125 (2005) (discussing recent developments in drug-resistant HIV and its treatment); Martin S. Hirsch et al., *Antiretroviral Drug Resistance Testing in Adults with HIV Infection: Implications for Clinical Management*, 279 JAMA 1984 (1998) (presenting guidelines for treating patients with drug-resistant HIV).

knowledge in one of these two ways. Clinical guidelines are based directly on scientific understanding of causal relationships; many other rules, for instance administrative rules and rules about the conduct of research, speak to the question of how people's actions should take account of clinical guidelines.<sup>75</sup>

As we move beyond these indigenous rules of medicine, however, we find two additional ways that rules can be related to knowledge. In some cases, rules or laws seem to be partly, but not fully, based on assumptions about cause and effect. In criminal law, for example, the meting out of punishments seems to be based on a series of assumptions about the positive effects these punishments will have in rehabilitating the offender, incapacitating the offender, and deterring similar actions by the offender or others. But a demonstration that the punishment does not have a deterrent effect may not lead to a change in the law, partly because the relationship between offense and punishment is constructed on a foundation including several alleged causal sequences and partly because some elements of the foundation, such as retribution, have no necessary factual basis.<sup>76</sup> When law has no strong relation to knowledge, then there is no particular reason to insist that law should change in response to new knowledge.

Finally, some bodies of rules apply inappropriate solutions because they misunderstand the situation they are aiming to correct. The Baby Doe Rules and the Child Abuse Amendments that eventually replaced them are an excellent example of this problem.<sup>77</sup> These rules were designed to ensure that handicapped newborns did not experience discrimination but, instead, received the care they would have gotten had they not been handicapped.<sup>78</sup> The rules, however, were based on two erroneous assumptions about infant intensive care units. Most of the infants in such nurseries are not

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75. See SHARON E. STRAUSS ET AL., EVIDENCE-BASED MEDICINE: HOW TO PRACTICE AND TEACH EBM 165 (3d ed. 2005); Finlay A. McAlister et al., *Users' Guides to the Medical Literature: XIX. Applying Clinical Trial Results, B. Guidelines for Determining Whether a Drug is Exerting (More Than) a Class Effect*, 282 JAMA 1371, 1371 (1999); Sandra J. Tanenbaum, *Knowing and Acting in Medical Practice: The Epistemological Politics of Outcomes Research*, 19 J. HEALTH POL. POL'Y & L. 27 (1994).

76. See generally FRANKLIN E. ZIMRING, THE CONTRADICTIONS OF AMERICAN CAPITAL PUNISHMENT 3-15 (2003) (providing a summary of research on capital punishment).

77. See generally ARTHUR L. CAPLAN et al., COMPELLED COMPASSION: GOVERNMENT INTERVENTION IN THE TREATMENT OF CRITICALLY ILL NEWBORNS (1992) (discussing the Baby Doe Rules and the Child Abuse Amendments); Stephen A. Newman, *Baby Doe, Congress and the States: Challenging the Federal Treatment Standard for Impaired Infants*, 15 AM. J.L. & MED. 1 (1989).

78. NEWMAN, *supra* note 77, at 1-4.

handicapped but only premature. Additionally, undertreatment is quite rare; most observers argue that overtreatment is a far more serious problem. In this case, the rules were largely irrelevant. One might argue that we should not trouble ourselves about rules that cannot be applied, because their assumptions are not met, yet such rules can have a deleterious effect on a work environment by making people feel that they are under suspicion. In other cases, if an incorrect understanding of the factual situation leads to a change that applies uniformly, the effect can be quite serious. Here, the example that comes to mind is tort reform based on misinformation about the frequency of medical malpractice claims, the magnitude of settlements, and the frequency of medical errors.<sup>79</sup>

Compared with other fields, health care is surely distinctive in the proportion of its indigenous rules that are guidelines quite solidly grounded in a cause and effect understanding of the world. Of course, we should always take these claims that rules have a solid scientific foundation with a grain of salt. Although medicine may inflate its claims about the solidity of its science, it does, nevertheless, have a different relation to scientific knowledge than do lawyers or teachers. This suggests that we might expect, and indeed encourage, a somewhat different relation between the indigenous rules of medicine and law than the indigenous rules of other professions and law. In fact, we might use the updating of medical guidelines as a model for flexible reformulation of rules as knowledge accumulates. Those who work with this new knowledge—the people who formulate the guidelines—often have the most nuanced understanding and the most accurate cognitive mapping. Science is often hard to understand, so the researchers themselves may understand recent findings better than ordinary physicians. At this crucial interface between formal law and indigenous medical quasi-law, such people are an important resource. Law needs to develop procedures for accessing, recognizing, and incorporating the best knowledge available and for enlisting the help of these experts.

*B. Uniformity with Just the Right Dose of Discretion*

All rule systems incorporate rigidity and discretion. Both discretion and rules make important contributions, and, as Carl Schneider points out, “[w]e will commonly want to secure the advantages of *both* discretion and rules while avoiding their disadvantages.”<sup>80</sup> Rather than choosing between discretion and

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79. BAKER, *supra* note 5, at 10-14, 24-38, 58-63, 110-11.

80. Carl E. Schneider, *Discretion and Rules: A Lawyer's View*, in *THE USES OF DISCRETION* 47, 49 (Keith Hawkins ed., 1992).

rules, Schneider argues, we will ordinarily be making “a choice between different mixes of discretion and rules.”<sup>81</sup> I have argued above that the formulation of rules is important in systematizing the information that ultimately guides action. Similarly, rules are crucial in articulating principles and in coordinating action. Yet discretion is also important in fine-tuning rules to individual circumstances, in deciding how to classify and code information to determine which rules apply, in deciding whether or not to follow an existing rule, and even in deciding whether to formulate a regulation, rule of thumb, or precedent.<sup>82</sup>

Not all rules need to be applied flexibly. In some instances, there may, in fact, be little important variability in the matter being governed, and, in other cases, we may decide as a matter of policy to forgo flexibility, classify people into a rigid system of categories, and apply rules uniformly to class members. Mandatory sentencing rules aim to reduce discretion by insisting that all those who are guilty of committing particular offenses receive very similar punishments, regardless of their unique characteristics or mitigating circumstances.<sup>83</sup> In the United States, only males have been subject to military draft.<sup>84</sup> Sexual intercourse with an underage female is statutory rape regardless of whether there is consent.<sup>85</sup> In these examples, uniformity is imposed as a matter of policy. It is not that there is no variability to attend to but, instead, that we have decided to ignore existing variability.

Rule systems that make flexibility a virtue may do so either because the variability of the phenomenon itself fundamentally shapes the rule system or because, as a matter of policy, we have decided it is important to attend to variability. We might, for instance, decide that it would be irresponsible to insist that a rule be applied uniformly in all circumstances. Adaptation to individual circumstances is hard to institutionalize, however. It is easier to follow a fixed rule than to put in the effort to determine whether and how a rule must be modified to fit the occasion.

How, then, can a rule system be designed to encourage such flexible adaptation? Here we make a brief digression into the world

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81. *Id.*

82. See Richard Lempert, *Discretion in a Behavioral Perspective: The Case of a Public Housing Eviction Board*, in *THE USES OF DISCRETION*, *supra* note 80, at 185 (providing a discussion of following rules and deciding whether to formulate regulations).

83. Nicola Lacey, *The Jurisprudence of Discretion: Escaping the Legal Paradigm*, in *THE USES OF DISCRETION*, *supra* note 80, at 361, 376-77.

84. Military Selective Service Act, 50 U.S.C. app. § 453(a) (2000).

85. See *e.g.*, *State v. Anthony*, 133 N.C. App. 573, 579, 516 S.E.2d 195, 198 (1999), *aff'd*, 351 N.C. 109, 528 S.E.2d 321 (2000).

of shipping rules because this system of rules is a model for mandated but constrained discretion. The shipping industry must work with substantial variability in terms of vessels, cargo, bodies of water being navigated, weather conditions, training of personnel, and the like, and it has developed a finely tuned system of rules that mandates adjustment to local circumstances. The industry is governed by an interconnected system of national and international rules: national laws about the registration of vessels, the law of admiralty, insurance regulations, and the rules of classification societies.<sup>86</sup>

At the core of this web of regulations is its most important element: the standard of seaworthiness.<sup>87</sup> The standard of seaworthiness is the “escape clause” in marine law. The gist of the standard is that rules are no defense if a vessel is not seaworthy and is not being operated in a safe manner.<sup>88</sup> Although marine insurance contracts specify that a ship must be seaworthy for the contract to hold, what constitutes seaworthiness varies by season, route, and trade.<sup>89</sup> Thus, the rule that the ship should be seaworthy, on closer examination, turns out to be not a single rule but a general principle, elaborated in numerous rules about what is appropriate to each combination of trade, season, and route. It is flexible because its analysis is complex, because each rule only governs a relatively narrow portion of the shipping world, and because it explicitly recognizes that the elaborate rules are not an exhaustive list. The principle itself must still be attended to. The stake in this case is recovery from an insurer should an accident occur. Captains and crew members are forced to use discretion because recovery depends not just on following the rules about staffing, preventive maintenance and inspections, sailing routes, and load limits, but also on adjusting to circumstances such as storms, visibility, season, and location—harbor versus open sea, for instance. Fixed rules might be clearer, but following rigid rules is not responsible in the variable, unpredictable, dangerous, evolving, and expensive world of shipping. Flexibility arises, then, not only from the radical particularism of the standard itself, but also from the division of labor between insured parties, who are responsible for ensuring that the vessel is maintained and sailed safely, insurers, who refuse

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86. See CAROL A. HEIMER, *REACTIVE RISK AND RATIONAL ACTION: MANAGING MORAL HAZARD IN INSURANCE CONTRACTS* 91-148 (1985) (detailing marine insurance rules, the standard of seaworthiness, and the relationship between shipping companies, marine insurers, and classification societies).

87. *Id.* at 103.

88. *Id.*; see also 45 C.J.S. *Insurance* § 764(a) (1993).

89. HEIMER, *supra* note 86, at 103-05.

coverage and reimbursement should the vessel not be seaworthy and should the crew not do its utmost to reduce losses during an accident, and classification societies, who make the assessments of whether a vessel is in fact seaworthy.

Do we find these same elements in the world of health care? We do, in fact, find rules tailored to a variety of circumstances. The discussion of the development of clinical guidelines in an earlier section supplied considerable evidence of how adjustment to individual patients is encouraged in health care. Clinical guidelines with their decision trees encourage attention to variability, as do tools such as the *Physicians' Desk Reference*, which presents several methods of calculating dosage (by age groups and/or by weight) and discusses indications and contraindications.<sup>90</sup>

The view that physicians should not mechanically follow recipes<sup>91</sup> bears a good deal of resemblance to the principle of seaworthiness in its insistence on radical adaptation to individual circumstances. Addressing this issue about the relationship between rules and principles, John Braithwaite and Valerie Braithwaite have argued that the Australian system of nursing home regulation with a few, very general standards encourages both more compliance and more thoughtful compliance than is secured in regulatory systems with larger numbers of more rigid rules.<sup>92</sup> These studies of Australian nursing home regulation provide an important counterpoint to discussions of nursing home regulation in the United States, where rules designed to curb the abuses of irresponsible nursing home owners are not helpful in maintaining or raising standards in well-run homes.<sup>93</sup> Braithwaite and Braithwaite argue against a counterproductive precision in rules even though such rules have the virtue of transparency.<sup>94</sup> Instead, they urge that:

Because there is no way of solving the problem of vagueness at the level of the wording of rules without also rendering the rules overinclusive and complex, the solution is to leave the words vague but to specify the interpretive evidence that is

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90. See, e.g., PHYSICIANS' DESK REFERENCE (59th ed., Thomson PDR 2005).

91. See MARC BERG, RATIONALIZING MEDICAL WORK: DECISION-SUPPORT TECHNIQUES AND MEDICAL PRACTICES 7 (1997).

92. John Braithwaite & Valerie Braithwaite, *The Politics of Legalism: Rules Versus Standards in Nursing-Home Regulation*, 4 SOC. & LEGAL STUD. 307 *passim* (1995).

93. See generally, e.g., BARDACH & KAGAN, *supra* note 66.

94. See Braithwaite & Braithwaite, *supra* note 92, at 335.

privileged<sup>95</sup> and to require a regulatory dialogue about this evidence.

The fit between the standards and concrete situations should, then, be worked out by those familiar with and invested in that situation, with regulators listening and responding to the regulated. Regulatory dialogue emerges here as a key element in *flexible precision*.

Finally, in health law, as in marine law, there is a division of labor between the major actors: regulatory bodies, such as JCAHO or the FDA, which establish some of the ground rules and carry out inspections or review documentation to see that these rules are being adopted and enforced as matters of organizational policy; physicians, nurses, and researchers, who are supposed to apply the rules to their daily work; insurers or other third parties, whose payment of bills depends on whether rules have been followed; and a court system that settles individual disputes about whether patients have received appropriate care and who should pay the bills. One might expect less consensus about standards in health care than in shipping, however, partly because responsibility for standard setting is widely diffused among regulatory bodies, professional societies, insurers, and health care organizations, rather than being concentrated in bodies analogous to the handful of classification societies of the shipping world. Ironically, the lack of consensus in health care may sometimes decrease flexibility when it tempts insurers into developing more rigid rules than physicians would promulgate themselves. Usually, such rules are not strictly about medical matters, though, but instead are about procedural matters and conditions for insurance coverage. There is often, however, a lack of formal dialogue about such administrative matters; similar dialogue about drug regulation between medical scientists and the FDA is formally organized.

To encourage responsibility to individual patients, the universalism of rules must be tempered by particularism. How much adjustment to individual circumstances is necessary and desirable depends on how variable the regulated phenomenon is and whether there are social policy considerations that require us to ignore variability in the interest of even distribution of especially desirable goods or opportunities or unusually onerous obligations.<sup>96</sup>

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95. *Id.* (citation omitted).

96. See generally Carol A. Heimer, *Doing Your Job and Helping Your Friends: Universalistic Norms About Obligations to Particular Others in Networks*, in NETWORKS AND ORGANIZATIONS: STRUCTURE, FORM, AND ACTION 143 (Nitin Nohria & Robert G. Eccles eds., 1992) (offering a fuller discussion of when particularism will be especially important and some of the difficulties

The question of how to balance responsibilities to individuals and responsibilities to groups is taken up in more detail below. The point here is that the regulatory structure itself should be designed with the assumption that discussion will be needed about whether, when, and how general rules should be particularized.

A requirement to adjust sensitively and sensibly to local or individual conditions is difficult to arrange, however, and I have discussed some of the features of rules themselves and of arrangements to administer rules that increase the likelihood of responsible adjustment. In particular, I have argued that the articulation of a small number of general principles is important in focusing attention on the impossibility of articulating a rule that fits all circumstances. Additionally, I have argued for the importance of independent experts, who collect and systematize the information necessary to apply the general principles and who assess the appropriateness of others' decisions about how to apply the principles.

*C. The Moral Competence of Powerful Actors: Rethinking the Conditions for Professional Self-Regulation*

Because there is always room for discretion, the moral qualities of those with whom we interact matter, particularly when they are powerful and knowledgeable and we are weak, ill informed, and vulnerable. Whether a person is a physician, nurse, lawyer, teacher, or some other kind of professional, professionalism is partly about having the proper relationship with the person or object entrusted to one's care. Professionals are expected to use their skills for the benefit of others; professionals are supposed to have inculcated occupation-specific standards of excellence and not to do a shoddy job just because others would be unable to tell the difference.<sup>97</sup>

Because they have skills and knowledge that others lack, many professional groups have argued for the right to regulate themselves. Such self-regulation is institutionalized in various forms of "peer review," ranging from the review of proposals and manuscripts in academic disciplines, to the development and administration of exams in medicine and law, and the formulation of a code of ethics to which members of the profession are expected to adhere.<sup>98</sup>

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encountered in making a legal system somewhat more particularistic).

97. See generally JAMES G. MARCH & JOHAN P. OLSEN, REDISCOVERING INSTITUTIONS: THE ORGANIZATIONAL BASIS OF POLITICS 127-29 (1989); PHILIP SELZNICK, THE MORAL COMMONWEALTH: SOCIAL THEORY AND THE PROMISE OF COMMUNITY 345-46 (1992).

98. See, e.g., ELIOT FREIDSON, PROFESSION OF MEDICINE: A STUDY OF THE

Although sociologists also argue that professional bodies are as much about protecting the markets for professional services as about regulating the quality of services,<sup>99</sup> professional associations do seem to reflect a recognition that the fates and reputations of the members of a profession are linked. In a careful study of the development of an “industrial morality” that accompanied the formation of the Institute of Nuclear Power Operations, Joseph Rees found that nuclear power executives took on the task of policing the performance of others in their industry only after seeing that they were linked in public perception.<sup>100</sup> Because the public did not distinguish one plant from another, poor performance by one affected the fate of others.

This analysis may place too much emphasis on strategic calculation, however. For many, being a professional means identifying with one’s occupation and others who work in the same field. One is not simply concerned that others in the same occupation do well because one’s own reputation is tarnished and one’s business prospects are damaged if they do not. One is also *ashamed* if they behave badly. Professional social control is, thus, also about identity—feeling good about oneself as a member of an honorable, humane, and responsible group—and professional irresponsibility often carries the outrage and moral indignation associated with threats to identity and to group boundaries.<sup>101</sup> We should not be surprised, then, that members of a profession develop especially hostile labels for incompetents, including moral incompetents, in their own profession.

Yet the problem is not simply to get professionals to hold each other responsible. “Responsibility is something more than accountability,” Selznick observes:<sup>102</sup>

To be accountable is to be subject to judgment or, as we sometimes say, to be held responsible. The focus is on

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SOCIOLOGY OF APPLIED KNOWLEDGE 137-57 (2d ed. 1988); ELIOT FREIDSON, DOCTORING TOGETHER: A STUDY OF PROFESSIONAL SOCIAL CONTROL 120-66 (1975).

99. See, e.g., MAGALI SARFATTI LARSON, THE RISE OF PROFESSIONALISM: A SOCIOLOGICAL ANALYSIS 83-99 (1977).

100. See JOSEPH V. REES, HOSTAGES OF EACH OTHER: THE TRANSFORMATION OF NUCLEAR SAFETY SINCE THREE MILE ISLAND 91-120 (1994).

101. See BOSK, *supra* note 39, at 148-65 (tracing the impact of residents’ normative and quasi-normative errors on their long-term possibility for advancement in surgical fields); cf. IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 102-28 (1992) (discussing the concept of self-regulation in industry and its dependence on collective moral standards of action).

102. SELZNICK, *supra* note 97, at 345.

conformity to an external standard. This requires only minimum conditions of moral agency, such as the capacity to distinguish right from wrong. We need not ask whether the person or organization wants to act responsibly. But a responsible enterprise, like a responsible person, must have an inner commitment to moral restraint and aspiration.<sup>103</sup>

It is perhaps in the institutionalization of mechanisms for developing moral competence, the inner commitment to responsible action, that rule systems are particularly weak. It is hard to formulate a rule that says with the proper degree of precision that a person must have the "right attitude." Yet, if it is not possible simply to legislate attitude, how can one create and support such an orientation?

Bosk's answer, developed in a study of the management of error in the training of surgeons, seems to be that professions teach what and whom they can and weed out the failures.<sup>104</sup> Surgeons identify four categories of errors—technical, judgmental, quasi-normative, and normative—the most serious of which are normative errors, instances in which a surgical resident's actions show that he or she does not have an appropriate attitude toward the work, the patients, or his or her colleagues.<sup>105</sup> Such breaches are considered especially serious because senior surgeons feel that they do not understand how to inculcate a responsible and professional orientation when it is missing.<sup>106</sup> One can teach medical judgment or technical skills, and one can even correct quasi-normative errors when a resident has failed to follow the rules of procedure of a particular surgery service.<sup>107</sup> But having the wrong moral orientation is a much more intractable problem. Absent a good technology for teaching moral competence, senior surgeons are obliged to dismiss those with the wrong attitude, at least once they have determined that this is, in fact, where the problem lies.<sup>108</sup>

If moral competence remains a weak link in systems of social control and if we do not know how to legislate or teach moral competence, might we instead reduce the space in which moral competence is important? Here, the contrast between the work of nurses and physicians is instructive. Daniel Chambliss argues that because nurses are constrained to follow doctors' orders and the rules of the organizations that employ them, they do not face moral

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103. *Id.*

104. *See* BOSK, *supra* note 39, at 168-92.

105. *Id.* at 168-72.

106. *Id.*

107. *Id.* at 169, 177-79.

108. *Id.* at 169, 179-80.

*dilemmas* but instead encounter moral *problems*.<sup>109</sup> Those who are positioned to make choices may face moral dilemmas, but those whose choices are constrained do not. The moral problems that nurses face arise from the internally conflicting demands to be caring professionals working as subordinate employees.<sup>110</sup> They are supposed to be caring, yet to keep care within limits, and to behave as autonomous professionals, yet only insofar as their independent judgments do not conflict with doctors' orders or violate organizational rules.<sup>111</sup>

By extension, Chambliss' argument suggests that doctors who are employees of health care organizations also face moral problems rather than moral dilemmas and, therefore, that their moral qualities will be less important than was the case when they were more independent. Although it is important to consider this possibility, I do not think we really believe that the moral competence of physician-employees is unimportant, and we likely do not believe it about nurses either. Indeed, we may need them to have even more refined moral sensibilities when we require them as allies against bureaucratized medicine. If we conclude that employees, bound as they are to follow organizational rules, cannot be expected to make moral judgments, then we displace moral responsibility from doctors, nurses, and other caregivers to HMOs, insurers, and drug companies. It is hardly obvious that we can expect greater success in teaching moral competence to corporate bodies than to individuals.

For now, professions seem to do the best they can with some combination of oaths and pledges, ethics codes, discipline-specific formulations about the essence of moral competence (for example, judicial temperament or bedside manner), the celebration of exemplars, and, perhaps most importantly, disciplinary practices that institutionalize discussions of uncertainty. In medicine, for instance, the Hippocratic Oath—"first, do no harm"<sup>112</sup>—seems to require physicians to make conservative, rather than risky or

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109. DANIEL F. CHAMBLISS, *BEYOND CARING: HOSPITALS, NURSES, AND THE SOCIAL ORGANIZATION OF ETHICS* 91-94 (1996).

110. *Id.* at 92.

111. *See id.* at 100-16.

112. Although this phrase is widely assumed to have been part of the Hippocratic Oath, Christine Ruggere assures us, in a letter to *Science*, that "neither those words nor that sentiment appears in any known version of the Hippocratic Oath." Christine A. Ruggere, *Quoting the Hippocratic Oath*, 286 *SCIENCE* 901, 901 (1999). The relevant authority on this point is Ludwig Edelstein. *See generally* LUDWIG EDELSTEIN, *ANCIENT MEDICINE: SELECTED PAPERS OF LUDWIG EDELSTEIN* (Owsei Temkin & C. Lilian Temkin eds., C. Lilian Temkin trans., 1967).

reckless, choices in times of true uncertainty. With frequent discussion in daily rounds and grand rounds, morbidity and mortality reviews, case conferences, and ethics consults, the *collective* practice of medicine subjects individual judgment to collective scrutiny.<sup>113</sup> Rather than being built into rule systems, then, the difficult enterprise of responsible “industrial morality” is, instead, administered through less formal systems and with the moral authority of respected leaders. A professional orientation, which I have argued is about attitudes and relationships, seems to be the core element of industrial morality. Enshrined in norms about how one should behave, this orientation is taught by identifying exemplars of the group’s ideals about collegueship, professionalism, and responsibility and by participation in rites of passage<sup>114</sup> and other rituals and ceremonies that emphasize the collective fate of the group, honor those who uphold the ideals, and shame those who transgress. That we have no sound technology for teaching, legislating, or even detecting moral competence does not make the subject any less important.

*D. Taking Account of Collective Concerns: Looking Beyond the Dyadic Physician-Patient Relationship*

Among the health care systems of developed countries, that of the United States is unusual in its nearly exclusive focus on individual patients, their rights, and their relationships with caregivers. This deep concern with individual rights and individual welfare is supported by payment schemes, arrangements for provision of services, and some legislation. What is missing is some counterbalancing set of mechanisms with a more collective focus that would, for example, put a floor under the population as a whole.

Despite this entrenched individualism, islands of collectivism do exist even in American health care. Modeled on battlefield medical triage with its collectivist goal of saving the lives of as many soldiers as possible, the triage systems of hospitals likewise allocate scarce resources—space in the emergency room, staff time, hospital beds—

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113. See BOSK, *supra* note 39, at 181-88; HEIMER & STAFFEN, *supra* note 67, at 48-49, 203-08 (describing collective efforts by different types of staff to construct labels for appropriate parenting); ZUSSMAN, *supra* note 9, at 44-48 (discussing cognitive and moral education of house staff through medical rounds).

114. Created in 1993, the “white coat ceremony” at the end of the first year of medical school is one such rite of passage. Its purpose is to “endorse and encourage professional development and humanism in medicine.” Sam Huber, *Through the Student’s Eyes: The White Coat Ceremony*, 4 VIRTUAL MENTOR 240 (2002), available at [www.ama-assn.org/ama/pub/category/7684.html](http://www.ama-assn.org/ama/pub/category/7684.html).

to those in desperate need and require others to wait.<sup>115</sup> The collective may not extend beyond the hospital walls, as is strikingly indicated by ambulances being told to “bypass” the emergency rooms of hospitals who declare themselves at or above capacity. There is, nevertheless, some parity and sharing among those acknowledged to be the responsibility of the hospital. Despite the strong pressure for insurers to abandon community rating in favor of experience rating and considerable pressure from insurers to retain a system of private payers, the United States health care system does include several very important state-supported insurance schemes. Two of these, Medicaid and Medicare, focus on payment while ignoring questions of where and by whom care is provided. The third, the Veterans Health Administration (“VHA”), pays for health care but also supplies the care in its own hospitals and clinics. Additionally, there continues to be some support for public health programs to combat threats of infectious diseases such as tuberculosis, influenza, meningitis, West Nile fever, and the like. Generally speaking, however, in the United States, private insurers are happier to offer coverage to those who are healthy, young, and rich and to leave to the government the problem of paying for the care of those who need it because they are sick, old, or poor. To characterize the three collectivist programs—Medicare, Medicaid, and VHA—as islands seems appropriate, then, because they are not linked into any unified national program to protect the health of the population.

A more collectivist approach would acknowledge that individual health depends, in part, on the health of other members of the society. This is, of course, a truism of public health, where the concern is as much to prevent the spread of infectious diseases as to treat particular patients who have acquired them. Likewise, public health experts have long recognized that investments in infrastructure, such as sewage systems and the provision of clean water, protect the health of the population collectively, rather than providing for such goods and services for individuals taken one at a time. Investments in safe workplaces offer benefits to groups of workers, not just to individuals. Insurance programs that compensate workers for injuries should enable workers to get back to work more quickly. Whatever savings come from a forward-looking and preventative approach to individual health, they are surely multiplied many times over in programs with a collective

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115. *E.g.*, James F. Childress, *Triage in Neonatal Intensive Care: The Limitations of a Metaphor*, 69 VA. L. REV. 547, 548 (1983); Kelley Jean Devers, *Triage in Adult Intensive Care Units: How Organizations Allocate Resources* (1994) (unpublished Ph.D. dissertation, Northwestern University) (on file with author).

approach.

To think of a collective approach as limited to concerns with infectious diseases, sanitation, and safe workplaces, however crucial these are, is still to underestimate the potential contribution of a collective approach. Consider, for example, the interdependence of mothers and children, the most obvious relationship in which a collective interest exists. Although it is widely acknowledged that mothers and infants are interdependent in the prenatal period and mothers are urged to seek prenatal care, once a child is born that collective focus is muted. Despite considerable evidence, for example, that the health and well-being of babies and small children are compromised when their mother is clinically depressed, we continue to treat mothers and children separately. With rare exceptions, pediatricians do not screen new mothers for postpartum depression. At this crucial transition, new mothers fall between stools, no longer being the patients of their obstetricians, not yet returned to the care of a pre-pregnancy provider, and certainly not the concern of their newborn's pediatrician.<sup>116</sup> When people are part of the caregiving and support system for each other, it seems obvious that the health of one family member, friend, or teacher affects the health and well-being of others with whom they are interdependent.<sup>117</sup> The AIDS epidemic supplies a chilling example here. In societies with high prevalence rates, those who are not themselves infected are, nevertheless, deeply affected when scarce health care resources must go to caring for the desperately ill, when schools and businesses lose staff to the disease, when families lose wage earners, and when orphaned children all too often are forced to leave school and fend for themselves. An individualistic focus hardly solves the problem.

Just as our individualism is apparent in a legal system that places more weight on adversarial protection of individual clients than on achieving collective goals, so our health care system seems in little danger of losing its focus on the dyadic relationship between

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116. Craig Garfield, Presentation at the Robert Wood Johnson Generalist Physician Faculty Scholars Annual Meeting, *Expanding the Safety Net for Identifying Mothers At-Risk for Postpartum Depression: The Role of the Pediatrician* (Nov. 2004); Amy M. Heneghan et al., *Do Pediatricians Recognize Mothers with Depressive Symptoms?*, 106 *PEDIATRICS* 1367, 1367-68 (2000) (finding that pediatric health care providers fail to recognize most mothers with elevated, self-reported symptoms of depression); Ardis L. Olson et al., *Primary Care Pediatricians' Roles and Perceived Responsibilities in the Identification and Management of Maternal Depression*, 110 *PEDIATRICS* 1169, 1169-70 (2002) (explaining the methods primary care pediatricians use in identifying and managing maternal depression).

117. See James S. House et al., *Social Relationships and Health*, 241 *SCIENCE* 540, 543 (1988).

caregiver and patient. In the United States, statutory and common law protections do much more to protect individuals and the doctor-patient relationship than to protect collectivities and public health. The same is true for the AMA Code of Ethics and the nine Principles—defined as “not laws, but standards of conduct which define the essentials of honorable behavior for the physician”<sup>118</sup>—that are the basis for the Code. Although the *AMA Revised Principles of Medical Ethics*, adopted in 2001, now includes provisions emphasizing physicians’ “responsibility to participate in activities contributing to . . . the betterment of public health” (Principle VII) and their obligation to “support access to medical care for all people” (Principle IX), physicians are also reminded that “while caring for a patient” they are to “regard responsibility to the patient as paramount” (Principle VII).<sup>119</sup> Indeed, it is concern about the loss of individual rights to choose caregivers and concern about protecting the dyadic relation between physician and patient that are often cited as a reason to shun both national health insurance and a national health service. Yet physicians can individually choose not to treat uninsured patients, depriving the patients of choice.

What, then, can law and legal actors do to shift the balance? Legislation creating a national health insurance system or national health service, charged with protecting the society’s health, would, of course, instantly shift the balance between individual and collective. Likewise, constitutional recognition of a state obligation to protect the health of the citizenry would create the possibility of claims against the state for neglect of this duty. Short of these unlikely measures, however, we might look for ways to expand, rather than shrink, eligibility for federal and state-level health insurance or health programs (as the State Children’s Health Insurance Program (“SCHIP”) does in providing health insurance for children who are uninsured but ineligible for Medicaid), ways to extend access to employment based-insurance (as occurs with Consolidated Omnibus Budget Reconciliation Act (“COBRA”) insurance, an amendment to Employee Retirement Security Act

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118. See American Medical Association, *AMA Code of Medical Ethics*, <http://www.ama-assn.org/ama/pub/category/2498.html> (last visited March 30, 2006); American Medical Association, *Principles of Medical Ethics*, <http://www.ama-assn.org/ama/pub/category/2512.html> (last visited March 30, 2006).

119. See American Medical Association, *Principles of Medical Ethics*, <http://www.ama-assn.org/ama/pub/category/2512.html> (last visited March 30, 2006); American Medical Association, *History of the Principle of Medical Ethics*, <http://www.ama-assn.org/ama/pub/category/4256.html> (last visited March 30, 2006).

(“ERISA”) which allows workers and their families to continue health coverage for a limited time after the loss of a job or similar event), and ways to recognize the interdependence of family members (as the Special Supplemental Nutrition Program for Women, Infants, and Children (“WIC”) did). The activists who uncovered the community-wide problems arising from industrial pollution provide yet another model for how to think about and bring claims on behalf of larger groups.<sup>120</sup>

*E. Finding Workable Alternatives: Compensating for Bounded Imagination*

Much has been made in organization theory of the limited capacities of human beings to process information. People must satisfice rather than optimize because they are only boundedly rational and are unable to consider fully very many alternatives.<sup>121</sup> Yet people also have rather limited capacities to imagine alternatives to the one that exists or that they have chosen and not much capacity to imagine the perspective of others. In short, people are only boundedly imaginative. The contrast between bounded rationality and bounded imagination is a contrast between a limited capacity to consider simultaneously a large number of alternatives and a limited capacity to think of and, even less, to flesh out, more than one. While organization theorists are pointing to the limited number of alternatives we can compare, I am pointing to our inability to make anything but shallow comparisons when any alternative to the status quo or the selected option is abstract or undeveloped.

Our limited capacity to envision alternative plans or alternative social arrangements is an important impediment to responsible and responsive health care. One could argue that it is this problem of bounded imagination that is at the heart of the critiques by critical legal studies and standpoint theory.<sup>122</sup> In each case, scholars are correctly pointing out the importance and difficulty of seeing social life or legal arrangements from the perspective of some group other

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120. See, e.g., Phil Brown, *Popular Epidemiology: Community Response to Toxic Waste-Induced Disease in Woburn, Massachusetts*, 12 SCI. TECH. & HUM. VALUES 78, 78 (1987).

121. JAMES G. MARCH & HERBERT A. SIMON, ORGANIZATIONS 140-41 (1958).

122. See generally THE FEMINIST STANDPOINT THEORY READER: INTELLECTUAL AND POLITICAL CONTROVERSIES (Sandra Harding ed., 2004); Critical Legal Studies Symposium, 36 STAN. L. REV. 1 (1984); Peter Fitzpatrick & Alan Hunt, *Critical Legal Studies: Introduction*, 14 J.L. & SOC. 1 (1987); Martin Krygier, *Critical Legal Studies and Social Theory—A Response to Alan Hunt*, 7 OXFORD J. LEGAL STUD. 26 (1987); Kim Lane Scheppele, *Legal Theory and Social Theory*, 20 ANN. REV. SOC. 383, 390-91 (1994).

than their own and demonstrating how limited our capacity is to do this. Martha Minow has suggested that, in “a world constructed with some groups, but not others, in mind,” those who are excluded because the activities were not designed with them in mind “seem not to fit because of something in their own nature.”<sup>123</sup> Minow then goes on to argue that the legal system has similarly been designed to take account of the interests and needs of only a limited group of people, illustrating her argument with such examples as housing arrangements for the mentally handicapped, parental leave policies, affirmative action policies, family law and children’s rights, and bilingual education.<sup>124</sup> Many of these dilemmas would look quite different had the law not been framed to take account only of the situation of the dominant group.<sup>125</sup> Although such narrowly conceived policies may responsibly solve the problems of the group on whose behalf they were originally formulated, they often impede responsible decisionmaking about other groups or about relations among groups. Similar problems pervade medicine. Focused on a Hmong family and their epileptic daughter, Anne Fadiman’s book, *The Spirit Catches You and You Fall Down*, vividly illustrates how American health care can fail immigrant groups if their understandings of sickness and health are radically different than those of their caregivers.<sup>126</sup> Clearly, we need ways for rules and laws to take account of people who are radically different, including those who are different in how they think about and understand medical problems.

The problem here is that, when an activity or rule is organized around the needs and interests of one group, the needs and interests of other groups receive short shrift. While the many details of the circumstances of the “included” group are considered as the activity or rule is carefully crafted, other groups are, at best, shadows of themselves, unable to give details, make objections, or propose alternatives. Under such circumstances, any alternative ways of designing the rule or activity are, at most, “stylized” alternatives, because they are organized around stereotyped understandings of nonincluded groups. Nel Noddings argues that working out an ethical position requires “a process of concretization that is the inverse of abstraction,” where facts and personal histories

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123. MARTHA MINOW, MAKING ALL THE DIFFERENCE: INCLUSION, EXCLUSION, AND AMERICAN LAW 20-21 (1990).

124. *Id.* at 20-23.

125. *Id.* at 56-60.

126. *See generally* ANNE FADIMAN, THE SPIRIT CATCHES YOU AND YOU FALL DOWN: A HMONG CHILD, HER AMERICAN DOCTORS, AND THE COLLISION OF TWO CULTURES (1997).

supplement consideration of general principles.<sup>127</sup>

How, then, might we design rule systems to require people to confront and solve the problem of bounded imagination? We can get some ideas about at least one way to induce consideration of alternatives by examining American environmental law, which is, of course, a deeply medical matter as well as a conservationist matter.<sup>128</sup> A variety of standards has been introduced in environmental regulation to encourage innovation and continuous improvement. For instance, the requirement that industries use the best available technology (“BAT”) or best available practice (“BAP”) can, in some instances, lead to a ratcheting upward of standards. A key component of a system of continuous improvement is a mechanism that ensures that organizations do not get fully locked into “business as usual.” Just as one data point is far superior to none, so one comparison point to the one considered for a decision is far superior to none. A practical adaptation to regulatory risk and the regulatory cost of continuous innovation that still addresses the human incapacity to imagine alternatives, then, is an insistence that an organization consider at least one or a small number of alternatives. It is better still if these alternatives build in attention to how other groups, not usually taken account of in the organization’s decisionmaking, might view the alternatives. Serge Taylor and Wendy Espeland both suggest that this is exactly the accomplishment of the environmental impact statement (“EIS”) required by the National Environmental Policy Act (“NEPA”).<sup>129</sup> Because NEPA rules require full consideration of the next-best alternative, engineers are forced to flesh out plans that otherwise would be rejected out of hand, sometimes making surprising discoveries.<sup>130</sup>

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127. NEL NODDINGS, *CARING: A FEMININE APPROACH TO ETHICS & MORAL EDUCATION* 36 (2d ed. 2003).

128. *See generally* JOHN BRAITHWAITE & PETER DRAHOS, *GLOBAL BUSINESS REGULATION* 256-96 (2000) (describing the state of international environmental regulation); NEIL GUNNINGHAM ET AL., *SMART REGULATION: DESIGNING ENVIRONMENTAL POLICY* (1998) (considering alternative incentive systems and evaluating their success in inducing mitigation of environmental harm).

129. WENDY NELSON ESPELAND, *THE STRUGGLE FOR WATER: POLITICS, RATIONALITY, AND IDENTITY IN THE AMERICAN SOUTHWEST* *passim* (1998) (discussing environmental impact statements as a tool used by the Yavapai to force Bureau of Reclamation engineers to consider alternatives to the Orme Dam); SERGE TAYLOR, *MAKING BUREAUCRACIES THINK: THE ENVIRONMENTAL IMPACT STATEMENT STRATEGY OF ADMINISTRATIVE REFORM 77-80* (1984) (arguing that the chief accomplishment of environmental impact statements is to induce careful consideration of alternatives in situations where bureaucrats have a preexisting and preferred course of action).

130. TAYLOR, *supra* note 129, at 77-80.

I have argued here that bounded imagination is a general problem that keeps people from receiving care that meets their needs, particularly when their needs are unusual. This is about cultural sensitivity, to be sure, but also about, for example, economic inequality, different preferences about end of life care, how much pain people should tolerate, and how much should be done to make people look or act “normal.” A reconfigured health law should encourage, or in some cases require, better understanding of diverse needs and wants and help caregivers figure out whether, when, and how to respond to them. Bounded imagination decreases our capacity to formulate rules and regulations that take account of diverse interests and perspectives, but it also cripples us in our attempts to apply rules in a truly fair way. Mechanisms that force a full consideration of at least one alternative, as the EIS does, or that enhance opportunities for people to insist on the consideration of other points of view will reduce the effects of bounded imagination.

Although they work in quite a different way than the EIS, informed consent procedures serve some of the same functions of providing an opening for patients and families to insist that health care providers consider other alternatives and take their perspectives seriously. Most scholars argue that informed consent procedures are at best a partial solution,<sup>131</sup> primarily useful to well-educated people who have done their “homework” and are prepared to be assertive. Although many medical associations have shown the same sort of resistance to informed consent<sup>132</sup> as engineers did to environmental impact statements, even a relatively weak mechanism can lead to significant changes. For example, although

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131. See RENEE R. ANSPACH, *DECIDING WHO LIVES: FATEFUL CHOICES IN THE INTENSIVE-CARE NURSERY* 36-37 *passim* (1993) (arguing that consent procedures do not produce full, informed consent); DAVID J. ROTHMAN, *STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING* 127-47 (1991) (arguing that informed consent is important because patients and doctors are no longer part of the same social world); Heimer, *supra* note 57, at 163-65 (claiming that consent procedures do not ensure that families are fully informed); Peter H. Schuck, *Rethinking Informed Consent*, 103 *YALE L.J.* 899, 921-22 (1994) (claiming that doctors lack sufficient information on patients' interests and thus cannot fulfill their fiduciary obligations to their patients).

132. See JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 23-25 (1984) (criticizing the lack of specific guidelines as to what disclosures are required in order to secure informed consent); Alan Meisel & Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 *U. PITT. L. REV.* 407, 467-68 (1980) (arguing that organized medicine views informed consent as simply a legal hurdle); Schuck, *supra* note 131, at 902-05 (arguing that most, but not all, medical groups have taken a defensive stance on informed consent).

the vast majority of physicians once felt no obligation to inform patients of a cancer diagnosis, the vast majority now feel compelled to share bad news forthrightly with patients. The secrecy and paternalism of the “culture of the ward” has, to some degree, been supplanted by the “culture of rights,”<sup>133</sup> almost certainly with the result that health care providers consider a wider range of treatments and are more likely to give full consideration to those especially favored by their patients, even when patients come from religious or ethnic subcultures.<sup>134</sup> When the bounded imaginations of physicians are to even a small degree unbounded by forced consideration of alternatives, the result will be more responsible health care.

#### V. CONCLUSION: THE ROLE OF LAW IN A “LEGALIZED” ENVIRONMENT

In outlining a series of aspirations for a reconfigured health law, I have argued that we need to remain mindful that contemporary American health care is a highly “legalized” environment in which there are rules about everything. Health law must, therefore, work hand in hand with other kinds of rules—clinical practice guidelines, protocols, regulations, organizational policies, and the like. In this morass of prescriptive statements, it is sometimes hard to discern which rules have the force of law, at one extreme, and which are merely suggestions, at the other. To make matters still more complex, rules intended to be applied flexibly may become increasingly rigid over time as they come to serve as a foundation upon which an edifice of other rules is constructed. The objective of this Article, then, is to refocus on what we might hope health law would achieve in this kind of legalized environment.

The aspirations articulated in this Article focus on ways of designing and supporting a legal system, broadly conceived, that attends to the updating of the laws and rules so that they remain consistent with evolving understandings of the empirical world, the balance of universal and particular in the application of laws and rules, the moral competence of key professionals, the balance between individual and collective interests, and adjustments to take account of diversity among individuals and groups. In thinking about each of these aspirations, I have hinted that law and legal

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133. ZUSSMAN, *supra* note 9, at 85-90.

134. See generally FRED M. FROHOCK, HEALING POWERS: ALTERNATIVE MEDICINE, SPIRITUAL COMMUNITIES, AND THE STATE (1992) (providing a good portrait of how the medical system might look to those with spiritually-based objections to many contemporary medical practices and how hard it is to get health care providers to understand the perspective of such groups).

actors can make an important and distinctive contribution. This concluding section draws together these hints and compares the contributions of law to achieving these five aspirations for reconfiguring health law.

What, then, is the distinctive contribution of law and legal actors? Interestingly, it is anything but uniform, sometimes requiring modesty and a decreased role for legal actors and in other cases requiring more engagement and visibility. In arguing for the importance of updating laws and rules, I have suggested that other rule systems have the edge on formal law. Many of the features required in a set of rules that are intended to be firm and durable—in the extreme, to apply to all and for all of eternity—are not helpful when rules need to change relatively quickly. In this situation, rather than formalizing the rules as law, what is required is that law add its weight to support the current rules and to quickly recognize their revision. What we want is a division of labor in which, on the one hand, standards of care are free to evolve as clinical trials yield new information about how to treat disease and, on the other hand, legislatures and courts insist that professional bodies and medical organizations employ sound procedures in crafting and promulgating guidelines and that professionals attend to these standards as they care for their patients. The job of law, then, is not to write the detailed rules. Rather, the job of legal actors is to recognize and support the expertise of others. In effect, this is a delegation of some parts of the legislative function. Thus, it is a double or reinstitutionalization, in Bohanan's terms, but also a scaling back in which the job of legal actors is to tell others modestly that they are the experts who have to write the rules and, moreover, that law has little or nothing to add.

In examining how law and other rules are applied, I have argued that we should look for a radical particularism in which variability in circumstances is acknowledged and people are expected to modify their behavior to take account of those variations. This variability both lessens and increases constraint. On the one hand, people are not expected to adhere to the letter of the law when it does not apply to their situation; on the other hand, they are charged with the obligation to figure out how to modify what they do to achieve the purpose of the law. What is called for, then, is an institutionalization of principles and delegation of decisionmaking to bodies with knowledge of local variability. This may require a deinstitutionalization of detailed rules and more explicit consideration of the circumstances in which discretion is required. We do not want ambulances to have to stop for red lights. The point is not that detailed rules will not sometimes be appropriate, but that legal actors must retreat from a hegemonic,

“father knows best” approach and instead empower local practitioners to use their expertise in making sensible adjustments. The special role of the law here should be in helping to create and protect a space for the sort of particularism that attempts to achieve the objectives of law by responsibly adapting details to fit local conditions.

This kind of fine tuning requires moral competence, however. Before we can empower legal or medical actors to make judgment calls about when to follow a rule exactly and when a modified course of action is called for, we need to be confident that they will act with the good sense that comes from careful and thorough training but also with the good will that we expect to be part and parcel of professionalism. What special role can the law play here? In our current system, moral competence is, for the most part, taught and assessed locally, a custom that creates system-wide problems when those judged morally unfit—prone to “normative errors” in Bosk’s terms—are shifted from one arena to another rather than being prohibited altogether from practicing. In extreme cases, professionals are brought before boards, which operate as state agencies that can discipline them.<sup>135</sup> If, as I suggest above, professionals must come to see themselves as fatefully linked to one another—that they are “hostages of each other,” to use Rees’ phrase, or part of a “community of fate,” to use my own—, they have incentives to control each other’s behavior lest they all lose in the court of public opinion. When they believe themselves to rise and fall together, professionals have several choices. They can either try to suppress information about their colleagues’ errors and improprieties, or they can try to prevent errors and improprieties. The special role of law should be to nudge professionals in the latter direction by facilitating the wide sharing of information about normative error, malfeasance, irresponsibility, and moral turpitude. The boundaries of organizations, municipalities, or states should not be allowed to contain information about moral incompetence when the professionals themselves are allowed easily to pass through those boundaries. Professional certifications are regularly checked by employing hospitals but, perhaps, not by smaller entities that might employ physicians or other health care workers.

There is also a problem, of course, about the ultimate purpose of all of this legal activity, about who is the intended beneficiary of all of this regulatory activity. Much regulatory activity seems designed to satisfy insurers, rather than to improve the health of patients, for example. Here the trouble is about balancing individual and

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135. See, e.g., BARRY R. FURROW ET AL., *THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE* 50-87 (5th ed. 2004).

collective interests. If health care is conceived more as a good to be bought and sold in a market than as a good to which all should have access as a matter of human rights, then a government will offer few and restricted opportunities for “free” health care. Under these conditions, a disproportionate share of regulatory activity will be focused on assessing eligibility and finding reasons to prevent people from using services. Moreover, in a highly fragmented system, ambiguities about which body should foot the bill result in a good deal of squabbling between private insurers, public programs, states, the federal government, and patients. The chief contribution of law here would be to support the creation of a basic right to health care, a move that would shift the orientation of the entire system in the direction of greater collectivism and reduce the incentive for each part of the system to offload responsibilities. There are ample models to build on here, including constitutionally established rights to health care, mandated insurance or other payment programs, and preexisting agreements about how to divide costs among insurers or other payers. Although constitutionally established rights to healthcare are admittedly often vacuous in poor countries, even there, such rights settle basic questions about equal access to the very limited resources and prevent waste on eligibility work.

Basic rights to health care do not mean that we should aim for a one-size-fits-all system. At the core of our rules on informed consent is an acknowledgement that health care workers cannot assume that they know what others would want and so cannot substitute their judgment for that of their patients. To this point, we have worried about substituted judgment at an individual level, with considerable agreement that health care workers may not make decisions without consulting patients and family members, when patients are not themselves competent to articulate preferences. Conflict has been concentrated on questions about which family members or other representatives have the right to participate in decisionmaking.

For the most part, however, we have not extended these concerns about substituted judgment beyond individual level decisions. What kind of extensions might be desirable, and what role might law play in supporting these extensions? Two extensions come to mind, one enlarging the group whose welfare and preferences are considered and the other extending the range of decisions about which affected parties are consulted. Because these matters have come before the court, we know that some societal subgroups, such as Jehovah’s Witnesses and Christian Scientists, have distinctive views on health care. We also know that there are variations in what people need, with more demand for reproductive

services in late adolescence and young adulthood, for example, and more interest in management of chronic diseases later in life. Furthermore, there is growing evidence that, however good-willed they are, health care workers treat African Americans and Hispanics differently, offering less aggressive therapies, for instance, than would be offered to whites.<sup>136</sup> All of this evidence that people, as individuals and as groups, are differently situated, have different needs, interests, and preferences, and receive care that differs in amount, kind, and quality, suggests a need for regular assessment of how well health care systems serve diverse groups and perhaps formal mechanisms for consulting groups as well as individuals. As a first step, we might borrow mechanisms from the EIS<sup>137</sup> to show impacts on various stakeholders or add outcome measures for key social groups to uncover evidence about where our health care arrangements seem to work less well for some groups than for others. Many of the big advances in increasing access to health care—for example, ending gross racial discrimination in the South—have come about because access to federal funds was denied to those entities whose policies and practices were overtly discriminatory. Those same purse strings can be used again to increase sensitivity to more subtle, but routine, forms of discrimination.

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136. See, e.g., G. Caleb Alexander & Ashwini R. Sehgal, *Barriers to Cadaveric Renal Transplantation Among Blacks, Women, and the Poor*, 280 JAMA 1148, 1148 (1998); Peter B. Bach et al., *Racial Differences in the Treatment of Early-Stage Lung Cancer*, 341 NEW ENG. J. MED. 1198, 1198 (1999); Eric D. Peterson et al., *Racial Variation in the Use of Coronary-Revascularization Procedures: Are the Differences Real? Do They Matter?*, 336 NEW ENG. J. MED. 480, 480 (1997). See generally COMM. ON UNDERSTANDING & ELIMINATING RACIAL & ETHNIC DISPARITIES IN HEALTH CARE, BD. ON HEALTH SCI. POLICY, INSTITUTE OF MEDICINE, *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* 160-79 (2003); Council on Ethical and Judicial Affairs, *Black-White Disparities in Health Care*, 263 JAMA 2344 (1990).

137. See *supra* note 129 and accompanying text.