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Professional Power and the Standard of Care in Medicine

Maxwell J. Mehlman

Case Western University School of Law, maxwell.mehlman@case.edu

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Maxwell J. Mehlman

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PROFESSIONAL POWER AND THE STANDARD OF CARE IN MEDICINE

Maxwell J. Mehlman^{*}

INTRODUCTION

Since before the founding of the Republic, American medicine¹ has been fighting a war to control the standard of care that physicians are expected to provide to their patients. It has waged battles on two fronts: against internal disagreements within the profession over what constitutes proper care, and against attempts to delineate the standard of care by forces outside the profession, such as private health insurers, the government, and the judicial system.²

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1. “American medicine” is a deliberately broad term. It refers primarily to organized medical groups that represent the views of their members in the political process, such as the American Medical Association and the National Medical Association, state and local medical associations, and specialty practice groups such as the American College of Physicians, the American Academy of Pediatrics, and the American Society of Clinical Oncology. The term also includes individual physicians. Given the supremacy of physicians in the hierarchy of the profession, the focus of this article is on physicians, rather than on other medical professionals such as nurses, physician assistants and other “physician extenders,” and non-physician medical researchers.

2. American medicine also has sought to combat other forms of external control. One battle has been against efforts to promote competition among health professionals. Physicians have long sought to prevent competition from non-physician rivals such as chiropractors, nurses, and physician assistants, whose ability to compete has been constrained by preventing them from working in hospitals, and by using licensure laws to limit the types of care that they are allowed to provide (their “scope of practice”). See Barbara J. Safriet, *Closing the Gap Between Can and May in Health-Care Providers’ Scopes of Practice: A Primer for Policymakers*, 19 *YALE J. ON REG.* 301, 303 (2002). Physicians also have sought to limit competition within the profession itself. These efforts have included restrictions on advertising and other forms of patient solicitation, along with conflicts between specialists and general practitioners, such as an attempt by the 47,000-member American College of Surgeons in the late 1970s to prevent the 59,000 members of the American Academy of Family Physicians from providing postsurgical care. See *Koefoot v. Am. Coll. of Surgeons*, 652 F. Supp. 882, 888–89 (N.D. Ill. 1986) (upholding the surgeons’ contention that the itinerant surgery rule is a legitimate ethical canon); *RICHARD L. ABEL, AMERICAN LAWYERS* 28 (1989). Prior to the Supreme Court’s decision in *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975), antitrust

In the early 1990s, forces within American medicine mounted an unprecedented attack on both fronts.³ They pushed for laws permitting designated professional medical associations to articulate “medical practice guidelines” that would define the standard of care and, more importantly, would serve as “safe harbors” so that physicians who demonstrated that they had complied with the guidelines would be protected from malpractice liability.⁴ If the drive had been successful, medicine would have achieved its twin ambitions simultaneously; it would have resolved uncertainty about the standard of care and, at the same time, secured the ability to set its own standards without interference by outside forces concerned that the standards might be economically unrealistic, self-servingly lax, or applicable only to a small number of cases. For a time it looked like the effort would succeed: several state legislatures enacted the proposal into law, Congress considered adopting it for the entire nation, and President

scrutiny of the medical profession was discouraged by the perception that the ability of organized medicine to restrict competition was limited by its largely local character, and by the similarity between the practice of medicine and the practice of law, which also claimed an exemption from the antitrust laws as a “learned profession.” See Carl F. Ameringer, *Organized Medicine on Trial: The Federal Trade Commission vs. the American Medical Association*, 12 J. POL’Y HIST. 445, 451 (2000); Robert Steinbuch, *Why Doctors Shouldn’t Practice Law: The American Medical Association’s Misdiagnosis of Physician Non-Compete Clauses*, 74 MO. L. REV. 1051, 1070 (2009). While *Goldfarb* addressed anticompetitive behavior by the bar, its rejection of the learned professions exemption ushered in a period of vigorous antitrust enforcement by the Federal Trade Commission against organized medicine, culminating in the commission’s attack on the American Medical Association in 1975. Ameringer, *supra* at 445.

Another fight waged by the medical profession has been against control of physicians by nonprofessional organizations. Originally, this took the form of efforts to prevent the formation of corporations offering medical services. In the early part of the twentieth century, the AMA was able to persuade state legislatures to adopt so-called “corporate practice of medicine laws” to forbid this. See John D. Blum, *Feng Shui and the Restructuring of the Hospital Corporation: A Call for Change in the Face of the Medical Error Epidemic*, 14 HEALTH MATRIX 5, 8 (2004). By the end of the century, most states were ignoring the laws, had repealed them, or had enacted laws enabling managed care plans to structure themselves as corporations. *Id.* at 9 (noting the “demise of the corporate practice of medicine”); Jeffrey F. Chase-Lubitz, *The Corporate Practice of Medicine Doctrine: An Anachronism in The Modern Health Care Industry*, 40 VAND. L. REV. 445, 478 (1987) (noting the “demise of the corporate practice of medicine doctrine”); Edward B. Hirshfeld & Gail H. Thomason, *Medical Necessity Determinations: The Need for A New Legal Structure*, 6 HEALTH MATRIX 3, 47 (1996) (“While the majority of states retain a bar on the corporate practice of medicine, corporate interests have managed to either find a way around, through, or ignored the intent behind the corporate bar.”). The advent of large private and governmental health insurance programs and their attempts to rein in costs ultimately defeated efforts by organized medicine to resist external controls over physician behavior.

3. See *infra* Part II and accompanying notes.

4. See *infra* Part II and accompanying notes.

Clinton endorsed the approach when he was running for office and included pilot programs in his 1993 health reform plan.⁵

By mid-decade, however, medicine's campaign was in tatters. Guidelines defining the legal standard of care were never promulgated or, for reasons that will be discussed later, proved incapable of insulating physicians from liability.⁶ Guideline development seemed to have come no further than it had at the beginning of the decade, when the prestigious Institute of Medicine of the National Academies of Science, the bastion of academic medicine,⁷ had derided the guideline effort as "a confusing mix of high expectations, competing organizations, conflicting philosophies, and ill-defined or incompatible objectives," and added that the guidelines initiative "suffers from imperfect and incomplete scientific knowledge as well as imperfect and uneven means of applying that knowledge."⁸ Even the American Medical Association (AMA) ended up withholding its support from the safe harbors projects.⁹

With encouragement from the Obama administration, however, the notion that medical practice guidelines can serve as "safe harbors" to insulate physicians from malpractice liability has once again resurfaced.¹⁰ Its champions sally forth, this time convinced that improved, "evidence-based" medical practice guidelines will be able to overcome the obstacles that prevented their earlier success.¹¹

This article explains why the renewed attack is doomed once again to defeat. It begins by describing the historical power struggle waged by

5. See Andrew L. Hyams, David W. Shapiro & Troyen A. Brennan, *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & L. 289, 308–10 (1996); see also *infra* note 152 and accompanying text.

6. See *infra* discussion accompanying notes 164–65.

7. See David E. Winickoff, *Bioethics and Stem Cell Banking in California*, 21 BERKELEY TECH. L.J. 1067, 1076 n.37 (2006) ("IOM is the pre-eminent academic society of health professionals, established in 1970 'to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health and [sic] the public.'") (quoting NATIONAL RESEARCH COUNCIL, *ET AL.*, GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH iii (2005)).

8. COMM. TO ADVISE THE PUB. HEALTH SERV. ON CLINICAL PRACTICE GUIDELINES, INST. OF MED., CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 15 (Marilyn J. Field & Kathleen N. Lohr eds., 1990) [hereinafter IOM 1990 REPORT].

9. See Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. 327, 343 (2001) (noting that AMA attorney Edward Hirshfeld believed that "the American Medical Association opposes, for the present at least, direct adoption of CPGs [clinical practice guidelines] as a legal standard and urges instead that they be used only as evidence of the customarily observed professional standard of practice and that their degree of authority be dependent upon the degree of their acceptance among medical practitioners.").

10. See *infra* Part III and accompanying notes.

11. See *infra* Part III and accompanying notes.

medicine over control of the standard of care. The article then describes the safe harbors concept and its historical background. Next, the article critically analyzes the safe harbors approach and explains its scientific weaknesses. The article then places the safe harbors concept in the context of medicine's historic power struggles. It concludes by defining the appropriate role for practice guidelines in malpractice disputes.

I. MEDICINE'S HISTORICAL QUEST FOR POWER

The self-regulatory powers of the professions date back to the Middle Ages, when merchants, and later craftsmen, established guilds to attain market power, which enabled them to limit outside competition, control entry, and maintain quality standards.¹² "Scholars' guilds" that included physicians and lawyers emerged beginning in the twelfth century and formed the core of what would become universities.¹³ Lawyers and doctors eventually split off from the universities in the late Middle Ages and early Renaissance to form their own guilds.¹⁴

As sociologist Elliott Krause observes, physicians "tended to come from lower social origins than lawyers. . . . And because the work of doctors inevitably involved handwork, their guild was not far removed from a regular craft organization."¹⁵ By the eighteenth century, physicians in England therefore sought to elevate their social status by creating two distinct medical guilds, one for physicians—"gentlemen . . . [who] declined to work with their hands and only observed, speculated, and prescribed"¹⁶—and the other for surgeons, the ones who did the dirty work, so to speak, and who until 1745 belonged to the same guild as barbers.¹⁷ The American colonies rejected the guild system, however, and physicians and surgeons reunited into one medical profession.¹⁸ It was this unified profession that began campaigning for control over its standard of care.

12. See generally ELLIOTT A. KRAUSE, DEATH OF THE GUILDS: PROFESSIONS, STATES, AND THE ADVANCE OF CAPITALISM, 1930 TO THE PRESENT 3–4 (1996) (explaining the organization and purpose of guilds).

13. See *id.* at 9.

14. See *id.* at 11.

15. See *id.* at 12. Krause explains that physicians were able to maintain their elite professional status in Europe because of their university background, whereas in England, nonprofessional university faculties expelled or "suppressed" their professional colleagues. *Id.* at 12–13.

16. PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 37–38 (1982).

17. *Id.* at 38. They were eventually joined by apothecaries, who obtained the right after 1703 to attend patients and prescribe and compound drugs, but not to provide medical advice.

18. See *id.* at 39.

A. *The Internal Struggle Over the Standard of Care*

In seeking to control its standard of care, American medicine has had to contend with forces both inside and outside the profession. Disputes within the profession have revolved around whether there is a single, correct overall approach to patient care, or instead, a number of correct approaches.¹⁹ Disagreement was especially acrimonious during the nineteenth century, when “irregulars” such as homeopaths and osteopaths sought to gain supremacy, or at least hold their own, against “regulars,” those who at the beginning of the nineteenth century adhered to “orthodox” or “mainstream” views²⁰ and who by the end of the century had adopted what has become known as the modern scientific medical approach.

The effort by American medicine to define the standard of care within the profession began with licensure.²¹ Interest in licensing laws grew in the eighteenth century, spurred on by the desire of colonial doctors to attain the same social status as their European counterparts.²² The first licensure law

19. A related set of disputes has concerned whether there is a single standard of care, the standard of care of the physician, or multiple standards associated with different types of health care professionals, such as nurses and physician assistants. As part of their effort to avoid competition from non-physician caregivers, physicians have sought to restrict medical practice to physicians by opposing the licensing of non-physicians. When this effort has proven unsuccessful, physicians have attempted to limit the types of care that non-physicians can provide, such as by preventing physician assistants from prescribing drugs. Another approach has been to hold non-physicians to a physician’s standard of care. This can be done directly, such as when medical students providing patient care are held to the standard of care of a physician on the theory that they are supposed to be supervised by a physician, or indirectly, such as when physicians are permitted to testify as experts in negligence cases against non-physicians. See generally, Phyllis Coleman & Ronald A. Shellow, *Extending Physician’s Standard of Care to Non-Physician Prescribers: The Rx for Protecting Patients*, 35 IDAHO L. REV. 37 (1998) (providing an overview of malpractice standards and arguments for and against non-physician prescribers).

20. In the early nineteenth century, orthodox practitioners emulated Dr. Benjamin Rush, a signer of the Declaration of Independence. Rush and his disciples advocated three principal remedies for whatever ailed the patient: phlebotomy or bleeding, the use of purgatives, and blistering. See ANN ANDERSON, *SNAKE OIL, HUSTLERS AND HAMBONES: THE AMERICAN MEDICINE SHOW* 22 (2000).

21. For description of the history of medical licensure, see Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?* 37 ARIZ. L. REV. 825, 827–28 (1995); Chase-Lubitz, *supra* note 2, at 450–56.

22. See STARR, *supra* note 16, at 39 (noting that colonial physicians returned from studying abroad with “the ambition to create in America a profession with the standards and dignity that physicians in Europe possessed.”). The first law regulating physician behavior, specifically the collection of physician fees, was passed in Virginia in 1639. The Virginia law also regulated vaccination, quarantine, and isolation hospitals. See Glenn E. Bradford & David G. Meyers, *The Legal and Regulatory Climate in the State of Missouri for Complementary and Alternative Medicine - Honest Disagreement Among Competent Physicians or Medical McCarthyism?*, 70 UMKC L. REV. 55, 60 (2001).

was enacted by the City of New York in 1760, but when physicians began forming medical societies, beginning in New Jersey in 1766,²³ they persuaded state legislatures to vest the power to license in these professional associations.²⁴ These medical licensure laws were weak, however. Kenneth De Ville explains this in his landmark study of nineteenth century medical malpractice:

Many of the statutes did not forbid unlicensed practice but merely provided certificates of legitimacy to “qualified” doctors. In some states unlicensed physicians were only prohibited from suing in court for unpaid fees. Unlicensed physicians in these jurisdictions could mitigate this handicap by requiring payment in advance. Even in states where licensure laws provided penalties for unsanctioned practice, juries generally would not convict violators.²⁵

Additionally, a diploma from a medical school served as a license.²⁶

The weak medical licensure laws enacted in this initial wave might have morphed into stricter strictures over time, but they fell prey to the anti-professional, anti-government sentiment that gripped the nation in the first half of the nineteenth century. These feelings were stoked by Andrew Jackson’s election as President in 1829, which ushered in an attack on elites, especially the “eastern elites,” including the professions of medicine and law.²⁷ The Jacksonians were joined by the followers of Samuel Thomson, a New Hampshire farmer-turned-physician who gained a following by declaring that illness resulted from physical imbalances in earth, water, fire, and air,²⁸ and that anybody who followed his teachings (and paid him a franchise fee) could be a healer. The Jacksonians opposed licensure on the ground that the laws merely created professional monopolies;²⁹ “[w]hat fundamentally destroyed licensure,” states Paul Starr, “was the suspicion that it was an expression of favor rather than competence.”³⁰ The Thomsonians objected that licensure impermissibly

23. See STARR, *supra* note 16, at 40.

24. *Id.* at 44.

25. KENNETH ALLEN DE VILLE, *MEDICAL MALPRACTICE IN NINETEENTH-CENTURY AMERICA: ORIGINS AND LEGACY* 85–86 (1990) (footnote omitted).

26. See STARR, *supra* note 16, at 44.

27. See WILLIAM M. SULLIVAN, *WORK AND INTEGRITY: THE CRISIS AND PROMISE OF PROFESSIONALISM IN AMERICA* 73 (2d ed. 2005); James C. Mohr, *American Medical Malpractice Litigation in Historical Perspective*, 283 *JAMA* 1731, 1732 (2000).

28. See DE VILLE, *supra* note 25, at 79.

29. See KRAUSE, *supra* note 12, at 30.

30. STARR, *supra* note 16, at 58. Theodore Ruger relates how “Pennsylvania never enacted regular licensure legislation because in 1824 the governor vetoed the plan, writing in his veto

interfered with individual liberty. One Boston newspaper proclaimed, for example, that “[a]ny man in the United States has not only a natural right, but a constitutional right to employ at pleasure, any person to administer medicine to himself or family; and any man has a natural and constitutional right to administer, when requested, such medicine as he judges best to cure the sick”³¹ The effect of these twin assaults was that juries refused to convict persons accused of violating the licensure laws,³² and state legislatures repealed them.³³ By 1840, none of the laws remained on the books.³⁴

Around mid-century, however, the picture started to change as the “regular” medical professionals began to assert power over their rivals. In 1847 they established the American Medical Association,³⁵ which began lobbying state legislatures to reenact licensure laws.³⁶ Steadily, the states did so; by the early part of the twentieth century, Mohr explains, “the so-

message that ‘the provisions of this bill seem to interfere with the undoubted right of our citizens, secured by the constitution and laws, to . . . employ[] the person, who, in [their] opinion, may be best qualified to afford relief to [their] sufferings.’” Theodore W. Ruger, *Plural Constitutionalism and the Pathologies of American Health Care*, 120 YALE L.J. ONLINE 347, 355 (2011) (quoting Governor John Andrew Shulze, *Veto Message* (Dec. 8, 1824), reprinted in PENNSYLVANIA ARCHIVES, PAPERS OF THE GOVERNORS 1817–1832, 543 (4th ser. 1900)).

31. *An Attempt To Infringe upon the Constitution of the United States Defeated: Or Real Republicanism*, MEDICAL NEWS-PAPER; OR THE DOCTOR AND THE PHYSICIAN (Boston), Feb. 15, 1824, at 1, quoted in Ruger, *supra* note 30, at 355.

32. See STARR, *supra* note 16, at 58, quoting the president of the New York Medical Society as stating in 1837 that “in trials for unlicensed practice, the testimony of physicians as prosecution witnesses was ‘received with suspicion and disfavor by juries,’ making laws against irregular practitioners ‘almost a dead letter.’”

33. See *id.*

34. As James Mohr observes, “the separate states made a virtue of opening the professions to any and all practitioners who could persuade fellow citizens to employ their services Consequently, by 1840, the entire United States had become a place where each profession had to shift for itself, and so did each individual professional. Physicians found themselves adrift as competitive agents, hustling for business in a market that included a wide spectrum of alternative and often antagonistic healers, trained and untrained, ranging typically from the woman down the lane who grew a few herbs in her garden to surgeons who had apprenticed in European hospitals.” Mohr, *supra* note 27, at 1732. The resulting free-for-all had important implications for the physicians’ risk of malpractice liability. See *infra* text accompanying notes 54–60.

35. See Mohr, *supra* note 27, at 1734. At the beginning of the 20th century, the AMA became a confederation of state and local medical societies. See STARR, *supra* note 16, at 109. As Abel describes, this “added the strength of state and local associations to the peak organization” ABEL, *supra* note 2, at 45. But he points out that it also discouraged antitrust enforcement against the AMA, discussed in note 2, *supra*, despite the fact that some commentators argue that “the AMA’s motives were more driven by notions of economic protectionism than by a good faith interest in the public health and the guarantee of quality medical care.” Bradford & Meyers, *supra* note 22, at 61.

36. See Mohr, *supra* note 27, at 1734.

called regular, science- and education-oriented AMA-type physicians had gained control over perhaps 80% of US medical practice, and by the early decades of the 20th century, they finally succeeded in gaining reasonably effective licensing laws at the state level.”³⁷

This second wave of licensure laws, which remain in force today, has played a major role in defining the standard of care by only permitting regulars to practice as physicians. Homeopaths, whom Starr describes as viewing disease “fundamentally as a matter of spirit,” were discredited and forced out of the practice altogether.³⁸ Osteopaths, who originally maintained that “most, if not all, diseases come from pressure on the nerves caused by vertebra deviating from the normal,”³⁹ threw in the towel and became regulars.⁴⁰ Chiropractors, who differed from osteopaths primarily in believing that illness was caused by problems in the joints rather than in the nerves,⁴¹ contented themselves with providing only limited types of care, typically not including prescribing drugs, treating infectious diseases, or performing surgery.⁴²

At the same time that it was pressing for the reinstatement of medical licensure, the AMA also mounted an effort to reform medical education. Due in part to sectarian strife between rival schools of medical thought and in part to entrepreneurial ambitions, physicians in nineteenth century America established a plethora of medical schools.⁴³ By 1850, Starr reports, there were 42 schools in the United States, compared to 3 in France;⁴⁴ by

37. *Id.* A 1984 study found that “the year a state enacted physician licensing laws was directly related to the number of AMA members in that state.” Bradford & Meyers, *supra* note 22, at 61. The AMA’s effort received important backing from the U.S. Supreme Court in 1889, when the Justices unanimously upheld a conviction under West Virginia’s licensure law for the unlicensed practice of medicine in *Dent v. West Virginia*, 129 U.S. 114, 128 (1889). Jost, *supra* note 21, at 827.

38. See STARR, *supra* note 16, at 96. According to the homeopaths, says Starr, what occurred inside the body did not follow physical laws. The homeopaths had three central doctrines. They maintained first that diseases could be cured by drugs which produced the same symptoms when given to a healthy person. This was the homeopathic “law of similars”—like cures like. Second, the effects of drugs could be heightened by administering them in minute doses. The more diluted the dose, the greater the “dynamic” effect. And third, nearly all diseases were the result of a suppressed itch, or “psora.” *Id.* at 96–97.

39. *Brown v. Shyne*, 151 N.E. 197, 200 (N.Y. 1926) (Crane, J., dissenting).

40. STARR, *supra* note 16, at 108–09.

41. See *id.* at 108.

42. See Richard Duenas, *United States Chiropractic Practice Acts and Institute of Medicine Defined Primary Care Practice*, 1 J. CHIROP. MED. 155, 156 (2002).

43. See STARR, *supra* note 16, at 42.

44. *Id.* The first medical school in the colonies was founded in Philadelphia in 1765. *Id.* at 40. In 1791, it became the medical school at the University of Pennsylvania. ABRAHAM FLEXNER, *MEDICAL EDUCATION IN THE UNITED STATES AND CANADA* 5 (1910) [hereinafter FLEXNER REPORT].

1900, there were more than 150.⁴⁵ Unlike their European counterparts, moreover, American medical schools were not part of universities, and they therefore lacked whatever rigor and legitimacy a university affiliation might have imparted.⁴⁶ Nor was there any system of accreditation.⁴⁷

In 1904, the AMA established a Council on Medical Education, which began agitating for uniform requirements for medical education.⁴⁸ It also began inspecting and evaluating the existing schools, fully approving of just over half.⁴⁹ Starr describes how the results of these reviews were disclosed at an AMA meeting but never made public for fear of the adverse effect on the profession; instead, he explains, the AMA asked the Carnegie Foundation for the Advancement of Teaching to conduct its own investigation, under the leadership of a young educator (though not a physician) named Abraham Flexner.⁵⁰ The resulting exposé, known as the Flexner Report, derided the growth of proprietary medical schools, the lack of rigorous educational standards, and the consequent overproduction of doctors,⁵¹ and urged that the poor schools be closed. Although as Starr points out, a reduction in the number of new physicians would appeal to the AMA because it “greatly enhanced the market position of private physicians,”⁵² Flexner emphasized the need to improve the quality of care: the surplus of doctors, he said, was “something worse than waste, for the superfluous doctor is usually a poor doctor.”⁵³

The AMA’s initiative was soon successful. In 1900, there were 160 medical schools with 25,213 students; by 1919, 75 of the schools had closed and medical school enrollment had dropped to 13,789.⁵⁴ By 1944, the number of schools stood at 69.⁵⁵ The AMA also gradually increased the prerequisites for enrollment.⁵⁶ Finally, state licensing boards adopted and

45. ABEL, *supra* note 2, at 48.

46. See STARR, *supra* note 16, at 40–41.

47. Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX 243, 250 (2004).

48. STARR, *supra* note 16, at 117–18.

49. See *id.*

50. See *id.* at 118. Flexner later helped found the Institute for Advanced Studies at Princeton. See John Stachel, *Heady Days at Princeton*, 445 NATURE 263 (2007).

51. See FLEXNER REPORT, *supra* note 44, at 14. The report decried the fact that, while in small towns in Germany there was one doctor for every 2,000 inhabitants, many towns in the United States with fewer than 200 residents had one.

52. STARR, *supra* note 16, at 120.

53. FLEXNER REPORT, *supra* note 44, at 14.

54. ABEL, *supra* note 2, at 48.

55. Bradford & Meyers, *supra* note 22, at 62.

56. See ABEL, *supra* note 2, at 48. Starr calls the notion that the dominant allopathic profession suppressed the irregulars a “myth,” claiming instead that the allopaths accepted the irregulars at the beginning of the twentieth century, such as by according them membership on

started to enforce educational requirements for physicians. Only applicants who had attended “approved” schools could be licensed, and after 1910, approval came to depend on a school receiving a satisfactory rating from the AMA’s Council on Medical Education.⁵⁷

Through its licensure and educational reform efforts, the medical profession by the early twentieth century had gained effective control not only over entry into the profession, but over the general contours of the standard of care expected of its members.⁵⁸ The upshot, according to William Sullivan, was that “[b]y early in the twentieth century, organized medicine achieved a guildlike monopoly over its sphere of interest.”⁵⁹ The new professionalism provided added benefits. Nicole Huberfeld explained:

The effect was to raise the bar for medical school applicants and entrants, which influenced the quality of students and, thus, the prestige of the medical profession as a whole. This contributed to the perception of physicians that arose in the early 1900s—and that remains today—of the physician as an omniscient healer and autonomous health care provider.⁶⁰

The internal battle over the standard of care, in short, largely had been won.

unitary state medical boards, and that the irregulars either were co-opted into mainstream practice or withered away of their own accord. *See* STARR, *supra* note 16, at 107–08. But Starr’s analysis misunderstands the passive-aggressive nature of co-optation: the destruction of the irregulars by incorporating the new standards for medical education into state licensing requirements was roundabout, but effective nonetheless. It heralded widespread recognition of the validity of the scientific approach to medicine followed by the regulars, which showed the irregulars that they either had to allow themselves to be co-opted, and thus play by these rules, or perish.

57. KENNETH M. LUDMERER, *LEARNING TO HEAL: THE DEVELOPMENT OF AMERICAN MEDICAL EDUCATION* 237 (1985). Ludmerer states that the Association of American Medical Colleges also worked with licensing boards on educational requirements but does not give details. *Id.*

58. “By [that time,]” states Mohr “the so-called regular, science- and education-oriented AMA-type physicians had gained control over perhaps 80% of US medical practice. . . .” Mohr, *supra* note 27, at 1734. Organized medicine also began to assert control over the standards for specialization. Jost states that “[t]he first specialty board, The American Board for Ophthalmic Examinations, was formally created in 1916. Though licensure by specialty was considered briefly in the late 1920s, it was rejected in favor of exclusive control over specialization by self-regulatory specialty boards. The system of private specialty boards that exercised this control was firmly established by the time the Advisory Board for Medical Specialties was formed in 1933.” Jost, *supra* note 21, at 830.

59. SULLIVAN, *supra* note 27, at 56.

60. Huberfeld, *supra* note 47, at 250.

B. *The Struggle Against External Forces*

While mainstream American medicine has engaged in consolidating its power over contending schools of thought within the profession, it has also sought to block efforts by external forces to influence the standard of care. One set of forces consists of public and private health insurers who, beginning in the second half of the twentieth century, have attempted to manipulate the standard of care in order to control their costs.⁶¹ This article focuses on the second major external force, the force of law, specifically, the legal standard of care to which defendants are held in medical malpractice cases.⁶²

Suits for medical malpractice were extremely rare in the new Republic:

Even at a theoretical level, the medicolegal concept of malpractice was so arcane and so unimportant in the United States that American writers on medical jurisprudence, those most likely to be interested in the subject as an aspect of legal medicine, did not bother to mention it through the first 4 decades of the 19th century.⁶³

Mohr adds that “[t]he vast majority of US lawyers would not have known how to draft an action for medical malpractice.”⁶⁴

61. In an effort to curb health care spending, for example, both government and private health insurers have promulgated guidelines on what care is appropriate in particular circumstances. See Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 652–53 (2001) (describing practice guidelines issued by health insurers); Rosoff, *supra* note 9, at 328–30 (describing guidelines issued by managed care plans and private and public health insurers). Mello also describes how medical malpractice insurers use guidelines. Mello, *supra*, at 652–53; see also John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421, 437 (1994) (“[S]ome payers use parameters, indeed develop them, as a method to maximize profits under the guise of reducing inefficient or unnecessary services.”).

62. Medical professionals have long confronted liability for providing substandard care. A 1374 case in which a surgeon was sued for improperly treating a patient’s hand wound was dismissed for using the wrong writ. Y.B. 48 Edw. 3, fol. 6, pl. 11 (1374), *cited in* Allan H. McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549, 550 (1959). Theodore Silver cites a malpractice case decided in 1440. Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 WIS. L. REV. 1193, 1197 n.16 (1992). Mohr notes that “[t]he general concept of professional malpractice was well embedded in English legal theory by the beginning of the 18th century,” and observes that Blackstone’s *Commentaries on the Laws of England*, which were widely read by the American colonists, “included under *mala praxis* (from which we derive the modern word *malpractice*), ‘Injuries . . . by the neglect or unskilful [sic] management of [a person’s] physician, surgeon, or apothecary . . . because it breaks the trust which the party had placed in his physician, and tends to the patient’s destruction.’” Mohr, *supra* note 27, at 1731.

63. Mohr, *supra* note 27, at 1731.

64. *Id.*

Around 1840, the interregnum ended.⁶⁵ Between 1840 and 1860, the number of reported cases increased by 950%.⁶⁶ Scholars attribute this first “malpractice crisis” to a number of factors. One was the elimination of licensing laws during the Jacksonian and Thompsonian period. “From the public’s point of view,” states Mohr, “this opening of the professions left few quality controls in place, good or bad.”⁶⁷ Individual action holding physicians accountable through malpractice suits was the main check that remained, and it resonated with the anti-elitist atmosphere of the time. As De Ville explains, “[l]icensure, in the Jacksonian mind, represented regulation from the top down and appeared to benefit the physician by creating an unfair monopoly and relying on artificial measures of merit. Malpractice suits, however, represented regulation from the bottom up.”⁶⁸ The public also had become disenchanted with orthodox medicine,⁶⁹ which consisted largely of harmful practices such as bleeding, purging, and blistering.⁷⁰ “[W]ith a long tradition of self-cure, home remedy, and folk healing,” writes De Ville, Americans “had little patience with doctors who demanded deference and privilege but offered few cures.”⁷¹ The loss of faith in mainstream medicine was accompanied by a shift in religious faith. De Ville observed:

Many Americans decisively changed their views on divine providence in the first half of the nineteenth century. This transformation allowed individuals to seek earthly causes for their misfortunes, assign blame, and demand compensation. At the same time, a variety of forces combined to make Americans dramatically more concerned with physical well-being and significantly more confident that they could do something about it.⁷²

65. See Allen D. Spiegel & Florence Kavalier, *America’s First Medical Malpractice Crisis, 1835-1865*, 22 J. CMTY. HEALTH 283, 283–84 (1997). The authors identify western New York State as the place where the proliferation of malpractice suits originated, *id.* at 284, but it is not clear why it began there. The most common type of case after 1835 involved errors alleged to have occurred in orthopedic care. *Id.* at 293.

66. Mohr, *supra* note 27, at 1732. Mohr points out that “[t]he population rose about 85% during that period, which suggests that the rate of malpractice suits jumped abruptly by a factor of roughly 10-fold during the middle 2 decades of the 19th century.”

67. *Id.*

68. DE VILLE, *supra* note 25, at 87.

69. *Id.* at 23–24 (“The antistatus, antiprofessional sentiment of the Jacksonian period increasingly turned the lay public against orthodox, trained practitioners.”).

70. See Maxwell J. Mehlman, *Quackery*, 31 AM. J.L. & MED. 349, 350–51 (2005).

71. DE VILLE, *supra* note 25, at 24.

72. *Id.*; see also Mohr, *supra* note 27, at 1732 (“The onset of medical malpractice litigation corresponded with a sharp decline of religious fatalism and a dramatic rise of religious

The medical profession stimulated malpractice suits in other ways than by relying on unsafe and ineffective treatments. Regulars seized upon malpractice liability as a way to curb the practice of irregulars. “In 1827, for example,” describes Mohr, “Nathan Smith, MD, at Yale University had complained to his medical students that the state of Connecticut was far too lax in bringing malpractice indictments. ‘Even the most egregious Quacks escape punishment as things now stand,’ he grumbled, and he hoped for more action on this front.”⁷³ The tactic backfired, however. Mohr adds:

[O]ver and over during the 1840s and 1850s, the nation’s best-educated and most professionally minded physicians observed with a sort of defensive incredulity and disbelieving horror that many, if not most, of the burgeoning numbers of malpractice suits were being lodged not against charlatans and amateur hacks, but against others like themselves, the best-educated and most successful physicians.⁷⁴

Moreover, growing competition led practitioners to encourage patients to bring malpractice suits against practitioners who followed the same doctrinal approach.⁷⁵ Physicians brought liability down on their heads less directly as well. Advances in medical science created unrealistic expectations among patients,⁷⁶ which practitioners fueled with self-promotion.⁷⁷ Ironically, the regulars’ success in seizing control of the

perfectionism, both of which were associated with the revivals of the 1820s and 1830s. As a result, even fervently religious Americans were less willing than earlier generations to accept physical afflictions as acts of divine providence. This same period also produced both the nation’s first widespread efforts to improve physical fitness and its first great food reforms. Americans were coming to the realization, or at least the hope, that bodily well-being could be controlled and, perhaps, even improved upon.”).

73. Mohr, *supra* note 27, at 1733; see DE VILLE, *supra* note 25, at 24 (“Physicians’ authority and public respect also declined as a parade of alternative medical practitioners offered their services to antebellum Americans.”).

74. Mohr, *supra* note 27, at 1732–33.

75. See DE VILLE, *supra* note 25, at 24 (“Physicians exacerbated their own descent in esteem and contributed to the litigious trend. As medical men of all types became more plentiful in the 1830s and 1840s, intraprofessional competition generated conflict, and many medical men incited suits against fellow practitioners.”); Spiegel & Kavalier, *supra* note 65, at 298–99 (“Competition for patients and fees among regular physicians and between regular and irregular doctors spurred the early increase in medical malpractice litigation. To improve their own status, individual physicians willingly denigrated the therapeutic practices of their competitors. Such public criticism may have encouraged patients to file lawsuits.”).

76. DE VILLE, *supra* note 25, at 24 (“Dramatic advances in several areas of medicine created unrealistic expectations in both physicians and patients and blurred standards of care.”).

77. “With the popular newspapers of the late 1830s and early 1840s full of hyperbolic claims and alleged success stories,” Mohr observes, “patients who failed to improve—or who even regressed—were no longer willing to dismiss unfavorable medical outcomes as either

standard of care from the irregulars also contributed to the problem. “Regular physicians utilized educational textbooks and manuals that could be considered norms or standards in court suits,” notes one pair of commentators.⁷⁸ “On the other hand, irregular physicians could not be sued for undesirable results because no standards existed.”⁷⁹

Yet the same forces of organized medicine that were pressing toward the end of the century for the reinstatement of licensure laws and the reform of medical education also were taking steps to curb the threat of malpractice suits.⁸⁰ The AMA and its affiliated medical societies encouraged their members to defend their colleagues against suits by patients rather than to use malpractice liability as a club with which to beat competitors.⁸¹

inevitable or normal.” Mohr, *supra* note 27, at 1732. Mohr describes medical advertising of the time as “aggressive and flamboyant.” *Id.*

78. Spiegel & Kavalier, *supra* note 65, at 301; see Mohr, *supra* note 27, at 1733 (“[T]here can be no malpractice without established practice; physicians cannot be convicted of deviating from accepted standards if no accepted standards exist. Amateurs and alternative healers had always delivered what patients came to them for, be it hot baths or herbal teas, and could not be sued for undesirable results. They claimed no fixed recipes and made a virtue of treating each case individually. Educated physicians, on the other hand, could have texts and advanced manuals (in steady production by 1840) used against them in court as codified norms from which they could be accused of diverging.”).

79. Spiegel & Kavalier, *supra* note 65, at 301.

80. Mohr draws a connection between malpractice liability and the founding of the AMA: “The American Medical Association (AMA) was founded in 1847, by no coincidence during the same decade that the nation’s first malpractice crisis burst on the American medical scene.” Mohr, *supra* note 27, at 1734. As the nineteenth century progressed, malpractice suits were spurred on by additional developments. The number of lawyers increased as well as the number of doctors, and the demographics of the legal profession began to change. At the beginning of the century, explains De Ville, lawyers and doctors tended to come from the same social class, and were further allied by both being targeted by the Jacksonians. But by the 1880s, more and more lawyers were being drawn from the working classes, and “the two professions lost some of their natural social affinity.” DE VILLE, *supra* note 25, at 194. The end of the century also saw the advent of medical malpractice insurance, which “quickly produced a situation in which nearly every physician was now worth suing.” Mohr, *supra* note 27, at 1735. Finally, judges abandoned the ancient writ system, making it easier to file complaints. *Id.* at 1732.

81. DE VILLE, *supra* note 25, at 90 (“Medical societies, which were weak and contentious in the 1840s, settled their differences, increased their membership, and successfully promoted professional harmony by 1900. Likewise, a reorganized AMA had a unifying and pacifying effect on the profession.”). Doctors sometimes resorted to rather odd forms of self-help to avoid malpractice liability. De Ville describes “a bizarre 1871 anecdote [in which] a fracture patient told his physician that he was going to sue for his badly healed leg. The physician asked the man in to his office and offered to operate on the limb and repair the deformity. When the patient refused, the doctor knocked him down, chloroformed him, and operated on the unconscious man’s leg. The patient recovered and dropped all charges against the physician. A medical journal praised the physician for having ‘the courage that many surgeons lack, to take the responsibility to act, and look up the law afterward.’ Of course, such approaches to the malpractice problem were rare.” *Id.* at 199–200.

Physicians who testified against other physicians were threatened with expulsion.⁸² Medical societies in New York, Chicago, and Cleveland also began defending suits on behalf of their members; in the decade after it began doing so, the Massachusetts Medical Society defended members in ninety-one out of ninety-four cases brought against them, and lost only one of the twelve that went to trial.⁸³ Members of these societies also could purchase cheaper malpractice insurance.⁸⁴

By far the profession's greatest achievement in combating malpractice, however, was to use its growing power to alter the physician's standard of care itself. This was accomplished by inducing the courts to adopt simultaneously the strict locality and customary care rules.

Prior to the torrent of malpractice cases around the middle of the nineteenth century, American jurisprudence had not been blind to the fact that patients received different medical care depending on where they lived. De Ville, for example, cites an 1824 case, *Lowell v. Faxon & Hawks*, in which the trial judge instructed the jury that "a physician in an 'obscure village' was not required to possess the same degree of skill as his urban counterpart,"⁸⁵ as well as an 1860 treatise stating that "[t]he opportunities by reason of locality, or other circumstances, of one portion [of the profession], may be many times more favorable than those of another; and the responsibilities resting upon them would be correspondingly greater."⁸⁶ As Theodore Silver points out, however, these were merely references to the traditional view that available knowledge and technology were factors to be considered in determining if a physician acted reasonably.⁸⁷

In the 1860s and 70s, however, organized medicine and receptive treatise writers mounted a campaign to convince courts that local conditions should replace the reasonableness standard altogether.⁸⁸ Then, in an 1876 decision by the Supreme Court of Vermont, *Hathorn v. Richmond*,⁸⁹ the locality rule, in Silver's words, actually "drew its first breath."⁹⁰ The trial court had

82. *Id.* at 213.

83. STARR, *supra* note 16, at 111.

84. *Id.*

85. DE VILLE, *supra* note 25, at 55.

86. *Id.* at 211.

87. Silver, *supra* note 62, at 1230.

88. See DE VILLE, *supra* note 25, at 55, 213. In criticizing an instruction to a jury that a physician was obligated to use "such ordinary care and skill as would best tend" to a patient's condition, the Kansas Supreme Court in 1870 quoted with approval a passage in a treatise emphasizing the limitations on practice in small towns and rural areas compared with "metropolitan towns." *Tefft v. Wilcox*, 6 Kan. 46, 47, 64 (1870), *cited in* Silver, *supra* note 62, at 1231.

89. 48 Vt. 557, 559 (1876).

90. Silver, *supra* note 62, at 1233.

instructed the jury, *inter alia*, that the defendant was expected to have “exercise[d] ordinary skill That being so, did Dr. Richmond use ordinary and reasonable care in [treating the patient] – that is, in doing what he did . . . did he [provide treatment] in the manner that doctors like himself *in the community* would have done the same thing, or are ordinarily accustomed to do the same thing?”⁹¹ The Vermont justices did not directly address this language, but instead reversed and remanded the case based on erroneous instructions relating to the relationship between the defendant and an accompanying physician.⁹² However, the court, “[p]aying little attention to the text” according to Silver,⁹³ stated the following:

We think the rule as laid down by the court is substantially correct, and in accordance with the well-settled law on the subject. There are certain expressions used in the charge which, taken by themselves, might seem to indicate a lower degree of skill than the law requires; but when the whole charge is taken together, it clearly gives the true rule, and so distinctly that the jury could not have mistaken it.⁹⁴

Courts around the country immediately began citing the *Hathorn* case and following its locality rule.⁹⁵ Coupled with the growing power of local medical societies, this change in the common law, which was never adopted in England,⁹⁶ made it difficult if not impossible for plaintiffs in malpractice cases to procure expert witnesses.⁹⁷

91. *Hathorn v. Raymond*, 48 Vt. 557, 559 (1876) (emphasis added).

92. *Id.* at 565.

93. Silver, *supra* note 62, at 1233.

94. *Hathorn*, 48 Vt. at 562.

95. Courts also adopted the customary care rule announced in the case. See *supra* text accompanying note 89.

96. Ruger, *supra* note 30, at 357 (“Thinly-sliced liability rules (such as the ‘locality rule,’ an invention of American common law never adopted in English law) permitted doctors to practice medicine differently from physicians in other towns in the same state.”).

97. Quoting a 1969 article by Jon Waltz, a Maryland court striking down the rule in 1975 observed that “[i]t effectively immunized from malpractice liability any doctor who happened to be the sole practitioner in his community. He could be treating bone fractures by the application of wet grape leaves and yet remain beyond the criticism of more enlightened practitioners from other communities.” *Shilkret v. Annapolis Emergency Hosp. Ass’n*, 349 A.2d 245, 249 (Md. 1975) (quoting Jon R. Waltz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DEPAUL L. REV. 408, 411 (1969)). Moreover, noted the court, “a ‘conspiracy of silence’ in the plaintiff’s locality could effectively preclude any possibility of obtaining expert medical testimony,” even in a community with more than one doctor. *Id.* (citing Note, *Michigan Abandons “Locality Rule” with Regard to Specialists*, 40 FORDHAM L. REV. 435, 438 (1971)); see also STARR, *supra* note 16, at 111 (“By adopting the ‘locality rule,’ the courts prepared the way for granting considerable power to the local medical

The second way in which the medical profession used its power to seize control of the standard of care was to shift from the prescriptive “reasonable” care standard to the descriptive standard of the care that physicians customarily provide. Once again, the *Hathorn* case is typically cited as the source of the new rule.⁹⁸ The trial judge had instructed the jury:

The question is, how much skill is [the physician] bound to have and to exercise in order that he should not be liable for a disastrous result? It is a little difficult to define it – you can only describe it or illustrate it. The ordinary expression is, *ordinary skill*. That means, such skill as doctors in the same general neighborhood, in the same general lines of practice, *ordinarily have and exercise in like cases*. If a doctor does in a case what the average class of doctors *are accustomed to do* and would do in such a case, then he exercises what is meant by ordinary skill in a given case. If he exercises such skill, then he is not liable⁹⁹

Stating that “[w]e think the rule as laid down by the court is substantially correct, and in accordance with the well-settled law on the subject,”¹⁰⁰ the Supreme Court of Vermont gave the trial court’s description of the law the same endorsement that it had given to the portion of the instruction that embodied the locality rule. Of course, the customary standard was not well-settled in the law; indeed, previous malpractice cases for the most part appear to have employed the same reasonableness standard that prevails in other areas of negligence law.¹⁰¹

society, for it became almost impossible for patients to get testimony against a physician who was a member.”).

98. See, e.g., Silver, *supra* note 62, at 1224.

99. *Hathorn*, 48 Vt. at 558–59 (second and third emphases added).

100. *Id.* at 562.

101. Spiegel and Kavalier, for example, note that “in 1860, the Illinois Supreme Court held that ‘the principle is plain and of uniform application, that when a person assumes the profession of physician and surgeon, he must, in its exercise, be held to employ a reasonable amount of care and skill.’” Spiegel & Kavalier, *supra* note 65, at 289. Silver explains somewhat cryptically that early nineteenth century cases held physicians to the “skill” of an “ordinarily competent and qualified physician” but shifted to the standard of “ordinary care” for how they should actually treat patients. Silver, *supra* note 62, at 1220. In *Pike v. Honsinger*, 49 N.E. 760, 762 (N.Y. 1898), for example, the court held that “[a] physician and surgeon, by taking charge of a case, impliedly represents that he possesses, and the law places upon him the duty of possessing, that reasonable degree of learning and skill that is ordinarily possessed by physicians and surgeons Upon consenting to treat a patient, it becomes his duty to use reasonable care and diligence in the exercise of his skill” Silver, *supra* note 62, at 1222. One commentator, however, cites an 1853 Pennsylvania case, *McCandless v. McWha*, 22 Pa. 261, 267–68 (1853), for the proposition that the obligation of physicians was “to treat the case with . . . such reasonable skill and diligence as are ordinarily exercised in his profession . . . such as thoroughly educated surgeons ordinarily employ.” McCoid, *supra* note 62, at 550. The court in *Hathorn* also had all but ignored the argument of the plaintiff’s attorney that “the

Acceptance of the customary standard of care became widespread not only in the subsequent case law but also in learned commentaries. As recently as 2002, for instance, James Blumstein, a leading authority on medical malpractice, stated that, while in ordinary tort cases “custom is a factor to be considered and evaluated by a fact-finder in the determination of negligence, but it is not determinative of the inquiry,” in medical malpractice actions, “conventional doctrine relies on the ‘customary practices of the medical profession as the benchmark of acceptable behavior.’”¹⁰²

While swapping reasonableness for what is customary was a major change in medical malpractice law, it is important to understand what the

charge conveys the idea that if the defendant w[as] ‘average in skill with the doctors in the neighborhood, he would not be liable.’ We insist that is not the criterion. If so, a bevy of quacks in any locality could establish the amount of requisite skill.” *Hathorn*, 48 Vt. at 560. The only potential acknowledgement of the attorney’s point was the court’s statement that “[t]here are certain expressions used in the charge which, taken by themselves, might seem to indicate a lower degree of skill than the law requires” *Id.* at 562. The court went on, it will be recalled, to state that “when the whole charge is taken together, it clearly gives the true rule, and so distinctly that the jury could not have mistaken it.” *Id.*

102. James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing In Assuring Quality, Accounting For Costs, and Coping With an Evolving Reality In The Health Care Marketplace?*, 11 ANNALS HEALTH L. 125, 130 (2002). See also Clark C. Havighurst, *Decentralizing Decision Making: Private Contract versus Professional Norms*, in MARKET REFORMS IN HEALTH CARE: CURRENT ISSUES, NEW DIRECTIONS, STRATEGIC DECISIONS 24 (Jack A. Meyer ed., 1983) (“[T]he courts draw the standards of care used in detecting professional negligence almost exclusively from prevailing professional custom and practice”); Bradford & Meyers, *supra* note 22, at 56 (“The standard of care is usually described as that which physicians actually do in their everyday practice of medicine.”); James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1384 (1994) (“Unlike some areas of negligence law where the jury’s wisdom or the legislature’s fiat define the standard of care, courts in medical malpractice cases have traditionally looked to the customary practice of the medical profession as the benchmark of acceptable behavior.”) [The beginning of the title was omitted from the final printed version]; McCoid, *supra* note 62, at 606 (“When we examine cases of medical negligence, however, we find that custom does become, almost exclusively, the measure of due care.”); Richard N. Pearson, *The Role of Custom in Medical Malpractice Cases*, 51 IND. L.J. 528, 528 (1976) (“The well-nigh universal rule in this country is that a physician will not be liable for negligence in a medical malpractice case unless he fails ‘to possess and employ such reasonable skill and care as are commonly had and exercised by reputable, average physicians in the same general system or school of practice’ Under this rule, the medical profession is able to establish its own standard of care. Thus, it is medical custom, rather than standards of reasonableness determined by judges and juries, against which the conduct of a physician is measured.”); Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 913 (2002) (“[T]he custom-based standard of care ‘gives the medical profession . . . the privilege, which is usually emphatically denied to other groups, of setting their own legal standards of conduct, merely by adopting their own practices.’”) (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS 189 (5th ed. 1984)).

customary standard means. Proving whether or not a physician adhered to the standard of care, it might be supposed, would require empirical data showing what doctors actually do, as Blumstein implies when he says that “the customary practice approach is ‘essentially an empirical inquiry that focuses on the ways things are customarily done in the medical community.’”¹⁰³ But this is incorrect.¹⁰⁴ Hardly any information exists about what physicians actually do. No one conducts surveys or polls to use as evidence in malpractice cases, and expert witnesses who testify about what is customary are not required to, and do not, introduce any such empirical evidence.¹⁰⁵

A review of reported cases bears this out. Only five reported cases have referred to the use of empirical evidence of physician practice as bearing on the standard of care, and a practice survey was introduced to establish the standard of care in only one: an Illinois appellate case from 1994.¹⁰⁶ On the

103. Blumstein, *supra* note 102, at 131. Blumstein disingenuously puts his claim in quotes as if to show that it has support; in fact, he is merely quoting himself. *See id.* at 131, n.28 (quoting James F. Blumstein, *Cost Containment and Medical Malpractice*, in *HEALTH CARE DELIVERY AND TORT: SYSTEMS ON A COLLISION COURSE?* 76, 89 (Elizabeth Rolph ed., 1993)).

104. For discussion of custom and recognition that empirical evidence of what doctors actually do is not provided, see Tim Cramm, Arthur J. Hartz & Michael Greene, *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 *WAKE FOREST L. REV.* 699, 711–12 (2002); Catherine T. Struve, *Doctors, the Adversary System, and Procedural Reform in Medical Liability Litigation*, 72 *FORDHAM L. REV.* 943, 978–79 (2004).

105. As Tim Cramm and his colleagues explain, “published research or formally collected data relevant to customary practice in a specific case are virtually never available, and the expert’s experience with the practice of others is limited. This experience consists of reviewing the medical records of patients who are shared with partners, referred for consultation, or referred by administrators because of patients’ complaints or cost. Medical witnesses do not have experience with how representative physicians generally practice and do not systematically record the experience they do have. Physicians’ opinions about medical practice come from their own training (including continuing education) and their own patient care. At best, an expert may understand the practical constraints or trade-offs involved in managing certain types of patients or have knowledge about available resources in specific settings (e.g., in a rural hospital). The expert can only guess at customary practice.” Cramm et al., *supra* note 104, at 710. Cramm and his colleagues cite Mark Hall, who states that “when the plaintiff’s witness states that the defendant’s conduct was not within the standards of the profession, he really means only that ‘he would not have treated the patient that way,’” Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 *LAW & CONTEMP. PROBS.* 119, 127 (1991), and prominent health services researcher David Eddy, who explains that “when an expert answers a question about a community standard it is extremely unlikely that he or she has any real data on actual practices. It is far more likely that what an expert believes is the practice in a community is what the expert personally believes *should be* the standard of care.” David M. Eddy, *The Use of Evidence and Cost Effectiveness by the Courts: How Can it Help Improve Health Care?*, 26 *J. HEALTH POL. POL’Y & L.* 387, 396 (2001).

106. *Kramer v. Milner*, 639 N.E.2d 157, 161 (Ill. App. Ct. 1994). Another case considered a nationwide survey of the practices of gastroenterologists potentially to be evidence of the standard of care, but refused to overturn the trial court’s denial of a motion for reconsideration

other hand, courts in several cases have explicitly held that evidence of actual custom is not probative. Tennessee courts of appeals have twice rejected the standard of “what [a majority of physicians in a community would consider to be reasonable medical care]” as the standard of care in favor of “the reasonable degree of learning, skill, and experience that is ordinarily possessed by others of his profession” because the former would “require a poll of physicians practicing in a community to determine the

to permit the survey to be introduced. *Mitchell v. United States*, 141 F.3d 8 (1st Cir. 1998). The court rejected the survey on the basis that it was not definitive, having only a 38.5% response rate which was described by the authors of a report of the survey as “less than ideal,” and because the survey “did not take into consideration the particulars of a patient’s medical history, even though the experts testifying before the trial judge agreed that such particulars are indispensable in determining the proper treatment to be followed.” *Id.* at 18–19. As will be seen, the failure to allow for individual patient differences is a common weakness in practice guidelines. See *infra* the discussion in the text accompanying notes 167, 190–91. The court in *Kramer* held that the trial court had erred in not instructing the jury that it could consider an American Cancer Society survey of practitioner compliance with its mammography guidelines as evidence of the standard of care, stating that “the expert testimony analyzing the compliance rates of doctors with ACS and other organization’s recommendations . . . constitutes ‘evidence of professional conduct’” as provided in an Illinois Pattern Jury Instruction. *Kramer*, 639 N.E.2d at 161. In a third case, the Supreme Court of Oregon held that it was not hearsay for an expert to describe as part of the basis for his opinion his conversations with colleagues, stating that “the appropriate medical practice is most commonly proven by learning what other specialists in the field do in the area. The appropriate medical practice in this case could have been observed by the physician at a hospital or in any other clinical setting; learned at a staff meeting at a hospital or at an educational seminar; ascertained from reading medical literature; and, finally, the appropriate medical practice could be ascertained by discussing the proper method for sorting out Pap smear reports with other doctors in the community as to what they do.” *Jefferis v. Marzano*, 696 P.2d 1087, 1092 (Or. 1985) (en banc). An Ohio case held that an expert’s description of discussions with “multiple colleagues” as evidence of the standard of care was not hearsay. *Deagan v. Dietz*, 94 C.A. 75, 1996 WL 148612 (Ohio Ct. App. Mar. 29, 1996). Finally, a case involving the alleged negligence of a blood bank, *Quintana v. United Blood Services*, 811 P.2d 424, 430 (Colo. App. 1991), *aff’d on other grounds* 827 P.2d 509 (Colo. 1992), asserted that proof of custom requires some sort of survey, but the assertion was merely dicta. The Court of Appeals quoted McCoid’s description of the “preferred position” of professions “in which the accepted or customary practices of similarly trained and situated professionals are generally taken as conclusive evidence of the professional standard of care.” *Id.* at 430; see *McCoid*, *supra* note 62. The court added that “the nature of professional activity insures that this professional negligence standard is a *fluctuating* standard defined *only* upon a contemporaneous survey of the practices of the profession’s members.” *Quintana*, 811 P.2d at 430 (emphasis in original). But the court proceeded to reject the plaintiff’s argument that the professional standard applies to blood banking. *Id.* at 431. On appeal, the Colorado Supreme Court held that the professional standard does apply, but that the standard of custom is subject to being rebutted as unreasonable. 827 P.2d at 524. See the discussion of the distinction between custom and reasonableness in the text *supra* at notes 98–100. As will be seen, the failure to keep guidelines up to date is another common weakness. See the discussion in the text accompanying *infra* note 196.

standard of care.”¹⁰⁷ The Supreme Court of Texas rejected the “respectable minority” standard of care because it “could convey to a jury the incorrect notion that the standard for malpractice is to be determined by a poll of the medical profession.”¹⁰⁸ Finally, a Washington court of appeals held that a trial judge had correctly refused to admit as an exhibit the results of a poll that the defendant conducted prior to trial and sought to introduce “to disclose what the standard of care was.”¹⁰⁹

Delinking the customary standard from empirical evidence of actual practice in fact diminishes the profession’s control over its internal standard of care by giving doctors greater freedom to practice as they please.¹¹⁰ It also reduces the profession’s ability to resist external forces by affording judges and juries more discretion to base the standard of care on their assessment of conflicting expert testimony. But the profession more than makes up for this loss of control by discouraging judges and juries from second-guessing medical experts about whether or not the standard of care that they endorse is reasonable. In negligence law generally, what is customary is not dispositive of the standard of care that is owed.¹¹¹ Under the custom standard, however, the only question is what in fact the standard of care is and whether or not the physician fulfilled it, not whether the standard is too high or too low to produce socially desirable results. As the California court stated in *Osborn v. Irwin Memorial Blood Bank*,¹¹² “in [medical negligence] cases like ours where experts are needed to show negligence, their testimony sets the standard of care . . . and is said to be

107. *Godbee v. Dimick*, 213 S.W.3d 865, 896 (Tenn. Ct. App. 2006); *Hopper v. Tabor*, 03A01-9801-CV-00049, 1998 WL 498211, at *3 (Tenn. Ct. App. Aug. 19, 1998).

108. *Hood v. Phillips*, 554 S.W.2d 160, 165 (Tex. 1977).

109. *Klink v. G.D. Searle & Co.*, 614 P.2d 701, 704 (Wash. Ct. App. 1980).

110. Theodore Ruger makes a similar point: “Like previous episodes of health reform in the United States, today’s emerging constitution of health security is imperiled by the persistence of a much older constitution of authority in American medicine, one that prioritizes individualistic therapeutic choice over other more systemic values.” Ruger, *supra* note 30, at 348.

111. Learned Hand famously stated, “There are, no doubt, cases where courts seem to make the general practice of the calling the standard of proper diligence; we have indeed given some currency to the notion ourselves. Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It may never set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.” *The T. J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932) (citation omitted).

112. 7 Cal. Rptr. 2d 101 (Cal. Ct. App. 1992).

‘conclusive.’”¹¹³ In Philip Peters’ words, “[D]eference to customary standards [places] the profession above the law.”¹¹⁴

For reasons that will be explained later, however, the pendulum swung back from the heyday of professional power that began in the late 19th century and reached its apogee in the 1950s and 1960s.¹¹⁵ Control within the profession over the legal standard of care slipped as government and private health insurance, and especially managed care, brought pressure on physicians to change their behavior for economic reasons.¹¹⁶ Irregulars, now called practitioners of “complementary and alternative medicine,” staged a comeback.¹¹⁷ The locality rule was abandoned in almost all states.¹¹⁸ In

113. *Osborn v. Irwin Mem’l Blood Bank*, 7 Cal. Rptr. 2d 101, 124 (Cal. Ct. App. 1992) (citation omitted).

114. Peters, *supra* note 102, at 958–59; *see also* M. Gregg Bloche, *The Emergent Logic of Health Law*, 82 S. CAL. L. REV. 389, 462 (2009) (“The malpractice system’s greatest failing, from a quality and value perspective, is its reliance on clinical practitioners to specify standards of care.”). The conclusive effect of proof of customary practice is especially evident in cases like *Osborn*, in which the experts agreed on what was customary. (“Here it is undisputed that no blood bank in the country was doing what the plaintiffs’ experts’ standard of care would require of Irwin” *Osborn*, 7 Cal. Rptr. 2d at 125.) This is why *Helling v. Carey*, 519 P.2d 981, 982–83 (Wash. 1974) (en banc), the lone case in which the court refused to accept custom as setting the standard of care despite agreement among the experts that the defendants did what was customary, stands so alone and has attracted such criticism. *See Osborn*, 7 Cal. Rptr. 2d at 126 (“Most of the commentary on this case has been unfavorable.”).

115. *See* JAMES C. ROBINSON, *THE CORPORATE PRACTICE OF MEDICINE: COMPETITION AND INNOVATION IN HEALTH CARE* 26 (1999).

116. *See generally* STARR, *supra* note 16, at 310–78.

117. In the last decade of the twentieth century, interest grew in non-mainstream medical practices. *See* Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J.L. & MED. 185, 194 (1998) (“The most recent alternative medicine resurgence largely results from a generational pursuit of independence and nonconformity.”); Andrew M. Knoll, *The Reawakening of Complementary and Alternative Medicine at the Turn of the Twenty-First Century: Filling the Void in Conventional Biomedicine*, 20 J. CONTEMP. HEALTH L. & POL’Y 329, 335 (2004) (“[S]ome explanation must be given to justify the resurgence of CAM as more than mere desire for caring without substantive curing.”). A Los Angeles Times Article states that sales of herbal remedies increased 100 percent between 1994 and 1998, and that “historians trace the resurgence of alternatives to the back-to-nature 1960s” Terence Monmaney & Shari Roan, *Hope or Hype?: Alternative Medicine is Edging into the Mainstream, with Californians Leading the Way. The Appeal is Complex, and Debate Rages About its Effectiveness and Scientific Oversight*, L.A. TIMES, Aug. 30, 1998, at A1.

118. Michelle Huckaby Lewis, John K. Gohagan & Daniel J. Merenstein, *The Locality Rule and the Physician’s Dilemma: Local Medical Practices vs the National Standard of Care*, 297 JAMA 2633, 2635 (2007). The box lists forty-five states that have adopted either a national or similar locality standard in place of a “same community” or “statewide” standard.

addition, judicial deference to professional custom began to disappear,¹¹⁹ which Peters regards as momentous:

Whether de jure or de facto, the shift away from the customary standard and toward a reasonable physician standard takes the task of standard-setting away from the profession and assigns it to the jury. The centrality of this doctrinal shift cannot be overstated. The delegation of standard-setting authority to the professions is unique in tort law. It is the foundation upon which the field of medical malpractice law has been built.¹²⁰

The “malpractice crises” that began in the 1970s, however, gave the profession an opportunity to reassert its power. By exaggerating the impact on physicians and patients and blaming the legal system,¹²¹ the profession lobbied successfully in many states for caps on damages, elimination of joint and several liability, reduction in the period of time allowed to file suit, offsets for amounts received from collateral sources, pretrial screening panels, periodic payments for future losses, and limitations on plaintiff attorneys’ contingent fee agreements.¹²² In addition, the profession also seized the chance to increase its control over the standard of care. It mounted a campaign against expert witnesses who testified for plaintiffs,¹²³ a tactic, it will be recalled, that medical societies employed at the end of the 19th century.¹²⁴ But more significantly, the profession set aside its historic opposition to “cookbook medicine” to support the use of medical practice guidelines as safe harbors against malpractice liability.¹²⁵ To understand how significant an expansion of professional power this would represent, it is first necessary to trace the history of the safe harbors concept.

119. Eleven states and the District of Columbia have expressly abandoned the standard of custom, while an additional nine states have done so implicitly by endorsing the “reasonable physician” standard. Peters, *supra* note 102, at 914.

120. *Id.* at 919–20.

121. For an analysis of the “crises,” see TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* (2005).

122. See MICHELLE M. MELLO, ROBERT WOOD JOHNSON FOUND., *MEDICAL MALPRACTICE: IMPACT OF THE CRISIS AND EFFECT OF STATE TORT REFORMS* 7 (May 2006).

123. At its April 2004 annual meeting, for example, the Federation of State Medical Boards adopted a resolution that false, fraudulent, or deceptive testimony given by a medical professional while serving as an expert witness should constitute unprofessional conduct, as defined in state licensure acts. Russell M. Pelton, *Medical Societies’ Self-Policing of Unprofessional Expert Testimony*, 13 *ANNALS HEALTH L.* 549 (2004); Jennifer A. Turner, *Going After the ‘Hired Guns’: Is Improper Expert Witness Testimony Unprofessional Conduct or the Negligent Practice of Medicine?* 33 *PEPP. L. REV.* 275, n. 189 (2006).

124. See *supra* discussion in the text accompanying notes 83–85.

125. See *infra* discussion in the text accompanying notes 172–78.

II. THE EARLY HISTORY OF PRACTICE GUIDELINES AS SAFE HARBORS

The practice of physicians receiving recommendations from learned colleagues on how to care for their patients is probably as old as medicine itself,¹²⁶ but beginning around 1990, it took on new urgency. The major impetus was the research conducted by John Wennberg and colleagues at the Dartmouth Medical School beginning in the 1970s, in which they investigated variations in the care that patients ostensibly suffering from the same afflictions received in different parts of the country. What they found were wide variations that could not be explained in any scientific manner. Shannon Brownlee detailed some of these occurrences in her book *Overtreated*:

Patients with back pain were 300 percent more likely to get surgery in Boise, Idaho, than in Manhattan. Doctors in hospitals affiliated with Harvard Medical School admitted patients to the intensive care unit four times more often than their colleagues at Yale University School of Medicine. Arthroscopic knee surgery—which would later be shown to be entirely ineffective at treating knee pain due to arthritis—was performed five times more often on arthritic patients in Miami than in Iowa City.¹²⁷

126. David Eddy says, “Practice policies have been used for centuries.” David Eddy, *Practice Policies: Where Do They Come From?* 263 JAMA 1265, 1265 (1990). Michelle M. Mello says clinical practice guidelines, a more formalized form of professional advice, “have been part of medical practice for more than half a century.” Mello, *supra* note 61, at 649.

127. SHANNON BROWNLEE, *OVERTREATED* 34 (2007). See James F. Blumstein, *supra* note 102, at 136–37 (“Dr. John Wennberg has pioneered research that shows dramatic and scientifically unexplained variations in medical practice across geographic regions. These data call into the question the hard scientific basis of much medical practice”); Mello, *supra* note 61, at 649 (“Interest in the possibilities of using CPGs to improve medical practice grew in the 1970s and 1980s after health services researchers discovered wide variations in care processes between different geographic locations within the United States. Practice variation is thought to imply an overuse of medical procedures in some geographic areas, and/or an underuse in other areas, that is attributable to physicians’ uncertainty regarding appropriate indications for particular treatments.”); Katherine Van Tassel, *Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines*, 36 SETON HALL L. REV. 1179, 1218–19 (2006) (“A series of startling scientific studies raises the question of whether the concept of ‘customary care’ is, in fact, a fiction. These studies reveal striking and unjustifiable variations in the choices that physicians made in the diagnosis and treatment of the same clinical condition.”). For Wennberg’s research findings and commentary on them, see John E. Wennberg et al., *Geography and the Debate over Medicare Reform*, HEALTH AFFAIRS (Feb. 13, 2002), available at <http://content.healthaffairs.org/content/early/2002/02/13/hlthaff.w2.96.short>; David Blumenthal, *The Variation Phenomenon in 1994*, 331 NEW ENG. J. MED. 1017, 1017–18 (1994); James M. Perrin et al., *Variations in Rates of Hospitalization of Children in Three Urban Communities*, 320 NEW ENG. J. MED. 1183 (1989); John E. Wennberg et al., *Are Hospital Services Rationed in New Haven or Over-Utilized in Boston?*, 329 LANCET 1185 (1987); Mark R. Chassin et al.,

When they analyzed Medicare data, Wennberg and his colleagues discovered that patients in Miami averaged six times more visits to specialists and spent twice as much time in the hospital and in intensive care units than comparable patients in Minneapolis, with no differences in outcomes.¹²⁸ Wide variations even occurred within the same state. “In Vermont, for example,” reports Peters, “eight percent of the people in one community had their tonsils taken out while seventy percent of the residents of a different community had the surgery. In Iowa, the rate of prostate removal ranged from 15% to 60%.”¹²⁹ As James Blumstein acknowledges, “[t]his, of course, has been an embarrassment to the profession . . . ,”¹³⁰ and “[w]hat ensued, of course,” explains Clark Havighurst, a leading health law scholar, “was a campaign by organized medicine to reestablish its credibility and maintain its authority over medical practice by producing ‘clinical practice guidelines.’”¹³¹ Rising health care costs, concerns about medical errors and the quality of care, and what some perceived to be

Variations in the Use of Medical and Surgical Services by the Medicare Population, 314 NEW ENG. J. MED. 285, 287 (1986); David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, HEALTH AFFAIRS, Fall 1984, at 74, 77–80; John E. Wennberg, *Dealing With Medical Practice Variations: A Proposal For Action*, HEALTH AFFAIRS, Summer 1984, at 6, 7; John E. Wennberg et al., *Professional Uncertainty and the Problem of Supplier-Induced Demand*, 16 SOC. SCI. MED. 811, 812–17 (1982); John E. Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCI. 1102 (1973).

128. Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145, 200–01 (2003).

129. Peters, *supra* note 102, at 946–47.

130. Blumstein, *supra* note 102, at 136. See Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J.L. MED. 7, 16 (2011) (“Medical guidelines have proliferated over the last fifty years, but starting in the 1990s, the number of guidelines being produced increased dramatically. This increase coincided with widely publicized studies that demonstrated a large variation in clinical practice across geographic areas and even within the same area.”); Clark C. Havighurst, *Practice Guidelines for Medical Care: Policy Rationale*, 34 ST. LOUIS U. L.J. 777, 779 (1990) (“The current [1989] consensus on the need for some kind of practice guidelines is directly traceable to the work of a handful of physician scholars who pioneered in the study of actual medical practice—what physicians actually do. These researchers demonstrated with striking evidence that physicians’ methods of treating many similar conditions vary widely for no apparent reason.”); Gary W. Kuc, Comment, *Practice Parameters as a Shield Against Physician Liability*, 10 J. CONTEMP. HEALTH L. & POL’Y 439, 444–45 (1994) (“Since the late 1980s, practice parameters have rapidly emerged as the medical profession’s response to the charge that the medical standard of care ‘appears to be arbitrary—highly variable, with no obvious explanation.’ Supporting this claim are studies by epidemiologists who have documented wide geographic variations in the rate of utilization of health care services and specific medical procedures. For example, in Maine the chance of a woman having a hysterectomy by the age of seventy varies across the state from less than 20% to more than 70%.”).

131. Clark C. Havighurst, *I’ve Seen Enough! My Life and Times in Health Care Law and Policy*, 14 HEALTH MATRIX 107, 121 (2004).

perverse effects of the malpractice system added to the pressure to find some means to rationalize medical practice. One solution that was put forward was for the profession to adopt practice guidelines, which the Institute of Medicine (IOM) defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”¹³²

Practice guidelines rapidly came to be viewed as a virtual panacea for the problems that beset modern medicine. Their “great promise,” states Arnold Rosoff, is “to improve the quality of care, help contain health care costs, reduce disputes about coverage under health plans, and ease the financial and other burdens of medical malpractice litigation on the health care system”¹³³ In 1990, Eddy predicted that they “have the potential to affect the quality and cost of medical care more profoundly than all the new treatments of the past or next decade.”¹³⁴

Both public and private entities took up the challenge. In 1990, Robert Brook of the RAND collaborated with the AMA in an effort to create guidelines, with the aim of establishing them for 50 to 100 of the most common, expensive, and controversial procedures.¹³⁵ The Blue Cross/Blue Shield Association, the umbrella organization for the dozens of BC/BS plans around the nation, asked the American College of Physicians to develop guidelines for fifteen of the most common diagnostic tests.¹³⁶ In

132. IOM 1990 REPORT, *supra* note 8, at 38. In contrast to informal advice from colleagues, practice guidelines supposedly represent the views of medical experts developed in a systematic manner. Similar efforts have included “technology assessment,” expert analyses focused on specific medical technologies such as new imaging devices or surgical procedures. For descriptions of federal medical technology assessment, see David Blumenthal, *Federal Policy Toward Health Care Technology: The Case of the National Center*, 61 MILBANK MEM’L FUND Q. 584, 595 (1983); Eleanor D. Kinney, *Comparative Effectiveness Research Under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine?*, 37 AM. J.L. & MED. 522, 525–26 (2011).

133. Rosoff, *supra* note 9, at 330.

134. Eddy, *supra* note 126, at 1265. See also Kevin C. Chung & Melissa J. Shauer, *Crafting Practice Guidelines in the World of Evidence-Based Medicine*, 124 PLASTIC & RECONSTRUCTIVE SURGERY 1349 (2009) (“Practice guidelines embrace evidence-based medicine by rigorously distilling the highest level of evidence from the literature in an effort to help physicians in the compassionate and scientific treatment of patients.”); William R. Trail & Brad A. Allen, *Government Created Medical Practice Guidelines: The Opening of Pandora’s Box*, 10 J.L. & HEALTH 231, 233, 258 (1995–1996) (“One solution that purports to provide cost containment, improved quality of care, and maintain physician responsibility is medical practice guidelines Medical practice guidelines are a truly rare reform concept that show real potential for improving the quality of care, decreasing costs, and reducing malpractice litigation all through one program.”).

135. See Harris Meyer, *AMA, Rand, Academic Centers to Develop Practice Guides*, AM. MED. NEWS, April 6, 1990, at 3, cited in Hall, *supra* note 105, at 124.

136. Hall, *supra* note 105, at 124.

1989, Congress created the Agency for Health Care Policy and Research (AHCPR), within which the Office of the Forum for Quality and Effectiveness in Health Care was supposed to “arrange for” the development and periodic review and updating of practice guidelines.¹³⁷

The potential for using practice guidelines to reduce doctors’ exposure to the risk of malpractice liability had already been recognized. Stung by a 1982 exposé on the ABC News program 20/20 entitled “The Deep Sleep, 6,000 Will Die or Suffer Brain Damage” that documented numerous cases of preventable anesthesia errors, and faced with high and rapidly rising malpractice insurance premiums,¹³⁸ anesthesiologists, through the American Society of Anesthesiologists, initiated a broad safety campaign that included promulgating practice guidelines that were adopted by the Harvard Medical School and its teaching hospitals.¹³⁹ The result was a dramatic reduction in both anesthesia-related errors and malpractice premiums.¹⁴⁰

137. The AHCPR was created by amendments (OBRA 1989, Pub. L. 101–239, § 6103) to the Public Health Service Act (Pub. L. 101–239). The charge of the Office of the Forum for Quality and Effectiveness in Health Care was to “arrange for” “clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically” IOM 1990 REPORT, *supra* note 8, at 3. The Institute of Medicine (“IOM”) report points to the use of term “arrange for” as “one key indicator of the extent to which the drafters of OBRA 89 sought to create a public-private enterprise with respect to guidelines development. Their vision was that the Forum would itself develop no guidelines; guidelines were not to be federal creations.” *Id.*

138. “Anesthesiology [malpractice] premiums were . . . among the very highest—in many areas, two to three times the average cost for all physicians,” explain David Hyman and Charles Silver. David A. Hyman & Charles Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893, 920 (2005). Ellison C. Pierce Jr., a retired professor of anesthesiology at Harvard Medical School who led the anesthesia guideline effort, described an Arizona anesthesiologist whose premiums abruptly rose from \$20,000 to \$50,000. Joseph T. Hallinan, *Heal Thyself: Once Seen as Risky, One Group Of Doctors Changes Its Ways—Anesthesiologists Now Offer Model of How to Improve Safety, Lower Premiums—Surgeons Are Following Suit*, WALL ST. J., June 21, 2005, at A1. This was the second wave of large premium increases in ten years. *Id.*

139. See HUMAN RESOURCES, U.S. GENERAL ACCOUNTING OFFICE GAO/HRD-94-8, MEDICAL MALPRACTICE: MAINE’S USE OF PRACTICE GUIDELINES TO REDUCE COSTS (1993) [hereinafter 1993 GAO REPORT]. The campaign included mandatory anesthesia patient monitoring standards and safety precautions, standardized operations for machines, and retrofitting machines with safety devices. Hyman & Silver, *supra* note 138, at 921. The ASA reviewed malpractice claims data and other information to identify areas where improvement was needed. *Id.*

140. Hyman and Silver describe how mortality rates fell from 1 in 10,000 to 20,000 to 1 in 200,000, malpractice insurance claims related to anesthesia dropped from 11% to 3.6% in fifteen years, and premiums for anesthesiologists at Harvard hospitals declined from \$17,690 to \$11,750 in one year. Hyman & Silver, *supra* note 138, at 918–19. For anesthesiologists in general, “the 2002 average premium was \$18,000—about the same as in 1985 and much lower than for most specialties.” *Id.* at 919. Today, add Hyman and Silver, “adverse events and

The anesthesia experience showed that practice guidelines could decrease medical errors, which in turn could diminish physicians' malpractice risk. But in 1990, the Maine State Legislature enacted a scheme that eliminated the critical step of having practice guidelines actually improve the quality of care. Instead, the legislation established a five-year-long demonstration project, renewed for another five years in 1997, which authorized physician specialty groups in Maine to create guidelines and permitted physicians to assert compliance with the guidelines as a defense in malpractice cases.¹⁴¹

The Maine demonstration project, as it became known, was supported by a coalition called the Healthcare Roundtable representing (1) the Maine Chamber of Commerce and Industry, (2) Blue Cross and Blue Shield of Maine, (3) the Maine Hospital Association, (4) the Maine Medical Association, (5) the Maine Ambulatory Care Coalition (representing rural health centers), and (6) the Maine State Employees Association;¹⁴² the prime mover, however, was the Maine Medical Association, which drafted the bill and persuaded an association ally in the Maine Senate to sponsor it.¹⁴³ The legislation initially authorized three medical specialty groups to promulgate guidelines: anesthesiologists, emergency physicians, and obstetricians and gynecologists.¹⁴⁴ These three specialties were chosen because of the frequency of malpractice suits against practitioners and the size of awards,¹⁴⁵ the willingness of specialists in these areas to participate

emergencies are so rare that anesthesiologists use simulators to practice responding to adverse, anesthesia-related events." *Id.* at 920. Hyman and Silver point out that "the ASA's actions cast serious doubt on the conventional wisdom that malpractice lawsuits impede error reduction. Anesthesiologists worked hard to protect patients because of malpractice exposure, not in spite of it." *Id.* at 921.

141. ME. REV. STAT. tit. 24, §§ 2971–2978 (repealed 1999). The original bill would have granted physicians immunity from malpractice suits if they could show that they had complied with the guidelines, but the Judiciary Committee rejected immunity in favor of allowing compliance to serve as an affirmative defense. For more discussion of the immunity approach, see Jennifer Begel, *Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation*, 47 ME. L. REV. 69, 77 (1995); Hall, *supra* note 105, at 134.

142. 1993 GAO REPORT, *supra* note 139, at 19, n.14.

143. Kuc, *supra* note 130, at 451.

144. *Id.* at 466.

145. See Trail & Allen, *supra* note 134, at 244 ("These four areas of medicine were selected because they are high risk areas of medicine . . ."); 1993 GAO REPORT, *supra* note 139, at 8–9 ("The respective specialty committees used malpractice insurers' claims data to identify the medical procedures that lead to malpractice claims, and adopted guidelines that cover these procedures.").

in the project (the cardiologists, for example, refused),¹⁴⁶ and the existence of guidelines issued by their national organizations.¹⁴⁷

Three features of the Maine legislation illustrate the degree to which it represented capture of the standard of care by the state's medical profession.¹⁴⁸ First, physicians controlled the process by which the specialty guidelines were created.¹⁴⁹ Second, the guidelines were adopted as

146. See 1993 GAO REPORT, *supra* note 139, at 8 (“Inclusion of cardiology was considered, but physicians in this specialty decided not to participate.”). At least fifty percent of the physicians in each specialty had to agree to participate in the demonstration project in order for the specialty to be included. *Id.* at 27.

147. See Trail & Allen, *supra* note 134, at 244 (“These four areas of medicine were selected because they are high risk areas of medicine that, for the most part, already operated under guidelines created on a national level.”); Begel, *supra* note 141, at 78–79 (“The guidelines referenced and adopted into the Maine statute are comprised of revised versions of the national standards of three medical specialties and their respective national organizations—the American Society of Anesthesiologists (ASA), the American College of Radiology (ACR), and the American College of Obstetricians and Gynecologists (ACOG). In addition, a group of emergency room physicians created their own protocols regarding: (1) cervical spine x-rays for acute trauma patients, (2) documentation of instructions to patients upon discharge, and (3) transferring patients pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1986 (C.O.B.R.A.)”); 1993 GAO REPORT, *supra* note 139, at 9 (“The guidelines adopted by the specialty committees are either drawn from guidelines written by national specialty societies or written by the committees themselves. For example, nationally developed guidelines include those pertaining to caesarean delivery for failure to progress and performance of a screening mammography. Committee-developed guidelines include those pertaining to cervical-spine X rays and preoperative testing for anesthesia.”). In 1991, a fourth specialty group, radiology, was added. See *id.* at 38–39 (“Radiology was not included in the original legislation that established the demonstration project. Maine radiologists subsequently asked the Board of Registration in Medicine for inclusion in the project because they wanted to address the problems they perceived with increasing health care costs and increasing numbers of malpractice claims. Legislation enacted in June 1991 added radiology as a participating specialty in the demonstration project.”).

148. Notwithstanding the unprecedented nature of the Maine legislation, Begel states that “[t]he final version of the project was adopted by the Legislature in the early morning hours of the closing 1990 legislative session and was the subject of little discussion.” Begel, *supra* note 141, at 76–77.

149. Each specialty group formed an advisory committee. As Gary Kuc explains, “[t]he Advisory Committees formulated draft versions of the practice parameters and sent them for comments to all physicians in Maine practicing in the respective specialty areas. On February 14, 1991, pursuant to the rulemaking requirements of the Maine Administrative Procedure Act, the Board of Registration in Medicine (Board) held public hearings on the preliminary drafts of the parameters. The Board considered written commentary to clarify technical language in the practice parameters and the requirements for eligibility for participation in the Project. Except for the chairpersons of the Advisory Committees, who spoke in favor of adopting the practice parameters as administrative rules, no other parties spoke either for or against the practice parameters.” Kuc, *supra* note 130, at 457. The number of physicians involved, moreover, was quite small; according to Gordon Smith, lawyer for Maine Medical Association, the Maine project was feasible because of special conditions: “Maine has fewer than 100 doctors in three of the four specialties involved, so it is actually possible to have a meeting, for example, with

administrative rules by the state medical board, meaning that once they were approved, plaintiffs could not challenge their substance, for example, as substandard.¹⁵⁰ This differentiated the medical guidelines from other industry standards, which are admissible as evidence of the standard of care, but not dispositive.¹⁵¹ Third, the legislation provided that the guidelines could be used only as a shield to protect physicians from liability; plaintiffs could not use a physician's failure to comply as evidence of malpractice.¹⁵² According to Arnold Rosoff, the one-sided approach was necessary in order to obtain the cooperation of the medical professionals.¹⁵³

While the Maine demonstration project was undertaken on behalf of the medical profession, it had some support within the legal academy. Havighurst wrote an article in 1991 in which he posited that "guidelines might provide a degree of protection against malpractice suits premised on the omission of an arguably beneficial diagnostic test or therapy,"¹⁵⁴ and

every anesthesiologist in the state." RAND INSTITUTE FOR CIVIL JUSTICE, CONFERENCE PROCEEDINGS: HEALTH CARE DELIVERY AND TORT: SYSTEMS ON COLLISION COURSE? 71 (Elizabeth Rolph ed., 1991) [hereinafter RAND REPORT].

150. See Kuc, *supra* note 130, at 457–58 ("At the conclusion of the rulemaking process, the Board adopted the practice parameters as administrative rules, thereby giving them the force and effect of law.").

151. See Mello, *supra* note 61, at 660–61 ("The state courts vary in their approaches to the admissibility of industry codes and standards. A large number of cases support the view that such codes and standards are admissible, probative evidence on the issue of the defendant's duty. Since such codes are believed to be 'objective standards representing a consensus of opinion carrying the approval of a significant segment of an industry,' they are deemed to 'contain the elements of trustworthiness and necessity which justify an exception to the hearsay rule.' Courts that admit written industry standards generally require an expert to testify as to the standards' acceptance in the industry. Moreover, compliance or noncompliance [sic] with the written standards is not viewed as conclusive evidence of negligence, or the absence thereof, only as some evidence of it. The rationale is that while the standards indicate the prevailing thinking in the industry about the appropriate level of precautions, and in some cases may codify industry custom, they do not rise to the level of substantive law. Violating an industry safety standard, therefore, is not the same thing as violating a statute, which may give rise to an inference of per se negligence. A few courts have declined to afford written industry standards even this degree of weight; they have opted to make such standards inadmissible even when expert authentication is proffered.").

152. ME. REV. STAT. tit. 24, § 2975(1) (repealed 1999) ("In any claim for professional negligence against a physician or the employer of a physician . . . in which a violation of a standard of care is alleged, only the physician or the physician's employer may introduce into evidence, as an affirmative defense, the existence of the practice parameters and risk management protocols developed and adopted pursuant to [the law] for that medical specialty area.").

153. See Rosoff, *supra* note 9, at 344 ("This uneven application of CPGs has come about as a political barter, with legislators assuring physicians, in effect, that if they will support the development and adoption of guidelines, those guidelines cannot be turned against them in litigation.") (citation omitted).

154. Havighurst, *supra* note 130, at 783.

therefore “there would be less reason for physicians, fearing liability for malpractice, to practice ‘defensive medicine’”¹⁵⁵ However, Havighurst did not believe that physicians should be allowed to establish their own standard of care but rather that it should be negotiated as part of a contractual agreement with their patients.¹⁵⁶ Up-and-coming law professor Mark Hall published an article in 1991 in which he argued that “[p]ractice policies would help close the gap between theory and practice by using authoritative statements of existing practice to remove the factual uncertainty that presently surrounds the determination of whether some given practices are acceptable.”¹⁵⁷ Hall preferred for guidelines to be irrefutable evidence of the standard of care, but he acknowledged that they might not be sufficiently “definite” to be entitled to conclusive effect.¹⁵⁸ Instead, therefore, he advocated a “variable immunity statute” in which a trial judge would be authorized to issue directed verdicts for defendants only if the judge considered the guideline proffered by the defendant to be sufficiently “authoritative” and applicable to the facts.¹⁵⁹ Unlike the Maine legislation, Hall would allow plaintiffs to use a defendant’s failure to comply with a guideline as evidence of negligence, but similar to the Maine program, under Hall’s approach a guideline could be conclusive evidence only if it were introduced by the defendant.¹⁶⁰

Along with Maine, Vermont, and Florida, Minnesota also enacted legislation in the early 1990s authorizing the creation of state-sanctioned practice guidelines and their use in malpractice cases. Like Maine, Minnesota provided for one-sided adherence to a guideline as an absolute defense to liability.¹⁶¹ The Minnesota program went even further than Maine’s; in fact, it authorized the state health commissioner to adopt guidelines promulgated by the AMA, a specialty group that was a member

155. *Id.* at 798. For a discussion of defensive medicine, see *infra* text accompanying notes 151–55.

156. E-mail from Clark Havighurst to author (December 11, 2011) (on file with author), in which he states that “I don’t recall any significant direct contacts with the folks in Maine, although I believe I talked with them on the phone. I’d published a fair amount on guidelines before 1990, but I’d guess they got their main idea from AMA or other medical sources. My idea was always that we shouldn’t let the medical profession alone lay down the guidelines (I had lots of contact with the AMA’s point person on guidelines but can’t remember his name) and that contracts might specify such things as the standard of care.”

157. Hall, *supra* note 105, at 130.

158. *Id.* at 133 (“The lack of support for giving [practice guidelines] conclusive effect may be due, in large measure, then, to the absence of sufficiently definite standards.”).

159. *Id.* at 135.

160. *Id.* at 131.

161. See MINN. STAT. ANN. § 62J (West 1993); Hyams, Shapiro & Brennan, *supra* note 5, at 307 (“Evidence of a departure from a practice parameter is admissible only on the issue of whether the provider is entitled to an absolute defense.”) (citation omitted).

of the American Board of Medical Specialties, or a similar “national health professional board or association,” without going through the rulemaking process at all, and it made adherence to the guidelines an “absolute defense” for physicians.¹⁶² Vermont took a less pro-physician approach than either Maine or Minnesota; guidelines would merely serve as expert opinion, rather than an affirmative defense, and both plaintiffs and defendants could introduce guidelines as evidence of the standard of care.¹⁶³ Florida authorized physicians to use compliance with guidelines designated by the Florida Agency for Health Care Administration as an “affirmative defense.”¹⁶⁴ Although one group of commentators states that the intent of the legislation was to make use of guidelines a one-way street for defendants, as had the laws in Minnesota and Maine, other commentators point out that, since the Florida law was silent on whether guidelines also could be used by plaintiffs, there was concern that the legislation actually could increase physicians’ malpractice exposure.¹⁶⁵

At the federal level, bills were introduced in 1991 by Senator Pete Domenici (R-N.M.),¹⁶⁶ and in 1993 by Alex McMillan (R-N.C.), Nancy Johnson (R-Conn.),¹⁶⁷ and Senator William Cohen (R-Me.).¹⁶⁸ Although most of the enthusiasm came from Republican legislators, Hyams and his

162. See Rosoff, *supra* note 9, at 340. Rosoff calls the Minnesota approach, which he describes as treating adherence to a guideline as an irrebuttable presumption that the physician followed the standard of care, “the most extreme” possible. *Id.* Minnesota delegated guideline setting to the commissioner of health, with advice from a committee composed of health care professionals and representatives from the research community and the medical technology industry, and from a “Health Care Analysis Unit” within the state health department. Hyams, Shapiro & Brennan, *supra* note 5, at 306. Minnesota regulators had planned to start with guidelines issued by the AHCPDR for treating low back pain and unstable angina. *Id.* at 307.

163. See 1991 Vt. Acts 160 [adjourned session], § 46; Trail & Allen, *supra* note 134, at 248 (“Type II guidelines may be challenged like any other evidence offered to establish the standard of care. Physician compliance with these guidelines does not create an affirmative defense. The guidelines function as expert testimony concerning the standard of care. Vermont created a Type II practice guidelines program with health care reform legislation in 1992. The program, implemented in 1994, allows the guideline to be admitted as evidence of the standard of care by either the plaintiff or the defendant.”).

164. See FLA. STAT. § 408.02 (2000) (repealed 2004); Hyams, Shapiro & Brennan, *supra* note 5, at 307–08.

165. Trail & Allen, *supra* note 134, at 244.

166. Domenici’s bill, the Medical Injury Compensation Fairness Act, “encouraged the development of medical practice guidelines to determine appropriate standards of care.” Hyams, Shapiro & Brennan, *supra* note 5, at 308.

167. McMillan and Johnson introduced H.R. 1969 and H.R. 1625 respectively; both would have allowed AHCPDR and state-developed guidelines as affirmative defenses to medical malpractice. *Id.*

168. Cohen “proposed a national ‘Maine-model’ to treat AHCPDR guidelines as ‘rebuttable evidence’ in court.” *Id.* (citation omitted).

colleagues describe how “[d]uring the 1992 presidential debates, then-candidate Bill Clinton stated, ‘I think you have to help doctors stop practicing defensive medicine. I’ve recommended that our doctors be given a set of national practice guidelines and if they follow these guidelines, it raises a presumption that they didn’t do anything wrong.’”¹⁶⁹ Section 5312 of the October 27, 1993, draft of President Clinton’s American Health Security Act would have established a pilot program at the state level in which compliance with guidelines would be a “complete defense” to liability.¹⁷⁰ A Republican counter-proposal by Senator John Chafee (R-R.I.) and Representative William Thomas (R-Cal.) would have required states to develop guidelines and made adherence to them a rebuttable presumption that the doctor met the standard of care,¹⁷¹ while the health reform plan put forward by Senator John Breaux (D-La.) and Representative James Cooper (D-Tenn.) would have given grants to the states to develop guidelines without dictating what weight they should be given in malpractice cases.¹⁷² In addition, a little-known provision in the Medicare laws authorized Peer Review Organizations—private contractors who performed quality assurance duties—to “apply” “professionally developed norms of care and treatment” and immunized physicians who complied with the norms from

169. *Id.* at 308–09.

170. *Id.* at 309. *See also* Ayres, *supra* note 61, at 422 (“Proposed federal legislation would apply practice parameters as the standard of care in an alternative dispute resolution system.”); Rosoff, *supra* note 9, at 340 (describing Republican proposals in 1993); 1993 GAO REPORT, *supra* note 139, at 1–2 (“In its recent health care reform plan, the Clinton Administration proposed a medical liability pilot program based on practice guidelines developed by the Agency for Health Care Policy and Research within the U.S. Department of Health and Human Services. Under the pilot program, physicians able to demonstrate that their professional conduct or treatment complied with appropriate practice guidelines would not be liable for medical malpractice.”).

171. Hyams, Shapiro & Brennan, *supra* note 5, at 309. *See also* Rosoff, *supra* note 9, at 340 (“A less prescriptive approach would be to treat compliance with a relevant guideline as raising a *rebuttable* presumption that the physician acted correctly; similarly, noncompliance would raise a rebuttable presumption that the physician acted negligently. Whichever party asserted the guideline, the opposing party could attempt to counter this presumption by appropriate evidence. This was the approach contemplated in the Health Equity and Access Reform Today (HEART) bill, proposed by Senator John Chafee (R-R.I.) and others in 1993. (S. 1770, 103d Cong., 1st Sess. § 4025 [1993]). Under HEART, adherence to state-developed guidelines which had been certified by the secretary of Health and Human Services would raise a rebuttable presumption of appropriate care that would be overcome only by ‘clear and convincing evidence,’ a stricter than normal evidentiary standard favoring the party complying with the guideline.”).

172. Hyams, Shapiro & Brennan, *supra* note 5, at 309–10. The Cooper-Breaux bill (H.R. 3222/S. 1579) provided that the resulting guidelines “*may* be applied to resolve” cases. *Id.*

civil liability, although the law went on to say that the physician would be immunized only if he “exercised due care.”¹⁷³

None of these efforts amounted to anything, however. The Peer Review Organization immunity provision has not been invoked in any reported case. The national health reform efforts of the 1990s came to naught. More importantly, none of the state programs were successful.¹⁷⁴ Neither Minnesota nor Florida appears to have issued any guidelines,¹⁷⁵ and the project in Vermont seems to have been abandoned.¹⁷⁶ The Maine project ran into interference from another malpractice reform that the state legislature had adopted in 1985,¹⁷⁷ a requirement that complaints be submitted to pretrial screening and mediation panels. As a result, a defendant wishing to assert an affirmative defense of adherence to a guideline would have to raise it at the pretrial screening stage.¹⁷⁸ The problem was that, under the pretrial screening law, if a panel unanimously rejected the defense because it concluded that the physician had failed to comply with the guideline, then that finding had to be made known to the jury.¹⁷⁹ In other words, despite the intent of the legislature to restrict the benefit of guidelines to defendants, a screening panel’s refusal to accept a guideline defense could be used offensively by the plaintiff as evidence of negligence. The only way to

173. This law remains in effect today, and now applies to norms “applied” by Quality Improvement Organizations, the successors to the Peer Review Organizations. *See* Social Security Act § 1157(c), 42 U.S.C.A. § 1320c-6(c) (West 2012). In 1991, Hall explained that the immunity provision had never been asserted by a defendant because the Peer Review Organizations had not promulgated any suitable “norms” and because of the “due care” requirement. Hall, *supra* note 105, at 137–38.

174. Mello and Kachalia state that the limited experimentation in several states during the early 1990s was not designed to facilitate a meaningful evaluation. Allen Kachalia & Michelle Mello, *New Directions in Medical Liability Reform*, 364 *NEW. ENG. J. MED.* 1564, 1570 (2011). However, there clearly were efforts at least under the Maine program to evaluate the impact on physicians’ malpractice costs. *See infra* text accompanying notes 184–88, 197–99.

175. *See* Hyams, Shapiro & Brennan, *supra* note 5, at 308 (“As of the beginning of May 1994, Florida has not adopted practice parameters for use in the demonstration project.”); Trail & Allen, *supra* note 134, at 247 (“As of March 1995, no guidelines had been approved in Minnesota.”).

176. *See* Mark Crane, *Clinical Guidelines: A Malpractice Safety Net?*, 76 *MED. EC.* 243 (1999) (“Similar experiments in Florida, Minnesota, and Vermont have been either repealed or abandoned”). A 2005 report by a Vermont Malpractice Study Committee to the Vermont General Assembly discusses the Maine program but makes no mention of Vermont’s. VERMONT MEDICAL MALPRACTICE STUDY COMMITTEE, *MEDICAL MALPRACTICE LIABILITY INSURANCE IN VERMONT* (2005), available at [http://www.dfr.vermont.gov/sites/default/files/MedMal-final-report%20\(2\).pdf](http://www.dfr.vermont.gov/sites/default/files/MedMal-final-report%20(2).pdf) [hereinafter VERMONT REPORT].

177. *See* the legislative history of ME. REV. STAT. tit. 24, § 2975(1), available at <http://www.mainelegislature.org/legis/statutes/24/title24ch21-1.pdf>.

178. *See* Begel, *supra* note 141, at 81–82.

179. *Id.* at 86.

avoid this risk would be for the doctor to refrain from asserting the guideline as a defense, and since only once did a physician in Maine assert adherence to a guideline as a defense,¹⁸⁰ evidently most defendants decided to take this more cautious approach.¹⁸¹ Additionally, a guideline defense in Maine was not absolute. The plaintiff could rebut it by showing that the guidelines in fact did not apply to the case in question, or that the physician in fact had not adhered to it.¹⁸² As Hall acknowledged, in short, adherence to a guideline “appears to provide only an additional piece of evidence for the jury to consider”¹⁸³ Not only was there little use of the guideline defense in Maine, but there is no evidence that the project significantly lowered malpractice insurance premiums or health care costs.¹⁸⁴ Skepticism

180. See Rosoff, *supra* note 9, at 343.

181. See Begel, *supra* note 141, at 82 (describing how the panel would review a guideline defense); Hyams, Shapiro & Brennan, *supra* note 5, at 306 (“The Demonstration Project’s interface with the operations of the Maine prelitigation screening panels appears to have been designed as an afterthought, and the screening panel operations may undermine the prohibition on plaintiffs’ use of demonstration guidelines. For instance, if the guideline affirmative defense is raised before the screening panel and the panel unanimously rejects it, then the trial court may have to admit this ‘unanimous’ finding, thus allowing inculpatory use of the guideline after all.”) (citation omitted); Rosoff, *supra* note 9, at 343 (“The paucity of malpractice litigation in Maine since the institution of the state’s CPG experiment is partly due to the fact that the same law that authorized it [sic] also mandated prelitigation screening and mediation panels.”). As a result of the pretrial screening requirement, malpractice attorneys informed the GAO that the Maine guideline legislation was most likely to affect litigation at the pretrial stage, since “in cases involving areas of practice covered by the guidelines, attorneys expect that a decision by the panel that the guidelines cover the claim and that the physician followed the guidelines and was, therefore, within the applicable standard of care, will discourage plaintiffs from pursuing their claims to trial.” 1993 GAO REPORT, *supra* note 139, at 19–20. However, the GAO reported that, as of September 1993, “there were no examples of the guidelines having affected malpractice litigation.” *Id.* at 19.

182. See Kuc, *supra* note 130, at 441 (“Although the physician may proffer the parameters as evidence, once the court admits them, the plaintiff may present evidence on the issue of compliance”); Trail & Allen, *supra* note 134, at 245 (“[I]f a doctor relies on the Ob/Gyn guidelines and the plaintiff can prove those are not the appropriate standards for that particular case, then the affirmative defense is not available. The plaintiff could provide such proof in one of two ways. First, the plaintiff could prove the case is not an Ob/Gyn case. A second argument would concede that the case is an Ob/Gyn case, but that the guidelines do not cover the particular treatment or scenario as presented in the plaintiff’s cause of action.”).

183. Hall, *supra* note 105, at 135.

184. Rosoff cites a report that physicians performed fewer procedures out of fear of liability, and a 1994 estimate by the state’s superintendent of insurance that the legislation would reduce premiums by .5%. Rosoff, *supra* note 9, at 343. Trail and Allen give the .5% estimate as a fact, and based on it and a comment by the Maine Medical Association that “‘people believe’[sic] that doctors are performing fewer medical procedures because of the guidelines,” they predicted that “significant savings should be calculable in the future.” Trail & Allen, *supra* note 134, at 257. However, Rosoff cites a Bureau of Insurance report “that it cannot distinguish the impact of the experiment from other factors affecting medical professional liability claim costs and premiums.” Rosoff, *supra* note 9, at 343. A 2005 report to

about the usefulness of guidelines in protecting physicians led the Maryland legislature in 1993 to create a program to encourage the development of practice guidelines but that prohibited their use by any party as evidence in malpractice cases.¹⁸⁵

What explains the failure of efforts in the early 1990s to allow practice guidelines to play a major role in malpractice litigation? In the case of federal legislation, the proposals had been hitched to national health reform, and they stalled when it did. The program in Maine, as noted earlier, was encumbered by other malpractice reform legislation.¹⁸⁶ In addition, although medical groups had instigated or supported the efforts, the AMA itself was not, as yet, enthusiastic.¹⁸⁷ In the first place, its leaders feared that government and private payers would issue guidelines that were aimed at saving money rather than articulating appropriate standards of care, so that James Todd, then the president of the AMA, declared in 1989 that “what we have to avoid is developing parameters based on economic considerations. That’s where the push is coming from the federal government. Effectiveness, appropriateness, necessity—to the federal government those are euphemisms for cost control and rationing.”¹⁸⁸

Moreover, the AMA was worried that guidelines would usher in an era of “cookbook medicine” in which forces beyond its control would use them to decrease physician discretion. Said Todd:

You cannot restrict physicians to one procedure or series of procedures for a specific condition. . . . No two patients are exactly alike and no two conditions are exactly alike. What we must do is provide physicians with parameters that give them the flexibility to utilize their own skills within an acceptable range of options.¹⁸⁹

the Vermont legislature states that “[i]n 2000, the Maine Superintendent of Insurance, issued an order finding that the medical malpractice professional liability cost savings attributed to the Medical Liability Demonstration Project was zero percent.” VERMONT REPORT, *supra* note 176, at 77.

185. Trail & Allen, *supra* note 134, at 248 (“The Maryland program, initiated on April 13, 1993, ‘mandates the development of state guidelines but explicitly prohibits introduction [of the guidelines] as evidence by any party in a malpractice suit.’”). Rosoff states that “a 1995 Maryland statute enacted to encourage guidelines development provided that CPGs developed under the program it established could not be used in litigation (Md. Code Ann. [Health-Gen.] Section 19-606), a restriction that has since been removed from the legislation.” Rosoff, *supra* note 9, at 335.

186. See *supra* notes 177–78 and accompanying text.

187. See *supra* notes 161–67 and accompanying text.

188. James S. Todd, *Only Parameters Will Give MDs Needed Flexibility*, AMERICAN MED. NEWS, Jan. 6, 1989, at 15.

189. *Id.* Trail and Allen agree: “[P]ractice guidelines establish a general standard of good/proper care and doctors should be able to deviate without penalty if that is what the

The AMA therefore pushed for guidelines to include “a disclaimer stating that they are not intended to displace the physician’s discretion to conform treatment to the particular clinical circumstances of the individual patient,”¹⁹⁰ which prompted Hall to complain that it renders guidelines “entirely advisory or equivocal by waffling phrases and general disclaimers,” and “deprives them of any relevance to malpractice litigation.”¹⁹¹ The AMA also wanted guidelines to play only a limited role in malpractice cases. In 1993, AMA attorney Edward Hirshfeld issued the following statement:

The American Medical Association opposes, for the present at least, direct adoption of CPGs [clinical practice guidelines] as a legal standard and urges instead that they be used only as evidence of the customarily observed professional standard of practice and that their degree of authority be dependent upon the degree of their acceptance among medical practitioners.¹⁹²

The AMA was even unwilling to support making adherence to guidelines an affirmative defense to malpractice liability.¹⁹³

III. THE REVIVAL OF PRACTICE GUIDELINES ON THE POLITICAL SCENE

Despite the failure of the initiatives in the 1990s, the idea that practice guidelines should serve as safe harbors recently has been revived by the Obama administration. The main reason for the Administration’s current interest in practice guidelines was President Obama’s efforts to obtain the backing of organized medicine for his health reform plan.¹⁹⁴ Senator Max Baucus (D-Mont.), chair of the Senate Finance Committee, held discussions

prudent doctor would do in that situation. The ability to deviate under unusual circumstances without penalty is a necessity for proper use of medical practice guidelines. Otherwise, the claims of ‘cookbook medicine’ would come to fruition.” Trail & Allen, *supra* note 134, at 246–47.

190. Hall, *supra* note 105, at 144.

191. *Id.* at 143–44.

192. Rosoff, *supra* note 9, at 340–41.

193. *Id.* at 341. The profession also probably feared that states would not follow Maine’s attempt to bar plaintiffs from using a failure to follow a guideline to inculpate a physician, which was borne out by the legislation in Vermont and Florida.

194. There had been some continued discussion in academic circles about the idea of using practice guidelines as defenses to malpractice after the debacle in the 1990s, but no consensus. Compare Rosoff, *supra* note 9, at 366 (who favored allowing government certification of guidelines “to introduce guidelines more prominently into the legal process and help courts decide which guidelines should be regarded as authoritative”), with Mello, *supra* note 61, at 708–09 (who felt that “increased reliance on clinical practice guidelines to establish the standard of care in medical malpractice cases would be undesirable”).

in 2009 on the “safe harbor” idea.¹⁹⁵ In May 2009, the President met with incoming AMA president J. James Rohack, and told him that the Administration was willing to offer liability protection to physicians who followed practice guidelines.¹⁹⁶ While as discussed earlier, the AMA had balked at the idea back in the 1990s,¹⁹⁷ the organization was now eager to cooperate. Likely, it viewed the safe harbors scheme as the most it could get, since the Democrats were unwilling to support the AMA’s top legislative priority, a federal cap on damages.¹⁹⁸ The AMA leadership also was worried that physicians would face pressure from the government and other third-party payers to adhere to guidelines aimed at cutting costs, making them vulnerable to malpractice liability if the guideline recommendations conflicted with what was thought to be the prevailing standard of care. “If everyone is focused on saying, ‘How do we get rid of unnecessary costs,’” Rohack remembers saying to President Obama, “if we as physicians are going to say, ‘Here’s our guidelines, we will follow them,’ then we need to have some protections.”¹⁹⁹ “[The President] listened,” says Rohack, and then replied: “Clearly, that concept is worthy of discussion.”²⁰⁰ Accordingly, on September 9, 2009, President Obama made the following statement to a joint session of Congress in which he outlined his health reform initiative:

I have talked to enough doctors to know that defensive medicine may be contributing to unnecessary costs. So I am proposing that we move forward on a range of ideas about how to put patient safety first and let doctors focus on practicing medicine. I know that the Bush Administration considered authorizing demonstration projects in individual states to test these issues. It’s a good idea, and I am directing my Secretary of Health and Human Services to move forward on this initiative today.²⁰¹

195. Ronen Avraham, *President Obama’s First Two Years: A Legal Reflection: Private Regulation*, 34 HARV. J.L. & PUB. POL’Y 543, 575 (2011).

196. *Id.*; Sheryl Gay Stolberg & Robert Pear, *Obama Open to Reining in Medical Suits*, N.Y. TIMES, June 15, 2009, at A1.

197. See *supra* text accompanying notes 192–93.

198. See Stolberg & Pear, *supra* note 196 (“the A.M.A.’s highest legislative priority is capping jury awards, highly unlikely under the Obama administration”).

199. *Id.*

200. *Id.*

201. President Barack Obama, Health Care Speech to Congress (Sept. 9, 2009), available at http://www.nytimes.com/2009/09/10/us/politics/10obama.text.html?pagewanted=1&%2360;!-Undefined%20dynamic%20function%20data_sanitationlib::sanitize_string:1%20called--&%2362.

On June 11, 2010, the Agency for Healthcare Research and Quality (AHRQ) in the Department of Health and Human Services²⁰² duly announced that it had awarded a number of demonstration and planning grants under the new health reform legislation, the Patient Protection and Affordable Care Act (PPACA).²⁰³ The purpose of the grants, according to AHRQ, was to test models that, among other things, “ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits; and . . . reduce liability premiums.”²⁰⁴ One of the AHRQ planning grants, worth \$299,458, was given to Lynn Marie Crider of the Office for Oregon Health Policy and Research (OHPR) to “develop and implement a method for setting priorities for developing evidence-based practice guidelines, craft a broadly supported safe harbor legislative proposal that will define the legal standard of care, and develop a plan to evaluate the effectiveness of the legislative proposal, if enacted.”²⁰⁵ According to an OHPR job posting for a student researcher,

202. This was the name adopted by Congress in 1999 for what previously had been called the Agency for Health Care Policy and Research when it lost its authority to “arrange for” the issuance of practice guidelines due to opposition from physicians. *See* Avraham, *supra* note 195, at 576–78.

203. Press Release, Agency for Healthcare Quality and Research, HHS Announces Patient Safety and Medical Liability Demonstration Projects (June 11, 2010), <http://www.ahrq.gov/news/press/pr2010/hhsliabawpr.htm> (hereinafter “AHRQ Press Release”).

204. *Id.*

205. Medical Liability Reform and Patient Safety, Planning Grants (June 2010), <http://www.ahrq.gov/qual/liability/planninggrants.htm>. PPACA states that demonstration grants must “not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation” 42 U.S.C.A. § 280g (West 2012), *amended by* Patient Protection and Affordable Care Act § 10607, *adding* § 399V-4(c)(2)(H). Therefore, the Oregon grant was in the form of a planning rather than a demonstration grant because implementing its proposal would require legislative changes to medical liability rules. Randall R. Bovbjerg, *Will the Patient Protection and Affordable Care Act Address the Problems Associated with Medical Malpractice?*, URBAN INSTITUTE, <http://www.rwjf.org/files/research/67188malpractice.pdf> (2010). In awarding planning grants, PPACA instructs the Department of Health and Human Services, of which the AHRQ is a part, to “give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation,” 42 U.S.C. § 399V-4(i). However, this section also states that the planning grant must be for a demonstration project that meets the criteria for a demonstration grant. *Id.* If the project would require a change in state law, it therefore appears that it could not be funded by a PPACA demonstration grant following the planning grant phase. Furthermore, PPACA demonstration projects must provide patients “the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative” § 399V-4(c)(2)(G). It is unlikely that a safe-harbors demonstration project could meet the opt-out requirement in any meaningful way, however. Most likely, the demonstration project would employ the same approach as the birth-related injury compensation programs adopted in Virginia and Florida in the late 1980s. These programs substituted for the malpractice system a workers-compensation-like administrative system to compensate victims for a narrow range of birth-related injuries. The enabling

the project will “explore a method for adopting evidence-based guidelines to address the clinical situations that result in significant numbers of patient injuries or medical liability claims.”²⁰⁶ To “reduce medical liability claims,” the project will explore “linking the legal standard of care to compliance with the guidelines,” the job description continues, in order to “provide physicians with greater clarity about the standard of care expected of them and assure them that, if they adhere to the guidelines, they will not be found liable for harm resulting from failure to do something that is inconsistent with the guidelines.”²⁰⁷ The failed experiments of the 1990s, in short, were to be tried again.

This time, however, the backers of the safe harbors initiative are confident of success because they plan to use new and improved guidelines that are “evidence-based,”²⁰⁸ that is, guidelines that are based on “impartial,” “rigorous” analysis of evidence from “well-designed studies” and from “deep clinical and scientific expertise.”²⁰⁹ The evidence itself is expected to come from an expanded program of federally funded comparative effectiveness research, another element of President Obama’s health agenda. The American Recovery and Reinvestment Act of 2009 (ARRA), for example, authorized the expenditure of \$1.1 billion to conduct research comparing “clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions.”²¹⁰

legislation required that patients be given the opportunity to opt out by choosing a physician and hospital that have chosen not to participate in the program, but since patients may not know in advance whether the provider is participating, and since virtually all eligible providers have chosen to participate, patients are unlikely to have any practical alternative. See Maxwell J. Mehlman, *Promoting Fairness in the Medical Malpractice System*, in *MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM* 137–53 (William M. Sage & Rogan Kersh, eds., 2006).

206. Overview of the Agency for Healthcare Research and Quality’s Medical Liability Reform and Patient Safety Planning Grant, http://cms.oregon.gov/oha/OHPR/grant/docs/medliabgrantoverview_4.14.11.pdf (last visited Sept. 11, 2012).

207. *Id.*

208. David Eddy is said to have coined the term and to have been the first person to produce a national guideline explicitly based on evidence. See David Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 *HEALTH AFF.* 9, 9 (2005).

209. Alan M. Garber, *Evidence-Based Guidelines As a Foundation For Performance Incentives*, 24 *HEALTH AFF.* 174, 175 (2005).

210. M.C. Weinstein & J.A. Skinner, *Comparative Effectiveness and Health Care Spending: Implications for Reform*, 326 *N. ENG. J. MED.* 460–65 (2010). ARRA also established the Federal Coordinating Council for Comparative Effectiveness Research to foster optimum coordination of comparative effectiveness research conducted or supported by federal departments and agencies, while the 2010 health care reform legislation established the Center for Comparative Effectiveness Research within AHRQ and an independent Comparative Effectiveness Research Commission. Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong., 2nd sess. (2010).

Will this new guidelines initiative succeed? What does the failure of the guidelines effort in the 1990s tell us about its chances of success? Is the safe harbors concept sound scientifically? Can guidelines truly be “evidence-based”? Finally, would the increase in professional power represented by the safe harbors approach be warranted?

IV. THE WEAKNESSES OF THE EARLY GUIDELINES

Experts who were familiar with the practice guidelines that were available in the early 1990s generally were not impressed. Guidelines were pouring forth; the AMA had documented 1600 of them, issued by more than sixty entities.²¹¹ But which ones were valid reflections of the standard of care? Many of the guidelines made conflicting recommendations. The Office of Technology Assessment (OTA), a research agency created in 1972 to advise Congress on scientific technology, warned that “[i]f courts and legislatures are not selective about which guidelines are introduced as evidence, these conflicts may find their way into the courts and further confuse rather than clarify the process of determining negligence.”²¹² One solution put forward to deal with multiple guidelines that covered the same subject was for courts to rely only on national guidelines, as Maine had attempted to do in selecting the specialty subjects for its program, but typically a number of national organizations were interested in a particular area of medicine, and these organizations often disagreed about what constituted proper care.²¹³ Moreover, physicians and legislators were concerned that reliance on national standards could ignore local differences that could make the national standards overly burdensome and unrealistic.²¹⁴ The OTA, predicting that this might cause state and local groups to modify national guidelines or to refuse to rely on them in programs such as Maine’s, cautioned:

State guidelines initiatives such as these raise . . . the potential for conflict between national, State, and even institutional [e.g.,

211. Trail & Allen, *supra* note 134, at 252.

212. OFFICE OF TECH. ASSESSMENT, IMPACT OF LEGAL REFORMS ON MEDICAL MALPRACTICE COSTS 33 (1993). Experts convened by the Rand Institute for Civil Justice similarly worried that “the competition in guidelines . . . could generate confusion in malpractice cases as to which guidelines are ‘better’ and should have been followed in the treatment setting giving rise to the specific malpractice claim. Instead of clarifying the issues regarding [the] standard of care in the malpractice suit, such competition between guidelines in the courtroom could simply elevate ‘the battle of experts’ that often occurs to a ‘battle of guidelines.’” RAND REPORT, *supra* note 149, at 58.

213. See Rosoff, *supra* note 9, at 345.

214. See OFFICE OF TECH. ASSESSMENT, *supra* note 212, at 33.

hospital] guidelines. Most of Maine's guidelines were modeled closely from nationally recognized standards, but others were developed de novo by Maine physicians and could be construed as setting a precedent for reconversion to a more local standard of care. Developers of guidelines in Minnesota anticipate using national guidelines as models and amending them if necessary to conform to the realities of health care delivery in the State. In Vermont, the statutory description of guidelines could be interpreted as including even written institutional protocols.²¹⁵

Concerned that national guidelines would impinge on the preferences of local medical societies, however, the AMA "published a pamphlet to assist local organizations with guideline modification processes."²¹⁶

Even if only one guideline covered a topic, physicians' concern that slavish adherence to the guideline would deprive them of their discretion to adjust care to suit the needs of individual patients resulted in the inclusion of loopholes and escape clauses. Hall lamented:

The difficulty encountered to date is that what might otherwise be sufficiently precise guidelines are rendered entirely advisory or equivocal by waffling phrases and general disclaimers. For instance, the anesthesiology standards described previously call for monitoring blood pressure and heart rate 'at least every five minutes,' but, 'under extenuating circumstances, the responsible anesthesiologist may waive the requirement.' These two qualifications render the standard incapable of offering a definitive statement of whether every five minutes is often enough or too often.²¹⁷

Built-in exceptions, which Hall blamed on what he called the "snowflake" theory that no two patients or conditions were exactly alike, made relying on a guideline to serve as the standard of care unworkable: "It is impossible," he pointed out, "for physicians to have both wide clinical discretion and, at the same time, freedom from scrutiny in malpractice litigation."²¹⁸

Another problem with the guidelines was that they could be biased by the interests of the medical groups that issued them. One observer at the time cautioned:

215. *Id.*

216. Ayres, *supra* note 61, at 429.

217. Hall, *supra* note 105, at 143. *See also* Begel, *supra* note 141, at 84 ("It is difficult to imagine a set of facts upon which compliance with the anesthesiology protocol would resolve all questions regarding compliance with the appropriate standard of care as a matter of law.").

218. Hall, *supra* note 105, at 144.

Physician specialists may realize economic gains when particular guidelines are promulgated. Currently, most guidelines are drafted by medical specialty organizations. To the extent that such guidelines purport to require the expertise of a specialist, the basis of such a requirement should be to assure high quality care, rather than to confer an economic advantage.²¹⁹

Other commentators pointed out that bias could be injected by differences in viewpoint as well as economic self-interest:

The value of the various outcomes may differ significantly depending on one's perspective, and such differences may explain differences in recommendations that have occurred. For example, an organization dedicated to reducing harm from cancer may place greater value on selected cancer screening interventions, even though such interventions might prove to be extremely costly for the magnitude of the benefit they provide. Another organization, whose purpose is to promote the overall health of society, may view the same evidence differently, preferring to concentrate on other proven interventions with greater impact on overall public health. Examples of this are the conflicting recommendations among current breast cancer and prostate cancer screening guidelines.²²⁰

The primary shortcoming of practice guidelines in the 1990s, however, was the lack of scientific evidence supporting their recommendations, without which guideline issuers were free to base them simply on bad habits. A study found that one problem was the failure of the guideline issuers to consult the evidence that was available:

Less than 10% of the guidelines used and described formal methods of combining scientific evidence or expert opinion. Many used informal techniques such as narrative summaries prepared by clinical experts, a type of review shown to be of low mean scientific quality and reproducibility. Indeed, it was difficult to determine if some of the guidelines made any attempt to review evidence, as less than 20% specified how evidence was identified, and more than 25% did not even cite any references.²²¹

219. Ayres, *supra* note 61, at 436.

220. Terrence M. Shaneyfelt, Michael F. Mayo-Smith & Jonathan Rothwangl, *Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature*, 281 JAMA 1900, 1904 (1999).

221. *Id.*

The authors evaluated 279 guidelines on a wide variety of topics according to twenty-five methodological standards²²² and found that, in 1997, the guidelines on average satisfied barely half of the standards.²²³

Even if a guideline at one time rested on a sound scientific foundation, the evidence might well have changed, making the guideline no longer valid. A 2001 study of the seventeen guidelines still in effect in 2000 out of the nineteen guidelines that had been issued by the AHCPR between 1990 and 1996 concluded that “more than three quarters need updating.”²²⁴ The staleness problem is a symptom of an even deeper problem: the risk that by freezing the standard of care, guidelines will discourage innovation. This was another reason why the AMA refused to back the safe harbors initiative. The AMA’s general counsel issued the following statement:

[A] substantial amount of uncertainty is inherent in the practice of medicine, and the uncertainty often gives rise to differing points of view about how to handle various types of clinical situations. These differences tend to be resolved through research and, more importantly, through experience in the practice of medicine. Usually a consensus begins to form about an area of disagreement based on cumulative research and the observations of physicians about what methods for handling a clinical situation yield the best results. There is some danger that the adoption of a given practice parameter as the legal standard of care would interfere with this evolutionary process. Physicians might disagree with a legally adopted standard, or they might have an idea about a new way to handle a problem, but would not feel free to test their beliefs with research or in their practices. They would feel constrained to follow the legal standard. That sense of restraint could make it more difficult for new ideas to emerge, be tested, and be accepted.²²⁵

222. The standards dealt with guideline format and development (ten standards), identification and summary of evidence (ten standards), and formulation of recommendations (five standards). *Id.* at 1901.

223. *Id.*

224. Paul G. Shekelle et al., *Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines: How Quickly Do Guidelines Become Outdated?*, 286 JAMA 1461, 1466 (2001). See also Avraham, *supra* note 195, at 568 (“A 2001 report assessed the reliability of seventeen CPGs developed between 1990 and 1996 by the AHRQ and concluded that thirteen were out of date with then current research. According to the study, approximately \$4 million per guideline was needed to adequately revise them through the AHRQ’s Evidence Based Practice Center Program. Unfortunately, medical research does not follow a set schedule, and agency guidelines can fall even further behind new developments in medicine.”).

225. Edward B. Hirshfeld, *Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886, 2889 (1991).

Given all these guideline deficiencies, in short, it is no surprise that, in the 1990s, hopes that professional guidelines could control physicians' standard of care were dashed. A report by the prestigious IOM in 1990 summarized the state of the art of practice guidelines development as follows:

Most generally, the process of systematic development, implementation, and evaluation of practice guidelines based on rigorous clinical research and soundly generated professional consensus, although progressing, has deficiencies in method, scope, and substance. Conflicts in terminology and technique characterize the field; they are notable for the confusion they create and for what they reflect about differences in values, experiences, and interests among different parties. Public and private development activities are multiplying, but the means for coordinating these efforts to resolve inconsistencies, fill in gaps, track applications and results, and assess the soundness of particular guidelines are limited. Disproportionately more attention is paid to developing guidelines than to implementing or evaluating them. Moreover, efforts to develop guidelines are necessarily constrained by inadequacies in the quality and quantity of scientific evidence on the effectiveness of many services.²²⁶

Accordingly, the IOM concluded, guidelines had a long way to go before they would be capable of meeting the goals of their proponents:

Today the field of guidelines development is a confusing mix of high expectations, competing organizations, conflicting philosophies, and ill-defined or incompatible objectives. It suffers from imperfect and incomplete scientific knowledge as well as imperfect and uneven means of applying that knowledge. Despite the good intentions of many involved parties, the enterprise lacks clearly articulated goals, coherent structures, and credible mechanisms for evaluating, improving, and coordinating guidelines development to meet social needs for good-quality, affordable health care.²²⁷

The fate of President Clinton's effort to employ practice guidelines as a defense to malpractice liability in his national health reform initiative bears this out; the White House Task Force on Health Care Reform ended up rejecting the idea, with the co-chair of the relevant working group observing that "[t]here's not a lot of evidence out there"²²⁸

226. IOM 1990 REPORT, *supra* note 8, at 6.

227. *Id.* at 15.

228. Hyams, Shapiro & Brennan, *supra* note 5, at 309.

Twenty years later, how far has the development of guidelines progressed? Have solutions been found to the problems that afflicted guidelines in the 1990s? Has medicine found ways around the issues of lack of uniformity, lack of specificity, bias, conflicts of interest, and most of all, the dearth of scientific support? The answer, for the most part, is that it has not.

V. SHORTCOMINGS OF CURRENT PRACTICE GUIDELINES

The same weaknesses that doomed the guidelines initiative in the 1990s continue to plague guidelines today. Many guidelines still make conflicting recommendations.²²⁹ A 2009 article in the *Journal of the American Medical Association* (JAMA) gives a good example:

Although unanimity is the rule in individual guidelines, it can be strikingly absent when different guidelines are compared. The debate as to whether low-density lipoprotein cholesterol (LDL-C) or apolipoprotein B (apoB) is a more powerful marker of the risk of vascular disease illustrates that guideline groups may not just disagree—they actually may contradict each other. For instance, in the past 6 months, 4 reports have compared LDL-C and apoB, with 2 supporting LDL-C over apoB and 2 in favor of apoB for predicting cardiovascular risk. The 2 reports that favor LDL-C state categorically that there is no published evidence allowing apoB treatment targets to be established. The 2 that chose apoB cite multiple studies supporting their position in favor of an apoB target. Only one presents a complete, detailed, organized review and analysis of the evidence including the technical accuracy and reproducibility of the 2 measures.²³⁰

Another group of researchers that looked at guidelines for preventive care found significant variability in screening recommendations:

The average number and range of lifetime screens [for cancer and cardiovascular disease] varied by issuing entity. For example, a healthy twenty-one-year-old woman who became sexually active at age eighteen would have twenty-five screens for cervical cancer during her lifetime if she followed American Cancer Society guidelines, but she would have only fifteen screens if she followed

229. See Finlay A. McAlister et al., *How Evidence-Based Are the Recommendations in Evidence-Based Guidelines?*, 4 PLOS MED. 1325, 1326 (2007) (“Unfortunately, recommendations may differ between guidelines, leaving the clinician with a decision to make about which guideline to follow.”).

230. Allan D. Sniderman & Curt D. Furberg, *Why Guideline-Making Requires Reform*, 301 JAMA 429, 430 (2009).

the US Preventive Services Task Force guidelines. Recommendations for prostate cancer were even more variable, ranging from the opinion that there was insufficient evidence to recommend for or against screening to a recommendation fifteen screens over a patient's lifetime. The variability was not confined to the number of recommended lifetime screens. The population for which screening was recommended also varied. For example, the American College of Obstetricians and Gynecologists calls for screening all women over age forty-five for diabetes every three years. The US Preventive Services Task Force guidelines call for screening adults whose blood pressure is greater than 135/80 mm Hg, without recommending how often screening should take place. And the American Diabetes Association calls for all patients over age forty-five, particularly those who are obese, to be screened every three years.²³¹

The researchers' explanations for these deficiencies echo criticisms similar to those that had been lodged against the earlier guideline efforts: "Insufficient available evidence may be responsible for some of the variability," but "[b]iases on the part of authors and too great a reliance on expert opinion where evidence is lacking may also contribute."²³² Bias stems partly from the lack of rules about the range of expertise and viewpoints that must be employed in the guideline-writing process.²³³ But bias also is attributable to the financial implications of guidelines for different specialties.²³⁴ As one research group observes, "[b]y favoring one test over another, or one therapy over another, guidelines often create commercial winners and losers, who cannot be disinterested in the result and who therefore must be separated from the process."²³⁵

231. Salomeh Keyhani et al., *A New Independent Authority Is Needed to Issue National Health Care Guidelines*, 30 HEALTH AFF. 256, 259–60 (2011).

232. *Id.* at 261. It is perhaps not surprising that preventive care guidelines should be so problematic "[g]iven that more than 500 CPGs exist just for preventive care across the lifespan . . ." John Fontanesi et al., *A New Model of Adoption of Clinical Practice Guidelines*, 13 J. PUB. HEALTH MGMT. PRAC. 605, 605 (2007).

233. See Sniderman & Furberg, *supra* note 230, at 429.

234. See William G. Carnett, *Clinical Practice Guidelines: A Tool to Improve Care*, 16 J. NURSING CARE QUALITY 60, 62 (2002) ("Those [guidelines] written by interdisciplinary, collaborative groups such as the Agency for Health Care Policy and Research (AHCPR) are viewed as written to specifically benefit patient care and general health practices. Others, however, are written by specialty societies that potentially could be focused on the 'proper' use or indications/credentialing for invasive and income-generating procedures.")

235. Sniderman & Furberg, *supra* note 230, at 430. See also Keyhani et al., *supra* note 231, at 263 (linking bias to vague guidelines).

In addition to professional biases, personal conflicts of interest continue to corrupt the guideline issuance process.²³⁶ A study of the seventeen cardiovascular guidelines issued most recently by the American College of Cardiology and the American Heart Association showed that 277 of the 498 (56%) individuals who participated in the PG [practice guideline] production process had a conflict of interest, most often as a consultant or advisory board member, followed by research grants, honoraria/speakers bureaus, and stock or other ownership.²³⁷ The investigators found that chairs, co-chairs, and first authors of peer reviews had an even higher rate (81%).²³⁸ This was particularly troublesome, the investigators pointed out, “given the fact that many of the newest ACC/AHA guideline recommendations are based more on expert opinion than on clinical trial data.”²³⁹ Financial relationships with drug companies are especially common sources of conflicts of interest. An investigation of guideline panels by the prestigious journal *Nature* published in 2005 reported that “one-third of authors declared financial links to relevant drug companies, with around 70% of panels being affected. In one case, every member of the panel had been paid by the company responsible for the drug that was ultimately recommended.”²⁴⁰ Yet of the more than 200 guidelines the journal examined, “[o]nly 90 contained details about individual authors’ conflicts of interest. Of those, just 31 were free of industry influence.”²⁴¹ The investigators warned that “these links with pharmaceutical companies are more worrying than the financial conflicts known to plague clinical trials and reviews, say public-health experts, because the guidelines have such a direct effect on the drugs that doctors prescribe.”²⁴²

236. Timothy Stolfus Jost, *Oversight of Marketing Relationships Between Physicians and the Drug and Device Industry: A Comparative Study*, 36 AM. J.L. & MED. 326, 327 (2010) (“Conflicts of interest may even infect practice guidelines.”).

237. Todd B. Mendelson et al., *Conflicts of Interest in Cardiovascular Clinical Practice Guidelines*, 171 ARCHIVES INTERNAL MED. 577, 578 (2011).

238. *Id.*

239. *Id.* at 579.

240. Rosie Taylor & Jim Giles, *Cash Interests Taint Drug Advice*, 437 NATURE 1070 (2005). See also Niteesh K. Choudhry, Henry Thomas Stelfox & Allan S. Detsky, *Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry*, 287 JAMA 612, 612–17 (2002) (reporting conflicts based on financial relationships with drug companies).

241. Taylor & Giles, *supra* note 240, at 1070.

242. *Id.* Among the more notorious recent examples of conflicts of interest in the creation of guidelines is a guideline published in a leading cardiology journal by the Screening for Heart Attack Prevention and Education Task Force, composed of prominent cardiologists. The publication of the guideline was paid for by a major drug company, the authors of the guideline failed to adequately disclose their financial relationships, and the guideline was never subjected to peer review. Mendelson et al., *supra* note 237, at 578–79. Another well-publicized incident was the disagreement between the Infectious Diseases Society of America (IDSA) and the

A fundamental impediment to conflict-free guidelines is the lack of impartial funding for their creation. Even if commercial interests were barred from sponsoring the guideline process directly, Timothy Jost points out that they “play a major role in funding medical specialty societies and even patient disease organizations.”²⁴³

In March of 2011, the Council of Medical Specialty Societies issued a new code governing conflicts of interest, among other things, in the production of practice guidelines.²⁴⁴ However, the code has several disturbing loopholes. For example, it requires only that a majority of the panelists and the chair, or at least one chair if there are co-chairs, “are free of conflicts of interest relevant to the subject matter of the guideline”;²⁴⁵ as Avraham scoffs, “[i]t is indeed disturbing to imagine an ethical code requiring that only the majority of the judges sitting in a case not have conflicts of interest.”²⁴⁶ The code also permits industry support of the “overall mission-based activities” of the specialty society,²⁴⁷ which could result in sufficient indirect pressure from industry to influence guideline recommendations. Moreover, it remains to be seen if there are enough experts who do not have industry conflicts to enable panels to produce scientifically well-informed guidelines.²⁴⁸

Another weakness in the guideline process, as observed by one article, is that disagreements within a guideline development panel tend to be papered over:

Unanimity is not a natural component of science. Given the number and complexity of issues reviewed and given that scientific knowledge is at any moment incomplete, unanimity is obviously a tactic, not a necessary result. Debate may have been

International Lyme and Associated Diseases Society (ILADS) over proper treatment for Lyme disease. See Susan Ronn, *In the Lymelight: Law and Clinical Practice Guidelines*, 102 S. MED. J. 626, 627 (2009).

243. Jost, *supra* note 236, at 332–33.

244. COUNCIL OF MED. SPECIALTY SOCIETIES, CODE FOR INTERACTIONS WITH COMPANIES (2011).

245. *Id.* §§ 7.7–.8 at 21–22.

246. Avraham, *supra* note 195, at 583.

247. CODE FOR INTERACTIONS WITH COMPANIES, *supra* note 244 at § 7.3, p. 20 (annotation).

248. See Taylor & Giles, *supra* note 240, at 1071 (“[T]he bodies that produce guidelines maintain that there just aren’t enough experts without conflicts of interest. Nathaniel Clark of the American Diabetes Association estimates that three-quarters of members eligible to write guidelines have industry links, and other organizations report a similar number.”). See also Mendelson et al., *supra* note 237, at 580 (“It has been argued that excluding or limiting individuals with COIs is unrealistic because there simply are not enough experts without COIs.”) (citing David Van Wyck et al., *Response to “Influence of Industry on Renal Guideline Development”*, 2 CLINICAL J. AM. SOC’Y NEPHROLOGY 13, 13–14 (2007)).

brisk within the committee but usually all evidence has been expunged from the final document.²⁴⁹

A greater deficiency in current guidelines, however, is the same major shortcoming that stymied the guidelines movement in the 1990s: the lack of scientific evidence backing up the recommendations. When the IOM examined the state of the art of evidence-based medicine in 2009 in the course of recommending a list of priorities for the comparative-effectiveness research initiative funded under ARRA, for example, it found that “less than half of all treatments delivered today are supported by evidence.”²⁵⁰ As for existing practice guidelines, the IOM observed that “[e]ven the most thoughtfully conceived and sophisticated practice guidelines have inadequacies in their evidence base”²⁵¹ The IOM then gave some specifics:

A recent review of practice guidelines developed by the American College of Cardiology and the American Heart Association found that relatively few recommendations were based on high-quality evidence—randomized controlled trials, for instance—and many were based solely on expert opinion, individual case studies, or standard of care. A similar study revealed that more than two-thirds of recommendations contained in 51 guidelines for treating lung cancer were not evidence-based.²⁵²

As stated earlier, however, guideline proponents are optimistic that the new emphasis on evidence-based guidelines, facilitated by federal investment in comparative effectiveness and other sophisticated clinical research, will remedy prior shortcomings.²⁵³ Unfortunately, as the next section explains, their optimism is misplaced.

249. Sniderman & Furberg, *supra* note 230, at 430.

250. INST. OF MED., INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH 30 (2009).

251. *Id.*

252. *Id.* (references omitted). See also Linda H. Harpole et al., *Assessment of the Scope and Quality of Clinical Practice Guidelines in Lung Cancer*, 123 CHEST J. (SUPP.) 7S, 9S (2003) (lack of evidence supporting lung cancer guidelines); McAlister et al., *supra* note 229, at 1328 (28% of cardiovascular guidelines supported by evidence); Pierluigi Tricoci et al., *Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines*, 301 JAMA 831, 835 (2009) (lack of evidence supporting cardiology guidelines despite fact that cardiology “has a large pool of research to draw on for its care recommendations”).

253. See *supra* text accompanying notes 208–10.

VI. THE FALSE PROMISE OF EVIDENCE-BASED GUIDELINES

The hope that guidelines can be “evidence-based” is illusory. In the first place, there is no consensus on what makes a guideline evidence-based. The authors of a 2009 JAMA article, for example, stated that disagreement between guidelines about markers for the risk of vascular disease was not surprising “given the failure to even agree on what constitutes evidence or how that evidence should be graded.”²⁵⁴ A group of commentators agreed:

While it is easy to say that one should follow only those guidelines that are ‘evidence based,’ very few guideline developers declare their documents to be non–evidence based, and there is ambiguity about what ‘evidence based’ really means in the context of guidelines. The term may be interpreted differently depending on who is referring to the guideline—the developer, who creates the guidelines, or the clinician, who uses them. To their developers, ‘evidence-based guidelines’ are defined as those that incorporate a systematic search for evidence, explicitly evaluate the quality of that evidence, and then espouse recommendations based on the best available evidence, even when that evidence is not high quality. However, to clinicians, ‘evidence based’ is frequently misinterpreted as meaning that the recommendations are based solely on high-quality evidence (i.e., randomized clinical trials [RCTs]).²⁵⁵

Even if there were general agreement on what counted as a valid evidentiary basis for guidelines, it is not clear that the clinical trials from which the evidence is supposed to be extracted are capable of providing the necessary knowledge. The hope that the evidence will be free of bias and conflicts of interest is undermined by the fact that the investigators who conduct these studies are themselves subject to industry conflicts.²⁵⁶

254. Sniderman & Furberg, *supra* note 230, at 430.

255. McAlister et al., *supra* note 229, at 1326. A 2008 critique in JAMA makes a similar point: “Underlying the logic of EBM [evidence-based medicine] is the vague definition of what qualifies as evidence-based standards. Who determines which practices to adopt and what standards to use; how are the relative risks, benefits, and costs considered, weighed, and reported? Organizations such as the Joint Commission, the National Quality Forum, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality have served as clearinghouses for the adoption of certain best practices. However, the methods are not fully developed to determine when evidence is sufficiently strong, the feasibility in varying contexts is sufficiently robust, the costs or risks are small enough to encourage physician compliance, and recommendations are free of conflicts of interest.” Simon C. Mathews & Peter J. Pronovost, *Physician Autonomy and Informed Decision Making: Finding the Right Balance for Patient Safety and Quality*, 300 JAMA 2913, 2915 (2008).

256. Anna M. Sawka et al., *Competing Interests in Development of Clinical Practice Guidelines for Diabetes Management: Report from a Multidisciplinary Workshop*, 1 J.

Moreover, clinical trials often bear little resemblance to real-world conditions or concerns. In one study, for example, the second most common reason that the investigators cited for downgrading recommendations in the supposedly evidence-based guidelines that they reviewed, a problem in 47% of their sample, was “concerns about the clinical relevance of the RCT [randomized controlled trial]—for example, the RCT reported the effect of the recommended therapy on surrogate outcomes only (e.g., levels of glucose, low-density lipoprotein cholesterol, or blood pressure) rather than patient-centered outcomes such as death, myocardial infarction, or stroke.”²⁵⁷ Beyond a disjuncture between the endpoints of experiments and the real concerns of patients and physicians, the experience of the subjects in clinical studies may not predict results in actual patient populations. “The most frequent reason for downgrading RCT-based therapy recommendations (64 [51%] of the 126 cases),” stated the same group of researchers, “were concerns about the need to extrapolate from a highly selected RCT population to the scenario and/or the target population specified in the guideline.”²⁵⁸ For example, “the RCT was conducted to answer a particular question in a restricted study population but was then extrapolated in the guideline to justify using the tested intervention in a related, but different, clinical scenario and/or in a more general population.”²⁵⁹

Even if a guideline is based on a clinical trial that was conducted on the relevant patient population, the results of the trial may not hold true for specific patients. It is a truism of medicine that patients differ in how an illness affects them (assuming that they actually have the same illness) and in how they respond to treatments, based on factors such as their genetic makeup, the way their bodies function, and environmental conditions that researchers are only beginning to understand.²⁶⁰ Clinical trials often do not take this into consideration,²⁶¹ and therefore nor would guidelines which were based upon them, with the result that recommendations in the

MULTIDISCIPLINARY HEALTHCARE 29, 33 (2008) (“[E]vidence-based approaches to developing CPG recommendations were favored in CPG development by our group in hopes of minimizing bias. Yet, the use of such approaches may not necessarily safeguard CPGs from the influence of CIs, as primary research and its interpretation may be subject to potential influences of CIs. For example, it has been reported in the literature that industry sponsorship of studies is associated with pro-industry conclusions.”).

257. McAlister et al., *supra* note 229, at 1329.

258. *Id.* at 1328.

259. *Id.* at 1329.

260. See Carnett, *supra* note 234, at 65–66; John R. Hampton, *Guidelines: For the Obedience of Fools and the Guidance of Wise Men?*, 3 CLINICAL MED. 279 (2003).

261. See Rosoff, *supra* note 9, at 347.

guidelines would not necessarily comply with the standard of care for that patient. In the words of one British author, “the fundamental aim of a guideline is to get away from individualized treatment.”²⁶² Furthermore, clinical trials rarely take into account patient preferences.²⁶³ With clinical trials largely deaf to the fact that some patients are more willing to take greater risks for a potential benefit than other patients, guidelines based on the outcomes of the trials therefore will fail to reflect a critical factor in clinical decision-making.

The need to allow physicians the flexibility to tailor care for individual patients continues to be a major limitation on the ability of guidelines to establish the standard of care. Frequently, guidelines include loopholes in order to enable clinicians to practice individualized medicine, and as noted earlier, this makes adherence to the guideline essentially useless as a defense to malpractice.²⁶⁴ Avraham makes this clear by acknowledging that “doctors would be able to deviate from the guidelines if they have to. They would do so with the knowledge that they would no longer be protected by the [safe harbors] defense, but they would be no less protected than they are currently.”²⁶⁵

262. Hampton, *supra* note 260, at 283. Hampton adds that “guidelines inappropriately applied are the antithesis of the concept that a patient should be treated as an individual. We therefore must ask ourselves whether a particular guideline makes sense in general, and sense for each particular patient” *Id.* at 279. See also Jerome Groopman, *Health Care: Who Knows ‘Best’?*, N.Y. REVIEW OF BOOKS (Feb. 11, 2010), <http://www.nybooks.com/articles/archives/2010/feb/11/health-care-who-knows-best/?page=2> (quoting director of AHRQ that clinical trials “often do not reflect the ‘real world’ of individual patients”).

263. An analysis in 1999 found that “[f]ew guidelines (21.5%) . . . discussed the role of patient preferences in choosing among the various health care options. Given the increasing appreciation of the importance of patient values in many clinical decisions, we believe this factor has not been adequately addressed in guidelines to date.” Shaneyfelt et al., *supra* note 220, at 1904. See also Harpole et al., *supra* note 252, at 17S (need for guidelines to factor in patient preferences); Pamela S. Hinds et al., *Translating Psychosocial Research Findings into Practice Guidelines*, 33 J. NURSING ADMIN. 397, 397–98 (2003) (same); Jost, *supra* note 21, at 846 (importance of considering patient as unique).

264. See *supra* notes 190–91 and accompanying text. A prime example of such a loophole is in the 1985 anesthesia guidelines that had such a salutary effect on the quality of patient care. See *supra* note 138 and accompanying text. The irony is that the experts convened by the Rand Institute for Civil Justice predicted that future guidelines would be unlikely to have the same positive effect on physicians’ risk of liability: “[n]or will guidelines have a dramatic effect on reducing exposure to liability for physicians who practice in conformity with guidelines. The past experience with guidelines in the anesthesia field, which did result in reduced malpractice claims and insurance premiums, is not likely to be replicated in other fields of medicine. These guidelines were very basic and made specific recommendations upon which there was nearly universal agreement. They were also specifically addressed at identifying and correcting conduct that resulted in malpractice claims, which generally has not been the ostensible purpose of most other guidelines to date.” RAND REPORT, *supra* note 149, at 58–59.

265. Avraham, *supra* note 130, at 37.

Finally, the problem of guidelines becoming stale persists. Even if evidence-based guidelines were valid at one point in time, they may no longer be valid when a physician seeks to be guided by them or to employ adherence to them as a defense.²⁶⁶ A good illustration of guideline obsolescence is a 2010 study of the effect of using guidelines issued at different times as measures of the appropriateness of percutaneous coronary intervention (PCI).²⁶⁷ The guidelines classify patients into different classes, which determine the appropriateness of giving them PCI.²⁶⁸ The authors explain that practice guidelines issued in 2001 were in force between 2003 and 2004, but it was not until the guidelines were revised in 2005 that they “most accurately capture the evidence available in 2003 – 2004 (and hence the most desirable approach to practice) [at that time].”²⁶⁹ As a result,

[if] care in 2003–2004 had been scored based on the evidence available at that time (reflected in the 2005 guidelines), over 40% of patients would have been judged to be in a different indication class than if that care had been scored based on the guidelines available at the time (the 2001 guidelines).²⁷⁰

In view of these persistent problems, it is likely that few current guidelines, if any, accurately describe the standard of care in a particular case. The Obama administration’s stimulus money is funding some comparative effectiveness studies that might provide additional evidence on which to base guidelines,²⁷¹ but this evidence is not yet available, and the methodological problems inherent in the evidence-gathering process make it far from certain that a substantial amount of suitable evidence will be produced in the foreseeable future. Efforts by the CMSS and others in the future may someday overcome the obstructive effects of bias and conflicts of interest, but again, this may take time, and it is not clear that enough impartial experts will be left to avoid too great a loss of relevant medical and scientific expertise in the guideline production process. In short, there are serious questions about whether practice guidelines can be designed well enough to serve as indicators of the standard of care.

266. *See id.* at 29 (citing lack of resources for updating).

267. G. A. Lin et al., *Impact of Changes in Clinical Practice Guidelines on Assessment of Quality of Care*, 48 *MED. CARE* 733, 733 (2010). The guidelines were being evaluated for use in a pay-for-performance system in which providers are compensated based on whether they followed best practices, and not in a safe harbors program. *Id.*

268. *Id.*

269. *Id.* at 734.

270. *Id.* at 735–36.

271. *See generally supra* notes 185, 205 and accompanying text.

Assume for the moment, however, that scientifically valid guidelines produced by disinterested parties do in fact exist, and that a solution somehow has been found to the problem of how guidelines meant to apply to population groups, rather than to individuals, can accommodate patient preferences and medically relevant patient differences without being too indefinite to be able to serve as conclusive evidence of the standard of care in malpractice cases. In other words, assume that there are indeed trustworthy guidelines that actually tell physicians what the standard of care is in particular cases. Physicians who complied with such guidelines clearly would be entitled to use them persuasively in their defense.

But how would a court know when it was seeing such a guideline? Under the current system, the task of ensuring that guidelines accurately reflect the applicable standard of care is a joint enterprise of both the judicial and the medical systems. The medical system supplies the guidelines and the factual and scientific expertise to enable judges to determine if they are sufficiently reliable to be admissible and, if so, if they are conclusive enough that the judge can dispense with a jury trial on the issue of whether or not the defendant met the standard of care. If the judge decides, based on the input from the medical profession, that the guideline is not entitled to conclusive weight, then the judge asks the jury to decide (or decides alone, if the case is being tried without a jury) how much weight to give evidence, as well as the critical issue of whether the defendant in fact followed the guideline.

How well does this joint enterprise between law and medicine work? The only published study to date of cases in which the parties sought to utilize practice guidelines, an analysis by Hyams, Shapiro, and Brennan in 1996, found twenty-eight cases in which guidelines were “used successfully” between 1980 and 1994, and cited no cases in which guidelines had been used improperly.²⁷² My research assistant Kelsey Marand and I updated this study by examining cases reported between 1995 and 2011. We found a total of twenty-four additional reported cases (listed in the appendix). Guidelines were used successfully as a defense by defendants in nine of the cases and by plaintiffs as inculpatory evidence in eleven. In four cases, the courts determined that guidelines offered by plaintiffs were not inculpatory. In four cases, guidelines were relied upon by both parties. In all of the cases in which guidelines were successfully asserted as inculpatory, the guidelines were deemed “some evidence.” In six of the cases in which guidelines were successfully used defensively, adherence to the guideline constituted some evidence; in two, it gave rise to

272. Hyams, Shapiro & Brennan, *supra* note 5, at 295.

a rebuttable presumption. These data are admittedly limited, since they only include reported cases, but they suggest that guidelines serve a useful role under the current legal regime.

The question, then, is whether a safe harbors approach, in which practice guidelines would be accepted as conclusive evidence of the applicable standard of care without first undergoing judicial scrutiny, would work better. To answer this, we need to know which guidelines would be given this determinative effect. The medical profession clearly is insisting on issuing the guidelines.²⁷³ Therefore, it will resist the use of guidelines issued by health insurers, managed care organizations, and malpractice insurers,²⁷⁴ as well guidelines issued by the government, despite arguments that government involvement either in producing or vetting guidelines is essential in order for the guidelines to be deemed authoritative.²⁷⁵ But then

273. Nancy H. Nielsen, *We Must Protect Guidelines Against Undue Influence*, AMEDNEWS.COM (Apr. 20, 2009), <http://www.ama-assn.org/amednews/2009/04/20/edca0420.htm> (“Establishing guidelines for medical practice should be the province of those most trained to evaluate scientific evidence, which includes medical specialty societies.”); see Cecil Wilson, *Letter to the Editor: Liability and Evidence-Based Standards in Medicine*, N.Y. TIMES, Oct. 22, 2010, available at <http://www.nytimes.com/2010/10/28/opinion/lweb28malpractice.html> (“The good news is that the medical profession is a decade into its effort to create scientific, physician-level quality measures in a collaborative process based on best-care practices for patients.”). Wilson is referring to the AMA-convened “Physician Consortium for Performance Improvement,” which “develops, tests, implements and disseminates evidence-based measures that reflect the best practice and best interest of medicine.” *Clinical Practice Quality Improvement and Patient Safety*, AMERICAN MED. ASS’N, <http://www.ama-assn.org/ama/pub/physician-resources/clinical-practice-improvement.page> (last visited Aug. 21, 2012).

274. Scholars generally agree that none of these entities can be trusted to set standards of care that serve the interests of the public rather than merely those of the issuer. See Avraham, *supra* note 195, at 589 (“[H]ospitals, HMOs, and health insurers are too preoccupied with cost containment to be adequately responsive to patient safety. On the other hand, liability insurers’ main motivations are to prevent liability and lawsuits, so their guidelines are overly cautious and disregard cost-effectiveness.”); Ayres, *supra* note 61, at 437 (“[S]ome payers use parameters, indeed develop them, as a method to maximize profits under the guise of reducing inefficient or unnecessary services.”); Keyhani et al., *supra* note 231, at 257 (insurance-sourced guidelines “are meant to apply only to their beneficiaries and may recommend limiting care based on cost concerns”). Only Hall seriously suggests that guidelines issued by insurers should be accepted as the standard of care, arguing that “a sizeable number of patients and physicians agree to be bound by the standard by choosing to enroll with or work under the particular insurance plan.” Hall, *supra* note 105, at 141.

275. See Rosoff, *supra* note 9, at 329 (proposing government certification program); Albert Tzeel, *Clinical Practice Guidelines and Medical Malpractice: Guidelines Gaining Credibility in Courtrooms, May Eliminate Expert Testimony (Doctors, Lawyers and Lawsuits)*, PHYSICIAN EXECUTIVE, Mar. 2002, at 36, 38 (noting that the use of guidelines in medical malpractice presupposes approval by state officials). Opponents of government involvement complain that guidelines issued by government agencies are inherently inefficient (see Avraham, *supra* note 130, at 635), intrusive (see Cecil B. Wilson, *Health System Reform: What Does the Future*

will any guideline issued by medical professionals establish the standard of care? The AHRQ maintains a database that currently contains more than 2,400 practice guidelines issued by more than 300 organizations,²⁷⁶ most of

Hold, AMERICAN MED. ASS'N. (Aug. 25, 2009), <http://www.ama-assn.org/ama/pub/news/speeches/winter-park-hsr-future.page>), and would be used to ration care (*see* Rosoff, *supra* note 9, at 328). Critics point to the firestorm over recommendations for mammograms issued by the U.S. Preventive Services Task Force and similar incidents as evidence of the high and potentially unsustainable political costs of government-issued guidelines. *See* Keyhani et al., *supra* note 231, at 262. Groopman gives the following example of government standard-setting gone awry: "Medicare specified that it was a 'best practice' to tightly control blood sugar levels in critically ill patients in intensive care. That measure of quality was not only shown to be wrong but resulted in a higher likelihood of death when compared to measures allowing a more flexible treatment and higher blood sugar. Similarly, government officials directed that normal blood sugar levels should be maintained in ambulatory diabetics with cardiovascular disease. Studies in Canada and the United States showed that this 'best practice' was misconceived. There were more deaths when doctors obeyed this rule than when patients received what the government had designated as subpar treatment (in which sugar levels were allowed to vary)." Groopman, *supra* note 262. Note, however, that the AHRQ described the Obama demonstration safe harbors project as supporting the development of a 'safe harbor' for physicians who can prove that they followed "state-endorsed evidence-based care guidelines." AHRQ Press Release, *supra* note 203 (emphasis added).

276. *News Release*, ECRI INSTITUTE (Aug. 4, 2010), https://www.ecri.org/press/pages/AHRQ_National_Guideline_Clearinghouse_and_National_Quality_Measures_Clearinghouse.aspx. ECRI operates the guidelines clearinghouse for the AHRQ. In an article in the December 14, 2011, issue of JAMA, the American Cancer Society claims that there are nearly 3000 guidelines in the Clearinghouse. Otis Brawley et al., *New American Cancer Society Process for Creating Trustworthy Cancer Screening Guidelines*, 306 JAMA 2495, 2495 (2011). In order to be included in the clearinghouse, a guideline must meet the following criteria:

1. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other health care practitioners and patients to make decisions about appropriate health care for specific clinical circumstances.
2. The clinical practice guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or health care organizations or plans. A clinical practice guideline developed and issued by an individual not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC.
3. Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development. A guideline is not excluded from NGC if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations.
4. The full text guideline is available upon request in print or electronic format (for free or for a fee), in the English language. The guideline is current and the most recent version produced. Documented evidence can

which are medical groups. Would all of these guidelines create safe harbors? Would judges have to accept, for example, a guideline issued by the Association of American Physicians and Surgeons, whose executive director states that “Comparative Effectiveness Research (CER) won’t buy anything for you; it will just pay bureaucrats and researchers,” and whose newsletter describes evidence-based medicine as “a greater merger of state and corporate power: Mussolini’s definition of fascism”?²⁷⁷

The alternative would be to authorize only some medical groups to issue legally binding guidelines, as was the case in the Maine guidelines project, where, it will be recalled, the legislature delegated guideline production to a handful of state specialty societies.²⁷⁸ But which societies would this be? Given the proliferation of conflicting recommendations issued by different groups, selecting only some groups would be tantamount to endorsing one set of recommendations over the others.²⁷⁹ How would the medical profession make this choice? The most highly respected source of medical expertise is probably the IOM,²⁸⁰ yet it is hard to imagine that even the distinguished members of the IOM could reconcile competing medical viewpoints, avoid bias and conflicts without losing the necessary expertise, keep up with changing science, and avoid slowing innovation by not updating recommendations often enough to accommodate medical advances.²⁸¹

More than likely, then, most, if not all, medical groups would want the right to issue legally binding guidelines, and physicians would want to insulate themselves from liability by following any one of them.²⁸² From the

be produced or verified that the guideline was developed, reviewed, or revised within the last five years.

Inclusion Criteria, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, <http://www.ngc.gov/about/inclusion-criteria.aspx> (last visited Aug. 27, 2012).

277. *The Standard of Care*, AAPS, Vol. 62, No. 1 (Jan. 2006), <http://www.aapsonline.org/newsletters/jan06.php>.

278. See *supra* note 177 and accompanying text.

279. Another alternative would be to give guidelines conclusive effect only if they were endorsed by all medical groups. Not only would such guidelines be rare, but they are likely to cover practices regarding which the standard of care would not be the subject of dispute between litigants, and therefore physicians would not have to seek shelter behind them.

280. Cf. Keyhani et al., *supra* note 231, at 264 (“[A]n independent, nonprofit institute working with multiple stakeholders—including the public and industry—might be able to overcome these obstacles.”).

281. See RAND REPORT, *supra* note 149, at 62 (“legislative mandating of specific guidelines in any fashion could contribute to the ossification of medical practice by ‘freezing’ the standard of care—clearly an undesirable eventuality in a field that changes as quickly as medicine”).

282. Safe harbors proponents in fact come close to saying this. Hall argues that “a defense is sufficiently established if the doctor shows only that she complied with at least one respectable body of opinion,” see Hall, *supra* note 105, at 131, while Rosoff states that “[w]hen

perspective of its historical battles over the standard of care, this approach represents an intriguing gamble by organized medicine: by embracing clinical diversity in this fashion, the mainstream profession would lose much of its control over the standard of care internally, but physicians as a whole would take control of the standard away from one of their major external foes—the judicial system.

The medical profession may be willing to play this game, but should we? A laissez-faire safe harbors program in which essentially any medical body could issue definitive guidelines would create a race to the bottom in which fringe medical groups immunize their members from suit by issuing unorthodox or minimalist recommendations at the expense of patients,²⁸³ and it would give the profession more power over the standard of care than it has ever enjoyed, and certainly more than any other profession has ever gained.²⁸⁴ Even in the heyday of medicine's professional control at the beginning of the twentieth century, courts still had the responsibility to determine if the evidence of custom submitted by defendants to establish

two (or more) groups, and thus their guidelines, are of equal stature and authority, a jury could be instructed that the defendant physician acted acceptably if he or she followed either guideline." Rosoff, *supra* note 9, at 345. But note that neither Hall nor Rosoff would allow *any* guideline to be accepted; Rosoff would require government certification, *id.* at 365–66, and while Hall does not explain what he means by "respectable," it is clear that he means for judges to determine if that term accurately describes the guideline issuer. See Hall, *supra* note 105, at 141–43.

283. See Havighurst, *supra* note 130, at 789 ("The medical profession . . . would be inclined to set relatively permissive standards.").

284. Most other professions have promulgated the equivalent of practice guidelines, but in no case are their guidelines accorded automatic admissibility and conclusive legal effect, let alone one-sided application. The rules governing the conduct of lawyers, in fact, contain explicit disclaimers against even giving them a presumptive effect. The Model Rules for Professional Conduct provide that "violation of a Rule should not itself give rise to a cause of action against a lawyer nor should it create any presumption in such a case that a legal duty has been breached The Rules are designed to provide guidance to lawyers and to provide a structure for regulating conduct through disciplinary agencies. They are not designed to be a basis for civil liability." MODEL RULES FOR PROF'L CONDUCT, Scope cmt. 20 (2010). The earlier Model Code of Professional Responsibility similarly stated that "[t]he Model Code makes no attempt to prescribe either disciplinary procedures or penalties for violation of a Disciplinary Rule, nor does it undertake to define standards for civil liability of lawyers for professional conduct." MODEL CODE OF PROF'L RESPONSIBILITY, Preliminary Statement (1980) (footnote omitted) available at <http://www.americanbar.org/content/dam/aba/migrated/cpr/mrpc/mcpr.authcheckdam.pdf>. Ann Peters states that one reason for this position is that "using the ethics rules [in legal malpractice actions] would be improper because the rules are overly protective of attorneys' interests, and thus the interests of nonlawyers would be inadequately protected." Ann Peters, *The Model Rules as a Guide for Legal Malpractice*, 6 GEO. J. LEGAL ETHICS 609, 623 (1993). Peters describes how the D.C. Bar in 1986 sought to delete the disclaimer in the Model Rules, but "stopped short of accepting ethical rules as a rebuttable presumption of legal malpractice." *Id.* at 616.

the standard of care was admissible and conclusive, and if the evidence were deemed admissible but not conclusive, juries still had to decide how much weight to give it. A safe harbors approach would take all of these functions away from the courts. What would justify giving the medical profession such unprecedented power?

VII. THE LEGITIMACY OF PROFESSIONAL SELF-REGULATION

Medicine is one of the three classic learned professions, the other two being law and the clergy.²⁸⁵ Scholars generally classify a profession as “learned” if it satisfies three criteria.²⁸⁶ First, its members must possess specialized expertise, achieved through a long period of study and training.²⁸⁷ Robinson, for example, observes that “a strong scientific foundation and long clinical apprenticeship make medicine esoteric for the ordinary citizen and create an asymmetry of information and authority between the physician and the patient.”²⁸⁸ The second criterion for a learned professional is that it must be committed to acting in the public interest.²⁸⁹ Physician and ethicist Samuel Packer thus explains that “these professions were elevated from trades over thousands of years, primarily because society felt that it would be better protected if these professions acted in the best interests of citizens who were in vulnerable circumstances.”²⁹⁰ These

285. See SULLIVAN, *supra* note 27, at 35 (“Originally, of course, [professional] referred to the classic honorific occupations of medicine, the bar, and the clergy.”).

286. See STARR, *supra* note 16, at 15 (“A profession, sociologists have suggested, is an occupation that regulates itself through systematic, required training and collegial discipline; that has a base in technical, specialized knowledge; and that has a service rather than profit orientation, enshrined in its code of ethics.”); see also SULLIVAN, *supra* note 27, at 36 (“A profession is typically described as an occupation characterized by three features: specialized training in a field of codified knowledge usually acquired by formal education and apprenticeship, public recognition of a certain autonomy on the part of the community of practitioners to regulate their own standards of practice, and a commitment to provide service to the public that goes beyond the economic welfare of the practitioner.”).

287. See ROBINSON, *supra* note 115, at 16 (stating that specialized expertise is obtained through a prolonged period of education and training).

288. *Id.*

289. See SULLIVAN, *supra* note 27, at 16 (“[A] profession is an occupation based upon formal knowledge and trained skill, organized in a collegial or guildlike way, and carried on in a spirit of service.”).

290. Samuel Packer, *Embryonic Stem Cells, Intellectual Property, and Patents: Ethical Concerns*, 37 HOFSTRA L. REV. 487, 490 (2008). Descriptions of the professional’s commitment to the public vary in terms of whether it is a fiduciary obligation to the patient, client, or parishioner, or instead a dual duty to the patient/client/parishioner and to the public, raising the question of whose welfare is paramount if the two conflict. *Compare id.* (“Those in need of healthcare, legal help, or religious guidance were felt to be vulnerable, and therefore special privileges were granted to these professions if they would act according to an agreed to social

two characteristics of the learned profession in turn give rise to the third; since learned professionals possess specialized expertise and can be trusted to act in the public interest, they are accorded a degree of self-regulation not delegated to other occupations:

The specialized skills that distinguish members of a profession require members of the profession to self-license and to self-regulate. The justification for self-regulation is tied to a distinctive skill set possessed by members in the profession—only individuals within the profession have the expertise to evaluate the conduct of other members. This autonomy is justified by and dependent upon the profession's elevation of the public good over its own self-interest.²⁹¹

Not surprisingly, the rationales that doctors have special expertise and that they act in the public interest are the primary justifications offered in support of the medical profession controlling its standard of care.²⁹²

covenant—that is, a contract. This fiduciary role for physicians, lawyers, and clergy evolved legally with licensure, codes of ethics, and external and internal mechanisms of compliance.”), with Melissa H. Weresh, *I'll Start Walking Your Way, You Start Walking Mine: Sociological Perspectives on Professional Identity Development and Influence of Generational Differences*, 61 S.C. L. REV. 337, 340 (2009) (quoting the ABA's statement: “the client's trust presupposes that the practitioner's self-interest is overbalanced by devotion to serving both the client's interest and the public good”). What is clear is that the profession must not regard self-interest as paramount. *Id.* Thus, the ABA declares that “fiduciary obligations to elevate the public good over the self-interest of the individual professional” are one of the “overriding themes that distinguish members of a profession.” *Id.*

291. Weresh, *supra* note 290, at 340–41; see SULLIVAN, *supra* note 27, at 4, 68 (“Formed by distinctive occupational cultures, professionals have aspired, as organized bodies, to set standards and manage the organization of their own work. The markets for professional labor, as in health care, law, accounting, architecture, or scientific fields, are largely structured by qualifications the professions themselves have set, even when regulated by the state. . . . [T]he professional (including a group of professionals providing a certain service) must persuade clients to accept the professional's definition and valuation of that service, even as the clients must acknowledge and trust the competence of the provider.”).

292. See McCoid, *supra* note 62, at 608 (“The ‘preferred position’ granted by the courts to the medical profession (and to other professions) may be in recognition of the peculiar nature of the ‘professional’ activity. The qualified practitioner of medicine has undertaken long years of study to acquire knowledge of man, his body and its illnesses and the means of combating such ailments, coupled with an intensive training of the senses and mind of the physician to respond to stimuli in a manner best described as ‘the healing art.’”); see also Peters, *supra* note 102, at 968 (“Tort law originally delegated the standard-setting power to physicians because of their expertise and their trustworthiness.”). Another justification offered to legitimize the standard of custom in medicine is that it reflects market forces, and therefore produces efficient results. See Peters, *supra* note 102, at 954–55 (referring to the views of Richard Posner, Patricia Danzon, and Richard Epstein). Pearson seems to embrace this view when he defends self-regulation of the medical profession over judicial oversight: “courts have generally functioned within their traditional limitations by refusing to become engaged in the establishment of standards of

Commentators assert that, in contrast to the members of the medical profession, lay persons do not possess the knowledge and experience to enable them to evaluate the appropriateness of care.²⁹³ Dean Prosser, for example, predicated the standard of custom on “the healthy respect which the courts have had for the learning of a fellow profession, and their reluctance to overburden it with liability based on uneducated judgment.”²⁹⁴ Furthermore, doctors, it is said, can be trusted to regard the welfare of their patients as paramount.²⁹⁵ James Henderson, Jr., thus argues that “[a]n important reason for allowing the medical profession to set its own standards is that courts can assume these standards are adequate to protect the interests of patients.”²⁹⁶

The problem the medical profession faces is that neither of these assumptions presently holds true.²⁹⁷ In the first place, the profession has far less knowledge and expertise than it claims,²⁹⁸ as shown by the practice

medical practice. If courts were to become so engaged, one likely result would be an increase in the cost of medical care with no assurance of a parallel increase in quality. Thus, any effort by courts to supervise the customary methods of medical practice is apt to be self-defeating.” Pearson, *supra* note 102, at 956. *But see* Clark C. Havighurst, *Decentralized Decision-Making: Private Contract versus Professional Norms*, in *MARKET REFORMS IN HEALTH CARE: CURRENT ISSUES, NEW DIRECTIONS, STRATEGIC DECISIONS* 22 (Jack A. Meyer ed., 1991) (arguing that custom does not control spending). Peters does a thorough job of demolishing the efficiency argument, noting the lack of consumer information, comprehension, and choice and physician conflicts of interest among the reasons for market failures in medicine. Peters, *supra* note 102, at 955–58.

293. W. PAGE KEETON ET AL., *PROSSER AND KEETON ON TORTS* 189 (5th ed. 1984), *quoted in* Peters, *supra* note 102, at 951.

294. *Id.*

295. *See* Cramm et al., *supra* note 104, at 703 (“Second, and considerably quainter given the current organization and delivery of health care, physicians are professionals whose first priority is dedication to the interests of their patients. From a deterrence standpoint, greater deference to the judgments of professionals is justified in contrast to others who produce products or provide services for gain, or even individuals acting in the personal sphere who pursue their own interests, all of which may pose risks to others.”).

296. James A. Henderson, Jr., *Process Constraints in Tort*, 67 *CORNELL L. REV.* 90, 926 (1982), *quoted in* Peters, *supra* note 102, at 951. Henderson’s torts casebook co-author Richard Pearson similarly asserts that “medical custom may be accepted as the standard of care in medical malpractice cases because physicians have been thought of as not exploiting the market for medical services for their own gain at the expense of the health of their patients. There is no need for courts to act as a source of pressure to compel the medical profession to give adequate consideration to patient safety and well-being, since the forces that operate within the profession make such extra-professional pressure unnecessary.” Pearson, *supra* note 102, at 537.

297. It may be questioned whether they ever did.

298. *See* Philip C. Kissam, *Antitrust Law and Professional Behavior*, 62 *TEX. L. REV.* 1, 13 (1983) (Although professional expertise is frequently cited as a rationale for professional self-regulation that is free from government intervention, the scope of professional expertise is often overstated. For example, the expertise of physicians consists primarily of understanding scientific laws governing the behavior of the human body. Applying these rules to individual

variations discovered by Wennberg, discussed earlier.²⁹⁹ Haavi Morreim, for example, lists a number of mainstream medical practices that lacked scientific support, including pulmonary artery catheterization, angioplasty, bypass surgery, arthroscopic debridement of the osteoarthritic knee, hormone replacement therapy, high-dose chemotherapy with autologous bone marrow transplantation for breast cancer, and the overuse and underuse of antibiotics.³⁰⁰ Even when data suggesting the proper course of action exist, doctors often fail to act on it.³⁰¹ Brownlee describes how “in one part of the country, practically every woman with breast cancer was still getting a mastectomy long after clinical trials had shown that a breast-sparing lumpectomy with radiation was just as effective. In another, babies were being put in neonatal intensive care units when they didn’t need it.”³⁰² A 2006 article in *Business Week* reports that most of the physicians interviewed said that only twenty to twenty-five percent of medicine has been proven effective, and quotes physician and health quality expert David Eddy as admitting that “[t]he problem is that we don’t know what we are doing.”³⁰³ In 2005, Eddy himself quoted an IOM estimate that “only 15 percent of medical practices [are] based on solid clinical trials”³⁰⁴

Not only do physicians possess less knowledge than at first blush, but lay persons seem be able to properly evaluate the quality of medical care, at least when they are jurors presented with evidence by medical experts. According to jury authorities Neil Vidmar and Shari Seidman Diamond, “there is no evidence that juries are incompetent to evaluate expert

circumstances requires varying degrees of judgment, particularly when a physician, in the absence of scientific knowledge or a known treatment, must respond to a medical problem. Thus, the expertise of physicians is a mastery of the technical solutions to patients’ problems, not of the manner in which the physician’s work should be organized. Furthermore, nonphysicians with less comprehensive and expensive training can competently undertake much of the physician’s routine work, and scientifically trained non-physicians may be able to evaluate many or most kinds of medical problems as competently as physicians.”). Richard Abel makes an additional point: “Professions rest their argument for self-regulation on two grounds. First, they insist that only fellow professionals possess the necessary expertise to judge professional performance. Even if true, this is self-serving, since the profession deliberately constructed the monopoly of expertise in the first place.” ABEL, *supra* note 2, at 37.

299. See *supra* notes 128–30 and accompanying text.

300. E. Haavi Morreim, *A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science*, 31 J.L. MED. & ETHICS 222, 223–25 (2003).

301. BROWNLEE, *supra* note 127, at 34.

302. *Id.*

303. John Carey, *Medical Guesswork*, BUSINESS WEEK, May 29, 2006, at 72–79.

304. Eddy, *supra* note 208, at 10.

testimony.”³⁰⁵ Moreover, empirical research shows that jurors are not naïve about experts or easily misled.³⁰⁶

If the premise that physicians are entitled to regulate themselves because only they have the expertise to evaluate the quality of their care is suspect, the assumption that they can be trusted to wield their regulatory authority in the public interest is even less defensible.³⁰⁷ Numerous critics complain, for example, about the profession’s unwillingness to sanction incompetent colleagues.³⁰⁸ “[T]he goal of self-regulation often appears to be to protect the inept members of the profession rather than the society they ostensibly serve,” observes Abel.³⁰⁹ The legitimacy of the profession began to erode,

305. Neil Vidmar & Shari Seidman Diamond, *Juries and Expert Evidence*, 66 BROOK. L. REV. 1121, 1175 (2001). Studies in which expert panels of physicians reviewed jury verdicts in medical malpractice cases show that they agreed in about seventy percent of the cases, only slightly lower than the seventy-three percent figure for all cases, whether tried, settled, or dismissed. See MAXWELL J. MEHLMAN & DALE A. NANCE, *MEDICAL INJUSTICE: THE CASE AGAINST HEALTH COURTS* 40, n.271 (2007), analyzing David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 N. ENG. J. MED. 2024 (2006).

306. Neil Vidmar, *Are Juries Competent to Decide Liability in Tort Cases Involving Scientific/Medical Issues? Some Data from Medical Malpractice*, 43 EMORY L.J. 885, 902–03 (1994).

307. The deferential portrayal of the professions, which Richard Abel calls “professional apologetics,” ABEL, *supra* note 2, at 17, derives from sociologists such as Emile Durkheim and Talcott Parsons and welfare economists such as Kenneth Arrow who viewed barriers against entry into the professions not as “the conscious, self-interested strategy of producers, but simply the means by which society ensures that consumers receive quality services,” *id.* at 21, and who felt that the professions “appeared to offer one antidote to the insidious poison of selfish materialism . . . as altruistic where others were egoistic, [as] self-regulating counterweights to an increasingly monolithic state.” *Id.* at 16. This account is rejected by “Chicago school” economists, who assert that professionals “have the same profit-maximizing interests as people in other businesses and that professional self-regulation, like any regulatory legislation, is more likely to result from ‘interest group’ bargaining than from a principled consideration of the public interest,” Kissam, *supra* note 298, at 11, and by Weberian sociologists, who hold that “governing bodies were unrepresentative and ineffective regulators, professions lacked the expertise they claimed, admission criteria bore little relevance to the profession’s actual work, ethical rules were motivated by economic self-interest and failed to ensure competence, and professionals repeatedly betrayed clients.” ABEL, *supra* note 2, at 17. In his famed study of the medical profession, Elliot Friedson calls it a “delinquent community” that has failed “to control the availability, cost, and quality of services of its members in the public interest—a failure tied directly to the internal laissez faire etiquette of its delinquent community” ELLIOT FRIEDSON, *DOCTORING TOGETHER: A STUDY OF PROFESSIONAL SOCIAL CONTROL* 246 (1975). Then there is George Bernard Shaw’s famous quip that “[a]ll professions are conspiracies against the laity.” GEORGE BERNARD SHAW, *DOCTOR’S DILEMMA: A TRAGEDY* 28 (Constable and Co. London 1920).

308. See generally Nadia N. Sawicki, *Character, Competence, and the Principles of Medical Discipline*, 13 J. HEALTH CARE L. & POL’Y 285 & nn.1–7(2010).

309. ABEL, *supra* note 2, at 38. He cites the fact that, “[a]lthough the number of physician license revocations increased 59 percent between 1984 and 1985, even the 1985 total was only

according to Robinson, “under increasingly severe criticism that interpreted the medical establishment less as a scientifically based benevolent society and more as a self-interested economic monopoly.”³¹⁰ Peters calls attention to recent research demonstrating “that physicians, like the rest of us, are driven not only by science and fidelity to patient interests, but also by habit, self-interest, and other competing considerations.”³¹¹ Jost decries the fact that “medical practitioners increasingly view themselves as businessmen engaging in commerce rather than as professionals and gentlemen.”³¹² The reality that the medical profession is self—rather than other—regarding was powerfully reinforced by Atul Gawande’s 2009 *New Yorker* article in which he investigated why care for patients in McAllen, Texas, cost Medicare twice as much as the national average: this was due to the fact that “a medical community came to treat patients the way subprime-mortgage lenders treated home buyers: as profit centers.”³¹³

The realization that medicine is less expert and more self-interested than it would like to believe is a major reason why the medical profession has lost a substantial degree of control over the standard of care, as reflected in the abandonment of the locality and customary care standards.³¹⁴ If the medical profession is unable to hold onto the powers that it once exercised because it can no longer satisfy the conditions that legitimize a substantial exercise of self-regulation, then it certainly does not seem entitled to the enormous increase in self-regulatory powers that would result if judges were no longer permitted to assess the validity of practice guidelines as evidence of the standard of care.

CONCLUSION

Medical practice guidelines have an important role to play as potential evidence of the standard of care, and the foregoing analysis does not preclude them from serving as definitive statements of the standard of care in malpractice actions. But in order for them to be able to do so, the judicial system must continue to play a major role. Judges must determine the admissibility and conclusiveness of guidelines, and they and juries must

406 out of 553,000 physicians; in 33 of the 51 jurisdictions fewer than 5 out of every 1000 physicians suffered any other penalty.” *Id.*

310. ROBINSON, *supra* note 115, at 26.

311. Peters, *supra* note 102, at 953.

312. Jost, *supra* note 21, at 840.

313. Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, NEW YORKER, June 1, 2009, available at http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande?currentPage=all.

314. See *supra* notes 103–04 and accompanying text.

decide the factual question of whether defendants actually followed the guidelines behind which they seek to shelter.

If judges and juries in malpractice cases must continue to play these key roles, then what could be different under a safe harbors approach? At most, judges might be instructed to give guidelines some degree of presumptive validity. But if the medical profession does not have the exclusivity of expertise and devotion to the public interest that would entitle it to validate guidelines on its own, it certainly cannot justify being given even more power by preventing plaintiffs from introducing the failure to comply as evidence of wrongdoing. Nor is it justifiable to prevent plaintiffs from offering expert evidence to rebut the authoritativeness of guidelines, to show why the guidelines should not apply in the case in question, or to question whether the defendants in fact followed them.³¹⁵ Only if the law

315. Such a distortion of the rules also would raise constitutional concerns. However, the question of whether a one-way safe harbors approach would be deemed unconstitutional is complex, and unfortunately the answer is likely to depend as much if not more on the political views of the judges hearing cases challenging the approach than on the merits. A few things are fairly clear: a challenge to a state's one-way-street safe harbors program on the basis of the right to a jury trial in the Seventh Amendment will not succeed since that amendment has not been held to apply to the states. Challenges asserted under state constitutional guarantees of the right to a jury trial and access to the courts may be more successful, since some courts have invalidated caps on damages on these grounds. See Michelle M. Mello et al., *Policy Experimentation with Administrative Compensation for Medical Injury: Issues under State Constitutional Law*, 45 HARV. J. ON LEGIS. 59 (2008); Nancy L. Zisk, *The Limitations of Legislatively Imposed Damages Caps: Proposing a Better Way to Control the Costs of Medical Malpractice*, 30 SEATTLE U. L. REV. 119, 127 (2006). Due process and equal protection challenges probably would be decided under a rational-basis standard of review. See Mello, *supra* note 61, at 705–08. While this standard is highly deferential to legislatures, it does not give them unlimited freedom, and a one-sided safe harbors law might not meet that standard unless the reviewing courts are convinced that one-sidedness is necessary in order to induce physicians to follow guidelines and to reduce defensive medicine. Neither of these arguments seems persuasive, since physician opposition to guidelines has markedly declined and there is no logical connection between defensive medicine and allowing both offensive and defensive use of guidelines. *Id.* at 695–702. Mello points out that “Permitting the introduction of *certain* evidence by one party to a lawsuit but not by the other party is an anomaly in the law. . . . There are exceptions to the rule of symmetry, but they are few and far between, and each is justified by an important policy concern. Arguably, no such policy justification exists for the one-way use of clinical practice guidelines evidence in medical malpractice cases.” *Id.* at 695 (emphasis added). None of the safe harbors programs in the 1990s were challenged on constitutional grounds. See Rosoff, *supra* note 9, at 343. In the case of Maine, the lack of a challenge may have been due to the fact that doctors did not take advantage of the program to defend themselves, and to the perception that it was not as one-sided as might have been thought: “The legal advisor of the demonstration project’s advisory committee stated . . . that he does not believe that there will be a successful constitutional challenge to the affirmative defense because patients still have an absolute right to a jury trial. Furthermore, the plaintiff can rebut the doctor’s argument in court that the practice guidelines admitted are the applicable standard of care. For example, if a doctor relies on the Ob/Gyn guidelines and the plaintiff can prove those

continues to perform its time-tested functions in a fair way can the proper balance of power between the medical profession and the public interest be maintained.

are not the appropriate standards for that particular case, then the affirmative defense is not available. The plaintiff could provide such proof in one of two ways. First, the plaintiff could prove the case is not an Ob/Gyn case. A second argument would concede that the case is an Ob/Gyn case, but that the guidelines do not cover the particular treatment or scenario as presented in the plaintiff's cause of action." Trail & Allen, *supra* note 134, at 245.

APPENDIX

Use of Practice Guidelines in Reported Cases: 1995-2011**Guidelines Used Successfully as Inculpatory**

Trowbridge v. United States, 703 F. Supp. 2d 1129 (D. Idaho 2010) (birth-related injury; American College of Obstetrics & Gynecology guidelines).

Van Horn v. Hornbeak, No. CV F 08-1622 LJO DLB, 2010 WL 599885 (E.D. Cal. Feb. 18, 2010) (malpractice in prenatal care and delivery; Center for Disease Control and American College of Obstetrics and Gynecology guidelines).

Smethers v. Champion, 108 P.3d 946 (Ariz. Ct. App. 2005), *review denied* (Sep. 27, 2005) (malpractice in LASIK surgery; FDA guidelines).

District of Columbia v. Wilson, 721 A.2d 591 (D.C. 1998) (malpractice in treating an asthma attack while incarcerated; guidelines included asthma guidelines issued by U.S. Public Health Service).

Bergman v. Kelsey, 873 N.E.2d 486 (Ill. App. Ct. 2007), *appeal denied*, 879 N.E.2d 929 (Ill. 2007) (birth-related injury; American College of Obstetrics and Gynecology and American Academy of Pediatrics guidelines).

Joyner–Wentland v. Waggoner, 890 N.E.2d 730 (Ind. Ct. App. 2008) (malpractice in breast lift; American Cancer Society guidelines).

Campbell v. Hosp. Serv. Dist. No. 1, Caldwell Parish, 768 So.2d 803 (La. Ct. App. 2000), *rehearing denied* (La. Ct. App. 2000), *writ denied*, 781 So.2d 558 (La. 2001) (malpractice in treating heart attack; source of guidelines not disclosed).

Collins v. State ex rel. Louisiana Health Care Auth., 774 S.2d 167 (La. Ct. App. 2000), *writ denied*, 775 So.2d 439 (La. 2000) (malpractice in treating infection in emergency room; CDC guidelines).

Feeley v. Baer, 669 N.E.2d 456 (Mass. App. Ct. 1996), *review granted*, 672 N.E.2d 539 (Mass. 1996), *aff'd in part and rev'd in part*, 679 N.E.2d 180 (Mass. 1997) (allegedly negligent prenatal care leading to death of newborn; American College of Obstetrics and Gynecology guidelines).

Darke v. Estate of Isner, 17 Mass. L. Rptr. 689 (Mass. Super. 2004) (malpractice in gene transfer experiment; American Society of Gene Therapy and other guidelines).

Jilek v. Stockson, 796 N.W.2d 267 (Mich. Ct. App. 2010), *rev'd sub nom.* Estate of Jilek ex rel. Jilek v. Stockson, 805 N.W.2d 852 (Mich. 2011) (malpractice in treating chest pain in emergency room; American College of Emergency Physicians guidelines).

Guidelines Offered Unsuccessfully as Inculpatory

Maynard v. Shook, No. 3:09-1004, 2011 WL 1230067 (S.D. W. Va. Mar. 30, 2011) (malpractice alleged in treating joint pain; American Medical Association guidelines).

Missan v. Dillon, 819 N.Y.S.2d 211 (N.Y. Sup. Ct. 2006) (malpractice alleged in treating prostate cancer; American Brachytherapy Society guidelines).

Kendall v. Cook, No. E2003-02227-COA-R3-CV, 2004 WL 1626256 (Tenn. Ct. App. July 21, 2004) (malpractice alleged in treating bipolar disorder; Expert Consensus Guidelines Series).

Thomas v. Alford, 230 S.W.3d 853 (Tex. App. 2007) (malpractice alleged in cancer treatment; American College of Radiology guidelines).

Guidelines Offered Successfully as Exculpatory

Woods v. U.S., 200 F. App'x 848 (11th Cir. 2006) (malpractice alleged in hip replacement; American Society of Anesthesiology guidelines).

Cashwell v. U.S., No. 1:CV-09-00728, 2009 WL 2929444 (M.D.Pa. Sept. 8, 2009) (malpractice alleged in treating Hepatitis C; Center for Disease Control guidelines)

Bond v. U.S., No. 06-1652-JO, 2008 WL 655609 (D. Or. March 10, 2008) (malpractice alleged in cardiac treatment; American College of Cardiologists/American Heart Association guidelines).

Becerra v. Contra Costa Cnty., No. A118013, 2008 WL 2546175 (Cal. Ct. App. June 26, 2008) (birth-related malpractice alleged; American College of Obstetrics and Gynecology guidelines).

Woldruff v. Banta, No. E038100, 2006 WL 2054344 (Cal. Ct. App. July 25, 2006) (malpractice alleged in cancer treatment; United States Health

Services Prevention Task Force and American Academy of Family Practice guidelines; rebuttable presumption).

Estate of Ford v. Eicher, 250 P.3d 262 (Colo. 2011), *rehearing denied* (Colo. May 9, 2011) (birth-related malpractice alleged; guideline issuer not specified).

Ellis v. Eng, 895 N.Y.S.2d 462 (N.Y. App. Div. 2010) (malpractice alleged in cancer treatment; American Society of Clinical Oncology guidelines; rebuttable presumption).

Hinlicky v. Dreyfuss, 848 N.E.2d 1285 (N.Y. 2006) (malpractice alleged in plaque removal surgery; American Heart Association/American College of Cardiology guidelines).

Frakes v. Cardiology Consultants, P.C., No. 01-A-01-9702-CV-00069, 1997 WL 536949 (Tenn. Ct. App. Aug. 29, 1997) (malpractice alleged in treating chest pain; American College of Cardiology/American Heart Association guidelines).