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Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?

Carter L. Williams

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Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?

Carter L. Williams*

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I. Introduction

Imagine that you are suffering from pneumonia and need an injection of a contrast medium prior to chest X-rays to examine your lungs. Imagine further that you have a choice between two physicians to perform the procedure. Physician A bases her performance of medical procedures on the accepted practices of the medical community and her personal experience. Thus, she relies on knowledge that she acquired years ago in medical school and what she has learned from her colleagues and through clinical experience. She will inject the contrast medium into your chest in accordance with traditional practice. Physician B also considers accepted practices and personal experience but additionally considers high-grade scientific evidence. She makes her decisions by integrating the best research evidence with clinical expertise and patient values. As such, she has read several studies cautioning against injection of contrast medium into the chest of patients with your physical characteristics because of a high risk of complications. She prefers an alternate site with proven efficacy and no safety risks. Do you have any doubt about which physician to choose?

This simple hypothetical scenario¹ introduces the difference between traditional eminence- or opinion-based medical practice² and evidence-based medicine (EBM),³ and suggests the desirability of the latter. EBM is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."⁴ EBM seeks to shift the focus of physician decisionmaking from experience and opinion to a more stringent review and application of high-grade scientific evidence garnered from randomized clinical trials (RCTs) and observational studies.⁵

1. This hypothetical scenario draws on the case *Brook v. St. John's Hickey Memorial Hospital*, 380 N.E.2d 72, 72 (Ind. 1978) (holding that radiologist was not negligent in choosing calf muscles as injection site for contrast medium instead of more common sites such as gluteal muscles or thighs). In *Brook*, the Supreme Court of Indiana considered an action alleging medical malpractice arising out of an injection of contrast medium into the two-year-old plaintiff's calf. *Id.* Prior to the events giving rise to the case, a specialist diagnosed Tracy Brook with a possible urological disorder. *Id.* at 73. In order to confirm the diagnosis, a radiologist had to inject Brook with a contrast medium and take X-rays. *Id.* The radiologist selected the patient's calves as the injection site instead of the gluteal muscles as the medium's manufacturer recommended. *Id.* at 74. Four months later, Brook experienced shortening of the achilles tendon, which calf trauma may have caused. *Id.* The radiologist defended his choice of the calves on the grounds that he had read warnings against injecting contrast medium into the gluteal muscles and thighs of young children, that he had previously used the calves as an injection site with no complications, and that he had not seen any evidence cautioning against use of the calves. *Id.* at 77. The *Brook* court affirmed the judgment of the trial court exonerating the radiologist. *Id.*

2. See John M. Eisenberg, *What Does Evidence Mean? Can the Law and Medicine Be Reconciled?*, 26 J. HEALTH POL., POL'Y & L. 369, 370 (2001) (contrasting practice of opinion-based medicine from practice of evidence-based medicine); Dan Mayer, *Evidence-Based Medicine*, 36 NEW ENG. L. REV. 601, 601 (2002) (defining eminence-based medicine). Mayer explains:

In the past, medicine was based on what a bunch of gray-haired experts believed and, since now I have gray hair, I can count myself among them. Basically, based on what "we" said medicine should be, "we" determined how medical practice should occur. I call this "Eminence-Based Medicine."

Id.

3. Scholars also refer to evidence-based medicine as evidence-based practice (EBP). See INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 147 (2001) (using terms evidence-based medicine and evidence-based practice interchangeably); Alan Pearson, *Nursing Takes the Lead: Redefining What Counts As Evidence in Australian Healthcare*, REFLECTIONS ON NURSING LEADERSHIP, Fourth Quarter 2002, at 18, 18 (discussing evidence-based practice in nursing in Australia).

4. David L. Sackett et al., *Evidence-Based Medicine: What It Is and What It Isn't*, 312 BRIT. MED. J. 71, 71 (1996).

5. See Eisenberg, *supra* note 2, at 369 ("Physicians have been encouraged to practice 'evidence-based medicine,' so that their clinical decisions would be based upon a foundation of solid science, especially using research that has applied rigorous epidemiologic methods, and has been published in peer-reviewed journals."); Lucian L. Leape et al., *What Practices Will Most Improve Safety?*, 288 JAMA 501, 501 (2002) ("Advocates of evidence-based medicine

The role of science in medicine has increased dramatically in recent decades.⁶ The increased prominence of science has improved health care by showing that many widely accepted medical practices are not only ineffective but, in some cases, injurious.⁷ Yet today, much of modern medicine remains unsupported by scientific evidence.⁸ EBM "arose from the realization that health care interventions, no matter how commonsense or physiologically sound, often lack benefit and sometimes even cause harm."⁹ In the absence of evidence of the efficacy of many treatments, physicians traditionally follow the pattern of Physician A, relying on anecdotal experience and knowledge acquired from mentors or peers to guide their practice.¹⁰ EBM encourages physicians to follow the paradigm of Physician B.

Indicators suggest that the EBM movement has altered medicine. For example, many medical schools have started teaching EBM.¹¹ In addition, one study suggests that the number of physicians practicing EBM has increased.¹² One scholar underscores the importance of the EBM movement by declaring it

(EBM) argue that medical decisions should be based, as much as possible, on a firm foundation of high-grade scientific evidence, rather than on experience or opinion."

6. See Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CAL. L. REV. 1483, 1487-88 (1989) (considering dramatic increase in role of science in medical care in recent decades).

7. See Leape et al., *supra* note 5, at 501 ("In the past, many experience-based and opinion-based practices have proved to be ineffective or even harmful.").

8. See *id.* (noting questionable value of many widely used practices due to lack of supporting evidence); William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1774 (1999) ("[O]nly a small percentage of medical therapies have been scientifically proven.").

9. Kaveh G. Shojania et al., *Safe But Sound: Patient Safety Meets Evidence-Based Medicine*, 288 JAMA 508, 508 (2002); see also Leape et al., *supra* note 5, at 506 (referring to use of lidocaine after myocardial infarction as one of several medical practices physicians discarded after rigorous studies established its ineffectiveness (citing Antman J. Lau et al., *Cumulative Meta-Analysis of Therapeutic Trials for Myocardial Infarction*, 327 N. ENG. J. MED. 248, 248-54 (1992))).

10. See Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 382 (2002) (recognizing physicians' traditional reliance on personal experience and anecdotal information).

11. See Eisenberg, *supra* note 2, at 370 (pointing to shift in culture of medical education toward constructing evidence base for medical practice built on science); Rose Hatala & Gordon Guyatt, *Evaluating the Teaching of Evidence-Based Medicine*, 288 JAMA 1110, 1110 (2002) (noting that increasing number of medical schools and residency programs are formulating curricula to teach principles and practice of EBM).

12. See Hatala & Guyatt, *supra* note 11, at 1111 (citing increase in number of EBM practitioners).

a "paradigm shift" in medical practice.¹³ Another boldly asserts that EBM is the most important advance in medicine in the last one-hundred years.¹⁴

Yet despite these potentially profound impacts of EBM on the practice of medicine, it is unclear how EBM will alter the law. So far, the legal community has not fully addressed this question because the primary legal response to the EBM movement has focused on clinical practice guidelines (CPGs).¹⁵ CPGs are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."¹⁶ This Note argues that the legal response to EBM must go beyond CPGs.¹⁷ First, the legal community must consider whether the traditional custom-based standard of care that courts use to determine liability in medical malpractice cases can co-exist with the shift in the medical community from practicing according to experience or opinion to practicing according to high-grade scientific evidence. The move from traditional practice to EBM is essentially a move from a custom-based approach to an evidence-based approach.¹⁸ Characterizing the shift this way underscores the potential incompatibility of legal and medical standards. But if the custom-based standard is insufficient, what should take its place? The answer will have significant implications for medical malpractice law.¹⁹ In addition, by paying closer attention to EBM, the legal community may provide society with multiple benefits, including easier resolution of medical malpractice litigation

13. Noah, *supra* note 10, at 374.

14. See Janet M. Torpy, *New Threats and Old Enemies: Challenges for Critical Care Medicine*, 287 JAMA 1513, 1514 (2002) (citing EBM as most important advance in modern medicine). Torpy quotes from Dennis Maki, MD, speaking at the USC School of Medicine's 40th Anniversary Symposium on Medical Care as follows:

The most important advance in medicine in the last 100 years is not antisepsis, or germ theory, vaccines, or treatment of the shock state. It is the buzzword of the 20th century, evidence-based medicine. Increasingly, everything we do has an underpinning of research; maybe it doesn't give us all the answers, maybe it gives controversy, but it gives us guidance.

Id.

15. Scholars also refer to CPGs as practice parameters or clinical pathways. See BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 179 (4th ed. 2001) (noting alternate terms for CPGs).

16. INST. OF MED., *GUIDELINES FOR CLINICAL PRACTICE: FROM DEVELOPMENT TO USE* 27 (Marilyn J. Field & Kathleen N. Lohr eds., 1992); see also FURROW ET AL., *supra* note 15, at 179 (defining guidelines further as "standardized specifications for using a procedure or managing a particular clinical problem").

17. See *infra* Part II (distinguishing CPGs from EBM).

18. See *infra* Part III.A (explaining EBM's shift away from reliance on custom).

19. See Noah, *supra* note 10, at 377 ("The debate over [EBM] may have important lessons for a variety of legal issues involving medical practice and technology.").

and increased production of biomedical research.²⁰ As one scholar states, "[H]ow the law regards and treats EBM will . . . greatly affect the pace and nature of its acceptance."²¹

This Note acknowledges that it is premature to consider imposing a duty to practice EBM but contends that courts should consider whether their current standard of care analysis is compatible with EBM. The potential incompatibility is double-edged. On the one hand, a custom-based standard of care may have a chilling effect on the practice of EBM, as physicians fear the threat of liability for deviating from consensus-based practices. On the other hand, courts have articulated a duty for physicians to stay abreast of the latest medical science, yet it is unclear how courts will construe this duty in light of EBM. Without clarification, this duty might engender fear of liability for not practicing EBM.

This Note considers potential inconsistencies between EBM and current standard of care analysis and suggests frameworks for altering the standard of care in light of EBM. Part II distinguishes CPGs from EBM.²² This Note argues that EBM and CPGs are distinguishable in most, if not all, contexts, and therefore the legal response to EBM must go beyond CPGs.²³ Part II.A provides a brief overview of the rise of CPGs and presents the views of both proponents and opponents of CPGs.²⁴ Part II.B provides a similar analysis of EBM.²⁵ Part II.C considers the current, limited legal response to EBM, which fails to acknowledge the import of EBM beyond CPGs.²⁶ Part III explains the potential incompatibility of current standard of care analysis and EBM.²⁷ It distinguishes EBM's movement away from reliance on custom as a measure of

20. See *id.* at 378 (explaining benefits to be gained by paying closer attention to EBM). Noah asserts that:

Greater attention to the insights of EBM may facilitate the resolution of tort litigation involving medical technologies and medical practice. In turn, the courts may help to encourage the production of biomedical research and perhaps also persuade physicians to align their practice patterns more closely with the ideals of evidence-based medicine.

Id.

21. Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL., POL'Y & L. 327, 330 (2001).

22. See *infra* Part II (distinguishing CPGs from EBM).

23. See *infra* Part II (distinguishing CPGs from EBM).

24. See *infra* Part II.A (discussing rise of CPGs and presenting opposing views thereof).

25. See *infra* Part II.B (discussing rise of EBM and presenting opposing views thereof).

26. See *infra* Part II.C (considering limited legal response to EBM).

27. See *infra* Part III (considering potential incompatibility between current standard of care analysis and EBM).

good practice from the custom-based standard of care that courts traditionally apply in medical malpractice actions, which maintains custom as the measure of good care.²⁸ Part IV considers methods of remedying the disjunction between legal theory and EBM.²⁹ Part IV.A argues that courts should clarify the duty to stay abreast of medical advances.³⁰ Part IV.B contrasts the physician's standard of care with care standards in other areas of law, in order to draw instructive parallels to help inform the search for a framework to modify standard of care analysis to successfully co-exist with EBM.³¹ Part IV.C presents five frameworks for altering current standard of care analysis in light of EBM.³² Ultimately, this Note argues that the most advantageous alteration of the standard of care analysis in light of EBM will diminish reliance on custom as evidence of good care and clarify the physician's duty to stay abreast of advances in medicine. It will advance the goals of clarity, ease of application, and dynamism, without being over- or under-inclusive.³³ This Note concludes by suggesting that courts should move to a modified custom or modified CPG standard in the near-term but should consider bifurcating the standard of care analysis into procedural and substantive components in the long-term, as EBM acquires more adherents.³⁴

II. Distinguishing Evidence-Based Medicine from Clinical Practice Guidelines

In order to consider properly the effect that EBM will have on the standard of care, it is necessary to first understand what EBM is and, conversely, what it is not. To this end, this Note seeks to distinguish CPGs from EBM as a threshold matter. The importance of the distinction is central to this Note's analysis. If EBM consisted solely, or even primarily, of practicing medicine in accordance with CPGs, this Note would serve little purpose. This Note

28. See *infra* Parts III.A–B (distinguishing medicine's shift away from reliance on custom from continued reliance on custom in standard of care determinations).

29. See *infra* Part IV (considering ways to remedy potential incompatibility of legal theory and EBM).

30. See *infra* Part IV.A (suggesting need to clarify duty to stay abreast).

31. See *infra* Part IV.B (contrasting legal treatment of physicians with other areas of law).

32. See *infra* Part IV.C (suggesting frameworks for altering standard of care analysis in light of EBM).

33. See *infra* Part IV.C (setting goals for framework for altering standard of care).

34. See *infra* Part V (proposing modified custom-based or modified CPG framework standard as best short-term alterations to standard of care analysis in light of EBM and suggesting consideration of bifurcated standard in long-term).

contends that EBM involves much more than CPGs; therefore, the legal response to EBM must go beyond recognizing CPGs.

To some extent, CPGs and EBM are two solutions to the same problem. Both are designed to improve physician decisionmaking. Furthermore, CPGs and EBM are closely related. Many CPGs are evidence-based³⁵ and facilitate the practice of EBM by serving as codifications of best evidence when written.³⁶ In this manner, CPGs are useful, if not essential components of EBM. In addition to this interrelation, and the shared goal of improving physician decisionmaking, the movements have inspired some of the same responses. Critics have praised EBM for many of the same reasons that they praise CPGs, and have criticized EBM for many of the reasons that they criticize CPGs.³⁷ But the similarities end there. Nevertheless, the general trend within the legal community is to think of EBM only in the context of CPGs and thereby miss important distinctions between the two movements. For example, much of the legal scholarship regarding EBM has cited CPGs as the most common embodiment of EBM and has failed to further distinguish the two terms.³⁸ So far, courts have followed suit by limiting their response to EBM to consideration of CPGs.³⁹ This Note contends that CPGs may help a physician practice EBM, but they are not the only, or perhaps even the most desirable manifestation of EBM.

The most frequently cited definition of EBM is "the conscientious, explicit, and judicious use of current best evidence in making decisions about

35. Not all CPGs are evidence-based. See Rosoff, *supra* note 21, at 329 (2001) ("CPGs are not necessarily based upon EBM."). Rosoff continues, "Guidelines generated primarily through a professional consensus process—the traditional approach—may differ from those based more directly on hard, empirical evidence—the EBM approach." *Id.*

36. See Noah, *supra* note 10, at 418 (noting important role of CPGs in disseminating information).

37. See *infra* notes 88–96 and accompanying text (comparing reactions to CPGs with EBM).

38. See Rosoff, *supra* note 21, at 328 ("Because CPGs are the most common practical embodiment of EBM, the terms 'clinical practice guidelines' and 'evidence-based medicine' and their acronyms have often been used interchangeably, or nearly so."); Daniel W. Shuman, *Expertise in Law, Medicine, and Health Care*, 26 J. HEALTH POL., POL'Y & L. 267, 273 (2001) (using terms interchangeably). To be sure, some scholars have recognized that a difference exists. For example, Noah explains that "[c]linical practice guidelines are not . . . synonymous with EBM, which represents something of a shift away from the more traditional consensus-based, experiential approach to medicine. Practice guidelines can facilitate EBM, but clinicians must know how to distinguish high quality guidelines from ones of a lesser caliber." Noah, *supra* note 10, at 419. Nonetheless, the author believes that the legal community as a whole has not yet fully recognized the distinction.

39. See *infra* Part II.C (considering limited legal response to EBM).

the care of individual patients."⁴⁰ The Institute of Medicine notes, "In response to concerns that this definition failed to recognize the importance of other factors in making clinical decisions, more recent definitions explicitly incorporate clinical expertise and patient values into the decisionmaking process."⁴¹ An example of such a definition is: "Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values."⁴² Both the original and more recent definitions emphasize the use of *current best evidence*.⁴³ Therefore, analytically one cannot limit EBM to CPGs. Current best evidence at any point in time may coincide with the standard of care expounded in a guideline, but they are not necessarily synonymous. Professional associations could take years to formulate and codify CPGs.⁴⁴ In the meantime, medical science is constantly evolving. As a result, CPGs cannot always reflect "current best evidence." Even if a guideline reflects current best evidence when written, medical advances could soon

40. Sackett et al., *supra* note 4, at 71; see also 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, 402 (2001) (stating that above definition is "[t]he most commonly cited definition of evidence-based medicine").

41. INST. OF MED., *supra* note 3, at 147 (citing Kathleen N. Lohr et al., *Health Policy Issues and Applications for Evidence-Based Medicine and Clinical Practice Guidelines*, 46 HEALTH POLICY 1, 1-19 (1998)).

42. DAVID L. SACKETT ET AL., *EVIDENCE-BASED MEDICINE: HOW TO PRACTICE AND TEACH EBM 1* (2nd ed. 2000). The authors explain the components of their definition as follows:

By *best research evidence* we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. New evidence from clinical research both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.

By *clinical expertise* we mean the ability to use our clinical skills and past experience to rapidly identify each patient's unique health state and diagnosis, their individual risks and benefits of potential interventions, and their personal values and expectations.

By *patient values* we mean the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient.

Id.

43. The first definition does so explicitly; the second does so implicitly by referring to "best research evidence," then explaining that new evidence invalidates and replaces previously accepted evidence. See *id.* (defining "best research evidence").

44. See Mark Kadzielski et al., *Peer Review and Practice Guidelines Under Health Care Reform*, 16 WHITTIER L. REV. 157, 176 (1995) (identifying concern that CPGs will be outdated before adopted).

render such a guideline obsolete.⁴⁵ Rather than advocating that physicians merely adhere to the direction of a CPG, EBM encourages physicians to keep informed of current medical knowledge and to practice accordingly. While valuable in their own right, CPGs are not the functional equivalent of EBM as some scholars have suggested. In fact, it is not only possible, but sometimes necessary to practice EBM without using CPGs.⁴⁶ In addition, one can practice according to a CPG and not be practicing EBM.⁴⁷

Perhaps the most significant distinction between EBM and CPGs is the difference between a content-focused analysis and a process-focused one. CPGs identify the preferred practice in a given situation; EBM specifies how a doctor should go about making a decision. CPGs focus on content, answering the question: What is the best practice? EBM, on the other hand, endeavors to improve decisionmaking by altering the process by which physicians make decisions. Thus, EBM addresses the question: How should a physician determine what the best practice is?

In summary, although EBM and CPGs are related, it is incorrect to think they are synonymous. The propensity to treat them as such presents not just a semantic mistake, but also could have a profound impact on the legal reaction to EBM. Before considering the current limited legal response to EBM, this Note briefly addresses the origins of the CPG and EBM movements and presents positive and negative reactions to each.

45. See Noah, *supra* note 10, at 424 ("[P]ractice guidelines may quickly become outdated."); 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) (assessing current validity of seventeen Agency for Healthcare Research and Quality guidelines and estimating that half became obsolete in 5.8 years).

46. Although thousands of guidelines exist, CPGs cannot possibly cover every potential situation. See Hal R. Arkes & Cindy A. Shipani, *Medical Malpractice v. The Business Judgment Rule: Differences in Hindsight Bias*, 73 OR. L. REV. 587, 631 (1994) ("[A] practice guideline cannot be expected to apply to every clinical situation."). In addition, a physician could face a situation in which a potentially relevant guideline is available, but for a variety of reasons the physician feels it is inappropriate for the particular patient. *Id.* ("A multitude of factors, including the gravity of the illness, co-occurring medical problems, and the prior condition of the patient provide legitimate reasons for the non-applicability of what may superficially appear to be a pertinent guideline.").

47. This situation could arise if a physician follows an outdated guideline or a guideline that is not evidence-based. See Rosoff, *supra* note 21, at 329 (recognizing that not all CPGs are evidence-based).

A. The Rise of Clinical Practice Guidelines

Scholars cite the twin problems of variation and lack of consensus regarding the best medical treatment as reasons for the recent proliferation of CPGs.⁴⁸ As to the former, studies have shown that standards of good practice may differ regionally, perhaps even significantly.⁴⁹ This variation is in part due to lack of consensus as to what constitutes best treatments and methods.⁵⁰ Recently, insurers and managed care organizations have put pressure on physicians to reduce variation by promulgating CPGs.⁵¹ The federal government joined the effort to develop CPGs in 1989 by creating a new agency within the Public Health Service to aid in guideline formulation, thus underscoring the importance of these efforts.⁵² CPGs fight the problems of variation and lack of consensus by expressing a consensus on best practices.⁵³

Scholars have identified several additional reasons for the rise of CPGs, including the following: combating the information explosion in medicine,⁵⁴

48. See FURROW ET AL., *supra* note 15, at 42 (citing "combined problems of variation in medical practice and lack of evidence of efficacy" of many treatments as impetus for "movement toward practice parameters"); Noah, *supra* note 10, at 417 (noting that CPGs were "[i]nspired initially by seemingly inexplicable geographic variations in practice patterns").

49. See Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millenium*, 57 WASH. & LEE L. REV. 163, 186–87 (2000) (identifying variations in physician practice patterns). Peters quotes Dr. Jack Wennberg's well-known study on this topic, which found:

[A] resident of New Haven, Connecticut, is about twice as likely to undergo a coronary bypass operation as is a resident of Boston; for carotid endarterectomy, the risks are the other way around. The numbers of knee and hip replacements per capita are much more common among Bostonians, while New Havenites experience substantially higher risks for hysterectomy and back surgery.

Id. at 187 (quoting Jack E. Wennberg, *Improving the Medical Decision-Making Process*, 7 HEALTH AFF. 99, 99 (1988)). See also FURROW ET AL., *supra* note 15, at 179 ("Different practice styles exist in different regions, and even within states, based on a local concept of good practice, as the locality rule litigation demonstrates.").

50. See FURROW ET AL., *supra* note 15, at 12 ("Although there are generally accepted treatments for many diseases, and doctors can agree that there has been bad care in some cases, for many others there are no generally agreed standards of what is 'the best' care.").

51. See *id.* at 179 (noting pressure placed on physicians by insurers and managed care organizations to reduce variation by setting standards that specify treatments for particular diseases).

52. See Noah, *supra* note 10, at 427 ("In 1989, Congress established the Agency for Health Care Policy and Research (AHCPR) in order to engage in outcomes research as well as to facilitate the creation and distribution of clinical practice guidelines."). The name of the agency is now the Agency for Healthcare Research and Quality. *Id.*

53. See FURROW ET AL., *supra* note 15, at 42 (suggesting ability of CPGs "to articulate consensus on acceptable practice, and to disseminate information on the consensus").

54. See Deborah W. Garnick et al., *Can Practice Guidelines Reduce the Number and*

coordinating technology assessment and clinical practice,⁵⁵ minimizing costs,⁵⁶ and most importantly, improving health care.⁵⁷ CPGs also have the potential to improve the medical malpractice system by reducing the amount and cost of litigation.⁵⁸

While the clear trend within the medical community is to formulate practice guidelines, one should not assume that every member of the community endorses this movement. In fact, CPGs have inspired mixed reactions in the medical community. On the one hand, physicians have welcomed CPGs as a potentially beneficial source of information.⁵⁹ Similarly, CPGs may provide a necessary abridgement of medical literature.⁶⁰ CPGs may also serve a signaling function by indicating the judgment of leaders in the medical community.⁶¹

Others in the medical community view CPGs in a less positive light. Some physicians see guidelines as an affront to professional autonomy or a transition to "cookbook" medicine.⁶² One source adeptly summarizes this

Costs of Malpractice Claims?, 266 JAMA 2856, 2857 (1991) (suggesting explosion of medical information necessitates CPGs); Leahy, *supra* note 6, at 1487–91 (explaining how information explosion in medicine has created need for practice guidelines).

55. See Leahy, *supra* note 6, at 1488–89 (explaining development and endorsement of practice guidelines as response to "apparent lack of coordination between technology assessment and clinical practice"). Leahy states, "The expanding application of sophisticated technology to medical practice, and its attendant costs, has created the need for medical practice guidelines for physicians." *Id.* at 1483.

56. See Edward B. Hirshfeld, *Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886, 2887 (1991) (explaining hope that practice parameters will enable improved efficiency and thereby help control healthcare expenditures).

57. See William Meadow, *Operationalizing the Standard of Medical Care: Uses and Limitations of Epidemiology to Guide Expert Testimony in Medical Negligence Allegations*, 37 WAKE FOREST L. REV. 675, 694 (2002) (noting recent focus on practice guidelines as tools to improve healthcare quality and patient outcomes).

58. See Garnick et al., *supra* note 54, at 2858 (suggesting that there are several ways in which practice guidelines could reduce number of malpractice cases and costs of settling such cases).

59. See Noah, *supra* note 10, at 418 (suggesting physicians appreciate CPGs as "source of useful information").

60. See *id.* ("If nothing else, practice guidelines provide a handy abridgement of the burgeoning biomedical literature.").

61. See Jodi Halpern, *Can the Development of Practice Guidelines Safeguard Patient Values?*, 23 J.L. MED. & ETHICS 75, 75–76 (1995) (stating that guidelines enable physicians to make decisions based on expert experience); Noah, *supra* note 10, at 418 (noting that CPGs "also serve a signaling function, reflecting the judgments of leading experts in the field").

62. See FURROW ET AL., *supra* note 15, at 12 ("Physicians reject suggestions of what they refer to as 'cookbook medicine'; recognizing the infinite variety of conditions, values, and uncertainties, they are understandably reluctant to impose such standards on one another."); Noah, *supra* note 10, at 418 (recognizing complaints that CPGs "promote 'cook book'

point: "Simply put, it is often asserted that the art of medicine cannot be relegated to the status of a cookbook."⁶³ Similarly, many physicians view guidelines as a challenge to clinical judgment.⁶⁴ The fact that there may be more than one effective treatment in many instances bolsters arguments that physicians should have flexibility in determining treatments.⁶⁵ Likewise, CPGs are based on generalities and therefore they may provide limited assistance for diagnosing or treating a particular patient.⁶⁶ Others suggest that guidelines place a substantial, if not unattainable, burden on physicians to read and keep up.⁶⁷ Scholars cite different figures for the number of guidelines currently in existence, but even by a conservative estimate, the numbers are large. One source puts the number at more than 1600 guidelines.⁶⁸ Another suggests there are more than 2000.⁶⁹ Not only do the sheer numbers of guidelines hinder

medicine"); Arnold J. Rosoff, *On Being a Physician in the Electronic Age: Peering into the Mists at Point-&-Click Medicine*, 46 ST. LOUIS U. L.J. 111, 115 (2002) ("Physicians have long put CPGs down with the pejorative label 'cookbook medicine.'" (citations omitted)); Edward Felsenthal, *Cookbook Care: Maine Limits Liability for Doctors Who Meet Treatment Guidelines*, WALL ST. J., May 3, 1993, at A1 ("Many physicians attack checklists as paint-by-numbers medicine that ignores the idiosyncracies of patients' conditions.").

63. Jeffrey O'Connell & Andrew S. Boutros, *Treating Medical Malpractice Claims Under a Variant of the Business Judgment Rule*, 77 NOTRE DAME L. REV. 373, 403 (2002).

64. See INST. OF MED., *supra* note 16, at 24 ("[M]any physicians, especially those longer in practice, see guidelines as a challenge to clinical judgment and resist them as a threat to the most fundamental element of professional autonomy.").

65. See FURROW ET AL., *supra* note 15, at 179 ("Substantial regional variations exist in the use of many procedures, with no apparent differences in outcome (life expectancy, morbidity, days missed from work)." (citing Pamela Paul-Shaheen et al., *Small Area Analysis: A Review and Analysis of the North American Literature*, 12 J. HEALTH POL., POL'Y & L. 741 (1987) and John Wennberg & A. Gittlesohn, *Small Area Variations in Health Care Delivery*, 182 SCIENCE 1102 (1973))).

66. See E. Haavi Morreim, *From the Clinics to the Courts: The Role Evidence Should Play in Litigating Medical Care*, 26 J. HEALTH POL., POL'Y & L. 409, 422 (2001) ("[E]ven the best CPGs cannot possibly dictate each patient's course of care. They are based on generalities that hold true on average, but have only limited room to accommodate the natural variations among individuals in any population.").

67. See Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825, 843-44 (1995) ("No one physician can comprehend the totality of what is known; each must act based on his or her limited base of knowledge and experience."); Rosoff, *supra* note 62, at 116 (recognizing "substantial burden" on physicians to stay current with new guidelines and interpretations).

68. See Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 685 (2001) (noting that more than 1600 guidelines exist).

69. See Noah, *supra* note 10, at 418 ("More than 2000 guidelines exist today.").

physicians, but guidelines also vary in quality.⁷⁰ Potential conflicts of interest may also create significant credibility problems with CPGs.⁷¹

Putting aside the above-mentioned problems with CPGs, perhaps the biggest question regarding the success of the standard-setting movement is whether physicians will actually use guidelines. A physician might not practice according to a guideline simply due to inertia or for financial reasons such as reimbursement.⁷² Recent studies suggest that the problem of physicians not using guidelines could be substantial.⁷³ A study of the effect of the 1986 Canadian guidelines encouraging a lower rate of cesarean sections found little impact on physician practice despite high physician awareness of the guidelines and generally positive attitudes toward them.⁷⁴ This study underscores the fact that "many forces besides research evidence affect physician decisions, including financial incentives favoring one approach over another, patient pressure, and fears of malpractice."⁷⁵ Other recent studies from the United Kingdom, the Netherlands, and Australia indicate similar situations.⁷⁶ In the

70. See Robert S.A. Hayward et al., *More Informative Abstracts of Articles Describing Clinical Practice Guidelines*, 118 ANNALS INTERNAL MED. 731, 731 (1993) ("Existing practice guidelines . . . vary widely in their quality."); Morreim, *supra* note 66, at 422 ("CPGs abound, many of them with dubious scientific credentials.").

71. See Noah, *supra* note 10, at 422 (noting that conflicts of interest can taint CPGs just as they can taint underlying biomedical research literature). Noah explains further:

When specialty medical societies sponsor clinical practice guidelines, the financial interests of their members may influence the resolution of contested issues In some instances, insurance companies develop guidelines, which makes the potential conflict of interest even more apparent It appears that pharmaceutical companies also have managed to affect the content of clinical practice guidelines in ways that give preference to the use of their products. Even if they do not directly influence the formulation of guidelines, primary research funded by industry will do so, and the disclosures of financial conflicts of interest in original journal articles will not reappear in the secondary literature or practice guidelines that emerge from this research.

Id. at 422–24 (citations omitted).

72. See FURROW ET AL., *supra* note 15, at 179 (citing inertia and reimbursement as reasons why physicians may continue to use old practices).

73. See *id.* (considering likelihood that physicians will adopt newly developed guidelines in practice).

74. See *id.* at 43 (explaining study and citing Jonathan Lomas et al., *Do Practice Guidelines Guide Practice? The Effect of a Consensus Statement on the Practice of Physicians*, 321 N. ENG. J. MED. 1306 (1989)).

75. *Id.*; see also Lomas et al., *supra* note 74, at 1310 ("In the absence of any accompanying strategies to overcome these other influences, the dissemination of research evidence in the form of practice guidelines issued by a national body is unlikely to have much effect on inappropriate practices that are sustained by powerful nonscientific forces.").

76. See Amit Kumar Ghosh, M.D., *Adherence to Evidence-Based Therapy: Some Practical Problems* (letter to the editor), ARCHIVES INTERNAL MED. (June 10, 2002) (stating that

United States, several studies indicate low rates of compliance with widely disseminated guidelines relating to treating common cardiovascular conditions.⁷⁷

B. *The Rise of Evidence-Based Medicine*

While the standard-setting movement developed recently, some scholars trace the EBM movement to the ancient Greek philosophers,⁷⁸ or to ancient Chinese medicine.⁷⁹ Others suggest origins in post-revolutionary France.⁸⁰ But

recent studies indicate many reasons why physicians do not implement evidence-based therapies in addition to subspecialty culture and increasing pharmaceutical promotions). Ghosh expounds upon the United Kingdom study:

In a qualitative analysis of physicians interviewed from the United Kingdom, 6 themes were identified that affected the implementation of evidence-based therapies. These included the personal and professional experiences of the physician, the patient-physician relationship, perceived tensions between primary care physicians and specialists, physicians' feelings about their patients and the evidence, words used by the physicians, and the logistics of general practice. Also, the perception that treatment should be patient specific and not "disease specific" could make certain physicians use their personal experience and incorporate patients' values in managing their clinical problems and deviate from guidelines. There is also a tendency to continue current treatment that the patient is accustomed to, rather than prescribe a new drug based on the best available evidence.

Id. (citations omitted).

77. See Michael W. Rich, *From Clinical Trials to Clinical Practice: Bridging the GAP*, 287 JAMA 1321, 1321 (2002) ("[S]tudy after study has demonstrated disconcertingly low rates of compliance with widely disseminated evidence-based treatment guidelines for managing common cardiovascular conditions including coronary heart disease, heart failure, and hypertension.").

78. See Jyoti Arya et al., *Evidence-Based Science: A Worthwhile Mode of Surgical Inquiry*, ARCHIVES OF SURGERY, Nov. 2002, at 1301 (tracing evidence-based decisionmaking to Aristotle and Lucretius). The authors state:

Arguably, Aristotle first created the discipline of science by insisting on a rigorous delineation of evidence and a logic for the use of evidence to create theory. Several hundred years later, Lucretius (in *On the Nature of Things*) dissected evidence-based thinking into strict analytical precepts of axiom, terminology, and corollary. Evidence-based thinking then hibernated in cold storage for almost 1500 years.

Id. at 1302.

79. See SACKETT ET AL., *supra* note 42, at 2 ("[A] colleague has nominated [an] origin in ancient Chinese medicine.").

80. See *id.* at 1–2 (noting expression of ideas behind EBM in post-revolutionary Paris "when clinicians like Pierre Louis rejected the pronouncements of authorities and sought the truth in systematic observation of patients"). The authors exclaim, "For us, Louis's most dramatic rejection was the authoritarian pronouncement that venesection was good for cholera!" *Id.* at 2 n*.

if EBM is not a new phenomenon, what explains all the recent attention? Perhaps the novelty credited to EBM stems from the general trend of equating the CPG movement and the EBM movement.⁸¹ Perhaps it is due to the rapid spread of EBM over the past decade.⁸² David L. Sackett, the physician who authored the most widely-accepted definition of EBM,⁸³ and his co-authors note that the current era of EBM began in Canada in 1992, when a group led by Gordon Guyatt at McMaster University consolidated the underlying ideas and named them EBM.⁸⁴ The authors cite a subsequent explosion in articles about evidence-based practice and an international outpouring of interest.⁸⁵

Much of the medical community sees great potential to improve patient care through EBM. Scholars praise EBM for its scientific rigor and its relatively unbiased approach to clinical problems.⁸⁶ But, detractors cite various problems with EBM.⁸⁷ Many of these problems are the same or similar to problems that critics cite regarding CPGs.⁸⁸ For example, the fear that physicians will have to sacrifice autonomy in order to practice according to guidelines echoes the fear that the EBM movement will alter the locus of decisionmaking power in the medical community.⁸⁹ Also, as noted above, critics have pointed out the potential for CPGs to overwhelm practitioners.⁹⁰

81. See *supra* notes 35–47 and accompanying text (distinguishing CPGs from EBM).

82. See SACKETT ET AL., *supra* note 42, at 2 (noting rapid spread of EBM since 1992).

83. See *supra* note 4 and accompanying text (defining EBM).

84. SACKETT ET AL., *supra* note 42, at 2.

85. *Id.* Sackett et al. explain:

Since [1992], the number of articles about evidence-based practice has grown exponentially (from one publication in 1992 to about 1000 in 1998) and international interest has led to the development of six evidence-based journals (published in up to six languages) that summarize the most relevant studies for clinical practice and have a combined worldwide circulation of over 175[,]000.

Id.

86. See 2 MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 20-2.4.1 (David L. Faigman et al. eds., 2d ed. 2002) [hereinafter MODERN SCIENTIFIC EVIDENCE] (noting positive aspects of EBM). The editors summarize the strengths of EBM as follows: "In short, the strengths of evidence-based medicine include its systematic and relatively unbiased approach to clinical questions, its scientific rigor, and the fact that it is a method of accurately reflecting clinical realities in an arithmetical way." *Id.*

87. See SACKETT ET AL., *supra* note 42, at 7 ("The examination of the concepts and practice of EBM by clinicians and academics has led to negative as well as positive reactions.").

88. See *supra* notes 62–77 and accompanying text (discussing cited problems with CPGs).

89. See Noah, *supra* note 10, at 386 ("Outcomes research, like the EBM movement more generally, may alter the locus of decisionmaking power in the health care community, threatening the traditional hegemony of physicians while empowering statisticians and managers.").

90. See *supra* note 67 and accompanying text (suggesting that guidelines place

Some have cited the same potential problem with EBM.⁹¹ Additionally, like CPGs, EBM may be difficult to apply to an individual patient.⁹² Both are also potentially subject to problems of bias and conflicts of interest because both EBM and CPGs require large clinical trials. Such trials are expensive and sponsoring corporations predominantly bear the expense.⁹³ Thus, great potential for financial conflicts of interest exists.⁹⁴ In addition to financial incentives, bias can also arise based on scientific beliefs.⁹⁵ Finally, like the physicians who are reluctant to use guidelines, some physicians maintain a "stubborn and unreflective adherence to well-entrenched habits" despite the increasing prominence of EBM.⁹⁶

C. *The Limited Legal Response to Evidence-Based Medicine*

By calling the legal response to EBM "limited," this Note refers to the fact that, thus far, the legal community has considered EBM only in the context of CPGs.⁹⁷ To date, only one reported case includes the phrase "evidence-based medicine,"⁹⁸ and it does so only in excerpting the affidavit of the defendant's

substantial, if not unattainable, burden on physicians to stay current).

91. See 2 MODERN SCIENTIFIC EVIDENCE, *supra* note 86, at § 20-2.4.1 ("[T]he volume of information required to be retained is monumental: no practitioner in the early 21st century has the time necessary to obtain all of this information, and more importantly, the ability to retain it."); Eisenberg, *supra* note 2, at 370 (2001) ("Practicing evidence-based medicine is not easy. No clinician alone can absorb and synthesize the vast amount of literature available, make judgments on its quality, and translate it into practice."); Noah, *supra* note 10, at 404 ("Although physicians should have the training and expertise necessary to manage large quantities of complex information, the pace of knowledge production and acquisition presents significant challenges for the medical profession.").

92. 2 MODERN SCIENTIFIC EVIDENCE, *supra* note 86, at § 20-2.4.1 (noting that EBM "is very challenging to apply to individual patients").

93. Joseph S. Alpert, *Conflicts of Interest: Science, Money, and Health*, 162 ARCHIVES OF INTERNAL MED. 635, 635 (2002) ("The large clinical trials required by evidence-based medicine involve major financial investment by the sponsoring corporation.").

94. *Id.* at 636 ("Because of the economic reality of clinical research, the potential for financial COI is substantial."). Alpert suggests that clearly identifying the potential conflicts may remedy the potential problem of financial conflicts of interest. *Id.*

95. *Id.* ("Bias in presentation of data and opinion may be based on strongly held scientific and medical opinion, or it may be based on financial considerations.").

96. Noah, *supra* note 10, at 383; see also FURROW ET AL., *supra* note 15, at 13 ("Scientific and balanced analysis of the costs, risks, and benefits of different treatments is still the exception, not the rule.").

97. See *supra* note 38 (noting failure of legal community to adequately distinguish EBM from CPGs).

98. The author conducted a computerized search of reported cases through September

expert witness.⁹⁹ Even the current judicial response to EBM involving CPGs as evidence of the standard of care has been sparse and inconsistent.¹⁰⁰ Nevertheless, over the past two decades, a great deal of scholarship has addressed the role of CPGs in medical malpractice actions.¹⁰¹ Eleanor Kinney

2003 and found only one case that included the term "evidence-based medicine." (Search "All State and Federal Cases" database on Westlaw for "evidence-based medicine"). No cases included the term "evidence-based practice." (Search same database for "evidence-based practice").

99. See *Gabbard v. Linn-Benton Hous. Auth.*, 219 F. Supp. 2d 1130, 1135–36 (D. Or. 2002) (including term "evidence-based medicine" in excerpt of affidavit of defendants' expert witness). In *Gabbard*, plaintiffs claimed to suffer from multiple chemical sensitivity syndrome. *Id.* at 1132. Plaintiff James Gabbard brought an action against the manager of his apartment complex contending that the manager's use of various chemicals violated the Fair Housing Act, the Americans with Disabilities Act, and the Rehabilitation Act. *Id.* Plaintiff Jan Wroncy brought an action against the Oregon Department of Transportation asserting that the Department's use of chemical herbicides along its highways violated the Americans with Disabilities Act. *Id.* The court granted the defendants' motion for summary judgment holding that the testimony of plaintiffs' expert concerning MCS was not sufficiently reliable. *Id.* at 1141. Although it does not discuss EBM further, the court cited counts 13–15 of the affidavit of defendants' expert, which alleged that plaintiff Gabbard's physicians and experts do not practice EBM and that claims of chemically-induced MCS are not supported by EBM. *Id.* at 1135–36.

100. See Rosoff, *supra* note 21, at 335. Rosoff explains:

The relatively few courts that have dealt with CPGs have varied widely in their treatment as evidence. In some instances, CPGs have simply been deemed inadmissible. . . . In future cases, pursuant to state legislation fostering CPG development and use, some courts will admit them only for use by the defense. Even where they can be introduced by both parties to a litigation, there is a range of alternatives as to how much weight they will be given. Certainly, it will be some time before there are settled conventions for the use of CPGs and for instructing juries on the matter.

Id.

101. Eleanor D. Kinney, *The Brave New World of Medical Standards of Care*, 29 J.L. MED. & ETHICS 323, 329 (2001) ("Since the 1980s, there has been a wealth of scholarship examining the role of medical practice guidelines and other standards of care in medical malpractice litigation."); see also Troyen A. Brennan, *Practice Guidelines and Malpractice Litigation: Collision or Cohesion?*, 16 J. HEALTH POL., POL'Y & L. 67, 67–86 (1991) (considering potential role of CPGs in medical malpractice litigation); Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 LAW & CONTEMP. PROBS. 119, 119–45 (1991) (exploring prospects for medical practice policies to reform malpractice law); Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 L. & CONTEMP. PROBS. 87, 87–117 (1991) (considering usefulness of practice guidelines in medical malpractice law); Hirshfeld, *supra* note 56, at 2886–91 (examining potential use of CPGs as standard of care); Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. OF HEALTH POL., POL'Y & L. 289, 289–313 (1996) (discussing use of guidelines by courts and state legislatures); Eleanor D. Kinney & Marilyn M. Wilder, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U.C. DAVIS L. REV. 421, 421–50 (1989) (analyzing how medical standards may be used in medical malpractice actions); Mello, *supra* note 68, at 645–710 (discussing role of CPGs in medical malpractice litigation); Megan L.

notes, "Much of this scholarship assesses the use of medical standards as evidence of the tort standard of care from the perspective of defendant physicians or plaintiffs."¹⁰² Kinney explains further that scholars see the "[u]se of medical practice guidelines in malpractice litigation . . . as an important reform to clarify the tort standard of care and even to serve as an affirmative defense to complying physicians."¹⁰³ Some states, "such as Florida, Kentucky, Maine, and Maryland, have adopted statutes to use medical practice guidelines in this manner."¹⁰⁴ However, despite enacting a statute in 1995 to encourage the promulgation of CPGs, the Maryland legislature initially mandated that parties could not use those guidelines in litigation.¹⁰⁵ The legislature subsequently removed this restriction.¹⁰⁶

Some courts allow the use of guidelines as evidence of the standard of care if an expert witness introduces them as testamentary anchors.¹⁰⁷ Although guidelines offer presumptive evidence of the duty of care, courts may still

Sheetz, Note, *Toward Controlled Clinical Care Through Clinical Practice Guidelines: The Legal Liability for Developers and Issuers of Clinical Pathways*, 63 BROOK. L. REV. 1341, 1341–80 (1997) (considering potential liability of developers of CPGs).

102. Kinney, *supra* note 101, at 329.

103. *Id.* (citing E.D. Kinney, *Malpractice Reform in the 1990s: Past Disappointments, Future Successes?*, 20 J. HEALTH POL., POL'Y & L. 99, 99–136 (1995)).

104. *Id.* (citing FLA. STAT. ch. 408.02 (1998); KY. REV. STAT. ANN. § 342.035 (Michie 1997); ME. REV. STAT. ANN. tit. 24, §§ 2971–79 (West Supp. 2000); MD. CODE ANN., Health-Gen. I § 19-1602 (2000); D.W. Shuman, *The Standard of Care in Medical Malpractice Claims, Clinical Practice Guidelines, and Managed Care: Towards a Therapeutic Harmony?*, 34 CAL. W. L. REV. 99, 105 (1997)).

105. See Rosoff, *supra* note 21, at 335 ("[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.").

106. *Id.*

107. See FURROW ET AL., *supra* note 15, at 178 ("Clinical practice guidelines, so long as they are developed by an expert witness as a testamentary anchor, will be allowed in evidence to help establish the standard of care. They can also be used to impeach the opinion of an expert witness."). The authors cite *Roper v. Blumenfeld*, 706 A.2d 1151, 1155 (N.J. Super. Ct. App. Div. 1998), in which the defendant used *1992 Parameters of Care for Oral and Maxiofacial Surgery: A Guide of Practice, Monitoring and Evaluation* during cross examination of plaintiff's expert. The authors explain the use of the guidelines as follows:

As used to impeach, it was permissible to counter the doctor's opinion that because plaintiff was injured during defendant's failed attempt at extraction, defendant must have deviated from the standard of care because the injury is not a medically accepted risk of the procedures he performed. "As to this claim, the article is quite relevant for it lists as a known risk and complication of 'erupted' teeth '[o]ral-facial neurologic dysfunction.'"

Id. (quoting *Roper*, 706 A.2d at 1156).

require expert testimony to introduce and explain the standard.¹⁰⁸ Although some commentators have suggested that CPGs should only be admissible for use by one side to a dispute,¹⁰⁹ "[c]ourts have allowed plaintiffs to introduce clinical practice guidelines as inculpatory evidence where physicians have deviated from those recommendations, and they have allowed defendants to make use of practice guidelines as exculpatory evidence."¹¹⁰

III. *The Potential Incompatibility of Current Standard of Care Analysis and EBM*

This Part considers the potential incompatibility between current standard of care analysis and EBM. In so doing, it first addresses the question of whether it is logical for courts to continue to use custom as a barometer to judge good medical practice when physicians themselves are questioning the reliability of custom as an indicator of good medicine. This Part suggests that a custom-based standard may have chilling effects on physicians' efforts to move away from accepted practice in favor of high-grade scientific evidence and therefore may be incompatible with EBM. This Part also considers the paradox of the largely undefined duty to stay abreast of medical advances and whether it affords courts the ability to impose liability for not practicing EBM.

A. *Medicine's Shift Away from Reliance on Custom*

EBM "challenges consensus-based judgments"¹¹¹ and "deemphasizes average practice as an adequate standard."¹¹² It is "portrayed as an alternative to medicine

108. See *id.* at 180 ("[G]uidelines provide a particularized source of standards against which to judge the conduct of the defendant physician. A widely accepted clinical standard may be presumptive evidence of due care, but expert testimony will still be required to introduce the standard and establish its sources and its relevancy.").

109. See Hirshfeld, *supra* note 56, at 2887 (noting arguments for use of CPGs only by defendant physicians).

110. Noah, *supra* note 10, at 462. As examples of cases allowing plaintiffs to introduce guidelines, Noah cites *James v. Woolley*, 523 So. 2d 110, 112 (Ala. 1988); *Pollard v. Goldsmith*, 572 P.2d 1201, 1203 (Ariz. Ct. App. 1977); *Nelson v. Hammon*, 802 P.2d 452, 454-57 (Colo. 1990); *Washington v. Washington Hosp. Ctr.*, 579 A.2d 177, 182 (D.C. 1990); *Williams v. Lallie Kemp Charity Hosp.*, 428 So. 2d 1000, 1005 (La. Ct. App. 1983); *Monusko v. Postle*, 437 N.W.2d 367, 368 (Mich. Ct. App. 1989) and *Birchfield v. Texarkana Mem. Hosp.*, 747 S.W.2d 361, 364 (Tex. 1988). *Id.* at 462 n.405. As examples of cases allowing defendants to use guidelines, Noah cites *Moore v. Baker*, 989 F.2d 1129, 1133 n.2 (11th Cir. 1993) and *Parker v. Southwest La. Hosp. Ass'n*, 540 So. 2d 1270, 1274 (La. Ct. App. 1989). *Id.* at 462 n.406.

111. Eisenberg, *supra* note 2, at 369.

112. Cynthia D. Mulrow & Kathleen N. Lohr, *Proof and Policy from Medical Research Evidence*, 26 J. HEALTH POL., POL'Y & L. 249, 253 (2001).

based on authority, tradition, and the physician's personal experience."¹¹³ EBM encourages physicians to apply "critical assessment of the available research to decide if there is methodologically sound evidence that the outcomes of a clinical option are favorable."¹¹⁴ While a physician practicing by traditional methods may base a decision first and foremost on "tradition, [his] most recent experience, what [he] learned years ago in medical school, or what [he has] heard from [his] friends,"¹¹⁵ a physician practicing EBM makes decisions based on an order of preference that descends from sources containing broader evidence to, eventually, personal experience.¹¹⁶

A physician begins by considering systematic reviews of randomized controlled trials (RCTs).¹¹⁷ Next, the physician examines individual controlled clinical trials followed by uncontrolled studies.¹¹⁸ Finally, the physician considers anecdotal evidence of clinical observations.¹¹⁹ Thus, a significant distinction between traditional practice and EBM is the reduced prominence of personal clinical experience. While personal experience remains a component of decisionmaking, it is no longer the primary component.¹²⁰ In addition, knowledge physicians acquire in medical school and from colleagues also loses prominence.

B. The Continuing Prevalence of Custom in Standard of Care Analysis

Having considered the extent to which EBM represents a departure from basing medical decisions on customary practices, this Note will now examine

113. Marc A. Rodwin, *The Politics of Evidence-Based Medicine*, 26 J. HEALTH POL., POL'Y & L. 439, 439 (2001).

114. Eisenberg, *supra* note 2, at 369.

115. *Id.* at 369–70.

116. See USERS' GUIDES TO THE MEDICAL LITERATURE: ESSENTIALS OF EVIDENCE-BASED CLINICAL PRACTICE 13 (Gordon Guyatt & Drummond Rennie eds., 2002) (presenting hierarchy of strength of evidence for treatment decisions and stating that "[t]he hierarchy implies a clear course of action for physicians addressing patient problems: they should look for the highest available evidence from the hierarchy"). Noah describes the decisionmaking process as follows: "When faced with a clinical problem, health care professionals should, in descending order of preference, look for guidance in systematic reviews of randomized controlled trials, the results of individual controlled clinical trials, observational (uncontrolled) studies, and anecdotal reports of clinical observations." Noah, *supra* note 10, at 381.

117. Noah, *supra* note 10, at 381.

118. *Id.*

119. *Id.*

120. *Id.* While "[p]ersonal clinical experience remains an essential predicate for the effective application of EBM . . . it should not provide the primary basis for making treatment decisions." *Id.* (citations omitted).

the extent to which medical custom remains prevalent in legal standard of care analysis. This Part presents an overview of the custom-based standard of care that courts have traditionally used to determine medical malpractice liability. This Part concludes that, while some evidence suggests judicial deference to custom may be weakening, custom remains integral to standard of care analysis either through the standard of care itself or through the current evidentiary framework. For these reasons, current standard of care analysis is potentially inconsistent with the practice of EBM.

1. Traditional Custom-Based Standard of Care

Traditionally, custom established the standard of care in medical malpractice actions. Under a custom-based standard, practicing in accordance with accepted practice generally precludes liability. Medical malpractice law is unique in this regard because in other areas of negligence law, defendants are subject to a standard of reasonable care under the circumstances.¹²¹ Physicians have "traditionally . . . needed only to conform to the customs of their peers."¹²² Esteemed torts scholar William Prosser explains that the traditional standard of care in medical malpractice actions is simply "what is customary and usual in the profession."¹²³ Many commentators suggest that the law, by allowing this custom-based standard, gives physicians a privilege that few others enjoy—that of determining their own legal standards.¹²⁴

121. Peters, *supra* note 49, at 163.

122. *Id.*

123. WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS § 32 (4th ed. 1971) (citations omitted).

124. *See id.* ("It has been pointed out often enough that this 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." (citations omitted)); *see also* PATRICIA DANZON, MEDICAL MALPRACTICE: THEORY, EVIDENCE AND PUBLIC POLICY 16, 139–40 (1985) (stating that deviation from reliance on custom-based standard is "rare"); FURROW ET AL., *supra* note 15, at 361 (same); DAVID M. HARNEY, MEDICAL MALPRACTICE 89 (1973) (stating that custom defines standard of care) (citations omitted); W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 32, at 189 (5th ed. 1984) (same); SYLVIA LAW & STEVEN POLAN, PAIN AND PROFIT: THE POLITICS OF MALPRACTICE 7, 101 (1978) (same); CLARENCE MORRIS & C. ROBERT MORRIS, JR., MORRIS ON TORTS 55 (2d ed. 1980) (stating that custom is rule in medical malpractice); 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) (same); Allan H. McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549, 560, 605–06 (1959) (same); Clarence Morris, *Custom and Negligence*, 42 COLUM. L. REV. 1147, 1147, 1158 (1942) (stating that custom normally should define standard of care); Peters, *supra* note 49, at 163 (citing *Osborn v. Irwin Mem'l Blood Bank*, 7 Cal. Rptr. 2d 101, 125 (Ct. App. 1992)); Theodore

Scholars identify several theories to explain this special treatment of the medical community. One of the most frequently cited explanations for judicial deference to medical custom is respect for medical professionals.¹²⁵ Another justification is "the inability of laymen to evaluate the technical judgments of specialists."¹²⁶ One commentator explains, "Courts have recognized the fact that laymen lack the capacity to adequately evaluate a physician's conduct or to adequately determine what a reasonable and prudent man under the same circumstances with specialized training and knowledge would have done."¹²⁷ Whatever the underlying rationale for this special treatment is, for the medical profession, customary practice is generally the barometer by which to measure good care, and courts instruct juries that the plaintiff cannot recover unless he or she proves that the defendant's conduct was "not in accord with recognized medical practice."¹²⁸ Thus, a plaintiff rarely can recover when the defendant physician complied with the customary standard of care.¹²⁹

Although some scholars suggest that adherence to the custom-based standard of care is waning,¹³⁰ legal texts and treatises still claim that a custom-

Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 WIS. L. REV. 1193, 1212 (stating that custom determines standard of care).

125. See Peters, *supra* note 49, at 195 ("An abiding trust in the professionalism and faithfulness of physicians resonated throughout the early legal commentary defending or explaining the customary standard of care."). Peters notes that later commentary echoed the same theme. *Id.* at 195.

126. DANZON, *supra* note 124, at 140.

127. Neil Meltzer, Case Comment, *Helling v. Carey: Landmark or Exception in Medical Malpractice; Compliance With The Medical Standard of Care May Not Protect The Specialist From Liability*, 11 NEW. ENG. L. REV. 301, 308 (1975).

128. VICTOR E. SCHWARTZ ET AL., PROSSER, WADE, AND SCHWARTZ'S TORTS 178 (10th ed. 2000).

129. *Id.*; see also Peter D. Jacobson & Matthew L. Kanna, *Cost-Effectiveness Analysis in the Courts: Recent Trends and Future Prospects*, 26 J. HEALTH POL., POL'Y & L. 291, 300 (2001) ("In relatively rare instances, courts will allow a plaintiff to challenge the adequacy of customary medical practice, resulting in a higher standard of care than that determined appropriate by the profession.").

130. See Peters, *supra* note 49, at 187-88 (arguing that deference to custom in setting standard of care in medical malpractice actions is declining). Peters states that courts are moving away from basing the standard of care on custom and moving towards employing a reasonable physician standard. *Id.* He explains:

The present state of affairs is complicated, but the trend is clear. One quarter of the states expressly have rejected deference to customary standards. Another twenty-percent have rephrased their standard of care in terms of reasonability rather than custom. Although the commitment of this last group of states has yet to be tested directly, these states certainly cannot be classified as custom-based states. In addition, confusing or contradictory case law in seven other states precludes confident classification. That leaves fewer than half of the states with law that clearly endorses a custom-based standard of care. Even in these states, the

based standard persists.¹³¹ Undoubtedly, the state of the law is confusing.¹³² Much of this confusion stems from the fact that at times courts have departed from custom in various ways. Perhaps the most famous example of judicial deviation from the traditional custom-based standard of care in a medical malpractice case is *Helling v. Carey*.¹³³ In *Helling*, the Supreme Court of Washington departed from a custom-based standard in favor of judicial risk/benefit analysis.¹³⁴ The *Helling* court held, as a matter of law, that two ophthalmologists were negligent for failing to give a simple pressure test to screen for glaucoma in a patient under the age forty despite the fact that it was not custom in the practice to give such a test to an individual under forty.¹³⁵ One scholar refers to *Helling* as "[t]he most extreme example of a court rejecting the customary practice standard."¹³⁶ Was *Helling* a "wake-up call" as some scholars claim,¹³⁷ or merely a "rogue case" as others assert?¹³⁸ The fact that few courts have followed the example of *Helling* suggests the latter.¹³⁹

In addition to departing from a custom-based standard in favor of judicial risk/benefit analysis, some courts have employed a reasonable

authority of the custom-based standard of care is illusory. Many courts in states with a custom-based standard do not appear to enforce it. The hegemony of custom-based standards is over.

Id. at 188 (citations omitted).

131. See 70 C.J.S. *Physicians, Surgeons, and Other Health-Care Providers* § 64 (1987) ("[A] physician or other health-care provider is required and is only required to possess and exercise the degree of skill and learning possessed and exercised, under similar circumstances, by the members of his profession."); 2002 MED. MALPRACTICE (MB) § 9.05 ("The reasonableness of a physician's conduct depends on the customary conduct of other physicians under the same or similar circumstances" (citing *Hales v. Pittman*, 576 P.2d 493 (Ariz. 1978); *Decker v. Gibbons*, 468 S.W.2d 252 (Ark. 1971); *Ruden v. Hansen*, 206 N.W.2d 713 (Iowa 1973); *Hood v. Phillips*, 554 S.W.2d 160 (Tex. 1977); *Gates v. Jensen*, 595 P.2d 919 (Wash. 1979))).

132. Compare *FURROW ET AL.*, *supra* note 15, at 170 ("Most jurisdictions give professional medical standards conclusive weight, so that the trier of fact is not allowed to reject the practice as improper.") with *Peters*, *supra* note 49, at 187-88 (arguing that courts no longer defer to custom).

133. *Helling v. Carey*, 519 P.2d 981 (Wash. 1974).

134. *Id.* at 983.

135. *Id.*

136. Donald E. Kacmar, Note, *The Impact of Computerized Medical Literature Databases on Medical Malpractice Litigation: Time for Another Helling v. Carey Wake-Up Call?*, 58 OHIO ST. L.J. 617, 636 (1997).

137. *Id.* at 617.

138. See *Peters*, *supra* note 49, at 171 (noting that scholarly literature has generally considered *Helling* a "rogue case").

139. See *FURROW ET AL.*, *supra* note 15, at 199 (citing *Helling* as "one of a small number of cases rejecting a customary medical practice").

physician standard to determine liability. In a recent article, Philip Peters conducts a fifty state survey and concludes that courts are rejecting a custom-based standard in favor of a reasonable physician standard.¹⁴⁰ This standard more closely resembles the ordinary negligence standard courts apply in cases not involving professionals.¹⁴¹ Another variation involves "courts utiliz[ing] the 'best judgment' wrinkle to find negligence, notwithstanding a physician's adherence to customary practice, where defendant's choice among the available alternatives was unreasonable in light of contrary data."¹⁴² Courts have also departed from a pure custom-based standard by imposing a duty to stay abreast of medical advances, which is discussed below.¹⁴³

Although each of these departures undermines the primacy of custom in standard of care determinations, this Note contends that custom remains a key component of the analysis. Regardless of how courts frame the standard, custom is still relevant, if not central.¹⁴⁴ In addition, Peters himself underscores the fact that really understanding what courts are doing involves making difficult empirical judgments.¹⁴⁵ Thus, the actual number of courts that have departed from a custom-based standard may be less than the number Peters has suggested.

140. See Peters, *supra* note 49, at 187–88 ("Modern malpractice law is moving slowly away from a custom-based standard of care and toward a reasonable physician standard.").

141. Tim Cramm et al., *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 WAKE FOREST L. REV. 699, 699–700 (2002) (describing standard courts apply to nonprofessionals as a "normative 'reasonable care' standard").

142. Kacmar, *supra* note 136, at 638.

143. See *infra* Part III.D (discussing duty to stay abreast).

144. See Cramm et al., *supra* note 141, at 708 (noting that "the incipient trend toward modifying custom as conclusive does not render it irrelevant"); Noah, *supra* note 10, at 458 (noting that even if the "tradition of complete judicial deference to medical custom may be waning, adherence (or non-adherence) to customary medical practice will continue to play a significant role in the resolution of most malpractice lawsuits").

145. See Peters, *supra* note 49, at 188 ("The classifications undertaken here required the personal interpretation of judicial and legislative text. Even under ideal circumstances, a considerable amount of discretion is inherent in this endeavor."). Peters continues:

Many of the judicial opinions surveyed for this Article had a proclivity for unclear or inconsistent language, sometimes using terms from both [the custom-based and the reasonable physician] tests interchangeably. Indeed, American courts historically have believed that compliance with customary practice defined reasonable care for professionals. As a result, the language used in many opinions contains elements of both formulations.

Id.

2. *The Perpetuation of Custom Through the Evidentiary Framework*

While some jurisdictions may be moving away from deference to custom in their phraseology of the standard of care, the degree to which a medical practice is unique or generally accepted remains part of the evidentiary framework.¹⁴⁶ Thus, even when courts claim to employ a standard of care that is not based on custom, they nonetheless may allow evidence of custom to play a paramount role in the analysis. Generally, courts allow evidence of custom and may exclude evidence of the effectiveness of the custom. As Peters explains, "Because the issue to be decided is what physicians do, not why they do it, evidence of the ineffectiveness of customary practices sometimes is excluded from evidence."¹⁴⁷

In addition, the use of expert witnesses may perpetuate the prevalence of custom. Unlike other areas of negligence, in medical malpractice cases courts ordinarily require expert testimony to establish the standard of care.¹⁴⁸ The fact that experts testify may not, in and of itself, perpetuate the role of custom. But, the substance of expert testimony may have that precise effect. Generally, experts do not testify as to what the expert himself would have done, or to whether what the defendant did was reasonable, but rather an expert testifies to what other physicians ordinarily do.¹⁴⁹ One source explains, "Normally, parties have to introduce expert testimony in order to identify customary practice."¹⁵⁰ In this manner, expert testimony is grounded in custom. As long as this remains the case, custom will remain inextricably linked to the physician's standard of care.

146. See *infra* note 154 and accompanying text (discussing "general acceptance criterion").

147. Peters, *supra* note 49, at 166 (citing *Schneider v. Revici*, 817 F.2d 987, 990–91 (2d Cir. 1987)); see also FURROW ET AL., *supra* note 15, at 169–70 (noting defendants do not offer evidence of effectiveness)).

148. 61 AM. JUR. 2D *Physicians, Surgeons and Other Healers* § 318 (2002) ("As a general rule, medical negligence may only be established by expert medical testimony." (citing *Gatlin v. Methodist Med. Ctr., Inc.*, 772 So. 2d 1023 (Miss. 2000); *Casey v. Levine*, 621 N.W.2d 482 (Neb. 2001))); *id.* at § 321 ("In the great majority of malpractice cases, a plaintiff must establish by expert testimony both the standard of care and the defendant's failure to conform to that standard." (citing *Smith v. United States*, 119 F. Supp. 2d 561 (D.S.C. 2000))).

149. *Id.* at § 319 ("[T]estimony may be introduced to establish that the defendant negligently carried out his professional duties and departed from the standard of care exercised by other physicians." (emphasis added) (citing *Freed v. Piore*, 372 A.2d 895 (Pa. Super 1977))). *But see* Cramm et al., *supra* note 141, at 710–11 (suggesting physicians do not actually know how other physicians practice and therefore experts can only guess at customary practice).

150. Noah, *supra* note 10, at 460 (citing *Cox v. Dela Cruz*, 406 A.2d 620, 622 (Me. 1979); *Harris v. Robert C. Groth, M.D., Inc.*, 663 P.2d 113, 118–19 (Wash. 1983); *Vassos v. Roussalis*, 658 P.2d 1284, 1288 (Wyo. 1983)).

Additionally, because the recent United States Supreme Court case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹⁵¹ includes a "general acceptance" criterion for the admissibility of scientific evidence, barriers to the introduction of novel medical evidence remain.¹⁵² One scholar suggests that through *Daubert*, the Supreme Court has asked courts to transition from an expectation of "general acceptance" to an expectation of reliable scientific evidence.¹⁵³ This statement suggests a move away from custom. However, "general acceptance remains a part of the admissibility gateway, and courts may attach inordinate weight to *Daubert's* general acceptance prong leaving [parties] with problems similar to those encountered in jurisdictions deferring to medical custom."¹⁵⁴ Thus, a physician desiring to defend a malpractice action on the basis that EBM led him to disregard custom might be hindered in his effort to introduce the scientific evidence that contributed to his decision if it has not yet reached "general acceptance." Likewise, a plaintiff asking a court to impose liability on a physician for not practicing EBM will be similarly hindered.

C. Illustrating the Dangers of Inconsistencies Between Custom-Based Standard of Care Analysis and EBM

To illustrate the potential inconsistencies between custom-based standard of care analysis and EBM, consider the dilemma a physician faces when high-

151. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). In *Daubert*, two minor children and their parents brought an action against the manufacturer of Bendectin, alleging that the mother's prenatal ingestion of Bendectin contributed to the children's birth defects. *Id.* at 579. The District Court granted summary judgment in favor of defendant based on expert testimony that extensive published scientific literature had not shown Bendectin to be a risk factor for human birth defects. *Id.* The District Court excluded testimony of eight other experts "who based their conclusion that Bendectin can cause birth defects on animal studies, chemical structure analyses, and the unpublished 'reanalysis' of previously published human statistical studies," on the ground that such evidence did not satisfy the "general acceptance" standard for the admissibility of expert witnesses. *Id.* The Court of Appeals affirmed. *Id.* In vacating the decisions of the lower courts, the Court held that the adoption of the Federal Rules of Evidence superceded the "general acceptance" test. *Id.* at 585-89. The Court then proposed a list of factors that judges could consider in weighing the admissibility of scientific evidence. *Id.* at 593-94. One of the factors is "general acceptance." *Id.*

152. See *id.* at 593-94 (providing list of factors judges may consider in determining admissibility of scientific evidence). Of course, *Daubert* affects only federal jurisdictions and those states that pattern their evidence rules on the Federal Rules of Evidence.

153. Moreim, *supra* note 66, at 421 ("[T]his expectation of reliable scientific evidence rather than 'general practice or acceptance' is precisely the transition that the Supreme Court has asked courts to make, in the move from *Frye* to *Daubert*.").

154. Kacmar, *supra* note 136, at 648.

grade scientific evidence suggests deviating from custom. In the physician's judgment, he can best serve the patient by departing from what other doctors would ordinarily do. However, the physician recognizes the danger of liability for such a deviation. Here, the law may perpetuate care that is less than the best available. As David Eddy explains, "Currently, many physicians claim to feel that a particular practice is inappropriate, and that they would personally prefer not to do it but are compelled to do it out of fear that they will be compared to a community standard."¹⁵⁵ He continues, "The result is that they all do it, which in turn makes it the community standard, which further entrenches the practice."¹⁵⁶

The normative question of the degree to which custom should set the standard of care is certainly not new. A century ago, Justice Holmes stated, "What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not."¹⁵⁷ Judge Learned Hand's comments in the well-known case of the *T. J. Hooper*¹⁵⁸ similarly illustrate the fact that many courts have long been skeptical about the validity of custom as a measuring stick.¹⁵⁹ Judge Hand stated:

There are, no doubt, cases where courts seem to make the general practice of the calling the standard of proper diligence Indeed in most cases reasonable prudence is in fact a 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 never may set its own test, however persuasive be its uses. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.¹⁶⁰

155. Eddy, *supra* note 40, at 401; *see also* FURROW ET AL., *supra* note 15, at 170 (noting tension that custom-based standard creates for physicians who desire to reject dangerous customary practices in favor of new practices when medical community has not yet generally accepted new practices).

156. Eddy, *supra* note 40, at 401.

157. *Tex. & Pac. Ry. v. Behymer*, 189 U.S. 468, 470 (1903).

158. *T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932). In the *T.J. Hooper*, the United States Court of Appeals for the Second Circuit considered a petition from the Eastern Transportation Company, the owner of two tugs that lost barges at sea during a storm, to exonerate, or at least limit liability. *Id.* at 737. The trial court found the tugs unseaworthy because they did not carry radio receiving sets through which to receive storm warnings. *Id.* The trial court reasoned that had the tugs carried radios, they could have avoided the storm and the ensuing loss of the barges. *Id.* The Second Circuit affirmed on similar reasoning. *Id.* at 740.

159. *See id.* at 740 (refusing to exonerate tugboat owners of negligence liability for failing to equip tugs with radio receivers).

160. *Id.* (citations omitted).

In addition to prominent justices and judges, commentators have also expressed concern over the wisdom of the prominence of custom. As one scholar argues, "[T]he bare fact that physicians commonly practice or accept a particular pattern of care unfortunately tells us too little about whether that pattern is salutary for patients."¹⁶¹ Despite these protests, courts have used custom as the predominant measure of appropriateness.¹⁶² However, the EBM movement, with its emphasis on the use of "current best evidence," provides new strength to the argument that reliance on custom to set the standard of care is inappropriate. In fact, it is not at all clear that a custom-based standard can co-exist harmoniously with EBM. If the goal of the EBM movement is to push physicians away from following the community or customary standard when science suggests a different approach, is not judicial reliance on custom a hindrance to EBM? In other words, if the professional custom is not backed by evidence or disregards science, does not the "continued focus [of courts] on professional custom for setting the legally recognized standard of care reinforce[] this disregard of scientific knowledge?"¹⁶³ If so, the legal community should begin to focus on "how the legal system might ease, or at least not impede, the adoption of evidence-based practices."¹⁶⁴ Arguably, custom-based standard of care analysis does little to encourage the adoption of evidence-based practice and may in fact impede its adoption. Therefore, deference to custom may simply not be dynamic enough to be an effective measure of appropriateness in light of EBM.

The counter-argument relies on the fact that a custom-based standard of care is a self-elevating standard. As evidence demonstrates the danger or efficacy of a treatment or procedure, the medical profession will either reject or adopt it. One scholar asserts that adherence to a custom-based standard does not mean that "dangerous practices will go unchecked or required procedures will be ignored."¹⁶⁵ The argument continues, "When the negative aspects of a medical technique have been demonstrated by systematic and reliable studies, the *accepted* practice standard would probably compel repudiation of the untoward practice."¹⁶⁶ However, for all but the most remarkable discoveries, there is undoubtedly a lag time between discovery and general acceptance by

161. Morreim, *supra* note 66, at 420–21.

162. *See supra* Part III.B (considering role of custom in medical malpractice law).

163. Clark C. Havighurst et al., *Evidence: Its Meanings in Health Care and in Law*, 26 J. HEALTH POL., POL'Y & L. 195, 203 (2001).

164. *Id.* at 209.

165. Joseph H. King, Jr., *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1251 (1975).

166. *Id.*

the profession.¹⁶⁷ Therefore, one consequence of the custom-based standard of care is that a doctor need not use the latest techniques or incorporate state-of-the-art procedures until the profession generally accepts them.¹⁶⁸ Conversely, a doctor employing old or outdated techniques need not fear liability as long as the profession still predominantly employs those techniques.¹⁶⁹ Thus, under a custom-based standard, malpractice liability determinations may lag behind the latest information and techniques available in a field.¹⁷⁰

D. The Duty to Stay Abreast

The above discussion has suggested current standard of care analysis might discourage physicians from practicing EBM. Paradoxically, the current situation also might mandate the practice of EBM. This counter-intuitive notion stems from the fact that courts have long asserted the power to impose liability upon a physician who does not remain abreast of the latest medical science. Courts began asserting the duty to stay abreast long before the EBM movement caught the attention of the legal community, some as early as the mid-nineteenth century.¹⁷¹ Although courts will not require a physician "to

167. See Amy Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine*, 23 J. LEGAL MED. 449, 485 (2002) ("Acceptance of new practice approaches engendered by new technology takes time.").

168. See *id.* at 471 (2002) (distinguishing medical malpractice standard of care from that of other areas of negligence law (citing Angela Roddey Holder, *Failure to "Keep Up" as Negligence*, 224 JAMA 1461, 1462 (1973))); Kacmar, *supra* note 136, at 621 ("Ordinarily, until the medical community adopts a particular procedure, technique, or methodology, a physician is not negligent for failing to discover, consider, or adopt it."). Sokol and Molzen note, "The medical standard of care, unlike traditional duty analysis in ordinary negligence cases, does not require the newest techniques or utilization of state-of-the-art procedures unless it can be shown that the techniques or procedures have gained general acceptance in the medical community." Sokol & Molzen, *supra* note 167, at 471.

169. *Id.*

170. See *id.* ("For this reason, standard of care determinations often trail the latest medical information and techniques being introduced into the practitioner's area of expertise.").

171. The earliest example is *McCandless v. McWha*, 22 Pa. 261, 266 (1853) (noting that physicians have duty to attune themselves to latest science). In *McCandless*, the Supreme Court of Pennsylvania stated:

[I]n a given case, regard is to be had to the advanced state of the profession at the time. Discoveries in the natural sciences for the last half-century have exerted a sensible influence on all the learned professions, but especially on that of medicine, whose circle of truths has been relatively much enlarged. And besides, there has been a positive progress in that profession resulting from the studies, the experiments, and the diversified practice of its professors. The patient is entitled to the benefit of these increased lights. The physician or surgeon who assumes to exercise the healing art, is bound to be up to the improvements of the day. The

possess extraordinary knowledge and ability that belongs to a few men of rare endowment, [courts may require him] 'to keep abreast of the times and to practice in accordance with the approved methods and means of treatment in general use.'¹⁷² A typical formulation of the duty to stay abreast qualifies a custom-based standard of care by adding language such as "taking into account," "having regard to," or "in light of" advances in medical science.¹⁷³

standard of ordinary skill is on the advance; and he who would not be found wanting, must apply himself with all diligence to the most accredited sources of knowledge.

Id. at 269.

172. STEVEN E. PEGALIS & H.F. WACHSMAN, *AMERICAN LAW OF MEDICAL MALPRACTICE* § 3:11 (1992) (citing *Pike v. Honsinger*, 49 N.E. 760 (N.Y. 1898); *Toth v. Cmty. Hosp. at Glen Cove*, 239 N.E.2d 368 (N.Y. 1968)); *see also Mitchell v. United States*, 141 F.3d 8, 13 (1st Cir. 1998) (applying Massachusetts law and stating, "A physician is held to the standard of care and skill of the average practitioner of the medical specialty in question, taking into account the advances in the profession" (citing *Poysner v. United States*, 602 F. Supp. 436, 438–39 (D. Mass. 1984))); *Ward v. United States*, 838 F.2d 182, 187 (6th Cir. 1988) (applying Tennessee law and stating, "In determining the degree of learning and skill required of a medical practitioner in the treatment of a particular case, regard must be given to the state of medical science at the time." (citing *Ogle v. Noe*, 6 Tenn. App. 485 (1927))); *Carr v. Shifflette*, 82 F.2d 874, 876 (D.C. Cir. 1936) ("It is established law that it is the duty of a physician when practicing his profession to exercise the ordinary care and skill of that profession in a similar locality, giving due consideration to modern advancement and learning.").

173. *See, e.g., McBride v. Saylin*, 56 P.2d 941, 941 (Cal. 1936) (stating that test to determine physician's liability for malpractice is whether "the treatment given by the defendant [was] consistent with that reasonable degree of learning and skill usually possessed and rendered by others of his profession . . . *having regard to the state of scientific learning at the time.*" (emphasis added)); *Tomer v. Am. Home Prods. Corp.*, 368 A.2d 35, 38 (Conn. 1976) ("[T]he standard of care which was applicable to the doctors in the use of Halothane was *dependent upon the state of their art at the time that they were allegedly negligent.*" (emphasis added) (citing *Geraty v. Kaufman*, 163 A. 33, 36 (Conn. 1932))); *Adkins v. Ropp*, 14 N.E.2d 727, 728 (Ind. Ct. App. 1938) ("In determining whether the physician or surgeon has exercised the degree of care and skill which the law requires, *regard must be had to the advanced state of the profession at the time of treatment.*" (emphasis added)); *Schwartz v. Goldstein*, 508 N.E.2d 97, 99 (Mass. 1987) ("A doctor undertakes to use a reasonable degree of care such as ordinarily possessed by others providing medical care and treatment, *having regard to the current state of care and treatment.*" (emphasis added) (quoting *Brune v. Belinkoff*, 235 N.E.2d 793 (Mass. 1968) and *Riggs v. Christie*, 173 N.E.2d 610 (Mass. 1961))); *Dietsch v. Mayberry*, 47 N.E.2d 404, 409 (Ohio Ct. App. 1942) (recognizing physician's duty "to exercise the average degree of skill, care, and diligence exercised by members of the same profession . . . *in the light of the present state of medical and surgical science*" (emphasis added) (quoting *Gillette v. Tucker*, 65 N.E. 865 (Ohio 1902))); *King v. Ditto*, 19 P.2d 1100, 1102 (Or. 1933) ("As a general rule, the degree of care and skill depends somewhat upon . . . *the advanced state of medical and surgical science at time services to patient were rendered* What might have been considered due care twenty ears ago would be gross negligence to-day." (emphasis added)); *Sinclair v. Haven*, 89 P.2d 820, 822 (Wash. 1939) (stating reasonable skill and learning is "measured by the *state of medical and surgical science at the time the service is rendered*" (emphasis added)).

*Nowatske v. Osterloh*¹⁷⁴ is more explicit in its pronouncement that physicians have a duty to stay abreast of medical advances. The *Nowatske* court stated, "[A] reasonably competent practitioner is one who keeps up with advances in medical knowledge."¹⁷⁵ In *Nowatske*, the plaintiff lost sight in his right eye after the defendant performed scleral buckling to reattach the plaintiff's retina.¹⁷⁶ The plaintiff brought a malpractice action that the trial court dismissed.¹⁷⁷ On appeal, the plaintiff argued that the circuit court's malpractice instruction to the jury was inadequate because it equated the legal standard of care with the custom of the medical profession without considering whether such custom was sufficient in light of current medical science.¹⁷⁸ The plaintiff argued that by not considering custom in light of current science, a court would allow an unreasonable and outdated custom to shield clearly negligent conduct from liability.¹⁷⁹ The Supreme Court of Wisconsin limited its review to the question of whether the standard jury instruction accurately stated the law of negligence for medical malpractice cases.¹⁸⁰

In considering the validity of the plaintiff's argument, the *Nowatske* court cited *Gates v. Fleischer*¹⁸¹ for the proposition that the current state of science is

174. *Nowatske v. Osterloh*, 543 N.W.2d 265 (Wis. 1996).

175. *Id.* at 273.

176. *Id.* at 266.

177. *Id.*

178. *Id.* at 270. The jury instruction was as follows:

In treating Kim Nowatske, Dr. Osterloh was required to use the degree of care, skill, and judgment which is usually exercised in the same or similar circumstances by the average specialist who practices the specialty which Dr. Osterloh practices, having due regard for the state of medical science at the time Kim Nowatske was treated. The burden in this case is on the plaintiffs to prove that Dr. Osterloh failed to conform to this standard.

Id. at 269-70.

179. *Id.*

180. *Id.* at 266.

181. *Gates v. Fleischer*, 30 N.W. 674 (Wis. 1886). In *Gates*, the plaintiff brought an action for damages allegedly caused by the defendant surgeon's malpractice in treating the plaintiff for uterine trouble. *Id.* at 675. The defendant diagnosed the plaintiff as having uterine disease and treated her by applying caustic to her cervical canal on the theory that there was uterine ulceration. *Id.* Evidence suggested that plaintiff had no ulcers, that the use of caustic to treat uterine ulcers was contrary to the advanced state of medical science at the time, and that even if the use of caustic had been proper, defendant improperly applied such treatment. *Id.* at 674. The trial court found for the plaintiff and awarded her \$350 in damages. *Id.* at 675. On appeal, the Wisconsin Supreme Court stated that the trial judge had properly instructed the jury. *Id.* The instruction was:

The defendant being a physician and surgeon, and as such called to prescribe for, and professionally treat, the plaintiff, he was bound to bring to her aid and relief such skill as is ordinarily possessed and used by physicians and surgeons in the

a factor in the standard of care.¹⁸² The *Nowatske* court then agreed with the plaintiff's assertion "that should customary medical practice fail to keep pace with developments and advances in medical science, adherence to custom might constitute a failure to exercise reasonable care."¹⁸³ The court explained further, "If what passes for customary or usual care lags behind developments in medical science, such care might be negligent, despite its customary nature."¹⁸⁴ The court next considered whether the jury instruction¹⁸⁵ accurately conveyed the message "that reasonable care, skill and judgment are not necessarily embodied by the customary practice of the profession but rather represent the practice of physicians who keep abreast of advances in medical knowledge."¹⁸⁶ The court concluded that the instruction was sufficient because the phrase "due regard for the state of medical science" accurately informed the jury that the competent physician is one who stays abreast of the advanced state of medical science.¹⁸⁷

A few courts have gone beyond mere recitation of a duty to stay abreast to actually hold physicians liable for negligence for not keeping up with the latest medical science. *Burton v. Brooklyn Doctors Hospital*¹⁸⁸ provides an example. In *Burton*, the court considered imposing liability on a physician and hospital for injuries plaintiff incurred due to prolonged liberal exposure of oxygen following plaintiff's premature birth.¹⁸⁹ The physician and hospital argued that they should escape liability because they had satisfied the standard of care by practicing in accordance with conventional medical wisdom that considered increased oxygen essential to the survival of premature babies.¹⁹⁰ The *Burton* court imposed liability because several studies had found that oxygen was unnecessary and dangerous.¹⁹¹

vicinity or locality in which he resides, *having regard to the advanced state of the profession at the time of treatment.*

Id. (emphasis added).

182. *See id.* at 675 (stating that regard to advanced state of profession is one component of standard of care).

183. *Nowatske v. Osterloh*, 543 N.W.2d 265, 271 (Wis. 1996).

184. *Id.*

185. *See supra* note 178 (quoting jury instruction, which is based on Wis JI-Civil 1023).

186. *Nowatske*, 543 N.W.2d at 272-73.

187. *Id.* at 273 ("The phrase 'due regard for the state of medical science' tells the jury that a reasonably competent practitioner is one who keeps up with advances in medical knowledge.").

188. *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875 (N.Y. App. Div. 1982).

189. *Id.*

190. *Id.* at 879-80.

191. *Id.*

By considering cases in which courts have held that physicians have a duty to stay abreast of the latest science, one might posit that the duty to stay abreast is, in effect, a duty to practice EBM. *Burton* bolsters the theory that the duties are synonymous because the *Burton* court essentially held the physician and hospital liable for not practicing in accordance with current best evidence.¹⁹² Aside from *Burton*, whether or not a court would employ the duty to stay abreast to impose liability for not practicing EBM is, at present, unclear. The confusion stems mainly from the fact that the duty to stay abreast is largely an untested tool. Examples of cases expressing the duty are far more frequent than cases turning on it.¹⁹³ In fact, the issue is rarely present in medical malpractice actions,¹⁹⁴ let alone determinative of liability. Additionally, courts have seldom been explicit in proclaiming what the duty entails.¹⁹⁵ Unlike other professionals, physicians are largely left in the dark as to what it means to stay abreast.¹⁹⁶ This lack of certainty takes on greater significance as medical science advances at an ever-increasing pace. Scholars suggest that "[f]ailure to access [online medical] databases is likely to become an important piece of evidence in a malpractice suit, since it is evidence that a physician has failed to stay current in his or her field of practice,"¹⁹⁷ but when or how courts will focus on such evidence is unclear.

IV. Remediating the Incompatibility of Current Standard of Care Analysis and EBM

Courts are cognizant of their role in altering tort law to reflect changes in society. As the Supreme Court of Florida explained, "This Court has consistently

192. See *supra* note 4 and accompanying text (defining EBM).

193. Holder, *supra* note 168, at 1462 ("Very few decisions have dealt with the sole question of whether or not a physician has been negligent simply because he did not use the latest methods of treatment.").

194. *Id.* at 1461 ("Whether or not failure to keep abreast of new developments in medicine or surgery alone can constitute a cause of action against a physician does not seem to have been directly decided in many cases."); Noah, *supra* note 10, at 463 (noting that extent to which physicians keep abreast is rarely litigated).

195. See *supra* note 173 (providing examples of formulations of duty to stay abreast). But see John C. Peck & Wyatt A. Hoch, *Liability of Engineers for Structural Design Errors: State of The Art Considerations in Defining the Standard of Care*, 30 VILL. L. REV. 403, 430–31 (1985) (stating that one "court required physicians to read journals, solicit product data from manufacturers' representatives, listen to tape record digests of current literature, and attend postgraduate courses and professional seminars" (citing *Pederson v. Dumouchal*, 431 P.2d 973, 977–78 (1967))).

196. See *infra* notes 209–14 and accompanying text (discussing attorney's duty to stay abreast).

197. FURROW ET AL., *supra* note 15, at 183.

recognized its 'continuing responsibility to the citizens of this state' to modernize traditional principles of tort law when such becomes necessary 'to ensure that the law remains both fair and realistic as society and technology change.'¹⁹⁸ This Note argues that if courts are to modify tort law to ensure it remains fair and realistic as the practice of medicine changes, they will need to consider the double-edged incompatibility of their current standard of care analysis and EBM. Today, a physician at the crossroads of a standard of care dominated by custom and a duty to stay abreast of the latest science might not know whether he is safe practicing EBM or whether he is obligated to practice EBM. The prevalence of custom may say to physicians "you're damned if you do;" whereas, the duty to stay abreast may say "you're damned if you don't."

This Part begins by suggesting that courts should clarify the duty to stay abreast. This Part then considers frameworks to replace the custom-based standard of care. Next, this Part contrasts the physician's standard of care with care standards applied in other areas of law in order to draw instructive parallels to inform the search for and evaluation of potential alterations to the physician's standard of care in light of EBM. This Part presents four goals for creating a standard of care that can co-exist with EBM and considers five frameworks that may accommodate those goals. After evaluating each of these frameworks, this Part concludes by recommending a modified custom-based or modified CPG-based standard in the short-term and proposing a bifurcated standard in the long-term.

A. Clarifying the Duty to Stay Abreast

This Note argues that in light of the information explosion in medicine,¹⁹⁹ courts should clarify the duty to stay abreast. The current doctrine does little to explain to a physician what he must do to keep up because courts define the duty in vague terms and there is little case law to inform physicians of exactly what it means to "stay abreast."²⁰⁰ The extent of the doctrine is also unclear because courts originally formulated the duty to stay abreast long ago, when medical knowledge was increasing at a much slower pace than it is today. At that time, staying abreast entailed much less than it might today. Consideration

198. *Conley v. Boyle Drug Co.*, 570 So. 2d 275, 284 (Fla. 1990) (quoting *Ins. Co. of N. Am. v. Pasakarnis*, 451 So. 2d 447, 451 (Fla. 1984)); *see also* *Schmitz v. Smentowski*, 785 P.2d 726, 736 (N.M. 1990) ("New Mexico has recognized that tort law is not static—it must expand to recognize changing circumstances that our evolving society brings to our attention.").

199. *See supra* note 54 (explaining information explosion in medicine).

200. *See supra* Part III.D (discussing physician's duty to stay abreast).

of the staggering increase in the number of medical journal articles in recent years illustrates this point.²⁰¹

That is not to say that the duty to stay abreast should fall in the face of rapid advances in medical science (such a paradox would belie the policy that led to the rule in the first place), but rather that a vague duty to stay abreast may need clarification to successfully alert physicians as to how to avoid liability in the face of the momentous task of staying abreast with the fast-paced advances in modern medicine. The current confusion over the extent of the duty to stay abreast is evident in legal scholarship—one source proclaims that the "duty to 'keep abreast' . . . would be more accurately labeled a duty to keep abreast of *customary medical practice*,"²⁰² while another suggests the duty to stay abreast, in effect, demands "adherence to the state-of-the-art rather than simply existing custom."²⁰³ If the EBM movement continues to grow and effectuates a "paradigm shift," as some commentators suggest it will,²⁰⁴ knowing which statement is accurate will become much more important. In the interest of serving the goal of clarity, this Note suggests that the prudent course for courts to take is to begin sharpening and elucidating the extent of this duty.

B. Contrasting the Physician's Standard of Care with Other Areas of Law

Before presenting potential frameworks for altering the medical malpractice standard of care in light of EBM, it is helpful to briefly consider three other areas of the law: the standard of care analysis used to determine malpractice liability of attorneys; the use of evidence of the state-of-the-art in products liability litigation; and the process-oriented business judgment rule of corporate law. As is often the case when dealing with uncharted areas of the law, reasoning by analogy aids the search for a framework that can successfully co-exist with EBM. This Note contends that lessons learned from these areas of law will help courts formulate an appropriate framework for altering the physician's standard of care in light of EBM.

201. See SACKETT ET AL., *supra* note 42, at 2 (noting exponential increase in number of journal articles over past decade).

202. Kacmar, *supra* note 136, at 641.

203. Noah, *supra* note 10, at 463.

204. *Id.* at 374.

1. Standards of Care for Non-Physician Professionals

An instructive parallel to consider is that between the law of professional malpractice as it applies to physicians and as it applies to other professionals. This Note will briefly compare liability determinations in medical malpractice cases with those in cases involving attorneys. Whereas the law has traditionally held physicians to a custom-based standard of care,²⁰⁵ it has not treated attorneys the same way. Although sources sometimes state that the attorney's standard of care is analogous to the physician's standard of care,²⁰⁶ in practice, the standard courts employ in legal malpractice actions appears to be closer to an ordinary negligence standard than a custom-based standard.²⁰⁷ Courts typically explain the attorney's duty as that of using "reasonable care, diligence, and skill in the performance of his professional duties."²⁰⁸ While custom is undoubtedly part of the analysis, it does not have the primacy in legal malpractice that it does in medical malpractice. To illustrate, consider how effective the following argument would be: "Your honor, despite the fact that the legislature recently decreased the statute of limitations for filing an action for [] from five years to two years, the custom has always been five years, therefore my failure to file on behalf of my client within two years cannot be negligence."

The law of legal malpractice also differs from that of medical malpractice in that the law holds attorneys to what appears to be a more pronounced duty to stay abreast. Although courts have recognized a duty for physicians to stay abreast of medical advances, as noted above, parties rarely litigate the issue, and thus the threat to a physician for failing to keep up is minimal.²⁰⁹ On the other hand, an attorney faces a very real possibility that liability will ensue if he does not stay aware of the latest changes in the law.²¹⁰ Courts have explained

205. See *supra* Part III.B (discussing traditional custom-based standard of care for medical malpractice).

206. See 7A C.J.S. *Attorney and Client* § 254 n.50 (2002) (stating that attorneys are liable to clients for negligence in same manner that physicians are liable to patients). The note continues, "[A]ttorneys are required to exercise that degree of skill and diligence in their profession which physicians and surgeons are required to exercise in theirs." *Id.* (citing *Olson v. North*, 276 Ill. App. 457 (1934) (stating that same rules of law govern liability for negligence and lack of professional skill and diligence in practice of law and in practice of medicine and surgery)).

207. See *supra* note 121 and accompanying text (explaining ordinary negligence standard).

208. 7A C.J.S., *supra* note 206, § 254.

209. See *Noah*, *supra* note 10, at 463 (stating parties rarely litigate issue of physician's duty to stay abreast).

210. See Brian Kibble-Smith & Arthur W. Hafner, *The Effect of the Information Age on Physicians' Professional Liability*, 36 DEPAUL L. REV. 69, 92 (1986) (citing failure to

the attorney's duty as that of "a specific duty to research"²¹¹ or "the duty of diligent investigation and research."²¹² An attorney must not only know "those plain and elementary principles of law which are commonly known by well informed attorneys"²¹³ but must also "discover those additional rules of law which, although not commonly known, may readily be found by standard research techniques."²¹⁴ In this respect, the law of legal malpractice is arguably a state-of-the-art standard, or at least more so than the law of medical malpractice. As the legal community begins to consider what effect EBM should have on the physician's standard of care, it may be useful to consider whether courts should treat physicians more like attorneys.

2. Evidence of State-of-the-Art in Products Liability Litigation

Perhaps the most prominent legal use of evidence of the state-of-the-art occurs in products liability cases asserting a design defect. The *Restatement (Third) of Torts: Products Liability* states that a product is defective in design "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor . . . and the omission of the alternative design renders the product not reasonably safe."²¹⁵ In determining manufacturer liability for a

Shepardize as one way in which "an attorney's failure to keep abreast in law can easily result in malpractice liability"); see also *State v. Traeger*, 29 P.3d 518, 525-26 (N.M. 2001) (noting that practitioners have obligation to keep abreast of current changes in law); *Frank v. Pepe*, 717 N.Y.S.2d 873, 877 (N.Y. Sup. Ct. 2000) (stating that attorney may be liable in malpractice for failure to conduct adequate legal research, and quoting *McCoy v. Tepper*, 690 N.Y.S.2d 678, 679 (N.Y. App. Div. 1999)); *Shopsin v. Siben & Siben*, 702 N.Y.S.2d 610, 612 (N.Y. App. Div. 2000) (same); *Fiorentino v. Rapoport*, 693 A.2d 208, 213 (Pa. Super. Ct. 1997) (stating that court does not expect attorney "to be infallible," but does expect him to conduct that degree of research sufficient to enable client "to make an informed decision") (citing *Collas v. Garnick*, 624 A.2d 117, 120 (Pa. Super. Ct. 1993)).

211. See *Dixon Ticonderoga Co. v. Estate of O'Connor*, 248 F.3d 151, 173 (3d Cir. 2001) (noting that attorney, under New Jersey law, has specific duty to research, monitor, and advise his clients about statutes of limitations).

212. See *Rock v. ATPIC Trucking Co.*, 739 So. 2d 874, 879 (La. Ct. App. 1999) (stating that attorney owes client "duty of diligent investigation and research"); *Finkelstein v. Collier*, 636 So. 2d 1053, 1058 (La. Ct. App. 1994) (same).

213. *Smith v. Lewis*, 530 P.2d 589, 595 (Cal. 1975) (citing *Lucas v. Hamm*, 364 P.2d 685 (Cal. 1961); *Lally v. Kuster*, 171 P. 961 (Cal. 1918); *Floro v. Lawton*, 10 Cal. Rptr. 98 (Cal. Ct. App. 1960); *Sprague v. Morgan*, 185 Cal. App. 2d 519, 523 (1960); *Armstrong v. Adams*, 283 P. 871 (Cal. Ct. App. 1929)).

214. *Id.*

215. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (defining categories of product defect).

design defect, courts may consider whether the manufacturer complied with the state-of-the-art.²¹⁶ The term "state-of-the-art" serves "as a label for the requirement that [manufacturers use] the best scientific and medical technology that is practically and economically feasible at the time the product was made or marketed."²¹⁷

The determination of whether or not the defendant complied with the state-of-the-art may involve consideration of industry customs. Generally, customs are relevant, but courts recognize that customs may be outdated.²¹⁸ Thus, a court in some situations may impose liability for not using an alternative design even though such alternative design is not custom.²¹⁹ The burden is on the plaintiff to prove a defective design.²²⁰ The burden is on the defendant to prove that the state-of-the-art and other factors justify marketing the product.²²¹ Compliance with state-of-the-art is not necessarily dispositive, as other factors are also relevant.²²²

3. *Judgmental Immunity in Corporate Law*

In corporate law, the business judgment rule operates to shield corporate directors from liability resulting from decisions they make as long as the directors

216. See SCHWARTZ ET AL., *supra* note 128, at 753 ("Most jurisdictions allow state of the art evidence to be considered in the determination of design defect, either by case law or statute." (citing COLO. REV. STAT. § 13-21-403(1)(a) (1987); KY. REV. STAT. ANN. § 411.310(2) (Michie 1978); MICH. COMP. LAWS ANN. § 600.2946 (West 1986); Beech v. Outboard Marine Corp., 584 So. 2d 447 (Ala. 1991); Sturm, Ruger & Co. v. Day, 594 P.2d 38 (Alaska 1979); Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204 (N.Y. 1983))).

217. See *id.* (defining "state-of-the-art").

218. See O'Brien v. Muskin Corp., 463 A.2d 298, 305 (N.J. 1983) (noting that while industry customs may be relevant to design defect determinations, customs are not determinative since they may lag behind technological development).

219. See *id.* ("A manufacturer may have a duty to make products pursuant to a safer design even if the custom of the industry is not to use that alternative.").

220. See Gawenda v. Werner Co., 932 F. Supp. 183, 187 (E.D. Mich. 1996) (explaining that under Michigan law, plaintiff has burden to establish, through risk-utility analysis, that manufacturer's design choice renders product defective and that safer, alternative design was available); Fine v. Facet Aerospace Prods. Co., 133 F.R.D. 439, 442 (S.D.N.Y. 1990) (stating that in products liability action alleging design defect, plaintiff has burden to prove feasible design alternatives existed).

221. See Cavanaugh v. Skil Corp., 751 A.2d 518, 519 (N.J. 2000) (stating that when defendant contends that plaintiff's suggested alternative design was unfeasible, defendant has burden of proving state-of-the-art at time of manufacturer).

222. See Crispin v. Volkswagenwerk AG, 591 A.2d 966, 973 (N.J. Super. Ct. App. Div. 1991) ("Although state of the art evidence may be dispositive on the facts of a particular case, it does not constitute an absolute defense apart from its appearance as one of the components of balancing risk with utility factors.").

were reasonably informed,²²³ not operating under a conflict of interest,²²⁴ and reasonably believed they were acting pursuant to the best interests of the corporation.²²⁵ In light of the business judgment rule, courts do not evaluate directorial decisions against a standard of care.²²⁶ Instead, courts apply a standard of care "to the process by which the directors 'become informed' in connection with making the decision."²²⁷ In other words, "the due care standard in corporate law is applied to the decisionmaking process and not to its result."²²⁸ This standard differs from a standard of ordinary prudence because, "[e]ven though a decision made or a result reached is not that of the hypothetical ordinarily prudent person, no liability will attach as long as the decisionmaking process meets the standard."²²⁹

The Official Comment to the revised Model Business Corporation Act § 8.31 explains the rationale behind the business judgment rule. It notes,

The courts recognize that boards of directors and corporate managers make numerous decisions that involve the balancing of risks and benefits for the enterprise. Although some decisions turn out to be unwise or the result of a mistake of judgment, it is not reasonable to reexamine an unsuccessful decision with the benefit of hindsight.²³⁰

Scholars further explain the rationale behind the business judgment rule by noting assertions that courts do not possess the expertise to make complex business decisions.²³¹ The business judgment rule and its supporting rationale suggest that courts will never impose liability on directors who followed the appropriate process in coming to such a decision. Although directorial liability under the business judgment rule is mainly process-based, courts will impose liability in spite of satisfactory process if the substance of a decision is not rational.²³²

223. MODEL BUS. CORP. ACT § 8.31(a)(2)(ii)(B) (1984).

224. *Id.* at § 8.31(a)(2)(iii).

225. *Id.* at § 8.31(a)(2)(ii)(A).

226. ROBERT W. HAMILTON, CASES AND MATERIALS ON CORPORATIONS 762 (7th ed. 2001).

227. *Id.*

228. Charles Hansen, *The ALI Corporate Governance Project: Of the Duty of Due Care and the Business Judgment Rule*, A Commentary, 41 BUS. LAW 1237, 1241 (1986).

229. *Id.*

230. MODEL BUS. CORP. ACT § 8.31 official cmt. (1984).

231. See Arkes & Shipani, *supra* note 46, at 622 (explaining rationales given to justify the business judgment rule).

232. See *Litwin v. Allen*, 25 N.Y.S.2d 667, 699 (N.Y. 1940) (imposing liability on bank directors due to fact that no sound reason supported their actions). The *Litwin* court notes that "[T]here is more here than a question of business judgment as to which men might differ. The directors plainly failed in this instance to bestow the care which the situation demanded." *Id.*

C. Frameworks for Altering Standard of Care Analysis in Light of EBM

As the legal community begins to consider appropriate legal responses to the growing prominence of EBM in the medical community, several options may emerge, as courts could employ various frameworks to analyze standard of care issues in light of EBM. This Note considers five possibilities ranging from modification of the traditional custom-based standard to a bifurcation of the standard of care into procedural and substantive components. Each of these options presents different positive and negative aspects, which this Note discusses below. To be sure, a myriad of other options are available, limited only by the bounds of judicial innovation. This Note does not intend to present an exhaustive list, but rather to present an exemplary range of alternatives.

Before considering each of these frameworks in turn, it is helpful to identify some goals that an appropriate framework should advance. This Note suggests that an appropriate framework should promote clarity, ease of application, dynamism, and avoid the problems of over- and under-inclusiveness. Clarity benefits physicians by informing them of the standard with which to comply. Ease of application benefits courts, juries, and litigants by facilitating resolution of malpractice actions. Dynamism ensures that the law adjusts to "changes and improvements in medical science."²³³ The avoidance of the problems of over- and under-inclusiveness, which loom behind all law-making efforts, entails tailoring the law as closely as possible to hold neither too many nor too few defendants accountable.

1. Modified Custom-Based Standard

One way to alter standard of care analysis in light of EBM is by modifying the traditional custom-based standard. Although potentially endless ways to modify this standard exist, this Note focuses on two modifications—moving toward a reasonable physician standard, and incorporating risk-utility (or cost-benefit) analysis. Essentially, these are the modifications Patricia Danzon advocates, although Danzon's suggestions predated EBM.²³⁴ Danzon states that the complexity of medical malpractice requires that custom remain part of

233. *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996) (quoting Brief for Defendant at 18). In considering the appropriateness of the jury instruction at issue in the case, the *Nowatske* court agrees with the defendant and an amicus brief of the State Medical Society of Wisconsin that the jury instruction requires that custom be dynamic in order to be reasonable. *Id.* at 271–72.

234. See DANZON, *supra* note 124, at 149 (advocating reasonable-man test or explicit cost-benefit analysis).

the analysis. She asserts, "Because of the complexity of the issues in medical malpractice cases, there is no practical alternative to customary norms as the standard of due care."²³⁵ However, she suggests that "courts should retain the right to override custom in specific cases in favor of a reasonable-man test or an explicit cost-benefit calculus."²³⁶

Shifting the medical malpractice standard of care towards an ordinary negligence standard would ameliorate rigid adherence to custom. Under this approach, custom remains important as evidence of reasonable care, but it is not conclusive. Courts may choose to follow the examples of Colorado and Nevada, where evidence of custom establishes a rebuttable presumption of reasonability.²³⁷ A party would have an opportunity to rebut this presumption "simply by offering expert testimony establishing that the prevailing custom is deficient."²³⁸ The jury then decides whether the custom was reasonable and allocates liability accordingly.²³⁹

This modification brings the standard in line with what Justice Holmes and Judge Hand advocated.²⁴⁰ It bases liability determinations on reasonableness, which includes consideration of what physicians ought to do, rather than what they actually do. In this manner, this framework serves to limit problems of over- and under-inclusiveness that might be present in a purely custom-based framework. That is, this modification frees up courts from having to hold every physician who deviates from custom liable and from having to exonerate every physician who follows custom. Also, this modification of the custom-based standard, like the custom-based standard itself, provides ease of administration because courts are familiar with judging individuals by standards of reasonable prudence.²⁴¹ Moreover, another advantage of this approach is that courts may be moving toward employing this type of standard.²⁴²

235. *Id.*

236. *Id.*

237. *See Peters, supra* note 49, at 175 ("[C]ustomary standards continue to benefit from a rebuttable presumption of reasonability in Colorado and Nevada.").

238. *Id.*

239. *Id.*

240. *See supra* notes 157–60 and accompanying text (noting concerns of Justice Holmes and Judge Hand over role of custom in determining standard of care).

241. *See DANZON, supra* note 124, at 139 ("In most cases of personal liability, the courts . . . use the . . . 'reasonable and prudent man' standard.").

242. *See Peters, supra* note 49, at 187–88 (arguing that courts are shifting away from custom-based standard in favor of ordinary negligence standard).

Modifying the custom-based standard to incorporate cost-benefit or risk-utility analysis into the standard of care evaluation might involve not only consideration of customary practice, but also consideration of the costs, risks, and benefits of alternatives. Courts could employ the *United States v. Carroll Towing Co.*²⁴³ formula to determine when deviation from custom is appropriate.²⁴⁴ In *Carroll Towing*, Judge Learned Hand defined negligence as failing to take precautions whose costs do not exceed the potential loss multiplied by the probability of that loss.²⁴⁵ Under this framework, courts would hold physicians liable for not practicing EBM to the extent that not doing so violates Hand's negligence formula. Essentially, this standard would look like the one employed in *Helling v. Carey*.²⁴⁶

Presumably, this modification would be easy to administer, as courts have employed the Hand negligence formula for over half a century. This modification might also avoid the problems of over- and under-inclusiveness in the same manner as the previous modification. Additionally, both of these modifications could improve standard of care evaluations in light of EBM by reducing the chilling effects that an unmodified custom-based standard places on physicians desiring to disregard customary practice. However, to the extent that custom remains central to the analysis in each, both modifications are susceptible to criticism. As long as custom remains vital to standard of care determinations, such determinations will lack a certain degree of dynamism.

243. See *United States v. Carroll Towing Co.*, 159 F.2d 169 (2nd Cir. 1947). In *Carroll Towing*, the United States Court of Appeals for the Second Circuit considered whether a barge owner should be partially responsible for losses incurred when its barge sank after a tug boat struck the barge thereby causing it to break free of its mooring line. *Id.* at 171. The owner of the lost cargo, the United States, sought compensation for its cargo, and the owner of the barge, Conners Co., sought compensation for the barge. *Id.* The defendant, Carroll Towing, argued that it should not be responsible for the entire loss because the loss of the vessel and its cargo would not have occurred if there had been a bargee on board at the time. *Id.* In considering the validity of the defendant's argument, Judge Learned Hand defined the owner's duty to protect against resulting injuries as a function of three variables: (1) the probability that the barge would break free; (2) the magnitude of resulting injuries if it does; and (3) the burden of taking adequate precautions. *Id.* at 173. Judge Hand restated the idea in algebraic form: "[I]f the probability be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P: i.e., whether B [is less than] PL." *Id.* Scholars refer to this formulation as the Learned Hand negligence formula.

244. See *id.* at 173 (defining duty to provide against resulting injuries as product of three variables).

245. *Id.*; see also DANZON, *supra* note 124, at 139 ("[A] defendant is negligent if the loss caused by the accident, multiplied by the probability of the accident's occurring, exceeds the cost of preventing the accident.").

246. See *supra* notes 133–35 and accompanying text (discussing *Helling v. Carey*).

2. Clinical Practice Guidelines Standard

Another framework could employ CPGs as measures of the standard of care. Such a framework would advance EBM at least to the extent that the CPGs employed are evidence-based. Scholars, legislatures, and courts seem to encourage this framework.²⁴⁷ But, even if judicial treatment of EBM is limited to CPGs, difficult questions remain as to how to use CPGs.²⁴⁸ For example, some scholars disagree over whether CPGs should be available to both sides in a dispute, or to only the plaintiff or to only the defendant.²⁴⁹ Additionally, regardless of whether courts allow one or both sides to use CPGs, the question of how courts should weigh them remains. As noted above, so far judicial treatment of CPGs has been inconsistent.²⁵⁰

Courts could use CPGs to help establish a standard of care in several ways.²⁵¹ For example, courts could allow guidelines to establish the standard of care conclusively. By allowing guidelines to conclusively establish the standard of care, courts would in effect allow guidelines to take the place of custom as the benchmark of the standard of care. Practicing in accordance with a CPG would preclude liability just as practicing in accord with custom.²⁵²

247. See Rosoff, *supra* note 21, at 337 (suggesting that courts should use CPGs as they use custom). Rosoff notes:

The most obvious possibility for the use of CPGs, then, is that a court could look to them as evidence of what is customary practice in the medical profession. A physician who practiced in conformity with a CPG would be shielded from liability to the same extent as one who could establish that she or he followed professional custom. Conversely, a physician's failure to conform to a recognized guideline could raise an inference that she or he did not perform up to the required standard; at the least, it would obligate the physician to explain why the CPG was not followed.

Id.

248. See FURROW ET AL., *supra* note 15, at 180 ("Clinical guidelines raise difficult legal questions, since they potentially offer an authoritative and settled statement of what the standard of care should be for a given treatment or illness.").

249. See Hirshfeld, *supra* note 56, at 2887 (noting frequent recommendations that CPGs should be available for use by physicians to defend against malpractice claims, but should not be available to plaintiffs to establish liability).

250. See Rosoff, *supra* note 21, at 335 (explaining sparse and inconsistent judicial response to CPGs).

251. See FURROW ET AL., *supra* note 15, at 180 (noting courts have several choices when parties offer CPGs into evidence).

252. See *id.* ("A doctor practicing in conformity with a guideline would be shielded from liability to the same extent as one who can establish that she or he followed professional custom."). The authors explain that the guideline under this approach "acts like an authoritative expert witness or a well-accepted review article." *Id.* In addition to using guidelines as evidence of customary practice, courts could allow parties to use guidelines to establish a

As noted above, scholars believe that CPGs may serve the goal of clarifying the tort standard of care.²⁵³ Arguably, there is no better method of clarifying the standard of care than allowing CPGs to serve as codified standards of care. Such an approach would also offer ease of administration. The standard of care would be predetermined, and a court would simply need to ascertain whether the defendant violated it. Such a framework might also eliminate under- and over-inclusiveness by only holding physicians liable for violating the letter of the CPG.

On the surface, this framework has a great deal of appeal. However, two questions remain: Is it practical and is it wise? As to the first question, scholars criticize the use of CPGs to conclusively establish the standard of care as a threat to standard of care analysis.²⁵⁴ One problem with using guidelines as conclusive evidence of the standard of care is that often no established guideline will exist.²⁵⁵ Conversely, problems could arise when conflicting guidelines exist. This situation is not as rare as one might expect.²⁵⁶ Thus, in the absence of an authoritative standard setting body, this framework may actually do little to advance the goal of clarity, or, for that matter, ease of administration.²⁵⁷ Consider the difficulty that a court might face when presented with conflicting guidelines. In that situation, the battle of the experts

respectable minority approach. *See id.* ("A guideline could also serve as evidence of a 'respectable' minority practice." (citing Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL., POL'Y & L. 289 (1996))).

253. *See supra* note 103 and accompanying text (noting that scholars see use of CPGs as important reform to clarify tort standard of care).

254. *See Sokol & Molzen, supra* note 167, at 484 (suggesting that arbitrarily designating guidelines as consensus of profession poses "tremendous threat" to standard of care analysis); *see also* Jacobson & Kanna, *supra* note 129, at 316. Jacobsen & Kanna assert:

As Rosoff (1995) and others have argued (Brennan 1991), it is unlikely that courts will rely solely on guidelines to set the standard of care but will allow the jury to weigh them as one piece of evidence in determining liability. Given the physician judgment inherent in any clinical situation, the potential multiplicity of competing and conflicting guidelines, the usual lack of uncertainty inherent in the guidelines development process, and direct physician testimony, it is improbable that any guideline will suffice to set the standard of care.

Id.

255. *See FURROW, supra* note 15, at 178 ("A national standard of practice does not exist for many procedures and tools, and the 'highest and best' practice may not be the safest or most effective in the long run.").

256. *See Arkes & Schipani, supra* note 46, at 632 (noting that "multiple guidelines exist on the same topic").

257. *See Rosoff, supra* note 21, at 355–66 (arguing for creation of authoritative standard setting body).

may simply become the battle of the guidelines, with no one the wiser.²⁵⁸ Noah cites two cases in which such battles occurred.²⁵⁹ Therefore, even if advocates are correct that this framework may advance objectives of clarifying tort law and perhaps lowering costs, it likely will not succeed if the suggested use of guidelines is to conclusively establish the standard of care.

Additional problems arise because many existing guidelines are consensus-based.²⁶⁰ One source defines clinical practice guidelines as "sets of suggestions, described in decision rules, based on current medical consensus."²⁶¹ If guidelines are merely codifications of custom, would shifting the standard of care from one based on custom to one based on guidelines make any difference? Additionally, even if it is prudent to use CPGs as conclusive evidence of the standard of care, many guidelines will not be available for this purpose, as they may be subject to disclaimers undermining their use in litigation.²⁶² Another argument against simply using a clinical practice guideline as the standard of care is that a guideline cannot prescribe the correct treatment in every instance because every patient is unique.²⁶³

258. See Michelle M. Mello, *Using Statistical Evidence to Prove the Malpractice Standard of Care: Bridging Legal, Clinical, and Statistical Thinking*, 37 WAKE FOREST L. REV. 821, 853 (2002) ("[T]he likely outcome of widespread reliance on practice guidelines would be the supplementation of the traditional battle of the experts with a new 'battle of the guidelines.'").

259. See Noah, *supra* note 10, at 462 ("In at least two cases the parties engaged in a battle of the guidelines where different organizations had made conflicting recommendations about the appropriate frequency for breast cancer screening." (citing *Kramer v. Milner*, 639 N.E.2d 157, 158–59 (Ill. App. Ct. 1994); *Levine v. Rosen*, 616 A.2d 623, 628 (Pa. 1993); Mark Crane, *Clinical Guidelines: A Malpractice Safety Net?*, MED. ECON., Apr. 12, 1999, at 236, 239–40; Nancy Volkens, *NCI Replaces Guidelines with Statement of Evidence*, 86 J. NAT'L CANCER INST. 14 (1994))).

260. See *supra* note 35 and accompanying text (distinguishing evidence- and consensus-based guidelines).

261. See FURROW ET AL., *supra* note 15, at 179 (defining "clinical practice guidelines").

262. See *id.* at 180–81 (recognizing limitations on use of guidelines as conclusive evidence of standard of care because of disclaimers). The authors explain this problem as follows:

Professional societies often attach disclaimers to their guidelines, thereby undercutting their defensive use in litigation. The American Medical Association, for instance, calls its guidelines "parameters" instead of protocols to indicate a large sphere of physician discretion, and further suggests that all guidelines contain disclaimers stating that they are not intended to displace physician discretion. Such guidelines therefore cannot be treated as conclusive.

Id.

263. See Sokol & Molzen, *supra* note 167, at 489 ("Outcome-based studies, formularies, clinical pathways, and managed care guidelines will not determine the best care for every patient and the legal liability standard ought not be premised on such an assumption.").

Practicality aside, this Note argues that this framework is not wise because it is not dynamic. EBM encourages the use of "current best evidence."²⁶⁴ As noted above, while CPGs might reflect current best evidence when written, advances in medical science might quickly render them obsolete.²⁶⁵ The lack of dynamism inherent in codifying the standard of care according to CPGs could perpetuate inconsistencies between standard of care analysis and EBM, and thus precludes total satisfaction with this framework. As one source explains, "[G]uidelines may have the effect of freezing the standard of care, thereby discouraging further research and innovation in areas about which the experts have reached a consensus."²⁶⁶ Thus, in order for the law "to promote genuine EBM, however, the courts will have to do more than simply latch on to clinical practice guidelines."²⁶⁷

3. Modified Clinical Practice Guidelines Standard

Recognizing the above-mentioned problems with using CPGs to conclusively establish the standard of care, a court may prefer a modified CPG framework. Instead of using guidelines as conclusive evidence of the standard of care, an arguably wiser course is to use guidelines as raising a rebuttable presumption of negligence.²⁶⁸ Thus, this framework would use CPGs as evidence of the standard of care just as the modified custom-based standard would use custom, as CPGs could take the place of custom in establishing a rebuttable presumption of due care.²⁶⁹

This approach remedies the lack of dynamism of the CPG standard by unfreezing the standard of care. CPGs remain significant, but not conclusive. This framework may be analogous to an attorney's duty to stay abreast.²⁷⁰ The analogy is as follows: attorneys must know the law as written by the legislature and as interpreted by the courts; similarly, physicians should know the recommendations of CPGs and how other evidence alters those recommendations. A statute may reflect common law at the time of its

264. See *supra* note 4 and accompanying text (defining EBM).

265. See *supra* note 45 and accompanying text (noting that CPGs become quickly outdated).

266. Noah, *supra* note 10, at 425.

267. *Id.* at 463.

268. See FURROW ET AL., *supra* note 15, at 180 (noting that courts could use guidelines to raise rebuttable presumptions).

269. See *supra* notes 237–39 and accompanying text (suggesting modifying custom-based standard to use custom to establish rebuttable presumption of standard of care).

270. See *supra* notes 209–13 (discussing attorney's duty to stay abreast).

codification, but the law will continually evolve as courts interpret it through cases. Previously formulated doctrine provides a baseline for the attorney, but he must stay current. Similarly, CPGs reflect current best evidence at the time that professional associations promulgate them. Advances in medical science may interpret, develop, or "over-turn" these CPGs. Thus, perhaps in light of EBM, courts should treat doctors like they treat attorneys and impose a stricter duty to stay abreast.²⁷¹

Because of the problems cited with the CPG standard, it would be imprudent for a court to begin "demanding lockstep adherence to any particular CPG."²⁷² A court should nevertheless "expect that, if a medically reasonable CPG suggests conduct from which the physician has deviated, the physician should be able to explain that deviation with something more than a flat assertion that 'in my professional judgment, the guideline did not apply.'"²⁷³ Scholars suggest that use of CPGs in this manner is more likely than use of CPGs as conclusive statements of the standard of care.²⁷⁴ For example, Noah states, "Although it seems unwise to treat such guidelines as definitive on questions of physician negligence, especially given the many limitations discussed previously, they can provide valuable evidence about the standard of care to which physicians should aspire."²⁷⁵

4. *State-of-the-Art Standard*

Although it may sound illogical to suggest a move to the state-of-the-art for medical malpractice law, it is important to note that at least one scholar has suggested that this is essentially what the traditional duty to stay abreast represents. Noah states that courts that insist that physicians stay abreast of "the latest clinically-relevant research in their fields" are "in effect demanding adherence to the state-of-the-art rather than simply existing custom."²⁷⁶ Noah explains further, "As true in products liability cases, courts do not demand that physicians take into account unknowable information, but the failure to conduct

271. See *supra* notes 209–13 (suggesting courts hold attorneys to stricter duty to stay abreast).

272. Morreim, *supra* note 66, at 422.

273. *Id.*

274. See *supra* note 254 (criticizing the use of guidelines to establish the standard of care).

275. Noah, *supra* note 10, at 463 (citing Mello, *supra* note 68, at 708–10); see also Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 377–91 (1995); Sheila R. Shulman, *Clinical Practice Guidelines and Malpractice Law: An Evolving Standard of Care*, 46 FOOD DRUG COSM. L.J. 97, 105–06 (1991).

276. Noah, *supra* note 10, at 463.

a literature search may provide the basis for a malpractice claim.²⁷⁷ As noted above, courts have rarely used this duty to find physicians liable.²⁷⁸ But, perhaps now that the medical community is moving toward adherence to the state-of-the-art through EBM, it is appropriate for the law to mandate such adherence.

By suggesting a move to the state-of-the-art, this Note does not recommend strict liability. Courts have previously rejected the application of the doctrine of strict liability to the performance of medical services.²⁷⁹ *Hoven v. Kelble*²⁸⁰ is one of a number of cases noting that the rule of strict liability does not apply to the rendition of medical services.²⁸¹ In *Hoven*, a patient and his wife sought to recover damages for injuries that the patient incurred during a lung biopsy.²⁸² The complaint alleged ten causes of action against three defendants—the surgeon, the anesthesiologist, and the hospital where the biopsy was performed.²⁸³ Three causes of action, one for each of the aforementioned defendants, advanced a strict liability theory based on defective medical services.²⁸⁴ The Circuit Court, Milwaukee County, sustained

277. *Id.* (citation omitted).

278. See *supra* notes 193–94 (discussing infrequency of finding liability based on duty to stay abreast).

279. See *Budding v. SSM Healthcare Sys.*, 19 S.W.3d 678, 682 (Mo. 2000) (stating that strict products liability is not applicable to health care providers and *overruling* *Bell v. Poplar Bluff Physicians Group*, 879 S.W.2d 618 (Mo. Ct. App. 1994); *Brandon v. Southeast Mo. Hosp., Inc.*, 926 S.W.2d 113 (Mo. Ct. App. 1996); *Pinkerton v. Southeast Mo. Hosp. Ass'n*, 926 S.W.2d 137 (Mo. Ct. App. 1996); and *Mulligan v. Truman Med. Ctr.*, 950 S.W.2d 576 (Mo. Ct. App. 1997)); see also David B. Harrison, Annotation, *Application of Rule of Strict Liability in Tort to Person or Entity Rendering Medical Services*, 100 A.L.R.3d 1205, 1210 (1980) (discussing doctrine of strict liability with regards to rendition of professional medical services).

280. *Hoven v. Kelble*, 256 N.W.2d 379 (Wis. 1977).

281. See *id.* at 392 (stating that "[a]lthough there may be general dissatisfaction with our present tort medical injury compensation system, moving from the malpractice concept—even with its many problems—to a strict liability system at the present time appears to be a dubious move"); see also, e.g., *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 390–91 (Cal. Ct. App. 1971) (stating that courts may not impose strict liability to find medical doctor liable if injury results but plaintiff does not establish negligence or fault); *Porter v. Rosenberg*, 650 So. 2d 79, 83 (Fla. Dist. Ct. App. 1995) (finding strict liability inapplicable in action against physician who supplies product to patient when physician could not perform medical services without product and when predominant purpose of transaction was provision of medical services); *Hershley v. Brown*, 655 S.W.2d 671, 675 (Mo. Ct. App. 1983) (refusing to apply strict liability to physicians); *Black v. Gundersen Clinic, Ltd.*, 448 N.W.2d 247, 249 (Wis. Ct. App. 1989) (noting that Wisconsin courts do not recognize cause of action in strict liability for physician's misrepresentation).

282. *Hoven*, 256 N.W.2d at 379.

283. *Id.* at 380–81.

284. The complaint stated the strict liability cause of action against the anesthesiologist as follows:

defendants' demurrers on the strict liability claims, and on appeal, the Supreme Court of Wisconsin held that the doctrine of strict liability is not applicable to the rendition of medical services.²⁸⁵

As the court explained, the essence of the plaintiffs' theory was "if a plaintiff could show that a hypothetical virtually perfectly informed doctor, working in a perfectly equipped hospital, could have avoided the untoward result, the plaintiff could recover, notwithstanding that the defendants exercised reasonable care in all respects."²⁸⁶ The court explained further, "If attainment of the goal, or avoidance of the maloccurrence is possible, then failure to attain the goal or to avoid the maloccurrence renders the service defective."²⁸⁷ In rejecting the plaintiffs' theory, the court noted that some cases have applied strict liability outside the context of products liability.²⁸⁸ The court also noted that courts in other jurisdictions have permitted recovery on the basis of strict liability or implied warranty for the rendition of "defective services," when the services were "of a relatively routine or simple nature."²⁸⁹ But, when the cases involve "professional services," courts have uniformly required the plaintiffs to show negligence.²⁹⁰ In addition to finding no authority for imposing strict

29. That Kelble is and was at the time of this occurrence a seller engaged in the business of selling medical services and at all times relevant hereto held himself out as a seller of the specialty medical service of anesthesiology.

30. That the medical services rendered by Kelble were expected to and did reach the plaintiff without substantial change in the condition when rendered.

31. That the medical services rendered by Kelble were defective when so rendered.

32. That the defects in said services were the cause of the plaintiffs' injuries, losses and damages.

Id. at 381 n.2. The court notes that this statement of the cause of action against the anesthesiologist is representative of those against the other two noninsurer defendants. *Id.*

285. *Id.* at 379.

286. *Id.* at 387.

287. *Id.*

288. *Id.* at 387-88.

289. *Id.* at 388 (citing *Broyles v. Brown Eng'g Co.*, 151 So.2d 767 (Ala. 1963); *Buckeye Union Fire Ins. Co. v. Detroit Edison Co.*, 196 N.W.2d 316 (Mich. Ct. App. 1972); *Hill v. Polar Pantries*, 64 S.E.2d 885 (S.C. 1951)).

290. *See id.* (citing *LaRossa v. Scientific Design Co.*, 402 F.2d 937 (3d Cir. 1968) (concluding that neither implied warranty nor strict liability should apply to professional services)); *Stuart v. Crestview Mut. Water Co.*, 110 Cal. Rptr. 543 (Cal. Ct. App. 1974) (denying strict liability for defective engineering services); *Allied Props. v. John A. Blume & Assoc.*, 102 Cal. Rptr. 259 (Cal. Ct. App. 1972) (same); *Magner v. Beth Israel Hosp.*, 295 A.2d 363 (N.J. Super. App. Div. 1972) (permitting recovery based on doctrine of *res ipsa loquitur* for injuries sustained during plastic surgery, but stating that neither implied warranty nor strict liability applied to medical or dental professions); *Magrine v. Krasnica*, 227 A.2d 539 (N.J. Super. Ct. Law Div. 1967), *aff'd sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968), *aff'd* 250 A.2d 129 (N.J. 1969) (stating that plaintiff could not recover against

liability to the rendition of professional medical services, the court expressed concern that adoption of the plaintiff's theory "would set the standard of performance for the entire medical profession at the zenith of that profession's achievement, a level at which by definition virtually no one could perform all the time."²⁹¹ Under such a standard, "[t]hat which might possibly have been done would be required, or liability would result, and inevitably, the matter would be judged with the acuity of vision which hindsight provides."²⁹²

Obviously, a move to a standard determined by the zenith of medical achievement would be unwise if for no other reason than for the fact that such a standard would be over-inclusive, imposing liability on all but the "hypothetical virtually perfectly informed doctor[s], working in [] perfectly equipped hospital[s]."²⁹³ Instead of suggesting strict liability, this framework could effectuate a higher standard of care than a custom-based standard, one that reflects the latest medical science but stops short of strict liability.²⁹⁴ This framework would require a court to apply the same analysis that it would in a products liability case when determining whether or not liability ensues from compliance or noncompliance with the state-of-the-art.²⁹⁵ A defendant would be able to show compliance with the state-of-the-art at the time of the diagnosis or treatment in question. Just as customs are relevant in products liability cases,²⁹⁶ here too, customs, or CPGs would be relevant to establishing the state-of-the-art. Also as in products cases, courts would recognize that customs may be outdated²⁹⁷ and would have the ability to impose a duty to use an alternative method of diagnosis or treatment even if it was not the custom. The burden would be on the plaintiff to prove a defective diagnosis or treatment. The

dentist based on strict liability for injuries suffered when hypodermic needle used to inject local anesthetic broke while in plaintiff's jaw due to no fault of dentist); *Hoover v. Montgomery Ward & Co.*, 528 P.2d 76 (Or. 1974) (refusing to apply strict liability to defendant's installation of wheel); *Barbee v. Rogers*, 425 S.W.2d 342 (Tex. 1968) (concluding strict liability inapplicable to optometrist's fitting of contact lenses). The court goes on to state, "We have found no decision of any court applying strict liability to the rendition of professional medical services." *Hoven v. Kelble*, 256 N.W.2d 379, 388-89 (Wis. 1977).

291. *Hoover*, 256 N.W.2d at 387.

292. *Id.*

293. *Id.*

294. For a similar proposal regarding liability of engineers, see Peck & Hoch, *supra* note 195, at 406 (advocating higher standard of care for engineers "that reflects advances in knowledge and design theory but that stops short of strict liability").

295. See *supra* Part IV.B.2 (discussing state-of-the-art in products liability litigation).

296. See *supra* note 218 and accompanying text (discussing role of custom in design defect cases).

297. See *supra* note 218 and accompanying text (discussing role of custom in design defect cases).

burden would be on the defendant to prove the state-of-the-art and other factors to justify the treatment given. Proof of compliance with the state-of-the-art would not be dispositive, as courts could consider other factors as relevant.

Arguments against this framework might echo the policy reasons the *Hoven* court cited for refusing to extend the doctrine of strict liability as the plaintiffs advocate. Not only does the court find no advancement of any social policy to be made by extending strict liability to medical services,²⁹⁸ it also notes potentially deleterious effects, such as deterring doctors from treating patients, especially in experimental ways.²⁹⁹ *Hoven* also expresses concerns over increasing the costs of medical services and hampering medical progress.³⁰⁰

5. Bifurcated Standard

Perhaps the most radical method of incorporating EBM into the standard of care would be to bifurcate the standard of care determination into substantive and procedural analyses. Recall the commonly cited definition of EBM: "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."³⁰¹ Conceptually, EBM has two components—one procedural and one substantive. The procedural component is "the conscientious, explicit, and judicious use" of current best evidence. The substantive component is "current best evidence." Recognizing these two components, courts could bifurcate their standard of care determinations by employing a process-oriented standard to judge the procedural aspects of a physician's decision and by using any of the aforementioned frameworks to judge the appropriateness of the substantive aspects of a physician's decision.

298. See *Hoven v. Kelble*, 256 N.W.2d 379, 389 (Wis. 1977) ("To hold medical professionals strictly liable under these circumstances would not promote any social benefit.").

299. See *id.* (suggesting that applying strict liability to physicians might make them reluctant to assume responsibility for treatment of patients, particularly when treatment involves new area of medicine).

300. *Id.* at 391. The court explains:

Medical services are an absolute necessity to society, and they must be readily available to the people. It is said that strict liability will inevitably increase the cost for medical services, which might make them beyond the means of many consumers, and that imposition of strict liability might hamper progress in developing new medicines and medical techniques.

Id.

301. See *supra* note 4 and accompanying text (defining EBM).

The analogy of the way courts could adjudicate liability with regards to the process-based component is to judicial treatment of actions of corporate directors under the business judgment rule.³⁰² Although many legal commentators have compared the medical malpractice standard of care to the business judgment rule,³⁰³ none has focused on the impact of EBM on the medical standard outside of the context of CPGs. As noted above, the business judgment rule operates to shield corporate directors from liability resulting from decisions they make as long as the directors were reasonably informed, not operating under a conflict of interest, and as long as they objectively believed their decisions were in the best interest of the corporation.³⁰⁴ There is no similar shield in medical malpractice law. To be sure, the law has long held that a mere error in judgment is not sufficient to impose liability on a physician.³⁰⁵ But, the law has not insulated physician's decisions to the same extent that it has insulated those of corporate directors. Perhaps EBM will provide an impetus to begin insulating physician decisions as long as the process by which physicians make decisions is appropriate. Recall that one rationale for the business judgment rule is that courts are presumably ill-equipped to understand the complexities underlying business decisions.³⁰⁶ Are not courts similarly ill-equipped to understand the complexities underlying decisions based on EBM?

Functionally, the process-based component of a bifurcated framework might involve judging a physician's decisionmaking process against the steps of EBM.³⁰⁷ If a physician makes a decision on a diagnosis or treatment according to EBM, then a court would not impose liability. Of course, like the business judgment rule, this standard should maintain a requirement of substantive reasonability.³⁰⁸ Courts could measure the substantive reasonability of a physician's decision by employing any of the abovementioned frameworks.

302. See *supra* Part IV.B.3. (discussing business judgment rule).

303. See, e.g., Arkes & Schipani, *supra* note 46, at 587 (considering parallels between medical malpractice standard of care and business judgment rule); Joseph H. King, Jr., *Reconciling the Exercise of Judgment and the Objective Standard of Care in Medical Malpractice*, 52 OKLA. L. REV. 49 (1999) (same); O'Connell & Boutros, *supra* note 63 (same).

304. See *supra* notes 223–25 (explaining business judgment rule).

305. See *Staloch v. Holm*, 111 N.W. 264, 266 (Minn. 1907) (noting that a physician "is not ordinarily liable for damages consequent upon an honest mistake or an error of judgment").

306. See *supra* note 231 and accompanying text (citing assertions that courts do not have expertise to make complex business decisions).

307. See *supra* notes 116–19 (describing steps involved in practice of EBM).

308. See *supra* note 232 and accompanying text (noting that even under business judgment rule decisions must be substantively rational).

While a move toward a bifurcated standard of care might not make sense as courts begin to grapple with determining how to alter the medical malpractice standard of care in light of EBM, as EBM acquires more adherents, it may provide the best course. Unlike a traditional, custom-based standard of care, a bifurcated standard encourages physicians to practice EBM by removing the threat of liability for deviating from accepted practice as long as the physician follows the appropriate procedures in coming to a decision. Nevertheless, it leaves courts able to impose liability when decisions are so substantively bad as to be irrational.

V. Conclusion

EBM has great potential to transform medicine and improve patient care. Undoubtedly, as medical science continues to advance, physicians will learn that more widely accepted practices are inefficacious or even harmful.³⁰⁹ However, as explicated above, EBM is not without detractors.³¹⁰ Additionally, not all, or even most physicians currently practice EBM.³¹¹ One scholar explains that "there is sufficient evidence to suggest that most clinicians' practices do not reflect the principles of evidence-based medicine but rather are based upon tradition, their most recent experience, what they learned years ago in medical school, or what they have heard from their friends."³¹² If this statement were to forever hold true, continuing to judge physician liability by a custom-based standard of care would make sense. But, EBM is a recent movement, and indicators suggest it is gaining steam.³¹³

309. See Eddy, *supra* note 40, at 396 (noting that new studies constantly show inefficacy or harm of accepted practices). Eddy states:

New studies continually reveal that practices that were once accepted without doubt can turn out to be worthless or even harmful. We were wrong about diethylstilbestrol, radical mastectomies, erythropoetin for anemia in end-stage renal disease, hyponatremic encephalopathy, treatment of ingested poisons, hormone replacement therapy for heart disease, and class I anti-arrhythmics for heart attacks. Experts from top universities with the most experience testified under oath that high-dose chemotherapy for late-stage breast cancer would produce 20 to 30 percent long-term cure rates. Randomized control trials later proved them wrong.

Id.

310. See *supra* notes 87–96 and accompanying text (noting criticisms of EBM).

311. See Noah, *supra* note 10, at 377 ("As it turns out, we already have evidence-based medicines, but we most certainly do not yet enjoy fully evidence-based medical practice.")

312. Eisenberg, *supra* note 2, at 369–70.

313. See *supra* notes 11–14 and accompanying text (discussing ways in which EBM has altered medicine).

As EBM acquires more adherents, the legal community must consider if the current standard of care analysis is compatible. If and when EBM effectuates a "paradigm shift" in medicine,³¹⁴ that is, as more and more physicians move toward making decisions based on high-grade scientific evidence rather than custom, custom will become a less valuable indicator of good medical practice. While it is unlikely that EBM will become the norm in the near-term, the legal community should take notice now³¹⁵ and begin to consider appropriate alterations to the medical malpractice standard of care.

Whatever changes are made should result in a standard of care that successfully co-exists with EBM. Courts may eventually decide to impose a duty to practice EBM, either on its own or by employing the duty to stay abreast. But at the very least courts should not discourage EBM by conclusively tying the standard of care to custom or to a CPG. Doing so has potential to retard medical progress, and thereby deprive society of improved medical care. At the same time, courts must be careful not to impose too great of a burden on physicians to do research. Doing so could compromise patient care rather than improve it. To balance these competing interests, this Note has suggested five possible frameworks for altering the standard of care in light of EBM. In the short-term, the easiest and most prudent approach is to diminish reliance on custom by moving toward a modified-custom or modified-CPG standard. In the long-term, courts should consider a bifurcated standard.

314. Noah, *supra* note 10, at 374.

315. As the introduction to a recent article in *Trial* states, "If You Don't Know What Evidence-Based Medicine is, Read On. Chances are it will soon play a part in one of your cases." J. Douglas Peters, *Evidence-Based Medicine in Court*, TRIAL 74 (Jul. 2002).

