

2018

What is Reasonable and What Can Be Proved as Reasonable: Reflections on the Role of Evidence- Based Medicine and Clinical Practice Guidelines in Medical Negligence Claims

Sira Grosso

Follow this and additional works at: <https://lawcommons.luc.edu/annals>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Sira Grosso *What is Reasonable and What Can Be Proved as Reasonable: Reflections on the Role of Evidence- Based Medicine and Clinical Practice Guidelines in Medical Negligence Claims*, 27 Annals Health L. 74 (2018).

Available at: <https://lawcommons.luc.edu/annals/vol27/iss1/5>

This Article is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in Annals of Health Law by an authorized editor of LAW eCommons. For more information, please contact law-library@luc.edu.

What is Reasonable and What Can Be Proved as Reasonable: Reflections on the Role of Evidence-Based Medicine and Clinical Practice Guidelines in Medical Negligence Claims

Sira Grosso, J.D., Ph.D., LL.M.

“Our medical-legal jurisprudence is based on images of health care that no longer exist.”¹

I. INTRODUCTION

Medical liability is based on the negligence standard.² To establish whether a physician is liable for a harmful event, the injured plaintiff must prove that: (1) the defendant-doctor owed a duty of care; (2) the defendant-doctor breached the duty of care; (3) the injury was caused by the breach; and (4) the harm was legally recognized.³ Evidence of a breach of the duty (or standard) is the crux of medical malpractice litigation.⁴ Proving this breach at trial presents an important challenge as currently, neither law nor jurisprudence clearly and uniformly define the standard of care medical practice.⁵ Traditionally, courts examined “customary” medical practice as the “standard of care” in medical malpractice litigation.⁶ However, judicial reference to physician customs has begun to fade.⁷

I sincerely thank Professor Lars Noah for the suggestions he gave me in our conversations, and for the several insights I received during his superb and unique lectures at the University of Florida. I thank Professor Wayne Losano and Maury Ivey for friendly editing the first draft of this article. I also thank Adrienne Testa and Christine Bulgozdi for their excellent editorial work.

1. *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1246 (N.J. 1999).

2. CLARK C. HAVIGHURST ET AL., *HEALTH CARE LAW AND POLICY*, 992 (2 ed. 1998).

3. *Id.*

4. Ralph Peeples et al., *The Process of Managing Medical Malpractice Cases: The Role of Standard of Care*, 37 WAKE FOREST L. REV. 877, 877 (2002) (stating that “how the standard of care is determined is of obvious importance, since failure by a defendant—physician to meet the relevant standard of care constitutes negligence.”)

5. *See generally Id.* (“‘Standard of care’ is the eight-hundred-pound gorilla in medical malpractice litigation.”).

6. *Id.* at 891.

7. Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 164 (2000). (indicating a net departure from

Ultimately, the emergence of Evidence-Based Medicine (EBM), an approach opposing the opinion-based practice that typically underlines the concept of customary medical practice,⁸ urged a shift in the definition of medicine's standard of care.⁹ Meanwhile, some within the academic community suggested that lingering uncertainty in the prevailing standard of care has catalyzed physicians to practice of "defensive medicine," which increases the cost of health care and potentially conflicts with a patient's best interest.¹⁰ In this regard, it has been argued that medical malpractice reforms aimed at better defining the standard of care¹¹ would be instrumental in lowering health care costs.¹²

This framework raises four questions. First, is customary practice still an appropriate benchmark in defining a physician's duty of care? Second, what level of care should be employed for assessing medical malpractice claims? Third, do the standard of care and its evidence at trial fully overlap? And finally, how may courts ensure that lay jurors rely only on expert testimony based on reliable science in rendering a decision?

This article considers means for defining a "reasonable" standard of care, and the appropriate standard for expert testimony in medical malpractice actions. First, I briefly analyze the phenomenon of defensive medicine as a trend deemed to increase the cost of health care and simultaneously create a further set of risks for the patient. I suggest that the postulated link between an uncertain legal standard and defensive medicine may be overstated, and that promoting a cultural shift in the doctor-patient relationship would be more effective in reducing the defensive medicine trend. I then discuss the

custom); *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996) (favoring the reasonable practice standard, explaining that the reasonable standard, "insures that custom will not shelter physicians who fail to adopt advances in their respective fields and who consequently fail to conform to the standard of care which both the profession and its patients have a right to expect."); Carter L. Williams, *Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?*, 61 WASH. & LEE L. REV. 479, 419–30 (2004) (emphasizing how some courts asserted the duty "to stay abreast" of the latest medical science and citing several decisions where the duty to follow customs is better qualified by adding formula as "taking to account" having regard to or "in light of advances in medical science"); HAVIGHURST, *supra* note 2, at 87, 97–99, 103 (1991) (arguing that, despite what courts usually use custom as standard of care in medical practice, customary practice is not the only standard applied at trial).

8. 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, 421 (2001).

9. See generally James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" as a New Role for QIOs?*, 59 VAND. L. REV. 1017 (2006).

10. For this postulated link between uncertainty regarding the standard of care and defensive medicine, see *id.*; Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV., 645, 646 (2001) (discussing how defensive medicine increases healthcare costs).

11. Peeples et al., *supra* note 4, at 877–78.

12. *Id.* at 888–89.

“customary practice” standard, which has been the traditional standard of care in the medical practice context. I maintain that the customary practice standard is no longer legally, nor medically, appropriate. Introducing a distinction between the reasonable standard of care and proof thereof at trial, I suggest that EBM and its Clinical Practice Guidelines (CPGs) are both essential, albeit different, concepts for establishing medical negligence in court. While EBM can *clarify* the standard of care in medical practice, CPGs may serve in *proving* this standard, as long as the CPGs’ are *carefully screened* in the pre-trial stage. In this screening process, the *Daubert* criteria may play an essential role.

II. BACKGROUND

A. *Legal Uncertainty and Defensive Medicine: Can We Abate Defensive Medicine by Merely Modifying the Standard of Care?*

Physicians’ practice of defensive medicine has been attributed to an increased rate of lawsuits against physicians.¹³ Defensive medicine manifests when physicians order unnecessary treatments and excessively rely on tests and procedures,¹⁴ or when they refuse to treat patients that present a high degree of risk, in an effort to avoid a malpractice suit rather than because they consider treatment medically appropriate.¹⁵ Defensive medicine is thereby extremely inefficient; it increases health care costs with no benefit to the patient, while also exposing the patient to additional risks posed by

13. U.S. CONGRESS, OFFICE OF TECHNOLOGICAL ASSESSMENT, DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE, OTA-H—602, at 3 (1994) [hereinafter, U.S. CONGRESS, *DEFENSIVE MEDICINE*] (explaining that defensive medicine is a result of a pressuring medical malpractice system). Several researchers substantiate the phenomenon of the defensive medicine. *See, e.g.*, David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2609 (2005). In a Harvard Medical Survey of 824 doctors operating in six Pennsylvania institutions, 93% admitted to practicing positive defensive medicine. More precisely, according to this research the 92% of the respondents stated that they prescribed tests and procedures and made referrals readily; 43% of the interviewed admitted prescribing unnecessary diagnostic procedures. A significant 42% of the doctors avoided procedures that patients perceived as dangerous based on liability concerns. Another study illustrates the worldwide spread of this phenomenon. *See* Toru Hiyama et al., *Defensive Medicine Practices among Gastroenterologists in Japan*, 12 WORLD J GASTROENTEROL 7671, 7671–75 (2006) (carrying out a survey on the practice of the defensive medicine among gastroenterologists in Japan: the 98% of the doctors interviewed declared that they have practiced the defensive medicine); Daniel P. Kessler et al., *Effects of the Medical Liability System in Australia, the UK, and the USA*, 368 LANCET 240, 240 (2006) (stating that “at least for the USA and the UK, there is systematic evidence of defensive medicine”).

14. U.S. CONGRESS, *DEFENSIVE MEDICINE*, *supra* note 13, at 13 (defining this form of defensive medicine as “positive” defensive medicine).

15. *Id.* (defining this form of defensive medicine as “negative” defensive medicine).

unnecessary treatments.¹⁶

Some scholars draw a direct link between defensive medicine and uncertainty in the legal standard of care. As explained, risk adverse physicians, unclear the legal standard by which their performance will be judged, strategize their treatment behavior to give hypothetical jurors the impression that they “did all they could” to avoid harming the patient.¹⁷ One scholar explains that, “[u]nsure about exactly what is required of them, and averse to the risk of being sued, physicians protect themselves by ordering tests and other services that may be unnecessary but that will create a ‘paper trail’ that they can later invoke in defense of the care rendered.”¹⁸ By this logic, greater clarity to a physician’s legally-imposed standard of care could abate the defensive medicine phenomenon.¹⁹ Motivated by this goal of greater clarity, some legal scholars have attempted to formulate more defined standards.²⁰

However, it may be too optimistic to expect that a clear *legal standard* of care would significantly lower the number of lawsuits against physicians, and consequently lessen the employment of defensive medicine.²¹ In fact, the number of lawsuits against doctors may be more reasonably and directly attributed to other factors.²² For example, advancements in medical knowledge may contribute to defensive medicine.²³ Progress in biomedical

16. For example, a study estimating that in 2008 defensive medicine cost the United States \$45.59 billion dollars. See Michelle M. Mello, et al, *National Costs of the Medical Liability System*, HEALTH AFFAIRS 29(9)15691574 (2009), <http://content.healthaffairs.org/content/29/9/1569.full.pdf+html>. For an expression of skepticism on the relation between defensive medicine and growth of the health care costs, see Tom Baker, *THE MEDICAL MALPRACTICE MYTH* 134 (2005) (arguing that “the overall impact of defensive medicine on health care costs is not very large”); and see, David A. Hyman-Charles Silver, *The Poor State of Health Care Quality*, 90 CORN. L. REV. 937, 893, 937 (stating that empirical evidence supporting defensive medicine is far from conclusive and grossly exaggerated).

17. See *Clark v. Gibbons*, 66 Cal. 2d 399, 418 n. 9 (1967) (quoting Justice Mathew Tobriner, “[w]hen every patient is viewed largely as a potential plaintiff the method of treatment chosen by the physician may well be that which appears the easiest to justify in court rather than that which seems best from a purely medical standpoint”). See also Michael D. Frakes, *The Surprising Relevance of Medical Malpractice Law*, U. CHI. L. REV. 82, 318, 321 (2015) (explaining the influence of the physicians’ fear to be sued and judged as negligent as follows: “Physicians may decide to conduct more treatments, tests, and so forth, because on a fear that courts may expect such behavior”).

18. Mello, *supra* note 10, at 648.

19. See HAVIGHURST, *supra* note 2, at 96 (arguing that the clarification of the standard of care, intended as a clarification of what the law expects, should reduce the cost of defensive medicine by improving physicians’ ability to estimate the limit of their legal duties).

20. See generally Blumstein, *supra* note 9.

21. *Id.* at 1024–26.

22. *Id.* at 1028–29.

23. Catherine T. Struve, *Doctors, the Adversary System, and Procedural Reform in Medical Liability Litigation*, 72 FORDHAM L. REV. 943, 948 (2004).

science has lead patients to expect arguably unrealistic results from their physicians, prompting patients to file lawsuits if the outcome fails to meet their expectations.²⁴ Scientific progress also increases the number of delicate and risky medical interventions, in turn, enhancing the possibility of adverse events caused at physicians' hands, regardless of negligence.²⁵ In fact, while at one time the death of a cardiac patient was attributed to his disease, the same negative outcome today may be attributed to the physician, if it occurs under the surgeon's care, after the performance of a heart transplant, or another kind of curative treatments.²⁶

If these alternative factors have such an effect, legal clarity of liability standards may only produce a modest impact, if any, on rates of medical malpractice litigation and thus, on defensive medicine. In fact, if the practice of defensive medicine is directly related to the number of lawsuits, a more proper analysis would focus on what motivates patients to ultimately pursue a claim.²⁷ Research demonstrates that four predominant factors motivate patients to file lawsuits:²⁸ (1) a desire to prevent a similar bad accident; (2) a need of explanation as to how and why an injury happened; (3) a desire for financial compensation to make up for the loss or injury; and (4) a desire to make doctors respond for their mistakes.²⁹ These studies indicate that a better communication between patients and doctors is a cornerstone in preventing patients from filing suit as patients tend to refrain from suing doctors they trust.³⁰ Moreover, other studies highlight how better communication between patients and doctors effectively prevents patients from filing claims against doctors. In fact, while patients are less likely to sue doctors they trust,³¹ the

24. *Id.*

25. It is important to note that even unmeritorious claims are litigated and that, according to a research, 30% of them receive compensation. See David. M. Studdert, et al, *Claims, Error, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2029–30 (2006) (graphing the type of claim from surgery to missed or delayed diagnosis).

26. See also Struve, *supra* note 23, at 950 (arguing that “advances in the treatment of fractures led physicians to save limbs, rather than amputate them, with the result that suits might be brought for limbs that healed imperfect.”The author also notes that changes in the business of the medicine has increased lawsuits, arguing that the increased number of physicians makes suits against a doctor more palatable, and also that some physicians may push and aid malpractice suits against competitors.).

27. Studdert et al., *supra* note 25, at 2027.

28. Charles Vincent, et al., *Why do people sue doctors? A study of patients and relatives taking legal action*, Lancet, 1609–13, (1994); Beckman, *The doctor-patient relationship and malpractice. Lessons from plaintiff depositions*, ARCH. INTERN. MED. 1365-70 (1994); Hickson, *Factors that prompted families to file medical malpractice claims following perinatal injuries*, JAMA, 1359–63 (1992).

29. Beth Huntington et al., *Communication Gaffes: A Root Cause of Malpractice Claims*, BAYLOR UNIV. MED. CTR. PROCEEDINGS (2003).

30. *Id.*

31. *Id.*; also, Haavi Morreim, *Holding Healthcare Accountable: Law and the New Medical Marketplace* 21 (2000) (stating that the “strongest predictor of whether a physician

communication itself may replace the lawsuit as a means to obtain explanation for unexpected tragedies.³² Additionally, an improved and more transparent relationship between physicians and patients may help to make patients aware of the risks inherent in the medical procedures, thereby reducing the gap between expectations and results.³³ Any decrease to defensive medicine would therefore require a cultural shift in the doctor-patient relationship.³⁴

Nevertheless, clarifying what constitutes due care is useful for purposes beyond its potential to reduce the practice of defensive medicine. Tort law purports to reduce inefficiency and encourage safety, lowering the level of avoidable injury.³⁵ Restated, an inherent function of the tort system is to guide physicians toward the *legal system's* reasonable standard of care, yet it bears noting that “liability reforms aimed at altering the way in which physicians are evaluated in the first instance may be especially influential in reshaping the norms of medical practices.”³⁶ Therefore, the next sections will focus on the standard of care that courts should use to incentivize quality in decision-making and promote safety in medical practice. I first analyze the role that customary practice has played so far in medical malpractice litigation, reporting criticisms against its central role in defining the standard of care.

III. CUSTOMARY PRACTICE AS THE STANDARD IN MEDICAL MALPRACTICE CLAIMS AND ITS CRITICISMS

Generally, the standard of care is the level of the due care by which a person is judged in a negligence action.³⁷ While the standard of care in general tort claims asks what a “reasonable person” would have done in the defendant’s position, medical malpractice claims rely on the level of due diligence traditionally embodied by the so-called “customary practice,”³⁸ or

will be sued is the extent to which patients feel they are being treated with honesty, respect, and personal interest”).

32. William M. Sage, *Medical Liability & Patient Safety*, 22 HEALTH AFFAIRS 26, 31 (2003).

33. *Id.*

34. *Id.* at 28.

35. Richard A. Posner, *A Theory of Negligence*, 1 J. LEG. STUD. 29, 33 (1972) (stating that the dominant function of the tort law is achieving an efficient level of safety).

36. Michael D. Frakes, *The Surprising Relevance of Medical Malpractice Law*, 82 U. CHI. L. REV. 317, 325 (2015), (arguing that physicians’ behavior is responsive to the parameters of the liability system).

37. See Blumstein, *supra* note 9, at 1039.

38. James A. Henderson Jr. & John A. Siciliano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1384 (1994); Tim Cramm et al., *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 WAKE FOREST L. REV. 699, 702–03 (2002); Blumstein, *supra*

what is usually done in a specific field.³⁹ Fundamentally, a physician's diligence is determined by how other physicians usually act under the same circumstances of the defendant.⁴⁰ Adherence to the customary practice approach in medical practice is "essentially an empirical inquiry that focuses on the ways things are customarily done in the medical community."⁴¹

Several factors allow the medical profession to enjoy this unique regime.⁴² First, medicine is highly specialized and complex.⁴³ Thus, lay jurors, who have no medical competence, can more easily identify medical custom.⁴⁴ Second, while other professionals act pursuant to their own interests, arguably, medical professionals' first priority is the interest of their patients.⁴⁵ Essentially, according to this standpoint, those who use the service and those who provide it share the same goals.⁴⁶ In this sense, custom would be naturally oriented toward efficient results.⁴⁷

note 9, at 8, (arguing that conventional malpractice doctrine adopts the customary practice as the due level of care); Williams, *supra* note 7, at 499–500; *but see*, Helling v. Carey, 83 Wash. 2d 514, 519 (Wash. 1974) (providing an exception to this trend by holding an ophthalmologist liable for medical negligence for not giving a glaucoma screening test to a young woman, even though the customary practice refraining to give the test in the case of the plaintiff). Prof. Philip Peters, with a maverick analysis, argues the departure of courts from customary practice in assessing the due level of diligence. *See* Peters, *supra* note 7.

39. *See* this exception, which consists of allowing the doctors to set their own standard of care, is considered a privilege of the medical profession WILLIAM PROSSER, HANDBOOK OF THE LAW OF TORTS 164–5, 165 (West Publishing Co. 4th ed. 1971); *see also* Peter D. Jacobson & Matthew L. Kanna, *Cost-Effectiveness Analysis in the Court: Recent Trends and Future Prospects*, 26 J. OF 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").

40. Blumstein, *supra* note 9, at 1030, 28; *see* Cramm et al., *supra* note 38, at 705 (arguing that the burden is quite modest: the defendant just needs an expert who testifies the existence of this other body of physicians that would have treat the patient in the same way of the defendant); *see also* Peters, *supra* note 7, at 168 (arguing that the plaintiff must prove that the defendant's conduct fell "entirely outside of all common practices"); *see* Douglas R. Brown, *Panacea or Pandora's Box: The "Two Schools of Medical Thought" Doctrine After Jones v. Chidester*, 610 A.2d 964 (Pa. 992), 44 J. OF URB. & CONTEMP. L. 223, 223–24 (1993) (discussing the "two schools of thoughts."). It is worthwhile to call attention to the existence of the defense named "two schools of thought" that allows the physician who followed an alternative treatment modality accepted among a minority body of physicians to escape liability. In order to use the "two schools of thought" or "respectable minority doctrine" as an affirmative defense, the defendant-doctor has the burden of demonstrating that, in treating the patient, a substantial body of respected professionals would advocate the same course of action of the physician-defendant.

41. Blumstein, *supra* note 9, at 1024.

42. Cramm et al., *supra* note 38, at 703.

43. *Id.*

44. *Id.*; Henderson & Siciliano, *supra* note 38, at 1389.

45. Cramm et al., *supra* note 38, at 703.

46. *Id.*

47. *Cf.* Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571, 611 (1998) (stating that an efficient custom is going to develop if the

Although many legal scholars support the customary practice standard,⁴⁸ there are several arguments in opposition.⁴⁹ The main counterargument is that factual parameters, rather than normative values, should be employed in setting the standard of care.⁵⁰ Accordingly, negligence law should satisfy the question of what *ought* to be done rather than what *is usually* done.⁵¹ Opposing legal scholars explain that customary practice may not only fail to incorporate a reasonable level of care, but may even embody the “unreasonable.”⁵² In fact, custom may, at times, reflect habits of “inadvertence, carelessness, indifference, cost-paring and corner-cutting,” which is the essence of negligence.⁵³ Furthermore, custom does not reflect a socially optimal level of care, but rather, the opposite.⁵⁴ Because of medical insurance, physicians do not directly cover the cost of the services that they offer, nor the damages deriving from their malpractice.⁵⁵ In other words, this system, which frees physicians from the costs of their services or malpractice, leads physicians and patients to overuse services and resources, spending more on marginal benefits.⁵⁶

*A. Basing Expert Testimony on the Customary Practice Standard
Beckons a Subjective Standard and Unreliable Scientific Evidence*

An additional category of arguments against using custom to set the due level of care relates to the nature of scientific evidence. It is well understood that the testimony of expert witnesses plays a crucial role in establishing the

transaction cost benefits the customers).

48. See e.g., *id.* at 612–14 (arguing that using compliance with customary practice as a standard of care, would reduce hindsight bias in medical practice claims because is not necessary to verify foreseeability); see also e.g., Mello, *supra* note 10, at 684 (pointing out that customary practice reduces uncertainty).

49. See WILLIAM PROSSER & W. PAGE KEETON, PROSSER AND KEETON ON TORTS 1, 193–94 (5th ed.1984).

50. See *Id.* at 194.

51. *Id.* (discussing that customs which are entirely reasonable under the ordinary circumstances which give rise to them in the first instance may become entirely unreasonable in the light of a single fact altering the situation).

52. *Id.* at 195.

53. *Id.* at 194 (stating that the tort law gives the doctors the privilege usually denied to other groups, of setting their own legal standard of conduct); see also Eric A. Posner, *Law, Economics, and Inefficient Norms*, 144 U. PA. L. REV. 1697, 1705–10 (1996) (stating that social norms tend to generate inefficiency).

54. Henderson, *supra* note 38, at 1393 (arguing that, in this field, decision makers lack the incentive to make appropriate choices among such solutions); see also The T.J. Hooper, 60 F.2d 737, 740 (2nd Cir. 1932) (opinion by Hand) (“Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.”).

55. Henderson, *supra* note 38, at 1393; HAVIGHURST, *supra* note 2, at 97–99 (arguing that “custom is a poor guide to establish what is economically justified”).

56. HAVIGHURST, *supra* note 2, at 97–98; Henderson, *supra* note 38, at 1393.

due level of care in medical malpractice litigation.⁵⁷ Given the essential role of the expert testimony in medical malpractice litigation, two other critical points render “custom” an inappropriate subject of expert testimony: (1) customary practice is a wholly subjective parameter; and (2) testimony based on custom is incompatible with the current tests of admissibility of scientific evidence.⁵⁸

1. The Customary Practice Standard is a Subjective Parameter

The first aspect to consider is *how* experts testify about customary practice at trial. Customary practice as the test to establish the level of due diligence does not require the expert to support his or her testimony with any written evidence.⁵⁹ Therefore, absent any documentation, customary practice is essentially created by the expert witness in court.⁶⁰ In other words, because no published research or formally collected data enumerates or defines customs themselves, experts testify about “standards” which derive only from their opinions, training, and experience.⁶¹ They only discuss how *they* would have treated the patients,⁶² making more of a subjective evaluation that, instead, should be objective.⁶³

Scholars analyzed patterns stemming from the use of medical customary practice as a standard of care. A survey carried out by William Meadow and Cass Sunstein demonstrates that experts make biased judgments about the

57. Sonny B. Bal, *An Introduction to Medical Malpractice in the United States*, 2 CLIN. ORTHOP. RELAT. RES. 339, 342 (2008) (explaining that expert witness testimony is essential when establishing breach of a standard of professional care).

58. *Id.* (“While the precise definition of “standard of care” can differ among jurisdictions and the concept can prove elusive in its application. . . .”); *see also* Blumstein, *supra* note 9, at 1031 (stating that the customary practice standard is ambiguous); *see also* Cramm et al., *supra* note 38, at 723–24 (citing *Gilkey v. Schweitzer*, 983 P.2d 869, 871–73 (Mont. 1999)) (“[T]he Daubert test should be used only to determine the admissibility of novel scientific evidence.”).

59. Blumstein, *supra* note 9, at 1028–29 (arguing that the customary practice is characterized by a structural uncertainty).

60. William Meadow & Cass R. Sunstein, *Statistics, Not Experts*, 51 DUKE L. J. 629, 630–31 (2001) (arguing that since the ordinary medical practice coming via statements from expert witnesses is inevitably affected by biases, the use of statistical data should replace the role of the experts in medical negligence lawsuits).

61. Cramm et al., *supra* note 38, at 710–11. (stating that published research or formally collected data relevant to customary practice in a specific case are virtually never available).

62. Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 L. & CONTEMP. PROBS. 119, 127 (1991) (“[W]hen the plaintiff’s witness states that the defendant’s conduct was not within the standard of the profession, he really means only that he would not have treated the patient that way”).

63. HAVIGHURST, *supra* note 2, at 96 (“Although expert witnesses are supposed in theory to rely upon objective professional standards, subjective judgment inevitably plays a large role”).

ordinary standard of care.⁶⁴ Meadow and Sunstein argue that experts, considering only how *they* would have treated the patients, tend to be too optimistic in evaluating risks.⁶⁵ In the survey, two groups of experts considered a hypothetical situation in which patients presented to a hospital with bacterial meningitis, and the experts were asked to estimate the time lapse between the patients' arrival to the emergency rooms and the administration of antibiotics with the assumption that quicker administration promotes more effective the treatment.⁶⁶ The experts' estimated time lapses were much lower than the custom time lapses evidenced by an empirical investigation of two emergency rooms.⁶⁷ Applying these results broadly, customary practice according to expert witnesses may not match, or even resemble, the actual practice of medicine at all.⁶⁸ Indeed, the estimation *raises* the expected level of care resulting in a biased opinion, leading to a more severe judgment of the defendant's actions.⁶⁹ As other experiments show, since customary practice is an *ex post* reality and depends on an extremely subjective judgment of the expert, its use to establish the standard of care in medical malpractice tends to increase the impact of the hindsight and outcome biases on verdicts.⁷⁰

64. Meadow & Sunstein, *supra* note 60, at 637–38 (discussing the authors' study in which they surveyed doctors' experiences in cases of childhood meningitis. The authors compared these responses to descriptions of physicians' actual behavior in such situation and concluded that potential expert witnesses were biased in favor of retrospectively describable responses).

65. *Id.* at 637, 639.

66. *Id.* at 637–38.

67. *Id.*

68. *Id.* at 639 (“Whatever ‘expert’ opinion means in this context, it does not mean an accurate opinion.”).

69. *Id.* at 645.

70. The hindsight bias—or the “I knew it all along” bias—refers to the tendency of people to overestimate the probability of an event, once they are aware of the fact that the event has occurred. The initial contribution to the study of this bias was presented by Fishhoff. See Baruch Fischhoff, *Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*, 1 J. EXPERIMENTAL PSYCHOL. HUM. PERCEPTION & PERFORMANCE 288, 29798 (1975) (observing that people are usually unaware of this changed perception because they immediately assimilate the outcome knowledge with what they already know about the event in order to make sense of the past. He noted: “[M]aking sense out of what one is told about the past seems so natural and effortless a response that one may be unaware that outcome knowledge has had any effect at all.”); see also Baruch Fischhoff & Ruth Beyth, “*I Knew It Would Happen*”—*Remembered Probabilities of Once-Future Things*, 13 ORG. BEHAV. & HUM. PERFORMANCE 1–16 (1975); Subsequent studies in a number of settings have elaborated on these findings. For a study of the incidence of the hindsight bias on medical negligence see Susan J. LaBine & Gary LaBine, *Determinations of Negligence and the Hindsight Bias*, 20 LAW & HUM. BEHAV. 501 (1996); Hal. R. Arkes & Cindy A. Schipani, *Medical Malpractice v. the Business Judgment Rule: Differences in Hindsight Bias*, 73 OR. L. REV. 587 (1994); Michael A. Haskel, *A Proposal for Addressing the Effects of Hindsight and Positive Outcome Biases in Medical Malpractice Cases*, TORT TRIAL & INS. PRAC. L.J., 895 (2007); Blumstein, *supra* note 9, at 1028; in general, on the interaction between the hindsight bias and law see Rachlinsky, *supra* note 47, at 571.

2. The Customary Practice Standard is an Unreliable Basis for Expert Testimony

Other arguments for overcoming customary practice relate to the legal discipline of scientific evidence. Admissibility requirements for scientific evidence aim, in part, at assuring that the expert testimony meets minimum standards of reliability.⁷¹ In assessing reliability, Courts follow two general approaches. The first uses the standard set forth in *Frye v. United States*;⁷² the second is governed by the test set forth in *Daubert v. Merrell Dow Pharmaceutical*.⁷³ With respect to *Frye*, the D.C. Circuit stated that the admissibility of expert testimony depends on the general acceptance of its content in the particular field in which the testimony belongs.⁷⁴ This test is still employed by some states,⁷⁵ but is no longer applicable in federal courts after becoming superseded by Federal Rule of Evidence 702 as interpreted by the Supreme Court in *Daubert*.⁷⁶

The second approach used by courts for scrutinizing the reliability of scientific evidence is the one adopted by the abovementioned *Daubert* decision, deemed by scholars as ushering in the “gatekeeping approach” in determining the admissibility of scientific evidence.⁷⁷ In particular, based on the assumption that the adversary model did not work in selecting reliable

71. See *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923); see also *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

72. *Frye*, 291 F. at 1014 (discussing the admissibility of a polygraph test as evidence and holding that expert testimony must be based on scientific methods that are sufficiently established and accepted. In *Frye*, the Court stated that “just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while the courts will go a long way in admitting experimental testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs”).

73. *Daubert*, 509 U.S. at 587 (stating that the prior *Frye* test was superseded by the adoption of the Federal Rules of Evidence).

74. *Frye*, 291 F. at 1014.

75. *Id.*; see also FED. R. EVID. 702(a–d) (“A witness who is qualified as an expert by knowledge, skills, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case”); see also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999) (extending the *Daubert* factors to all expert testimony, not distinguishing between “scientific” knowledge and “technical” or “other specialized” knowledge).

76. *Daubert*, 509 U.S. at 589 (holding that the Court of Appeals decision based exclusively on “general acceptance” was vacated).

77. Daniel W. Shuman, *Expertise in Law, Medicine, and Health Care*, 26 J. HEALTH POL. & L. 268, 274 (2001), [hereinafter, *Expertise in Law, Medicine, and Health Care*].

scientific evidence, the *Daubert* standard requires the judge to scrutinize in the pre-trial stage all scientific evidence that parties want to use at trial.⁷⁸ According to *Daubert*, an expert's theory is reliable if it meets the following criteria: (1) it is possible to test the theory; (2) it was submitted to peer review and publication; (3) it indicates the potential rate of error; and (4) it is generally accepted in the relevant scientific community.⁷⁹ Holding a high threshold for scientific evidence, the multi-factor approach upheld by *Daubert*—at least if taken seriously—should improve the quality of the scientific evidence that enters the courtrooms' door.

The standard of care based on customary practice renders expert testimony patently inconsistent with *Daubert*'s parameters.⁸⁰ In fact, when an expert witness testifies about customary practice, his or her testimony meets at most only one of the four *Daubert* criteria: general acceptance.⁸¹ The current “customary practice” test inquires *only* how a defendant physician's peers would typically perform in similar circumstances, while there is no documentation on what constitutes a customary practice.⁸² Therefore, a judge

78. *Id.* (“The gatekeeping approach to the admission of expert testimony rests on the belief that the traditional adversary model has not worked well in scrutinizing expert testimony. Its critique of the operation of the traditional adversary model is that many judges have been willing or unable to exclude unreliable claims of expertise; that there are large numbers of experts willing to offer testimony that would not satisfy the standards for work in their profession's laboratories, clinics, or journals; that attorneys operating under the ethos of the adversary system have sought experts to support their case without regard to their professional competence; the jurors lacking scientific or technical expertise have relied on irrational, superficial criteria to assess the believability of experts; and, accordingly, heightened scrutiny of the admissibility of expert testimony is necessary. In contrast with the traditional adversarial approach the gatekeeping approach assumes that it is appropriate for the judge to impose a demanding standard of scrutiny for the admissibility of expert testimony, and given doubts about the abilities of juries that characterize the gatekeeping model, the role of the jury in assessing the reliability of expert testimony is more circumscribed”).

79. *Daubert*, 509 U.S. at 593–95 (enumerating four rules embodied in FED. R. EVID. 702).

80. Nichole Hines, *Why Technology Provides Compelling Reasons to Apply a Daubert Analysis to the Legal Standard of Care in Medical Malpractice Cases*, 18 DUKE L. J. 1, 14 (2006) (suggesting an application of the *Daubert* test to the standard of care in medical malpractice claims). *Cf. Palandjian v. Foster*, 842 N.E.2d 916, 922 (Mass. 2006) (stating that the standard of care generally does not need to be subject to the *Daubert* analysis, unless the proponent of such testimony incorporates scientific fact into a statement concerning the standard of care).

81. *Cf. Id.* (noting that “general acceptance” and “customary practice” are substantially similar, if not the same, and fit under the same prong within the *Daubert* analysis).

82. John W. Ely et al., *Determining the Standard of Care in Medical Malpractice: The Physician's Perspective*, 37 WAKE FOREST L. REV. 861, 872 (2002) (“Experts can pretty much with impunity say the most outrageous things regarding standard of care and there is really no consequence to that. There is not peer review from the physician side, and I have never heard or seen legal reports taken against such an expert witness. So certainly some oversight or peer review of the testimonial expert witnesses would be one way to change the current system”); *see also* Cramm et al., *supra* note 38, at 710 (arguing that published research or formally collected data on customary practice in a specific case are virtually never available); *see also*

or jury has no potential to scrutinize expert testimony relying on customary practice on rate of error, peer review, publication process, or falsifiability.⁸³ Although inadmissible under *Daubert* for failing to meet its several parameters,⁸⁴ it may appear that testimony relying on custom meets the *Frye* standard that, as discussed, only requires general acceptance. Deeper consideration, however, suggests otherwise.

First, it is worthy of consideration that courts, when adopting customary practice, do not rely anymore on the local practice of the place where the physician was operating (the “locality rule”). Due to the national basis of medical education, training, feasibility of travel, and globalization of medical knowledge, the majority of jurisdictions abandoned the locality rule as a parameter to evaluate the physician’s course of action,⁸⁵ instead adopting a *nationwide* practice standard.⁸⁶ This framework calls into question whether and how an expert witness can accurately speak about performance on a national scale. In fact, on the one hand, experts normally lack direct experience of nationwide practices, and on the other hand – as argued⁸⁷ – does not exist actual, data-based documentation on which to base their opinions. In other words, no accurate methodology to establish customary practice on a national scale exists. For the remaining courts that still employ a customary practice standard related to a local community, the testimony on local practices would still lack, by definition, the general acceptance required by *Frye*, since by the locution “general acceptance,” it is required general consensus within a particular field, not restricted, therefore, to a local geographical area.

Following the abovementioned considerations, expert testimony referring

David M. Eddy, *The Use of Evidence and Cost Effectiveness by the Courts: How Can it Help Improve Health Care?*, 26 J. HEALTH POL. POL’Y & L. 387, 396 (2001) (“When an expert answers a questions about a community standard it is extremely unlikely that he or she has any real data on actual practices. It is far more likely that what an expert believes is the practice in a community is what the expert personally believes should be the standard of care.”).

83. *Daubert*, 509 U.S. at 580 (presenting some considerations for preliminary assessment to determine whether a testimony is scientifically valid – ability to be tested, subjected to peer review or publication, knowledge of potential error rate, existence of standards controlling its operation and status of widespread acceptance within the scientific community).

84. *Expertise in Law, Medicine, and Health Care*, *supra* note 77, at 280 (asserting that even jurisdictions adopting the *Daubert* test don’t properly use the test’s criterion to admit the expert testimony in medical malpractice claims).

85. HAVIGHURST, *supra* note 2 (explaining that when the standard of care referred to custom prevailing in a particular locality, plaintiffs had a hard time finding expert witnesses in the same community to testify against their colleagues and because of this, courts eventually decided to adopt national standards).

86. Cramm et al., *supra* note 38, at 706 (stating that the locality rule is no longer employed for several reasons such as the concerns that local physicians would loathe testifying against colleagues in the same community recognizing the national basis of medical education, the globalization of the information and the feasibility of travel).

87. See *supra* nt 61 and accompanying text.

to customary practice should not be admissible either in jurisdictions that have endorsed the *Daubert* test or in those that continue to use the *Frye* test, failing to fulfill the prongs of both the abovementioned tests.

IV. THE REASONABLE STANDARD IN MEDICAL MALPRACTICE CLAIMS AND ITS PROOF

If the reported arguments against the customary practice standard's ability to embody the due level of diligence in medical malpractice claims are sound, and, thus, customary practice is no longer suitable in establishing a physician's standard of care, the question becomes what exactly should replace this standard. This part will address the *pars construens* of the article: what parameter should embody the reasonable standard of care in medical practice and malpractice law. The next sections will clarify: (1) physicians' duties in the medical scope of their practice and in the legal scope of potential malpractice claims; and (2) which terms, within this standard that uses the medical lexicon, can be simply translated so as to be effectively understood by lay people, the judge and jurors, who must evaluate the medical appropriateness of the physicians-defendant's conduct.⁸⁸ The following sections conceptually separate and distinguish the standard of care authorized by substantive law from the standard's evidence in court.⁸⁹ In this sense, what is reasonable expresses a conceptually different from what can be proved as such.

A. Evidence-Based Medicine and Reasonableness

The adoption of the *Daubert* test ushered in a shift in the judiciary approach to scientific evidence, toward greater reliability of the expert testimony.⁹⁰ In parallel, through the Evidence-Based Medicine (EBM) movement, the biomedical field similarly began to prioritize more objective and scientifically supported evidence in lieu of an opinion-based approach.⁹¹

88. Cramm et al., *supra* note 38 at 750–51 (describing attempts to create an objective source of standard of care under clinical practice guidelines to assist practitioner decide about appropriate care, but noting that its flexible terms that work for the medical community may be “too vague to be useful as a standard of care in a legal sense”).

89. Daniel 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, 114 (1997), [hereinafter, *The Standard of Care in Medical Malpractice Claims*].

90. *Expertise in Law, Medicine, and Health Care*, *supra* note 77 at 278 (noting that *Daubert* demands “that the proponent of the evidence show that the expert’s conclusions has been arrived at in a scientifically sound and methodologically reliable fashion”).

91. *Id.* at 287; see also Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 382 (2002); see also Morreim, *supra* note 8, at 420 (claiming “the movement toward evidence-based medicine is a bit overdue”).

The EBM movement began in 1991 and the term “Evidence-Based Medicine” was first used in a paper published by Gordon H. Guyatt.⁹² In his pioneering paper, Guyatt described efforts to identify the best use of scientific literature and biomedical development in medical decision-making.⁹³ EBM is defined as the “conscientious, explicit, and judicious use of the current best evidence in making decisions about treatments of individual patients.”⁹⁴ As a new movement that opposes the traditional practice of medicine based on mere experience, EBM replaces anecdotal knowledge and the opinion-based approach with high-grade scientific evidence coming from clinical research.⁹⁵ In this sense, randomized controlled trials (RCTs) and observational studies become central in the treatment of patients.⁹⁶ Physicians are encouraged to “use research that has applied rigorous epidemiologic methods, and has been published in peer-reviewed journals.”⁹⁷

A hypothetical scenario, based on a real case, was effectively used by a scholar⁹⁸ to illustrate the differences between the custom-based approach and

92. Roger Sur & Philipp Dahm, *History of Evidenced-Based Medicine*, 27 INDIAN J. UROL. 487, 489 (2011).

93. Gordon H. Guyatt, *Evidenced-Based Medicine*, 114 ACP J. CLUB A16, A16 (1991).

94. David L. Sackett et al., *Evidence Based Medicine: What It Is and What It Isn't*, 312 BMJ 71, 71 (1996) (“By best research we mean clinically relevant research, often from the basic science of medicine, but especially from patient-centered clinical research into the accuracy and precision of diagnostic test 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 test 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 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.”).

95. *Id.* (asserting that evidence based medicine implements external clinical evidence which “both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer”).

96. Noah, *supra* note 91, at 391 (“[B]iomedical researchers contend that placebo-controlled trials provide the best method for judging efficacy. . . [N]o one really doubts the value of RCTs. . . in producing useful data about therapeutic interventions. . .”).

97. John M. Eisenberg, *What Does Evidence Mean? Can the Law and Medicine Be Reconciled?*, AHRQ, <https://archive.ahrq.gov/research/findings/evidence-based-reports/jhpl/eisenbrg.html> (last visited Dec. 5, 2013).

98. *See Brook v. St. John's Hickey Memorial Hospital*, 380 N.E.2d 72, 72 (Ind. 1978) (In this case the defendant, a radiologist, injected a contrast medium into calves of the two years old plaintiff. The physician chose the mentioned site because literature showed warnings against injecting contrast medium in the gluteal muscles of young children, although the latter was the common site where perform the injection. Months later plaintiff developed an Achilles tendon, which calf trauma may have caused. The patient sued the doctor for malpractice. The trial court rejected the instruction offered by Plaintiff that injection in a site other than the site recommended by the medical community constituted improper experimentation on Plaintiff. A jury rendered a verdict for the defense. The radiologist was exonerated).

the evidence-based approach.⁹⁹ In this scenario, a person suffering from pneumonia needs an injection of a contrast medium prior to chest X-rays to examine the lungs. She can choose one of two doctors available, both having different approaches to the practice of medicine. The first physician bases his performance on what he learned at medical school, as well as from his colleagues and clinical experience. The second physician uses the same knowledge and clinical experience but additionally considers high-grade scientific evidence from the best research available. This research informs the second doctor of the high risk that could result from the injection into a specific site, even though injecting at that site constitutes the usual practice. Thus, he chooses an alternative site with proven efficacy and no safety risk. The scholar concluded that there was little doubt that the pneumonic person-and everyone- would choose the second doctor who follows EBM.¹⁰⁰

This example shows the superiority of the EBM movement and its departure from “general acceptance” as a means to evaluate scientific evidence.¹⁰¹ After *Daubert* and with EBM, judges and doctors are called on to carry out an evaluation of the method they are using that is independent from the judgment of the relevant professional community or from what embodies the “general acceptance.”¹⁰² In other words, both judges and physicians become gatekeepers of the reliable science available.¹⁰³

Several factors support substantive law to mandate EBM as the appropriate standard of care, finally abandoning customary practice.¹⁰⁴ First,

99. Williams, *supra* note 7, at 480–81 (using a hypothetical scenario based on *Brook v. St. John's Hickey Memorial Hospital*, 380 N.E.2d 72 (Ind. 1978) to introduce the difference between traditional eminence or opinion-based medical practice and evidence-based medicine and suggesting the desirability of the latter).

100. *Id.*

101. Noah, *supra* note 91, at 382 (claiming that “EBM has instructive parallels to the shift in the judiciary’s approach to scientific expert testimony”).

102. Eisenberg, *supra* note 97 (presenting that the “test of credibility is flexible and the role of judges as gatekeepers allows them substantial discretion in what they allow to be admitted as evidence”).

103. Noah, *supra* note 91, at 382.

104. Blumstein, *supra* note 9, at 1030 (stating that, absent an ability to defend against a medical malpractice claim on the ground of reasonableness, physicians have strong incentive to conform their conduct to the obligatory custom standard); Arnold J. Rosoff, *Evidence-Based Medicine And The Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL., POL’Y & L., 327, 337 (2001) (stating that as long as courts use “customary practice” as an acceptable legal standard for medical practice, EBM-derived CPGs will have a limited or questionable utility in the legal system). Conversely, considering customary practice as the due standard of care does not encourage adoption of EBM in medical practice, but also may even impede it. Even when a physician assumes that he or she needs to deviate from custom in order to serve the best interest of the patient, he or she is, at the same time, aware that such a deviation could leave him or her without any defense in case of a lawsuit for medical negligence. The physician could reasonably be discouraged from following what he or she determines to be the best course of action. In other words, as long as customary practice is

epidemiological studies, like other forms of outcomes research, offer a better foundation for making treatment decisions than the physicians' traditional tendency to rely, only, on their more limited experience.¹⁰⁵ Furthermore, EBM is considered the most important advancement in medicine in the last one hundred years.¹⁰⁶ Comparable to antisepsis, germ theory, vaccines, or treatment of the shock state,¹⁰⁷ EBM has been proven extremely valuable in saving lives.¹⁰⁸ Differently, supporting the use of the customary practice as standard of care, not only discourages the adoption of EBM in medical practice, but may even impede it.¹⁰⁹ When a physician recognizes the need to deviate from custom to serve a patient's best interest, he or she is, at the same time, may fear that such a deviation could render him or her defenseless in a lawsuit for medical negligence,¹¹⁰ therefore deciding to conform his or her performance to custom.

Though EBM is widely deemed as valuable, EBM has also been criticized for its tendency to standardize clinical responses, promoting – according to detractors – a “cookbook” approach to medicine, and discouraging models of a more individualized care.¹¹¹ However, criticism of EBM as an overly standardized practice of medicine fails to consider the fact that that EBM emphasizes the use of the best available external evidence as a method that *accompanies*, rather than *replaces*, a physicians' clinical expertise and

considered suitable for embodying the standard of care, physicians will continue to follow it even when it is not the best option available for the patient. For this reason, the affirmation of EBM in the practice of medicine requests a definitive shift from custom, both in medical practice and in law. For these considerations, *see* Williams, *supra* note 7, at 505–08; *see also*, *Id.* at 527 (noting that “now that medical community is moving toward adherence to the state-of-the-art through EBM, it is appropriate for the law to mandate such adherence”).

105. Noah, *supra* note 91, at 387.

106. Janet M. Torpy, *New Threats and Old Enemies: Challenges for Critical Care Medicine*, 287 JAMA 1513, 1517 (2002).

107. *Id.*

108. *Id.*; Williams, *supra* note 7, at 482–83 (stating that many medical schools have started teaching EBM and that EBM movement is a “paradigm shift” in medical practice).

109. *Id.* at 507; *see also* Blumstein, *supra* note 9, at 1030 (stating that, absent an ability to defend against a medical malpractice claim on the ground of reasonableness, physicians have strong incentive to conform their conduct to the obligatory custom standard); Rosoff, *supra* note 104 (stating that as long as Courts will use “customary practice” as an acceptable legal standard for medical practice, EBM-derived CPGs will have a limited or questionable utility in the legal system).

110. WILLIAM PROSSER, *supra* note 39, at 166.

111. For a critical approach to the EBM, *see* David Grahame Smith, *Evidence Based Medicine: Socratic Dissent*, i310 BMJ, 1126–27 (1995); *Evidence-Based Medicine, In Its Place*, 346 THE LANCET 8978, 785 (1995); *see also* Romana Hasnain-Wynia, *Is Evidence-Based Medicine Patient-Centered and Is Patient-Centered Care Evidence-Based?* HEALTH SERV. RES. 41:1, 3 (2006); Robert R. Weaver, *Reconciling Evidence-Based Medicine and Patient-Centered Care: Defining Evidence-Based Inputs to Patient-Centered Decisions*, J. OF EVALUATION IN CLINICAL PRACTICE 1076, 1077 (2015) (suggesting ways to reconcile EBM to a more patient centered fashion to practice medicine).

experience.¹¹² Moreover, the individual patient's particular predicament and conditions are the starting point for applying an evidence based approach.¹¹³

Even if an EBM standard is desirable, its complexities suggests why endorsing EBM may be problematic in establishing in court whether the physician's defendant conduct met that standard. A first problem in dealing with EBM in a courtroom would be making highly specialized and complex concepts understandable for lay persons.¹¹⁴ The question thus becomes: how can one prove to a trier of fact that a physician followed the best scientific knowledge available, and how can the reliability of this evidence be ensured?

B. Clinical Practice Guidelines and their Relationship with EBM

Clinical practice guidelines (CPGs) may present a first step toward an evidentiary framework based on an EBM standard. According to the Institute of Medicine, CPGs are "systematically developed statements to assist practitioner and patient decisions about the appropriate health care for specific clinical circumstances."¹¹⁵ Further, the Institute of Medicine contextualized CPGs as "a part of a significant cultural shift, a move away from unexamined reliance on professional judgment toward more structured support and accountability for such judgment."¹¹⁶ The importance of CPGs emerged in the late 1980s as the medical community's response to claims that the medical level of diligence was seemingly "arbitrary—highly variable, with no obvious explanation."¹¹⁷ CPGs purported to foster the provision of high quality and uniform medical procedures by measuring appropriate conduct in a given clinical situation.¹¹⁸ As such, they have been deemed crucial in the distribution of EBM information.¹¹⁹ In fact, they distill and convey the

112. Sackett, *supra* note 94 (arguing that EBM "requires a bottom-up approach that integrates the best external evidence with individual clinical expertise and patient choice, [and] cannot result in slavish, cookbook approaches to individual patient care.").

113. *Id.*

114. Rosoff, *supra* note 104, at 341.

115. Kathleen N. Lohr and Marilyn J. Field, *Guidelines for Clinical Practice: From Development to Use*, NATIONAL ACADEMY OF SCIENCES 1, 346 (1992); *see also* Ash Samantha, *The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from The Bolam Standard?* 14 MED. L. REV. 321, 321 (2006) (defining clinical practice guidelines as "consensus statements developed to assist clinicians in making decisions about treatment for specific conditions.").

116. Marilyn J. Field and Kathleen N. Lohr, *Clinical Practice Guidelines: Directions for a New Program*, NATIONAL ACADEMY OF SCIENCES 1, 2 (1990).

117. David M. Eddy, *The Challenge*, 263 JAMA 287, 287 (1990).

118. Sam McConkey, *Simplifying the Law in Medical Malpractice*, 97 W. VA. L. REV. 491, 506 (1995).

119. Deborah W. Garnik et al., *Can Practice Guidelines Reduce the Number and Cost of Malpractice Claims?*, 266 JAMA 2856, 2857 (1991) (stating that the explosion of medical information makes the guidelines necessary); Noah, *supra* note 91, at 417 (stating that "clinical practice guidelines can serve an important role in disseminating information. In both their

available research and translate it for clinical practice.¹²⁰ Moreover, CPGs usually reflect informed opinions on how to treat a certain illness or condition, and are “generally derived from scientific studies comparing the effectiveness of various clinical approaches to treat a particular medical situation.”¹²¹

Although CPGs are recognized as essential in the diffusion of EBM, these tools imbue skepticism in some scholars,¹²² mostly related to the consideration that EBM and CPGs are not synonymous.¹²³ First, skeptics argue that CPGs do not always focus on the patient’s best interest.¹²⁴ In this regard, it has been argued that when the promulgators of CPGs are health care payers or providers,¹²⁵ they may be influenced by cost-control concerns,¹²⁶ and oriented toward profit maximization.¹²⁷ Second, skeptics question the fact that a CPGs’ information may not always represent an up-

scope and the rigor of peer scrutiny, these guidelines typically go beyond textbook and review articles published in the biomedical journals”); 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, 1488–89 (1989) (noting that “[b]ecause of [an] apparent lack of coordination between technology assessment and clinical practice, the medical profession, private insurers, and the federal government have begun to develop reliable methods to evaluate the efficacy and cost-efficiency of various forms of medical practice. These studies have already led to the development and endorsement of a wide range of recommended practice guidelines”); see generally David M. Eddy, *Practice Policies – Guidelines for Methods*, 263 JAMA 1839 (1990) (describing the goals and outcomes of practice policies).

120. Noah, *supra* note 91, at 416; see Eddy, *supra* note 119 (stating that “practice policies are the central nervous system of medical practice.”) (stating that they can connect each practitioner to a collective consciousness, bringing order, direction, and consistency to their decision. Practice policies provide an intellectual vehicle through which the profession can distill the lessons of research and clinical experiences and pool the knowledge and preferences of many people into conclusions about appropriate practices. They provide a natural pathway to convey that information to practitioners).

121. Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 370 (1995) [hereinafter, *The Role of Clinical Practice Guidelines in Health Care Reform*].

122. For a skeptical view see Mello, *supra* note 10, at 652–57; Noah, *supra* note 91, at 421–26; *The Role of Clinical Practice Guidelines in Healthcare Reform*, *supra* note 121 (arguing that the concept of CPGs is not universally supported).

123. Noah, *supra* note 91, at 419.

124. *Id.* at 422 (stating that while guidelines developed by professional medical societies are focused primarily on achieving the best medical outcomes, guidelines developed by health care payers are heavily influenced by cost-control concerns).

125. Promulgators of CPGs can be grouped into three categories: professional societies, government bodies, and health care payers. See Mello, *supra* note 10, at 650; see also Noah, *supra* note 91, 427–28 (highlighting the federal agencies’ role in the development and dissemination of practice guidelines).

126. *The Standard of Care in Medical Malpractice Claims*, *supra* note 89, at 103.

127. John D. Ayres, *The Use and Abuse of Medical Malpractice Guidelines*, 15 J. LEG. MED. 421, 437 (1994); see also Noah, *supra* note 91, at 422 (stating that conflict of interest may taint practice guidelines, especially when the promulgators of guidelines are health insurance or pharmaceutical companies).

to-date standard.¹²⁸ In fact, while medical science is constantly evolving, the codification of CPGs could take years,¹²⁹ resulting in reflecting potentially outdated evidence.¹³⁰ Opponents have also argued that certain CPGs are extremely vague, and that there is a multiplicity of CPGs for any given medical condition or intervention.¹³¹

In light of the abovementioned potential flaws, the use of CPGs in court has been seen as extremely problematic.¹³² In fact, their use could increase, rather than reduce, the level of uncertainty in medical malpractice litigation¹³³ or to rely on cost-control, rather than patient oriented, influenced standard.

Recognizing the rationality of the critics' concerns over the use of the CPGs in court, the following sections address these perplexities. Critically analyzing some proposals regarding the use of CPGs within the area of medical negligence, I suggest the preferable way to use CPGs in court, indicating ways to help better-select them, in order to present more reliable evidence to jurors. The suggested approach bears the recognition that, despite the use of CPGs is highly helpful in defining medical negligence in court, we should still be mindful of the peculiar and structural asymmetry of medicine that, itself does not allow to have a ultra-defined standard of care.

C. CPGs as a "One-Way Street" Affirmative Defense

One proposed method for using CPGs in medical malpractice litigation is to allow proof of a physician's compliance with the CPGs to serve as an absolute defense. This use of CPGs was addressed for the first time by a Maine statutory project,¹³⁴ adopted in 1990 and repealed in 1999.¹³⁵ This model was emulated by other states.¹³⁶ Maine's project contemplated Clinical

128. Williams, *supra* note 7, at 487.

129. *Id.*

130. *Id.*; see also Noah, *supra* note 91, at 422–23.

131. Mello, *supra* note 10, at 687–88; see also Williams, *supra* note 7, at 490.

132. Mello, *supra* note 10, at 654; Edward B. Hirshfeld, *Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886, 2888 (1991).

133. Mello, *supra* note 10, at 685.

134. *Medical Liability Demonstration Project*, 24 ME. REV. STAT. ANN. Tit. § 2971–79 (West 1990); see Jennifer Begel, *Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation*, 47 ME. L. REV. 69 (1995) (providing an analysis of the Maine Model).

135. Gordon H. Smith, *Maine's Medical Liability Demonstration Project - Linking Practice Guidelines to Liability Protection*, 13 AMA J. ETHICS 792, 792 (2011).

136. See, e.g., KY. REV. STAT. ANN. § 342.035 (1996), in which the state of Kentucky states that "[a]ny provider of medical services . . . who has followed the practice parameters or guidelines developed or adopted . . . shall be presumed to have met the appropriate legal standard of care in medical malpractice cases regardless of any unanticipated complication that may thereafter develop or be discovered" and MD. CODE ANN. HEALTH-GEN., § 19-1602 (1996), that set out "to study the development of practice parameters for medical specialties and to provide information for and make recommendations . . . on the adoption and use of

Practice Guidelines, in four medical areas,¹³⁷ as an absolute affirmative defense for physicians.¹³⁸ The adopted approach allowed physician-defendants to use CPGs as a complete shield from liability in cases of compliance with CPGs.¹³⁹ At the same time, according to this model, patient-plaintiffs were prevented from using CPGs for inculpatory purposes.¹⁴⁰ More specifically, the plaintiff was precluded from introducing defendant's noncompliance with CPGs as evidence of malpractice and could, at most, either contest the applicability of CPGs invoked by the physician as a shield against negligence, or challenge the physician's compliance with the introduced CPGs.¹⁴¹

Scholarly objections clarify reasons for which the physician-defendant's use of CPGs as a shield (the so-called "one-way street") is undesirable.¹⁴² First, allowing the use of certain evidence by only one of the parties of a lawsuit would raise fairness and anomaly issues under the law.¹⁴³ Essentially, it would lead to the plaintiff and defendant being treated differently regarding the evidence they can use in their respective cases.¹⁴⁴ For this reason, it has been argued that adopting this model may raise questions of "due process" and "equal protection of the law."¹⁴⁵ More practically, has also been demonstrated that this model is useless in achieving the goal it was meant to accomplish: reducing defensive medicine.¹⁴⁶ On the other hand, it may foster the opposite result, encouraging clinicians to follow guidelines from a defensive perspective. Under this standpoint a bureaucratic compliance with CPGs may also conflict with the best interest of the patient.

practice parameters."

137. Anesthesiology, emergency medicine, obstetrics and gynecology, and radiology; Smith, *supra* note 135, at 792.

138. *Id.*

139. *See id.*

140. *Id.* at 793.

141. *See Medical Liability Demonstration Project*, *supra* note 134, at § 2975; *See generally* Smith, *supra* note 135.

142. Mello, *supra* note 10, at 648.

143. *Id.* at 695 (arguing that the exception to the rule of symmetry, in this case, would not be justified by any persuasive policy concern).

144. *Id.* at 677, 695–704 (offering a discussion of different, but justified, asymmetrical rules and how the Maine model differs and lends itself to unequal treatment of parties in medical malpractice cases).

145. *See* Begel, *supra* note 134, at 100–01 (arguing that the admissibility of CPGs to be used only in favor of the defendant could reasonably alter the outcome of any given case: "Certainly the right to a jury trial and access to the judicial process are meaningless if the procedures afforded fail to give the litigants a complete opportunity to have their claims fairly and impartially. Allowing evidence to be used only by one party and not by the other, without any sufficient articulable justification, would seem to make the proceedings constitutionally suspect"); Rosoff, *supra* note 104, at 344.

146. Mello, *supra* note 10, at 676.

In conclusion, this one-way street for the use of CPGs in court is an inappropriate means for tort reform because it poses constitutional concerns, does not achieve the scope of reducing defensive medicine, and it may even discourage physicians from providing a reasonable level of care.

D. CPGs as the Standard of Care

One proposal advanced by legal scholarship starts by considering uncertainty in the legal standard of care as the main factor contributing to the practice of determining defensive medicine.¹⁴⁷ According to this view, CPGs represent a possible means to abate the phenomenon at issue.¹⁴⁸ As *ex ante* parameters, CPGs would clarify standards of practice, eliminating uncertainty in medical decision making.¹⁴⁹ In this sense, CPGs should deliver perfectly symmetrical impacts for plaintiff and defendant, and should be considered as having the “force of law.”¹⁵⁰ Under this framework, CPGs should not be used as *evidence* of the standard of care, but as the standard of care *itself*.¹⁵¹ The way to achieve this result would be to endorse CPGs through legislation,¹⁵² or more precisely, to assign force of law to standards established by Quality Improvement Organizations.¹⁵³ Moreover, to be effective against defensive medicine, CPGs must not be characterized by comprehensiveness and flexibility, which is detrimental in defeating defensive medicine.¹⁵⁴ Instead, according to proponents of CPGs, they “must be targeted as a laser beam at narrow and specific circumstances, providing specific guidance to practitioners in carefully circumscribed situations.”¹⁵⁵

However, this proposal, entrenched primarily in the effort to abate the defensive medicine phenomenon, is not persuasive. First, as discussed, the link between defensive medicine and the standard of care is weak, and other factors have a more direct incidence on this phenomenon; therefore, the hoped scope of abating defensive medicine may result unachievable through a more rigid and certain parameter to evaluate the physicians conduct in court.

147. Blumstein, *supra* note 9, at 1028.

148. *See id.* at 1031–34.

149. *Id.* at 1031 (stating that CPGs as *ex ante* standards can reduce clinical uncertainty).

150. *Id.* at 1036.

151. *Id.* at 1036, 1048.

152. Rosoff, *supra* note 104, at 382–83 (suggesting that the use of CPGs as applicable legal standard would require a legislative intervention).

153. *See* Blumstein, *supra* note 9, at 1039, 1041 (explaining that a Quality Improvement Organization (QIO) is a group of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare) (also explaining that QIO possess the “statutory authority to develop standards that would serve as controlling legal standards in medical malpractice litigation”).

154. *Id.* at 1049 (recognizing, however, that flexibility is desirable for improving the quality of medical decision-making)

155. *Id.*

Second, the rigid standard proposed by the analyzed scholarship conflicts with medical reality, in which the variety of organisms,¹⁵⁶ organisms' different responses to the same medical treatment,¹⁵⁷ and the lack of causal determinism requires physicians to exercise flexibility in adopting solutions in their cases. Such flexibility is necessary to better individualize the curative response and, therefore, serve the best interest of the patient. In this sense, imposing rigid parameters by law may yield detrimental effects to the quality of health care treatments.

Unlike the reported position, the following section keeps the golden standard of care separate from its evidence in Court, and adopts a flexible approach that better aligns with the medical reality. While employing an EBM standard abandons the mediocrity of the customary practice standard, doing so does not automatically suggest that complying with CPGs represent the only way to practice EBM, or that they should tie physicians' actions. In fact, even if CPGs represent an expression of EBM, because of the imperfect overlapping of EBM and CPGs, it is unfeasible to conclude that CPGs represent the standard of care itself.¹⁵⁸ However, as an expression of EBM, they may nevertheless have a strong probative value in medical malpractice litigation.¹⁵⁹

E. Flexible Use of CPGs at the Bar

1. How to use CPGs at Trial

The preferable approach to using CPGs in court relies on the recognition of CPGs as one of the several expressions of EBM and the asymmetric nature of medicine. In this context, CPGs may be used in medical malpractice trials to help establish or disprove the breach of the duty of care. In this sense, CPGs can be utilized in both an inculpatory and exculpatory way.¹⁶⁰ In case of noncompliance with CPGs, the plaintiff can offer evidence of the physician's deviation from EBM.¹⁶¹ As exculpatory evidence, the physician-defendant can offer her compliance with CPGs in order to prove she met the

156. Edward B. Hirshfeld, *Should Practice Parameters be the Standard of Care in Malpractice Litigation?*, 266 JAMA, 2886, 2887 (1991).

157. *Id.* (stating that patients dealing with the same general category of disease may be treated differently according to "the gravity of the symptoms, the general health of the patient, the nature of any other medical problems being experienced by the patient, and other characteristics.").

158. *See generally* Rosoff, *supra* note 104, at 327 (explaining that not all CPGs are based upon EBM).

159. *See id.* at 337 (stating that most jurisdictions see that adherence to these professional standards can be an adequate defense to malpractice negligence claims).

160. *Id.* at 341.

161. *See* Noah, *supra* note 91, at 462.

due level of care.¹⁶² In essence, CPGs can serve as a sword or a shield; however, *compliance or noncompliance with CPGs represent only a starting point* in proving diligence or negligence, respectively.¹⁶³ CPGs essentially function as rebuttable evidence. In this dialectic, compliance with CPGs should free the physician from liability, unless the plaintiff can prove that the CPGs were *not* the expression of the best knowledge available at the time, demonstrating, for example, that the proffered guidelines the defendant followed were outdated, or that there was medical literature more appropriate to the case the doctor was facing. Similarly, if a plaintiff alleges a violation of guidelines proven to be the best representation of available scientific knowledge, then a physician may be held negligent for the injury, unless there is proof that according to other evidence-based information, the guideline did not apply in that case,¹⁶⁴ or that the peculiar conditions of the patient urged an individualized solution not standardized in guidelines.¹⁶⁵ This dialectical use of CPGs, that considers these tools as an essential starting point and meaningful evidence of reasonableness, despite not conclusive nor exclusive, can be also seen as a means to higher the quality of the scientific evidence introduced in courtrooms dealing with medical malpractice.¹⁶⁶ In fact, the party who wishes effectively disprove the information contained in the proffered guideline should use comparable high quality evidence.

The following notes aim to better explain how to ensure that only high quality safety oriented CPGs will be introduced at trial.

2. The Reliability and Relevance of CPGs

The considerable variety of CPGs underscores the need to tailor their selection in the application to actual cases. In fact, for CPGs to adequately assist lay people in determining whether the physician acted according to the

162. *Id.*

163. *See id.* at 462–63.

164. *See Rosoff, supra* note 104, at 345 (arguing that in establishing the due standard of care courts have to verify: a) whether the specific CPG proffered was appropriate to the case at issue and, if so, whether the defendant complied with guidelines; b) whether there was non-compliance with the guidelines and, if so, what harm resulted from non-compliance).

165. Samanta, et al., *supra* note 115, at 350 (stating that EBM cannot fully capture the art of medical practice and that there's still the need for clinical judgment and discretion).

¹⁶⁶ In this sense, other desirable evidence, medical malpractice cases involving the use of pharmaceutical products, may also be represented by the package insert accompanying pharmaceutical products. In fact, the package insert is subjected to a rigorous control governed by the FDA. *See Noah, supra* note 91, at 435 (critically noting that “notwithstanding the clear rigor of this process, proponents of EBM never mention package inserts as a valuable source of evidence-based recommendations for practitioners” and that, despite the package insert provides detailed guidance about appropriate uses and potential risks, courts struggle in determining the appropriate status of such labeling).

best evidence available, only good quality, and thus, reliable guidelines must be selected.¹⁶⁷

Under this standpoint, a first selection method may be to evaluate the CPGs' sources. In fact, if CPGs issued by insurance and pharmaceutical companies raise doubts regarding reliability, these perplexities should lose their strength with regard to guidelines issued by federal agencies or international associations devoted to medical research.¹⁶⁸

Another way for selecting CPGs may be the application of the *Daubert* standard.¹⁶⁹ Particularly, the judge, treating the information underlying the guidelines as scientific knowledge, should first carry out an accurate screening during the pre-trial stage.¹⁷⁰ In this process, the judge should verify that the *information* contained in the proffered guideline indicates a rate of error, went through a peer review process, is suitable to be tested, and is generally accepted in the relevant scientific community.¹⁷¹ If the only CPGs admitted at trial are those that, at least *prima facie*, are grounded in reliable science,¹⁷² then problems related to the multitude of CPGs lose strength, or, at least, these critical points of using CPGs in medical malpractice claims would be common to the great part of scientific information that approaches the courtroom doors.¹⁷³ Moreover, this process, aimed at establishing reliability of guidelines, would also support the qualification of CPGs as "learned treaties," overcoming concerns about their status as hearsay evidence.¹⁷⁴

Other considerations during the screening of CPGs should be related to their relevance. If "relevance" is the quality of evidence having the tendency to make a fact more or less probable than it would be without the evidence,¹⁷⁵ then in medical negligence cases, only "safety oriented" guidelines, aimed at avoiding the same harm suffered by the plaintiff, or at least aimed at treating

167. Rosoff, *supra* note 104, at 389.

168. *See id.* at 390 (explaining that the Agency for Healthcare Research and Quality was created to help develop, refine and disseminate the methodology for creating CPGs).

169. Samanta et al., *supra* note 115, at 363–64; Morreim, *supra* note 8, at 415 (stating, "if courts are to bring *Daubert* standards to evaluate the adequacy of the guidelines by which plans shape clinicians' care and make their coverage decisions, those CPGs should be anchored in a "reliable foundation" not just the vague "general acceptance.").

170. Samanta et al., *supra* note 115, at 363–64.

171. *Id.*

172. Hines, *supra* note 81, at 7.

173. *See generally* Sheila Jasanoff, *SCIENCE AT THE BAR: LAW, SCIENCE AND TECHNOLOGY IN AMERICA*, Harvard University Press (1998).

174. FED. R. EVID. 801-805 (The Federal Rules of Evidence establish that hearsay is inadmissible evidence, unless some exception applies, learned treaties rule is one of those); *see* Mello, *supra* note 10, at 663.

175. FED. R. EVID. 401 (The Federal Rules of Evidence state the test of relevance is evidence making a fact more or less probable than it would be without that evidence).

the patient's medical condition, should be admissible in court. Consequently, those CPGs that are mostly profit and cost-oriented would not be admissible in court, because they would not be relevant to prove or disprove the level of care in a negligence case.

If only reasonably reliable and relevant CPGs are admissible in court, their use become extremely suitable in proving the standard of care at trial, especially when compared to customary practice standard. From an objective standpoint, CPGs' schematic nature, relating certain conduct to specific circumstances, makes them particularly appropriate in explaining the expected level of physician diligence to lay people. Additionally, their documented nature makes them fitting in control and limit the abuses of expert testimony.¹⁷⁶ Under this framework, CPGs are rather desirable tools to use at trial because they are flexible, available to both parties in proving or disproving negligence,¹⁷⁷ and do not impede the use of other possible evidence in establishing what conduct, in the specific case faced by the doctor, constituted the reasonable standard of care according to the best evidence available and the actual conditions of the patient.

V. CONCLUSION

In medical malpractice cases, the physician-defendant is traditionally judged using the "customary practice" standard.

However, customary practice is no longer suitable to represent the standard of care in medical malpractice cases.¹⁷⁸ First, in the legal field, the mere "general acceptance" approach (the legal equivalent of the medical opinion-based approach) is no longer sufficient to scrutinize scientific evidence at trial to determine admissibility.¹⁷⁹ Moreover, when expert witnesses testify about customary practice, they cannot even express what is generally accepted nationwide.¹⁸⁰ Expert testimony to customary practice should, therefore, fail the admissibility tests as established in both the *Daubert* and the *Frye* decisions.¹⁸¹

Similarly, the customary practice standard of care has been rejected by the medical field, with clinical practice shifting from an opinion-based to an

176. *Contra* Mello, *supra* note 10, at 703 (explaining that using CPGs could supplement problems related to the abuses of the expert testimonies, transforming the "battle of the experts," acting as "hired guns, to the "battle of guidelines").

177. Williams, *supra* note 7, at 525.

178. *Id.* at 533 (explaining that, as EBM acquires more followers, custom is becoming less indicative of what qualifies as good medical practice).

179. *See id.* at 505 (explaining one scholar's view that *Daubert* has asked courts to move away from "general acceptance" to an expectation of "reliable scientific evidence").

180. Cf. paragraph III.2. .

181. *See* Williams, *supra* note 7, at 505 (explaining that interpretations of *Daubert* suggest a move away from custom); Frye, 293 F. at 1013.

evidence-based approach, or Evidence-Based Medicine. Fittingly, the “reasonable care” standard applied in medical malpractice cases aligns most closely with EBM, which uses an opposite approach from the customary practice standard of care.

In this framework, Clinical Practice Guidelines, as expressions of EBM, may constitute an essential tool for establishing the reasonable level of care at trial. Since CPGs are not the ultimate authority on EBM, they do not embody the standard of care, but merely provide *evidence* thereof. Therefore, they can be used by both the plaintiffs and defendants as inculpatory and exculpatory evidence, respectively. However, the diversity of guidelines in structure, quality, source, and scope makes it essential to limit their use at trial to *only* those that are issued by sources concerned with patients’ health, and that are deemed to be founded on reliable science.

Limiting admissible CPGs to only those that are relevant and reasonably reliable would bring a great number of advantages, especially when compared with the use of customary practice. In particular, their schematic nature, relating certain conduct to specific circumstances, renders them particularly useful in explaining levels of a physician’s due diligence to lay people, according to an objective standpoint.