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ARTICLE

A BRIDGE TOO FAR: Practice Guidelines in the New ALI Medical Malpractice Restatement

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Abstract

The new American Law Institute Medical Malpractice Restatement posits a novel rule in § 6(b) that would authorize the use of medical-practice guidelines as a standard of care for medical-malpractice litigation. However, it would only be a "safe harbor" shield; guidelines could not be similarly used by plaintiffs as a sword. For defendants, the rule would transform what heretofore has been indisputably hearsay evidence into prima facie proof that would serve as a substitute for expert testimony, and which would be sufficient to defeat a malpractice claim. Plaintiffs wishing to use practice guidelines would be relegated to the "learned treatise" exception of the hearsay rule.

Practice guidelines are not however the panacea that the Restatement envisions. In the present-day proliferation of guidelines, there are many objectivity and credibility issues, resulting in severe criticism of the guideline promulgation process within the profession. Many guidelines offer inconsistent and conflicting recommendations, contain inherent conflicts of interest and mixed purposes, and some are even blatant attempts to tilt the playing field in favor of defendants.

There is no jurisdictional support for this rule. No case has ever held that practice guidelines constitute a standard of care or that they can be introduced as substantive proof or that their use is different depending on whether they are offered by a defendant or a plaintiff. Nor is there any sound reason or public policy that would support the rule or to believe any guideline is more authoritative than expert testimony, which can be tested in the crucible of the courtroom. The guidelines rule also suffers from practical problems and still requires expert testimony for support. The rule would also violate fundamental principles of equal justice and fairness by compromising the right to cross-examination and by allowing the medical profession to set its own variable standards of care. It is more akin to tort reform that a common law rule of evidence. For those reasons, courts should not accept the invitation to adopt § 6(b).

Keywords: Medical malpractice; standard of care; practice guidelines; hearsay; defendant-only; self-authenticating; stand-alone; cross-examination; equal justice; learned treatise

Introduction

The Medical Malpractice Restatement of the American Law Institute, formally known as the Restatement (Third) of Torts: Medical Malpractice, and approved in May 2024, presents the Institute's first treatment of the law of medical malpractice litigation.[1] Advocates will ask courts to adopt it, and many of

[1]Restatements First and Second of Torts contained only minimal references to medical malpractice issues. However, since 1965, when Restatement Second was published, there has been a large volume of medical malpractice cases and case law. As Restatement Third of Torts was winding down, to finish tort treatment, the ALI Council in January 2019 approved work on what was then termed "Concluding Provisions" (since renamed "Miscellaneous Provisions"). *See Torts: Medical Malpractice Is Approved*, A.L.I. (May 21, 2024), https://www.ali.org/news/articles/alis-torts-medical-malpractice-approved/. Medical

its provisions will have a salutary effect.[2] One provision, however, would have the opposite effect. § 6 (b) attempts a sea change in the law to create a special, defendant-only rule that would authorize the use of practice guidelines as a substitute for expert testimony about the standard of care.[3] This article explains why courts should reject requests to adopt § 6(b).

As out-of-court statements about medical practice not subject to cross-examination, practice guidelines are undisputably hearsay documents that would be excluded under the rules of evidence in every federal and state court save for a rule-based exception.[4] Since their advent, courts have treated them as equivalent to "learned treaties" and, under that exception to the rule against hearsay, allowed both plaintiffs and defendants to use them periodically as either exculpating or inculpating evidence when they are established as reliable by an expert's admission on cross-examination or by another expert's testimony.[5] Ordinarily Restatements deal only with common law issues and do not apply when there is specific statutory law but, notwithstanding that stricture, the Medical Malpractice Restatement adopted § 6(b).[6] If adopted by courts, it would create a two-tier system of evidence for practice guidelines.

For plaintiffs, practice guidelines would remain hearsay documents that could still be used but only under the learned treatise hearsay exception. For defendants, there would be a sharp, controversial departure from the hearsay rules that would create a new "one-sided" defensive shield which would: (1) elevate practice guidelines to stand-alone, non-hearsay evidence if promulgated from an "authoritative" entity, and (2) authorize only defendants to use that evidence as a substitute for expert testimony. Thus, when practice guidelines are relied upon by defendants, they would *ipso facto* be transformed into non-hearsay, prima facie evidence. But documents do not change their hearsay character depending on who offers them into evidence.

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malpractice began as a part of that project but in 2022 the Institute decided to present the medical malpractice provisions as a free-standing Restatement. *Id.*

[2]*See, e.g.*, Philip G. Peters, Jr., *Modernizing the Medical Malpractice Standard of Care*, 52 Sw. L. Rev. 465, 465-73 (2024) (explaining that the change from a problematic custom-based standard to one based on competency among similar medical providers in the same or similar circumstances in the Restatement is an improvement that reflects the shift in state law).

[3]"§ 6. Establishing Breach of, or Compliance with, the Standard of Care …

(b) Evidence that the provider complied with a relevant and authoritative practice guideline may be:

(1) used to rebut the plaintiff's claim that the provider breached the standard of care as provided in § 5; or

(2) sufficient to find that the provider met an acceptable alternative standard of care, as provided in § 5, Comment *k*."

Restatement of the Law Third Torts: Medical Malpractice § 6(b) (Am. L. Inst., Draft Practice Guidelines, 2024) [hereinafter Medical Malpractice Practice Guidelines].

[4]For example, Fed. R. Evid. § 802 and its state counterparts do not permit the admission of hearsay evidence except under severely constricted circumstances. *See* Fed. R. Evid. 802; *See also, e.g.*, *Commonwealth v. Markvart*, 771 N.E.2d 778, 782 (Mass. 2002) ("[H]earsay not otherwise admissible under the rules of evidence is inadmissible at the trial … unless specifically made admissible by statute."); Cal. Evid. Code § 1200(b) (West 2024) ("Except as provided by law, hearsay evidence is inadmissible."). Fed. R. Evid. § 801 adopts the classic elements of hearsay: a statement, oral, written, or nonverbal, not made in the hearing or trial offered to prove the truth of the matter asserted. *See* Robert P. Mosteller et al., McCormick On Evidence § 246 (8th ed. 2020).

[5]*See, e.g.*, Fed. R. Evid. 803(18):

"The following are not excluded by the rule against hearsay, regardless of whether the declarant is available as a witness: …

(18) Statements in Learned Treatises, Periodicals, or Pamphlets. A statement contained in a treatise, periodical, or pamphlet if:

(A) the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination; and

(B) the publication is established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice.

If admitted, the statement may be read into evidence but not received as an exhibit."

There are similar provisions in all state rules of evidence. *See* Mosteller et al., *supra* note 4, § 321.

[6]The reporters for the new Restatement explain, in a comment, that this provision concerns only the "substantive legal principles rather than rules of evidence." Medical Malpractice Practice Guidelines, *supra* note 3, § 6, Reporters' Note, cmt. *f.* The authors still should explain how admission of the guidelines comports with the rules of evidence if the substantive legal principle is more than an abstract enterprise.

However, practice guidelines are not the panacea that the Restatement envisions. Many guidelines, even when developed by "authoritative sources," are replete with objectivity and credibility issues; others promote special-interest agendas; some conflict with each other; and many miss the mark of accounting for individual variations in patients that are necessary for proper care. Some guidelines are even promulgated to give their members litigation advantages over plaintiffs. More important, there is no precedential support for this new provision, and the reasons given for it in the new Restatement do not withstand critical analysis. § 6(b) would also violate a number of the foundational principles of the civil justice system, rendering it more akin to tort reform than a restatement of the law. This article shall embark on a deeper discussion below.

Part I of this article begins with an overview of the Institute's approach to Restatements. Part II examines practice guidelines that provide the basis for the controversy within the Medical Malpractice Restatement. Part III then details the lack of jurisprudential support for the rule. Part IV critically analyzes the reasoning put forth to support the rule. Part V explains how the rule would violate foundational principles. And finally, Part VI explains why the Restatement's approach is law revision, rather than a restatement of the law. The article concludes with the recommendation that courts not adopt § 6(b) and, instead, continue to treat practice guidelines as hearsay evidence that is admissible only under the specific circumstances of Federal Rules of Evidence § 803(18) or its cognate state rules, to be read into evidence, not themselves entered as evidence.

I. Developing and Using Restatements of the Law

The ALI does not lightly venture into new areas of law at the level of a Restatement.[7] The development of a Restatement is "often a grueling, expensive and time-consuming task."[8] The current project to update tort law and produce a Restatement (Third) of Torts, which includes the recently adopted Medical Malpractice Restatement, is now in its thirty-second year.[9]

A Restatement seeks to create greater certainty in the law, overcome obsolete or purposeless legal complexities, and advance legal change that accords with the demands of modern life.[10] But while the process to produce a Restatement is rigorous, it does not guarantee consensus about the resulting Restatement provisions.[11] Moreover, a Restatement is not law; it is only a "recommendation to courts to adopt sections of the Restatement in the process of common-law adjudication."[12]

[7]The Institute has undertaken to produce its well-known Restatements since its founding in 1923, but has produced other forms of legal guidance as well. *See* Bennett Boskey, *The American Law Institute: A Glimpse at Its Future*, 12 Green Bag 2d 255, 256-58 (2009). For example, its Principles projects have "more flexibility; they fit well in areas where the law is somewhat less settled, or more emerging, than in Restatement areas." *Id.* at 261.

[8]Mark E. Budnitz, *The Restatement of the Law of Consumer Contracts: The American Law Institute's Impossible Dream*, 32 Loy. Consumer L. Rev. 369, 371 (2020).

[9]*See* Michael D. Green, Symposium Remarks, *The American Law Institute and the Restatement (Third) of Torts: Presentation of Michael Green*, *in* 52 Sw. L. Rev. 364, 365–66 (2024). The original Restatement of Torts spanned sixteen years, while its successor took more than two decades to finalize. Stephen D. Sugarman, *Rethinking Tort Doctrine: Visions of a Restatement (Fourth) of Torts*, 50 UCLA L. Rev. 585, 586–87 (2002).

[10]Hon. Goodwin H. Liu, Symposium Remarks, *A Brief Introduction to the American Law Institute and the Restatements of Torts*, *in* 52 Sw. L. Rev. 358, 360 (2024).

[11]There have been controversial Restatements provisions before, most notably relating to product design defect liability. *See, e.g.*, Philip H. Corboy, *The Not-So-Quiet Revolution: Rebuilding Barriers to Jury Trial in the Proposed Restatement (Third) of Torts: Products Liability*, 61 Tenn. L. Rev. 1043 (1994); Douglas E. Schmidt et al., *A Critical Analysis of the Proposed Restatement (Third) of Torts: Products Liability*, 21 Wm. Mitchell L. Rev. 411 (1995); John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorns a "New Cloth" for Section 402A Products Liability Design Defects— A Survey of the States Reveals a Different Weave*, 26 U. Mem. L. Rev. 493 (1996); Frank J. Vandall, *Constructing a Roof Before the Foundation Is Prepared: The Restatement (Third) of Torts: Products Liability, Section 2(b) Design Defect*, 30 U. Mich. J. L. Reform 261 (1997). In the decade following its adoption, courts roundly rejected the core elements of those provisions. Larry S. Stewart, *Strict Liability for Defective Product Design: The Quest for a Well-Ordered Regime*, 74 Brook. L. Rev. 1039, 1040 (2009).

[12]Alan Schwartz & Robert E. Scott, *The Political Economy of Private Legislatures*, 143 U. Pa. L. Rev. 595, 600 (1995).

A Restatement's content is heavily defined by a Reporter or Reporters, who "structure the project, define its scope, prepare drafts, and present their work for review by various stakeholders."[13] The reality is "that every Restatement is necessarily the brainchild of the Reporter and his or her associates."[14] However, Reporters do not enjoy unrestrained discretion in drafting a Restatement. The prime source of law for Restatements is the case law of American courts.[15] And while Restatements are not bound to existing law, in proposing variations to clarify and simplify the law and secure the better administration of justice, Restatements are constrained by the need to find support in existing law.[16]

In keeping with those strictures, much of the Medical Malpractice Restatement adheres, as it should, to established law, particularly § 5(a),[17] which provides that the all-important applicable standard of care "is the care, skill, and knowledge regarded as competent among similar medical providers in the same or similar circumstances."[18] For several years, many states had relied on a locality standard, which required that a physician "possess and exercise that degree of skill and care ordinarily employed in similar circumstances by physicians in good standing in his own community."[19] That rule thwarted many meritorious claims, but courts drew justification for the rule from differences in experience and conditions of practice among local health care providers that contrasted with those in other locations.[20]

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[13]Liu, *supra* note 10, at 361.

[14]Lawrence J. Latto, *The Restatement of the Law Governing Lawyers: A View from the Trenches*, 26 Hofstra L. Rev. 697, 707 (1998).

[15]Am. L. Inst., Capturing the Voice of The American Law Institute: A Handbook for ALI Reporters and Those Who Review Their Work 7 (rev. ed. 2015).

[16]*Id.* at 4-6.

[17]Restatement of the Law Third Torts: Medical Malpractice § 5(a) (Am. L. Inst., Tentative Draft No. 2, 2024) [hereinafter Medical Malpractice].

[18]This reasonable provider standard has been adopted in the pattern jury instructions of all U.S. jurisdictions. *See*: Alabama: § 25.01 "Standard of Care for Physician;" Alaska: Alaska Civil Pattern Jury Instructions § 8.02 "Health Care Provider Malpractice – Negligence Defined;" Arizona: RAJI (Civil) Medical Negligence 1 (7th ed.): "Definition of Medical Negligence;" Arkansas: § 1501 "Duty of Physician, Surgeon, Dentist or Other Medical Care Provider;" California: § 501 "Standard of Care for Health Care Professionals;" Colorado: §15:2 "Negligence—Nonspecialist—Defined" and § 15:3 Negligence—"Specialist or One Who Has or Claims to Have Special Skill—Defined;" Connecticut: § 3,8-3 "Medical Malpractice;" Delaware: § 7.1A (2000) "Definition of Medical Negligence;" District of Columbia: § 9.02 General Standard of Care of Professionals;" Florida: § 402.4 "Medical Negligence;" Georgia: § 62.300 "Physician, Skill Required of;" Hawaii: § 14.2. "Standard of Care;" Illinois: § 105.01 "Professional Negligence—Duty;" Idaho: § 1600.2 "Negligence - Duty Of Physician" and § 1600.3 "Negligence— Duty Of Specialist;" Indiana: § 1511 "Medical Negligence—Health Care Provider;" Iowa: § 1600.2 "Negligence— Duty of Physician;" Kansas: § 123.01 "Duty of Health Care Provider;" Kentucky: § 23.09 "Liability of Physician or Surgeon to Patient;" Louisiana: § 13:1. "Duty of physician (surgeon) in general practice" and § 13:2. "Duty of physician (surgeon) practicing a specialty;" Maine: § 7–75 "Medical Malpractice: Instruction;" Maryland: § 27:2 "Standard of Care—Defined:" Massachusetts: § 4.3.1 "Duty/Standard of Care;" Michigan: § 30.01 "Professional Negligence/Malpractice;" Minnesota: § 80,10 "Duty of a Doctor, Dentist, or Healthcare Provider Definition of "negligence" by a (professional healthcare provider);" Mississippi: § 2700. "Medical Malpractice—Standard of Care;" Missouri: § 11.06 "Negligence—Health Care Providers;" Nebraska: § 12.01 "Duty of a Health Care Provider;" Nevada: § 9.1 "Definitions;" New Hampshire: § 13.1 "Legal Fault: Negligence and Causation (Professional Negligence Cases);" New Jersey: § 5.50A "Duty and Negligence;" New Mexico: § 13-1101 "Duty of Doctor or Other Health Care Provider;" New York: § 2:150 "Malpractice—Physician;" North Carolina: § 809.00A "Medical Malpractice--Direct Evidence of Negligence Only;" North Dakota: § 14.10 "Physician's Standard of Care;" Ohio: § 417.03 "Standards of care: physician/surgeon;" Oklahoma: No. 14.1 "Standard of Care—Non-specialist" and No. 14.2 "Standard of Care—Specialist;" Oregon: § 44.01 Duty of Medical Professional" and § 44.02 Duty of Specialist;" Pennsylvania: § 14.10 "Medical Malpractice—Standard of Care;" Rhode Island: § 1701.1 "Duty to Exercise Professional Skill in Treatment;" South Carolina: § 27-2 "Medical Malpractice - Standard of Care of a Physician;" South Dakota: § 14.10 "Physician's Standard of Care;" Tennessee: § 6.10A "Duty of Physician" and § 6.11 "Duty of Specialist;" Texas: § 50.1 "Physician's Degree of Care;" Utah: § 301C "'Standard of care' defined;" Vermont § 7–7.0 "Elements of a Medical Malpractice Claim;" Virgina: No. 35.000 "Statewide Standard of Care for Health Care Providers;" Washington: § 105.01 "Negligence—General Health Care Provider" and § 105.02 "Negligence—Health Care Provider—Specialist;" West Virgina: § 502. "Standard of Care;" Wisconsin: § 1023 "Medical Negligence;" and Wyoming: § 14.02. "Medical Malpractice— Standard of Care— Defined" and § 14.03 "Standard of Care—Duty of a Specialist."

[19]James O. Pearson, Jr., Annotation, *Modern Status of "Locality Rule" in Malpractice Action Against Physician Who is Not a Specialist*, 99 A.L.R.3d 1133 (1980).

[20]*Id.*

But that rule has now been largely debunked. As one court explained more than four decades ago, the "locality rule has been quite properly criticized as a relic of the nineteenth century which has no relevance to the realities of modern medical practice."[21] Or, as more practically stated by the Mississippi Supreme Court in its landmark decision of *Hall v. Hilbun*:

> We would have to put our heads in the sand to ignore the "nationalization" of medical education and training. Medical school admission standards are similar across the country. Curricula are substantially the same. Internship and residency programs for those entering medical specialties have substantially common components. Nationally uniform standards are enforced in the case of certification of specialists… . Regarding the basic matter of the learning, skill and competence a physician may bring to bear in the treatment of a given patient, state lines are largely irrelevant.[22]

The new Restatement makes clear that the locality rule is no longer sustainable and that, instead, a national reasonable physician standard of care defines the obligations of a healthcare provider.[23] Nonetheless, as discussed in Section V(C) below, by allowing the medical profession or other "authoritative" sources to craft practice guidelines that could then be used as a standard of care, § 6(b) could resurrect locality rules through the back door.

The new class of defendant-only, potentially dispositive evidence that is envisioned by § 6(b) will tilt the scales of justice in favor of the medical profession, not just by opening the door to locality rules, but also by providing defendants with a new class of prima facie evidence that would eliminate the need for expert testimony and by stripping away plaintiffs' rights to cross-examination. And this is being proposed for a fraught area of law where plaintiffs already face significant disadvantages.[24]

II. The Rise and Problematic Nature of Practice Guidelines

A. The Advent and Theory of Practice Guidelines

Practice guidelines came to the fore in the latter half of the twentieth century, although their existence took form earlier.[25] They developed in response to studies that demonstrated that medical care was

[21]Morrison v. MacNamara, 407 A.2d 555, 563 (D.C. Cir. 1979).

[22]Hall v. Hilbun, 466 So. 2d 856, 870 (Miss. 1985).

[23]Medical Malpractice, *supra* note 17, at § 5, cmt. *m*.

[24]Studies conducted by the Justice Department's Bureau of Justice Statistics consistently show that medical-malpractice plaintiffs prevail in only twenty-three to twenty-seven percent of cases, as compared to an even split in other tort cases. Carol J. DeFrances & Marika F.X. Litras, Bureau Just. Stats., Civil Trial Cases and Verdicts in Large Counties, 1996 6 (1999); Thomas H. Cohen, Bureau Just. Stats., Tort Trials and Verdicts in Large Counties, 2001 4 (2004); Thomas H. Cohen, Bureau Just. Stats., Medical Malpractice Trials and Verdicts in Large Counties, 2001 1 (2004). Moreover, most states have adopted or imposed special and intensive requirements before a medical-malpractice lawsuit may be filed. *See generally* Steven E. Pegalis, American Law of Medical Malpractice § 9:1 (3d ed. 2024) (discussing malpractice statutes); *see also* Gabriel H. Teninbaum & Benjamin R. Zimmermann, *A Tale of Two Lawsuits*, 8 J. Health & Biomedical L. 443, 443 (2013) (describing the differences between "bringing a garden-variety lawsuit for negligence, and bringing a claim for negligent medical care"). In addition, medical-malpractice lawyers must "invest thousands of dollars in deciding whether to take a case, and that expenditure does not include the internalized costs of having nurses, nurse-lawyers, or physician-lawyers on staff." Stephen Daniels & Joanne Martin, *Plaintiffs' Lawyers, Specialization, and Medical Malpractice*, 59 Vand. L. Rev. 1051, 1063 (2006). And then, many states impose artificial limitations on damages solely in medical-malpractice cases. *See* Carly N. Kelly & Michelle M. Mello, *Are Medical Malpractice Damages Caps Constitutional? An Overview of State Litigation*, 33 J.L. Med. & Ethics 515, 516 (2005) (reporting that more than half the states cap noneconomic damages as of 2005).

[25]A consensus appears to have emerged that the first modern practice guidelines emerged in the 1940s. *See* John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. Legal Med. 421, 421 (1994) (indicating the use of medical practice guidelines over the preceding fifty years); Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. Pa. L. Rev. 645, 649 (2001) (noting that clinical practice guidelines have been "part of medical practice for more than half a century").

wildly uneven, that customary medical practices lacked solid scientific support, and that some medical and surgical procedures were overused as a habitual response that lacked legitimate bases.[26] Research demonstrated, for example, inexplicably large differences in diagnostic procedures utilized and treatment options pursued, including when to perform surgery, among Medicare beneficiaries across medical and surgical specialties and that medical providers used quite different diagnostic and treatment approaches for the same patient issues, yet nothing in medical science supported many of the approaches that were followed.[27] As a result of that growing disaffection with the quality of health care, medical groups, starting with the American College of Physicians, began to craft practice guidelines intended to improve the state of medical care.[28]

The federal government joined the efforts, creating the Agency for Health Care Policy & Research ("AHCPR")[29] in 1989 "to enhance the quality, appropriateness, and effectiveness of health care services and access to those services."[30] Congress charged an office within the AHCPR with responsibility for "facilitating the development, periodic review, and updating of clinical practice guidelines," in order to "assist practitioners in the prevention, diagnosis, treatment, and management of clinical conditions."[31]

Soon, different medical organizations and groups decided to participate in the act, resulting in a "plethora of diagnostic and therapeutic treatment recommendations from many national medical organizations."[32] Among those attempting to develop guidelines were the American College of Physicians, the Blue Cross and Blue Shield Association, and the American Medical Association, which worked with a wide range of medical specialty societies.[33] The American Council of Medical Specialty Societies urged even broader participation throughout the medical profession and their groups in defining medical standards through guidelines in 1987.[34] By 1994, more than 1600 guidelines developed by more than sixty organizations existed,[35] causing the American Medical Association to attempt to catalog them in an effort to assist doctors in narrowing their choices to an appropriate set of guidelines.[36] A short seventeen years later, the Editorial Board of the *Annals of Internal Medicine* stated that "the development of thousands of clinical practice guidelines by hundreds of groups in dozens of countries creates its own tangle for clinicians to unravel."[37] The editors of the *Annals* explained that this "dizzying array of diagnostic and therapeutic options, along with the wide variation in evidence to support them, challenges the provision of rational medical care" and "could very well become part of the very problem they aim to solve."[38] In fact, the National Guideline Clearinghouse, created as part of the AHCPR, reported the existence of so many guidelines that cataloging them no longer made sense and funding for the effort

[26] *See* Jerome P. Kassirer, *The Quality of Care and the Quality of Measuring It*, 329 New Eng. J. Med. 1263, 1263 (1993); Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 Law & Contemp. Probs. 87, 88-89 (1991).

[27] Mark R. Chassin et al., *Variations in the Use of Medical and Surgical Services by the Medicare Population*, 314 New Eng. J. Med. 285, 286–89 (1986).

[28] Havighurst, *supra* note 26, at 89.

[29] Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 901, 103 Stat. 2106, 2189 (1989) (codified as amended at 42 U.S.C. § 299).

[30] William R. Trail & Brad A. Allen, *Government Created Medical Practice Guidelines: The Opening of Pandora's Box*, 10 J.L. & Health 231, 233–34 (1996).

[31] *Id.* at 234 (quoting Agency for Health Care Policy and Research, U.S. Dep't of Health and Human Services, Public Health Service, Clinical Practice Guideline: Depression in Primary Care: Treatment of Major Depression (inside cover) (1993)).

[32] Ayres, *supra* note 25, at 421.

[33] Eleanor D. Kinney, *The Brave New World of Medical Standards of Care*, 29 J.L. Med. & Ethics 323, 324 (2001).

[34] *Id.*

[35] Ayres, *supra* note 25, at 421. Practice guidelines have continued to grow. They have now burgeoned to a staggering number, numbering nearly 3000, promulgated by more than 350 different entities. Ronen Avraham, *Overlooked and Underused: Clinical Practice Guidelines and Malpractice Liability for Independent Physicians*, 20 Conn. Ins. L.J. 273, 275 (2014).

[36] Ayres, *supra* note 25, at 421.

[37] Christine Laine et al., *Trustworthy Clinical Guidelines*, 154 Annals Internal Med. 774, 774 (2011).

[38] *Id.*

expired.[39] As reported by the Clearinghouse, there were 471 different guidelines for hypertension and 276 for stroke as of 2013.[40]

As guidelines proliferated, litigation critics and special interest groups sought to convert them into defensive tools that would provide safe harbors for medical defendants. Although intended to assist physicians and patients in reviewing care alternatives and strategies, they quickly were co-opted by insurers to determine health insurance coverage.[41] Tort reformers quickly latched onto them to use in tort-reform defensive shield laws[42] but as policy makers came to understand the inherent problems with practice guidelines, those efforts fritted away.[43] Later, some academics, including the main Medical Malpractice Restatement Reporter,[44] argued for litigation reforms based on practice guidelines; other commentators demurred pointing to the many problems that made that an impossibility.[45] But the problems inherent in practice guidelines do not end with their proliferation; they go much deeper.

B. Quality and Credibility Problems with Practice Guidelines

It is self-evident that all practice guidelines are not equal. As Professor Dan Dobbs, a leading torts authority, recognizes, "[a]ny organization—a local medical society, a hospital, a national association of medical specialists, or state-organized commissions can publish protocols or guidelines."[46] Even actuarial service firms, utilizing actuarial methodologies rather than medical science, can develop practice guidelines.[47] Different guidelines addressing the same topic provide inconsistent and conflicting blueprints for diagnosis and treatment because there is no "centralized authority to coordinate, vet, approve, and catalog guidelines," and there is "an absence of a universal methodology to create guidelines."[48] Each professional organization that chooses to promulgate a guideline "decides freely which, if any, framework they will use to construct guidelines," and the guidelines produced remain "susceptibl[e] to bias and conflicts of interest," while they also often "suffer from a lack of rigor and applicability."[49]

Clinical Practice Guidelines (CPGs), are deemed the closest to the gold standard in the medical profession because they are supposedly evidence-based, rather than consensus documents from a

[39] *See* Melissa Ballengee Alexander, *Disclosing Deviations: Using Guidelines to Nudge and Empower Physician-Patient Decision Making*, 19 Nev. L.J. 867, 915–16 (2019).

[40] Gilbert Benavidez & Austin B. Frakt, *Fixing Clinical Practice Guidelines*, Health Affs. (Aug. 5, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20190730.874541/full/.

[41] Ayres, *supra* note 25, at 422.

[42] *See* Mello, *supra* note 25, at 668–77.

[43] For example, the Office of Technology Assessment (OTA), a congressional research agency, advised that "[i]f courts and legislatures are not selective about which guidelines are introduced as evidence, these conflicts may find their way into the courts and further confuse rather than clarify the process of determining negligence." Off. of Tech. Assessment, Impact of Legal Reforms on Medical Malpractice Costs, 33 (1993). The RAND Institute for Civil Justice similarly warned that competing guidelines with vastly different advice would not clarify the standard of care but "simply elevate the 'battle of experts' that often occurs to a 'battle of guidelines.'" Eleanor D. Kinney et al., *Report of the Medical Guidelines Panel*, *in* RAND Institute for Civil Justice, Conference Proceedings: Health Care Delivery and Tort: Systems on a Collision Course?, 58 (Elizabeth Rolph ed., 1992).

[44] *See* Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 L. & Contemp. Probs. 119, 120–21 (1991) (arguing that the optimal use of practice guidelines would be as conclusive evidence of the medical standard of care); Medical Malpractice, *supra* note 17, at iv (listing the reporters of the Medical Malpractice Restatement).

[45] *E.g.*, Mello, *supra* note 25, at 648 (use of practice guidelines as a legal standard of care "is deeply problematic"); Maxwell J. Mehlman, *Professional Power and the Standard of Care in Medicine*, 44 Ariz. St. L. J. 1165, 1211-25 (2012) (describing the many problems in the use of practice guidelines to establish a standard of care).

[46] Dan B. Dobbs et al., The Law of Torts § 295 (2d ed. 2011).

[47] *See* Jodi M. Finder, *The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?*, 10 Health Matrix 67, 72 (2000).

[48] Benavidez & Frakt, *supra* note 40.

[49] *Id.*

medical association's leaders.[50] Even so, as a committee of the Institute of Medicine found in 1990, "the process of systematic development, implementation, and evaluation of practice guidelines based on rigorous clinical research and soundly generated professional consensus, although progressing, has deficiencies in method, scope, and substance."[51] The validity of CPGs has not improved in the intervening decades. In 2012, a study of 130 CPGs found that they failed to meet the quality standards set by the Institute of Medicine.[52] A recent, respected study on the efficacy and propriety of clinical practice guidelines, published in *Injury*, showed that up to fifty percent of guidelines are considered untrustworthy within the profession.[53]

In fact, researchers found that CPGs often "promote more care rather than more effective care," prioritize "use as marketing and opinion-based pieces rather than roadmaps to improved medical care," and display an inability to overcome "population-based recommendations" in favor of actual individualized needs.[54] Researchers also complain that "it remains unclear which CPGs are still authoritative," given that "[o]ptimal medical procedures change over time," and the difficulty in "determin[ing] when the weight of evidence has caused a justifiable shift against a certain treatment that should result in a change to the relevant CPGs."[55] A factor that explains why CPGs may remain unchanged long after their useful life has ended is that CPGs typically "cost at least $200,000 to produce and substantial amounts to revise."[56]

CPGs, as well as other practice guidelines, can also reflect different standards of care for the same diagnosis. Some seek optimal care, while others, such as the Federal Guidelines for Opioid Treatment Programs, explicitly state that they "describe a minimum acceptable standard for the operation of OTPs."[57] The Institute for Medicine's famous study, *To Err is Human*, declares that "[t]he development and availability of standards for patient safety can serve several purposes."[58] One of those purposes seeks to "establish minimum levels of performance."[59] For example, the American Psychological Association's CPG for Treatment of Depression indicates only that the guidelines are "aspirational," not "exhaustive" or "definitive" and "may not be applicable to every professional and clinical situation."[60]

Perhaps one explanation for the vote of no confidence is that even the more rigorous CPGs engender uneven methodologies,[61] variance in quality,[62] and a failure to keep up with advances in scientific and

[50]Viviane C. Pereira et al., *Strategies for the Implementation of Clinical Practice Guidelines in Public Health: An Overview of Systematic Reviews*, 20 Health Rsch. Pol'y & Sys. at 2 (2022).

[51]Institute of Medicine, Clinical Practice Guidelines: Directions for a New Program 6 (Marilyn J. Field & Kathleen N. Lohr eds., 1990).

[52]Justin Kung et al., *Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards: Two More Decades of Little, if Any, Progress*, 172 Archives of Internal Med. 1628, 1628 (2012).

[53]Ernesto Guerra-Farfan et al., *Clinical Practice Guidelines: The Good, The Bad, and The Ugly*, 54 Inj. S26, S27 (2023); *cf.* Stephen H. Woolf et al., *Clinical Guidelines: Potential Benefits, Limitations, and Harms of Clinical Guidelines*, 318 Brit. Med. J. 527 (1999) (finding that guidelines rely on the absence of scientific evidence or misinterpret that evidence, often fail to account what individual patients require, and frequently adopt "suboptimal, ineffective, or harmful practices" to control costs or "protect special interests," such as risk managers).

[54]Kung, *supra* note 52, at 1628.

[55]Avraham, *supra* note 35, at 284.

[56]*Id.*

[57]Substance Abuse & Mental Health Servs. Admin., HHS Pub. No. PEP15-FEDGUIDEOTP, Federal Guidelines for Opioid Treatment Programs 4 (2015)

[58]Comm. on Quality of Health Care in Am., Inst. of Med., To Err is Human: Building a Safer Health System 132 (Linda T. Kohn et al. eds., 2000).

[59]*Id.*

[60]Am. Psych. Ass'n, APA Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts II (2019).

[61]*See* Comm. on Standards for Developing Trustworthy Clinical Prac. Guidelines, Inst. of Med., Clinical Practice Guidelines We Can Trust 65–66 (Robin Graham et al. eds., 2011).

[62]Melissa C. Brouwers et al., *AGREE II: Advancing Guideline Development, Reporting and Evaluation in Health Care*, 182 Canadian Med. Ass'n J. E839, E839 (2010).

medical knowledge.[63] In fact, researchers uniformly recommend that CPGs be updated every three to five years.[64]

Beyond that, many guidelines are riddled with objectivity and credibility issues that cast serious doubt on any claim to self-authentication. For example, one study of practice guidelines led by Dr. Justin Kung disclosed that ninety-one percent of co-chairs of guideline drafting committees and many other guideline committee members had serious conflicts of interest, guideline committees rarely included patient representatives or information scientists, and many guidelines were outdated.[65] And as found by Professor Avraham:

> Authors [of practice guidelines] often have conflicts of interest that may or may not be disclosed, guidelines are created that recommend conflicting treatments, and there is no system in place to ensure that CPGs are updated or that outdated recommendations are removed from circulation.[66]

Take, for example, oncology, which has competing CPGs for lung cancer which use different update protocols so that the choice of the guideline will reflect different snapshots of contemporary treatment knowledge.[67] Thus, their conflicts do not reflect differences in philosophy, as other guidelines might, as much as differences based on the timing of their publication.

One set of oncology guidelines, promulgated by the National Comprehensive Cancer Network, is updated several times a year to keep up with rapid advances, which takes on high importance given the nature of modern cancer research.[68] The other set, offered by the American Society of Clinical Oncologists, is revisited significantly less often.[69] As a result, the first would appear to reflect the latest science, while the other seems to lag behind. Yet, a study in the *Journal of Thoracic Disease* discusses the relative weaknesses of both guidelines, as well as some alternatives developed by foreign medical organizations.[70] It found the American Society's CPG "lack[s] a continuous or time-predefined updating, and, at least at some time points, their applicability in this rapid evolving field is substantially limited," noting that at the time of this 2018 study, the guidelines were still based on 2015 knowledge.[71] At the same time, the National Network's CPG, which had been updated in December 2017, provides different recommendations for treatment yet provided weaker comparative tools to help clinicians make decisions on courses of treatment.[72] Yet another criticism of the National Network's CPG is the absence of as robust a methodologic background as others employed.[73] There may be instances where a healthcare provider could justifiably use either CPG, but there are also times where, based on representations made to the patient about the currency of the treatment or the depth of rigor employed, that only one would be appropriate. The approach taken by the Restatement leaves no room for those types of considerations, especially if the guidelines are introduced as stand-alone evidence.

Still, both are likely to be viewed as "authoritative" under § 6(b) and, in places, may demonstrate express differences, not unlike the experts that plaintiffs and defendants would call to the stand. In

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[63] *See* Robin W.M. Vernooij et al., *Guidance for Updating Clinical Practice Guidelines: A Systemic Review of Methodological Handbooks*, 9 Implementation Sci. art. no. 3, at 6–7 (2014).

[64] Pablo Alonso-Coello et al., *The Updating of Clinical Practice Guidelines: Insights from an International Survey*, 6 Implementation Sci. art. no. 107, at 1 (2011); *see also* Paul G. Shekelle et al., *When Should Clinical Guidelines be Updated?*, 323 Brit. Med. J. 155 (2001)[; Paul G. Shekelle et al., *Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines: How Quickly Do Guidelines Become Outdated?*, 286 J. Am. Med. Ass'n 1461 (2001).

[65] Kung, *supra* note 52, at 1630.

[66] Avraham, *supra* note 35, at 277.

[67] *See* Paolo Bironzo & Massimo Di Maio, *A Review of Guidelines for Lung Cancer*, 10 J. Thoracic Disease S1556 (2018).

[68] *See id.* at S1560.

[69] *See id.* at S1561.

[70] *Id.* at S1556.

[71] *Id.* at S1561.

[72] *Id.*

[73] *Id.*

testimony, defense experts sometimes testify that the defendant conformed to the standard of care.[74] Yet, in a significant number of states, plaintiffs are then entitled on cross-examination to ask about the expert's personal practices, which might involve a higher standard of care than his testimony suggested was sufficient.[75] Thus, for example, Illinois courts recognize that "where the expert says the standard of care requires procedure A and only procedure A, but that he personally performs procedure A and, for various reasons, additionally performs test B," that has relevance to the expert's credibility on the applicable standard of care.[76] Other states take the same approach.[77]

More troubling, practice guidelines have often been devised for the express purpose of providing defendants with litigation advantages. The American Colleges of Medicine, with its various specialty practices, are thought to be among the premier medical organizations of the United States. Clearly, they meet § 6(b)'s definition for authoritativeness, yet even they can devise practice guidelines to skew litigation against plaintiffs.[78]

Even when guidelines do not suffer from objectivity and credibility issues, due to the *sui generis* nature of medical illnesses and conditions, many guidelines will not have sufficient specificity to address the same or similar conditions in the case at hand, a point that is at least partially conceded in the Restatement.[79] Researchers have noted that progenitors of guidelines do not account for "personal circumstances and medical history" and therefore fail to "tailor care" appropriately, while typically providing "blanket recommendations" that can be contraindicated by a patient's individualized needs.[80] Instead, practice guidelines are "best suited for clinical scenarios that are simple and standardized," rather than those that involve additional levels of complexity due to multiple health issues.[81]

Apart from the objectivity and credibility issues, there is also the problem created by conflicting guidelines. In 2009, the United States Preventive Services Task Force recommended a guideline that women, ages forty to forty-nine, who do not have family histories of breast cancer, should no longer routinely receive mammograms or be encouraged to perform breast self-exams.[82] The American

[74]*See* B. Sonny Bal, *The Expert Witness in Medical Malpractice Litigation*, 467 Clinical Orthopaedics & Related Rsch. 383, 384 (2008).

[75]*See* Benjamin Ikuta, *An Opposing Expert's Personal Practices Are Always Relevant and Should Be Admissible in Your Medical Malpractice Case*, 54 Consumer Att'ys Cal. F. 44 (2024).

[76]Schmitz v. Binette, 857 N.E.2d 846, 856 (Ill. App. Ct. 2006).

[77]*See, e.g.*, Oaks v. Chamberlain, 76 N.E.3d 941, 950–51 (Ind. Ct. App. 2017); Condra v. Atlanta Orthopaedic Grp., 681 S.E.2d 152, 154 (Ga. 2009); Smethers v. Campion, 108 P.3d 946, 955 (Ariz. Ct. App. 2005); Wallbank v. Rothenberg, 74 P.3d 413, 416–17 (Colo. App. 2003) (letting jury consider whether all the testifying experts personally would have performed additional testing even though the defense experts testified that the additional testing was a personal preference and not a requirement of the standard of care).

[78]*See* Adams v. Lab'y Corp. of Am., 760 F.3d 1322, 1331 (11th Cir. 2014) (finding that College of American Pathologists and the American Society of Cytopathology guidelines were created "to limit how the courts can find the members of the organizations liable for professional negligence when they are sued."). In *Adams*, the purpose of the guidelines was apparent from the face of the documents. Given the outcome in *Adams*, it is doubtful that any future guidelines will be even remotely as transparent.

[79]Medical Malpractice Practice Guidelines, *supra* note 3, § 6(b), Reporter's Note, cmt. *f.* (noting that ("Clinical guidelines often have only limited bearing on disputed aspects of a particular medical situation because they address only some aspects" of the case). The uniqueness of patient cases is sometimes referred to as the "snowflake" effect. For that reason, customary practices do not determine the standard of care. *See, e.g.*, Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 Wash. & Lee L. Rev. 163, 187 (2000) (noting that for customary practices, the "variability in patients, illnesses, and possible therapeutic responses often will make the notion of an established custom a quaint fairy tale."). The same difficulty arises in trying to craft standards of care from practice guidelines.

[80]Woolf, *supra* note 53, at 529.

[81]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, 847 (2002).

[82]U.S. Preventive Servs. Task Force, *Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement*, 151 Annals Internal Med. 716, 716 (2009). The Restatement treats the U.S. Preventive Services Task Force as an authoritative source of guidelines that courts should accept. *See* Medical Malpractice Practice Guidelines, *supra* note 3, § 6, Illustration 4. We note, however, that on January 10, the Supreme Court granted certiorari to consider whether appointments to that task force complied with constitutional requirements. Becerra v. Braidwood Mgmt., Inc., No. 24-316, 2025 WL 65913, at *1 (U.S. Jan. 10, 2025). The Fifth Circuit held that the task force members are principal officers who must be constitutionally

Medical Association called the change from a guideline issued seven years earlier that recommended screening every one to two years "ill-advised."[83] The American Cancer Society reached the opposite conclusion with the same data and recommended a completely different guideline.[84] Today, the United States Preventive Services Task Force recommends screening every other year beginning at age forty,[85] while the American Cancer Society endorses yearly screening no later than age forty-five.[86] Despite those changed guidelines, individual patients may require different recommendations based on family history, other health issues, and their environment[87]—essentially a more individualized assessment than guidelines could provide. Similar issues have arisen with respect to prostate-specific antigen (PSA) tests as a means to detect prostate cancer.[88] Three national guidelines, promulgated by the United States Preventive Services Task Force, the American Cancer Society, and the American Urological Association, recommend that men start prostate cancer testing at age fifty or fifty-five years old, but discontinue it at age seventy.[89] Yet guidelines also exist from at least 607 cancer centers accredited by the Commission on Cancer, seventy-eight percent of which have no upper limit on when to cease screening.[90]

Another well-publicized conflict was the disagreement between the Infectious Diseases Society of America (IDSA) and the International Lyme and Associated Diseases Society (ILADS) over proper treatment for Lyme disease.[91] The IDSA adopted restrictive guidelines that seemed to deny that chronic Lyme disease existed.[92] The panel it convened to develop guidelines "believed that Lyme disease can be easily treated, and cured, with short-term antibiotics."[93] After receiving complaints that insurers did not cover those treated under the IDSA guidelines, while doctors prescribing long-term antibiotics to treat it as a chronic condition were subjected to investigation and prosecution because they departed from the guidelines, the Connecticut Attorney General became involved, eventually threatening an antitrust action against the IDSA.[94] His investigation found that the IDSA guidelines substantially ignored or diminished the science to reach its conclusions, utilized people who had substantial financial interests in companies making relevant drugs or diagnostic tests, or consulted insurance companies, which were chosen to be part of the panel to draw the guidelines because of a predisposition to deny that Lyme disease was a chronic condition, and froze out those who might dissent from that predisposition.[95] To settle the matter, the IDSA agreed to reassess its guidelines using an neutral review panel,[96] but the old

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nominated by the president and approved by the Senate. *See* Braidwood Mgmt., Inc. v. Becerra, 104 F. 4th 930, 947 (5th Cir. 2024), *cert. granted*, No. 24-316, 2025 WL 65913 (U.S. Jan. 10, 2025), and *cert. denied sub nom.* Braidwood Mgmt. Inc v. Becerra, No. 24-475, 2025 WL 76462 (U.S. Jan. 13, 2025). If upheld, the task force had and will have no authority to issue "official" or "authoritative" guidelines.

[83]Natalia Gray & Gabriel Picone, *The Effect of the 2009 U.S. Preventive Services Task Force Breast Cancer Screening Recommendations on Mammography Rates*, 51 Health Servs. Rsch. 1533, 1534 (2016).

[84]*History of ACS Recommendations for the Early Detection of Cancer in People Without Symptoms*, Am. Cancer Soc'y (Nov. 1, 2023), https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/overview/chronological-history-of-acs-recommendations.html [https://perma.cc/5PB9-PXGM].

[85]*A & B Recommendations*, U.S. Preventive Servs. Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations [https://perma.cc/EC2S-2PQS].

[86]Kevin C. Oeffinger et al., *Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update from the American Cancer Society*, 314 J. Am. Med. Ass'n 1599, 1603 (2015).

[87]*See id.* at 1609.

[88]*See* Elizabeth S. Koh et al., *Comparison of US Cancer Center Recommendations for Prostate Cancer Screening with Evidence-Based Guidelines*, 182 J. Am. Med. Ass'n Internal Med. 555, 556 (2022).

[89]*Id.*

[90]*Id.* at 557.

[91]*See* Susan Ronn, *In the Lymelight: Law and Clinical Practice Guidelines*, 102 S. Med. J. 626, 626 (2009).

[92]Tammy Asher, *Unprecedented Antitrust Investigation into the Lyme Disease Treatment Guidelines Development Process*, 46 Gonz. L. Rev. 117, 122–24 (2010/11).

[93]*Id.* at 122.

[94]*Id.* at 124.

[95]Conn. Att'y Gen.'s Off., *Press Release: Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines, Install Independent Arbiter*, Richard Wolfram, Esq. (May 1, 2008), https://www.rwolframlex.com/images/Lyme_CT_AG_press_release_re-settlement.pdf [https://perma.cc/8ZKP-T8JK].

[96]*Id.*

problematic guidelines remained in place in the interim.[97] Even the process for approving the revised guidelines proved problematic, with the Connecticut Attorney General suggesting that it was inconsistent with the settlement.[98] Despite these problems, § 6(b) would treat the guidelines with a preferential status capable of rebutting alternative standards of medicine.

None of this should be surprising given that there is no structural mechanism or standards for the development and maintenance of practice guidelines. To fill the gap, the Institute of Medicine issued guideline standards[99] but, without an enforcement mechanism, guideline promulgators remained free to do as they like. Others have called for a guideline-certifying agency or for government control but that is practically and politically inconceivable.[100] The resistance to the loss of professional autonomy and independence that could happen with "cookbook medicine" is too ingrained in the medical profession, to say nothing of the distrust of government processes.[101]

With scant acknowledgement of these inherent problems,[102] the Institute has endorsed this controversial and problematic experiment as a recommendation to courts that puts a heavy thumb on the scale in favor of malpractice defendants.[103] Of equal concern, the approach adopted in the Restatement lacks jurisprudential support.

III. The Restatement's Approach to Practice Guidelines Lacks Jurisprudential Support

As the Medical Malpractice Restatement concedes, there is little case law support for § 6(b).[104] It justifies proceeding with a rule change anyway by claiming this dearth of support is because defendants have greater access to medical experts, do not bear the burden of proof, and, therefore, have seldom pressed the use of practice guidelines on appeal.[105] And while Restatements historically do not address matters of evidence, leaving that to advisory committees and local law,[106] it claims that § 6(b) is not delving into matters of evidence because it is not a rule of evidence but rather a substantive legal change. We examine these claims, as well as the relevant case law.

A. No Jurisdictional Support for Changing Hearsay to Prima Facie Evidence

The proposition that defendants have not pressed for judicial approval for the use of practice guidelines as substantive evidence does not justify launching a new rule creating exculpatory evidence for them. If

[97] Asher, *supra* note 92, at 125–26.

[98] Lisa Chamoff, *AG Chides Lyme Panel for Not Following Settlement Agreement*, CTPOST (Feb. 10, 2010), https://www.ctpost.com/local/article/ag-chides-lyme-panel-for-not-following-settlement-360029.php.https://www.ctpost.com/local/article/ag-chides-lyme-panel-for-not-following-settlement-360029.php., https://www.ctpost.com/local/article/ag-chides-lyme-panel-for-not-following-settlement-360029.php.

[99] COMM. ON STANDARDS FOR DEVELOPING TRUSTWORTHY CLINICAL PRAC. GUIDELINES, *supra* note 61, at ix.

[100] *See* Megan L. Sheetz, *Toward Controlled Clinical Care Through Clinical Practice Guidelines: The Legal Liability for Developers and Issuers of Clinical Pathways*, 63 BROOK. L. REV. 1341, 1378–80 (1997).

[101] Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POLS., POL'Y & L. 327, 345, 349 (2001).

[102] The Reporters' Note for Section 6(b) acknowledges that some have criticized clinical guidelines as "biased by professional or industry self-interest, or for not being developed with sufficient rigor," citing only two of the many critiques, and then quickly suggests that "additional case-law development will be needed" to address that problem. MEDICAL MALPRACTICE PRACTICE GUIDELINES, *supra* note 3, § 6, Reporters' Note, cmt. *f*.

[103] MEDICAL MALPRACTICE, *supra* note 17, §6, cmt. *f* ("Subsection (b)'s endorsement of authoritative guidelines is asymmetric. Although such evidence can also be relevant to a plaintiff's case to reinforce or rebut expert testimony, this Subsection permits authoritative practice guidelines to substitute for expert testimony only when the guidelines support compliance with, but not to establish a violation of, § 5's standard of care.").

[104] *Id.* § 6, Reporters' Note, Cmt. *f* ("[C]ase law is not well developed on the defensive use of authoritative standard-of-care guidelines.").

[105] *Id.* § 6, cmt. *f*.

[106] *Id.* §§ 5, cmt. *a*, 6, cmt. *a* ("This Section does not address the characteristics required to qualify as an expert. It leaves that matter to the evidence law in each jurisdiction.").

anything, that defendants have not sought this change should be a strong indication that it is not needed, at least in the view of defendants. And rather than enjoy limited case law support, as the Reporters suggest,[107] there in fact is *no* case law support for recharacterizing practice guidelines as non-hearsay documents when they are offered by defendants. The main authority cited in support of § 6(b) is a concurring opinion in an unreported case, *Frakes v. Cardiology Consultants, P.C.*[108]

However, the claim of support is imaginary. In *Frakes*, in apparent compliance with the hearsay exception for learned treatises, the defense used a table from the American College of Cardiology "very effectively to impeach" the plaintiff's expert.[109] The defense then had their experts testify that the table represented the standard of care and offered it into evidence.[110] In affirming a defense verdict because no expert questioned the table and deferring to the trial court's sound discretion in admitting evidence, the court nonetheless held, "[w]e hesitate to give an unqualified endorsement to the concept that a hearsay document can be transmitted into non-hearsay by virtue of its adoption by a witness."[111]

In his concurring opinion, Judge Koch observed that "[p]roperly authenticated clinical practice guidelines are relevant to the question of the proper standard of care and should be admitted as substantive evidence if introduced through a witness who can lay a proper foundation."[112] Although he suggested the guidelines "can be extremely helpful in cases calling into question whether a physician chose the wrong course of diagnosis or treatment or should have gone further in attempting to understand or correct the situation," he still denied that they should be viewed as "conclusive evidence of the standard of care."[113] He further stated that "[p]roof of compliance with practice guidelines should not necessarily establish due care; just as proof of non-compliance should not establish negligence per se."[114] Calling this concurrence the "most direct authority" to support the Restatement's position on practice guidelines,[115] stretches this one-judge, four-paragraph opinion beyond all recognition. Judge Koch did not posit that practice guidelines could be self-authenticating or that, standing alone, they could be a substitute for expert testimony or that they could be sufficient to defeat a plaintiff's claim. Significantly however, after more than a quarter of a century, no subsequent decision in Tennessee or in any other jurisdiction has relied on Judge Koch's suggestion that practice guidelines should be admitted as substantive evidence.

It is also a stretch to claim, as the Restatement does,[116] that two other cases, *Arpin v. U.S.*,[117] and *Dalmia v Palffy*,[118] partially support allowing practice guidelines to substitute for the standard of care. Both decisions involve expert-witness qualifications—[119] neither call for practice guidelines to serve as stand-alone substitutes for expert testimony or as establishing a standard of care. In *Arpin*, where plaintiff's decedent husband was seen by a resident physician who misdiagnosed the patient but not by the supervising physician, it was held that the plaintiff's expert was unqualified to opine that the supervising physician had a duty to examine the plaintiff.[120] In a passing comment, the court noted that Medicare reimbursement rules excuse attending physicians from having to examine or otherwise observe a resident's patient.[121] The court pointedly did not hold, as the Restatement reporters claim,[122]

[107] *Id.* § 6, cmt. *f* ("[T]here is only limited case-law support for Subsection (b).").

[108] Frakes v. Cardiology Consultants, P.C., No. 01-A-01-9702-CV-00069, 1997 WL 536949, at *5–6 (Tenn. Ct. App. Aug. 29, 1997) (Koch, Jr., J., concurring).

[109] *Id.* at *4 (majority opinion).

[110] *Id.*

[111] *Id.* at *4–5.

[112] *Id.* at *6 (Koch, Jr., J., concurring).

[113] *Id.*

[114] *Id.*

[115] Medical Malpractice, *supra* note 17, §6, Reporters' Note, cmt. *f.*

[116] *Id.*

[117] Arpin v. United States, 521 F.3d 769 (7th Cir. 2008).

[118] Dalmia v. Palffy, No. 281706, 2009 WL 4344088 (Mich. Ct. App. Dec. 1, 2009).

[119] *Arpin*, 521 F.3d at 772-73; *Dalmia*, 2009 WL 4344088, at *1.

[120] *Arpin*, 521 F.3d at 772-73.

[121] *Id.* at 773.

[122] Medical Malpractice, *supra* note 17, § 6, Reporters' Note, cmt. *f.*

that the Medicare rule established a standard of care,[123] but held, based on the facts presented, that the "breach of the duty of care [was] so fundamental as not to require expert evidence to establish."[124] And in *Dalmia*, the court held that it was not an abuse of discretion for the trial court to find that plaintiff's expert opinion was not generally accepted or supported by strong science methods.[125] Although the defense offered some practice guidelines that confirmed issues with the plaintiff's expert's testimony, there was no holding that practice guidelines constituted a standard of care because the "[p]laintiff failed to offer any reliable evidence to support his opinion."[126]

While no court has approved the use of practice guidelines as prima facie evidence of the standard of care, courts in New York, Ohio, and the Eleventh Circuit reviewing a *Daubert* determination have rejected claims that practice guidelines constitute the standard of care that can, standing alone, compel the rejection of a plaintiff's evidence or case.[127] None of these cases are referenced in the comment or Reporters' Note to § 6(b).[128]

The proposed rule would also be a sharp departure from all other Restatements on professional liability. There is no such prima facie provision or, for that matter, defendant-only provision, for lawyers, accountants, or other professionals and those practicing skilled trades.[129] For all other professionals, there is no special rule for guidelines and industry standards; if used by either party, either inculpatorily and exculpatorily, it occurs under the learned treatise exception to the rule against hearsay.[130]

B. Asymmetry is Unfounded Because the Value of Guidelines from an Authoritative Source Does Not Differ When Used by a Plaintiff or Defendant

Turning to the asymmetrical aspect of this new rule, the Restatement does not cite a single case to support the limitation of § 6(b) that would prevent plaintiffs from also using practice guidelines in an inculpatory manner. That "one-way street" feature has been a common element in tort reform proposals, driven by legislators' desires to assure physicians that practice guidelines could not be used against them.[131] But those politics are not supposed to be part of the common law calculus.

In general tort law, as set forth in Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 13, Comment *e*, industry standards are available for use as non-conclusionary evidence of negligence by both plaintiffs and defendants;[132] that is, they can be used as both inculpatory and exculpatory evidence. That rule is an extension of the general rule that all relevant, probative evidence is

[123] *Arpin*, 521 F.3d at 773.

[124] *Id.* at 774.

[125] *Dalmia*, 2009 WL 4344088, at *5.

[126] *Id.* at *4.

[127] Yi v. N.Y. State Bd. for Pro. Med. Conduct, 210 N.Y.S.3d 790 (N.Y. App. Div. 2024) (On review of a physician's license revocation, the court rejected the reviewing physicians' claim that practice guidelines from the National Comprehensive Cancer Network and the American College of Radiology constituted the standard of care but, based on other evidence presented, affirmed the license revocation); Jewett v. Our Lady of Mercy Hosp. of Mariemont, 612 N.E.2d 724, 727 (Ohio Ct. App. 1992) (In reversing a directed verdict, the court rejected defendants' contention that American College of Obstetricians and Gynecologist (ACOG) guidelines constituted the applicable standard of care, holding that testimony from plaintiff's expert created an issue fact notwithstanding the provisions of the ACOG guidelines); Adams v. Lab'y Corp. of Am., 760 F.3d 1332, 1332–34 (11th Cir. 2014) (In reversing a summary judgment, the court rejected defendants' claim that guidelines from the College of American Pathologists and American Society of Cytopathology constituted a standard of care that compelled rejection of plaintiff expert's testimony).

[128] Medical Malpractice, *supra* note 17, § 6, Reporters' Note, cmt. *f*.

[129] Restatement (Third) of The L. Governing Laws. § 52.2 (Am. L. Inst. 2000) ("(2) Proof of a violation of a rule or statute regulating the conduct of lawyers… (c) may be considered by a trier of fact as an aid in understanding and applying the standard [of care]."); Restatement (Third) of Torts: Liab. for Econ. Harm § 4 cmt. *c* (Am. L. Inst. 2020) ("A violation of a profession's internal code of conduct can itself be admitted as evidence of professional negligence, though it is not dispositive."); Restatement (Third) Torts: Miscellaneous Provisions, § (#) (Am. L. Inst., Preliminary Draft No. 5, 2024).

[130] Fed. R. Evid. 803(18).

[131] Rosoff, *supra* note 101, at 344.

[132] Restatement (Third) of Torts: Liability for Physical & Emotional Harm § 13 cmt. *e* (Am. L. Inst. 2010).

admissible both ways, by both parties, to the litigation.[133] But § 6(b) would change that by nonsensically decreeing that practice guidelines offered by defendants would be non-hearsay, prima facie evidence sufficient to defeat a claim while practice guidelines offered by plaintiffs would remain hearsay that could only be utilized under the learned treatise exception.

There is not a single case in American jurisprudence holding that practice guidelines can only be used as a shield and that plaintiffs could not make equal use of them as a sword. Indeed, there are cases such as those cited in the Reporters' Note to § 6(b),[134] that recognized the exculpatory use of guidelines. However, none of those cases held that plaintiffs could not also make inculpatory use of them. To the contrary, empirical evidence shows that practice guidelines have been relied upon routinely as a basis for or to support inculpatory standards of care. In fact, studies of all the cases decided in the nearly two decades from January 1, 1980 through May 31, 1994 that involved practice guidelines, showed that a majority involved plaintiffs using guidelines.[135] Another study of records conducted by malpractice insurance companies from January 2000 through March 2010 found that guidelines were used as inculpatory evidence at three times the rate they were used exculpatorily.[136]

Indeed, the concurring opinion in *Frakes* which the Reporters claim is the most direct support for the use of practice guidelines, supports plaintiff's usage: "[Practice guidelines] can be extremely helpful in cases calling into question whether a physician chose the wrong course of diagnosis or treatment or should have gone further in attempting to understand or correct the situation."[137]

Support for symmetrical use is widespread.[138] Indeed, even the plaintiff-oriented cases collected in the Reporters' Note all indirectly hold that plaintiffs have equal access to practice guidelines to prove the standard of care;[139] otherwise, the decisions would have simply held that guidelines cannot be used by plaintiffs to establish a standard of care rather than explaining why they were not proper in those particular cases. As noted by Professor Rosoff:

> Should the use of CPGs be a "two-way street," with this form of evidence available equally to both parties? The answer would appear clearly to be "yes." In virtually every other context evidence that is seen as legitimate and admissible by the court is allowed on an equal basis to both parties. Giving providers assurances that guidelines can be used only in their favor may be an important step toward gaining their support; but allowing such one-sided use of evidence in a court of law raises

[133] *See generally* Fed. R. Evid. 401 ("Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." There is no party requirement in the determination of relevant and admissible evidence).

[134] Medical Malpractice, *supra* note 17, § 6, Reporters' Note, cmt. *f.*

[135] Avraham, *supra* note 35, at 299–300.

[136] Andrew L. Hyams et al., *Practice Guidelines and Malpractice Litigation: A Two-Way Street*, 122 Annals Internal Med. 450, 451–52 (1995) (noting that practice guidelines have been used "for both inculpatory and exculpatory purposes."); *see also* Mello, *supra* note 25, at 648 (noting that "empirical evidence indicates that CPGs currently are being used both as exculpatory evidence (by physician defendants) and as inculpatory evidence (by plaintiffs)").

[137] Frakes v. Cardiology Consultants, P.C., No. 01-A-01-9702-CV-00069, 1997 WL 536949, at *6 (Tenn. Ct. App. Aug. 29, 1997) (Koch, Jr., J., concurring).

[138] *See* Smethers v. Campion, 108 P.3d 946 (Ariz. Ct. App. 2005) (FDA guidelines in LASIK surgery); Van Horn v. Hornbeak, No. CV F 08-1622 LJO DLB, 2010 WL 599885 (E.D. Cal. Feb. 18, 2010) (CDC and ACOG guidelines in prenatal care and delivery); District of Columbia v. Wilson, 721 A.2d 591 (D.C. 1998) (U.S. Public Health Service guidelines in treating an asthma attack); Johnson v. Thompson, 650 S.E.2d 322 (Ga. Ct. App. 2007) (ACOG guidelines in birth-related injury); Trowbridge v. United States, 703 F. Supp. 2d 1129 (D. Idaho 2010) (ACOG guidelines in birth-related injury); Bergman v. Kelsey, 873 N.E.2d 486 (Ill. App. Ct. 2007) (ACOG and AAP guidelines in birth-related injury); Joyner-Wentland v. Waggoner, 890 N.E.2d 730 (Ind. Ct. App. 2008) (American Cancer Society guidelines in breast lift); Campbell v. Hosp. Serv. Dist. No. 1, Caldwell Parish, 768 So.2d 803 (La. Ct. App. 2000) (unidentified heart attack guidelines); Collins v. La. *ex rel.* La. Health Care Auth., 774 So.2d 167 (La. Ct. App. 2000) (CDC guidelines in treating infection in emergency room); Feeley v. Baer, 669 N.E.2d 456 (Mass. App. Ct. 1996), *aff'd in part, rev'd in part*, 679 N.E.2d 180 (Mass. 1997) (ACOG guidelines for prenatal care involving newborn death); Darke v. Estate of Isner, 17 Mass. L. Rptr. 689 (Mass. Super. Ct. 2004) (American Society Of Gene Therapy and other guidelines in gene transfer experiment).

[139] Medical Malpractice, *supra* note 17, § 6, Reporters' Note, cmt. *f.*

> disturbing questions of fairness and of validity under the U.S. Constitution's Fifth and Fourteenth Amendments' due process and equal protection mandates, and under state constitutional principles as well."[140]

Others who have studied the issue agree:

> [P]ermitting physicians to use CPGs as an affirmative defense in malpractice litigation while denying plaintiffs the right to use this evidence to prove their own case would also be problematic. Restricting one party's access to relevant, probative, and otherwise admissible evidence on a key element of a legal claim is an anomaly in the law and requires strong justification. There is no such justification for restricting the use of CPGs. Thus, CPGs should either be available to all parties or to none.[141]

There have been prior attempts to restrict the use of practice guidelines to just shields for defendant providers, similar to the asymmetrical provisions of § 6(b), but those have been part of partisan tort-reform agendas. Beginning in the early 1990s, medical and related organizations began to push for practice guideline shield laws.[142] Four states—Maine, Florida, Minnesota and Vermont—enacted such laws as part of tort-reform campaigns but the Florida, Minnesota and Vermont programs failed and were abandoned.[143] And in Maine, guidelines were only promulgated for approximately one to two percent of medical practice, and the law was allowed to expire.[144] Maryland also enacted a statute to encourage guideline development but the statute provided that any practice guidelines developed could not be used in litigation, and was thereafter repealed in 1999.[145]

As far as the so-called substantive law distinction is concerned, while transforming the characterization of practice guidelines to substantive evidence when used by defendants is technically substantive, the fact remains that § 6(b) would change the hearsay rules of evidence, since the new rule would authorize what is undeniably hearsay to be used as substantive non-hearsay evidence. Therefore, however characterized, this new rule still transgresses the prohibition against using learned authorities as substantive evidence and would constitute an evidence rule modification.

Given the lack of authority for transforming practice guidelines into non-hearsay evidence, the absence of a single case authorizing the restriction of practice guidelines for standard of care purposes solely to defendant providers, and the multiplicity of cases allowing their use by plaintiffs, there is no jurisprudential basis for § 6(b).

IV. Section 6(b) Relies on Flawed Reasoning

With the scarcity, indeed absence, of case law support, the Restatement makes two arguments in support of § 6(b): (1) practice guidelines represent aggregate experts' views that are better than those of experts hired for litigation purposes; and (2) practice guidelines may represent a higher level of competence so that compliance would reflect a higher level of care.[146] However, there is no empirical evidence to support either of those contentions; they are merely rank speculation. The Restatement also contends

[140]Rosoff, *supra* note 101, at 344.

[141]Mello, *supra* note 25, at 648.

[142]Mehlman, *supra* note 45, at 1167.

[143]*Id.* at 1199: ("More importantly, none of the state programs were successful. Neither Minnesota nor Florida appears to have issued any guidelines, and the project in Vermont seems to have been abandoned.").

[144]Gordon H. Smith, *Maine's Medical Liability Demonstration Project – Linking Practice Guidelines to Liability Protection*, 13 Virtual Mentor 792, 792, 795 (2011). ("The [Maine] project was eventually extended to 8 years, but was allowed to expire by the year 2000 when supporters of the law concluded that the affirmative defense intended to assist physicians had not been used in a single case in court.").

[145]Md. Code Ann., Health-Gen. §19-1601 – 19-1606 (LexisNexis 2013) (repealed 1999).

[146]Medical Malpractice, *supra* note 17, § 6, Reporters' Note, cmt. *f.*

that the possible higher level of competence, and the possibility that guidelines may only capture one of several alternative approaches, are reasons for the asymmetrical defendant-only limitation.[147] None of that makes any sense.

A. The Criticism of Litigation Experts is Unfounded and Does Not Support the Rule

Given the wide range of practice guidelines and their frequent objectivity and credibility issues, it does not follow that they represent a "better view" than an expert who has studied the particulars of a case at issue, especially when no empirical evidence exists to support that conclusion. And, since defendants have a greater access to credentialed experts,[148] this seems to be a complaint that is primarily directed at plaintiff's experts, when, in fact, it is not uncommon for plaintiff's experts to be some of the leaders in their field of medicine.[149] Indeed, the difficulties that already exist in prevailing as a plaintiff in a medical malpractice lawsuit and the tremendous costs required,[150] incentivize plaintiff lawyers to retain the best experts available. In that sense, plaintiff's lawyers perform a gatekeeping function to weed out incompetent and unqualified expert witnesses.[151]

In addition, significant disincentives exist to deter any but the most well-credentialed experts from participating as plaintiff's experts. Among other things, defendants regularly refer opposing experts to professional organizations and state medical boards, who treat the testimony as the practice of medicine.[152] In addition, experts have been sued by defendants who claim that the testimony breached a duty of professional competence.[153] If anything, this argument reveals an inherent prejudice against plaintiff's experts, not sound reasoning on which to launch substantial changes in the law.

Beyond that, the complaint about litigation experts is not well thought out. Given the wide range of practice guidelines available,[154] guidelines chosen by defendants are likely be a "hand-picked" judgment about competent medical care that validates what the physician did. There is no requirement that the defendant have been aware of the practice guideline being offered in court or that the defendant testify that he relied upon it in the belief it provided the standard of care. Instead, the treatment accorded practice guidelines by § 6(b) will guarantee that defense counsel or defense experts will scour the panoply of available guidelines to identify one that accords with the defendant's conduct. Furthermore, because authoritativeness, applicability, relevance, and compliance will likely be contested issues, expert testimony will still be needed. Thus, either way there will be hand-picking and expert testimony. The subjective stereotyping of plaintiff experts is therefore a slim reed on which to predicate a policy change. Rather, expert credentials and qualifications of litigation experts are matters for cross-examination and the adversarial system, not the basis for a new law.

B. That practice guidelines may represent a higher level of competence is just more speculation

There is no empirical evidence that guidelines represent a higher level of care. Indeed, given the many inherent problems, conflicts of interest, and non-medical considerations involved with practice

[147] *Id.*

[148] *Id.*, Reporters' Note.

[149] *See, e.g.*, Adams v. Lab'y Corp. of Am., 760 F.3d 1322, 1330 (11th Cir. 2014) ("It is difficult to imagine how Dr. Rosenthal's experience could have been more extensive and relevant or contributed more to the reliability of the methodology she used.").

[150] *See* Daniels & Martin, *supra* note 24, at 1052.

[151] *See generally* Herbert Jacob, Law and Politics in the United States 118-19 (2d ed. 1995) (discussing the gatekeeping roles of lawyers); *see also* Herbert M. Kritzer, *Contingency Fee Lawyers as Gatekeepers in the Civil Justice System*, 81 Judicature 22 (1997); Joanne Martin & Stephen Daniels, *Access Denied*, 33 Trial 26; Philip H. Corboy, *Contingency Fees: The Individual's Key to the Courthouse Door*, 2 Litig. 27 (1976).

[152] *See* B. Sonny Bal, *The Expert Witness in Medical Malpractice Litigation*, 467 Clinical Orthopaedics & Related Rsch. 383, 383, 385–87 (2009).

[153] *Id.* at 384–85.

[154] *See* discussion *supra* Part II.A.

guidelines,[155] it can be equally argued that at least some practice guidelines from "authoritative" sources represent a potentially lower level of competence. If, however, alleged over-competence is the stated reason to deny plaintiffs equal access to § 6(b), and the Restatement was true to this reasoning, it would have provided that where practice guidelines represent the normal level of competence in the practice of medicine they could be used as well by plaintiffs as inculpatory evidence. That it does not reveals that this is just straw-grasping, not sound reasoning.

C. Relevancy and Authoritativeness Add No Support to the Rule

Much of the comment to § 6(b) involves the requirement that a guideline be relevant and authoritative,[156] as though that provided some foundation or support for the rule, but that is not the case. Requiring relevancy adds nothing since in all cases only relevant evidence is admissible.[157] Relevancy therefore is already a requirement both generally and under the learned treatise hearsay exception. So too for the authenticity requirement. For a guideline to be used under the learned treatise exception it must be "established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice."[158] There was no need to change that rule or propose an allegedly new substantive rule to realize those requirements.

But the authenticity requirement points out a major flaw in § 6(b). Under its provisions, the focus of authoritativeness is on the issuing entity, while under Rule 803(18) the focus is on the reliability of the guideline.[159] Thus, under § 6(b) authoritative guidelines are those from entities that have "appropriate expertise and integrity and speaks with authority in a relevant portion of the medical-provider community."[160] This is entirely circular and would seem to confer authoritative status on guidelines devised by any coterie of medical providers that form an association.

Consider, for example, the Alliance for Hippocratic Medicine, the group that challenged the Food and Drug Administration's approval and rules for use of mifepristone to end a pregnancy and its OTC availability.[161] The group was formed in 2022 and claims its purpose is to uphold and promote the "fundamental principles of Hippocratic medicine" and to provide "healthcare with the highest standards of excellence based on medical science."[162] It boasts a nationwide membership of "approximately 30,000 physicians,"[163] "many of whom are OB/GYNs or emergency-room doctors."[164] Under the entity-only focus of the § 6(b) standards, any guidelines this group of well-credentialed health care providers developed would receive authoritative status and asymmetrical treatment, despite a transparently political purpose anchored in a self-described "pro-life" agenda. Granting such authoritativeness merely because the group claims to be an expert national advisory association of medical specialists makes little sense. It is possible that their guidelines could be sterling, unaffected by their political slant, but it is also possible that they would adhere to an agenda that promotes a political goal at the expense of patient care. That is why much more is required than simply an inquiry into whether the issuing organization is an expert entity. Even Judge Koch's concurrence, which the Reporters claim supports them, recognized that

[155] *See* discussion *supra* Part II.B.

[156] Medical Malpractice, *supra* note 17, § 6 cmt. *f*.

[157] *See* Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 5191.3 (2d ed. Supp. 2024) (showing that all states have adopted a version of Fed. R. Evid. 402, which limits admissibility to relevant evidence and specifically states that "[i]rrelvant evidence is not admissible.").

[158] Fed. R. Evid. 803(18)(B).

[159] *Id.*

[160] Medical Malpractice, *supra* note 17, § 6 cmt. *f*.

[161] FDA v. All. for Hippocratic Med., 602 U.S. 367 (2024) (holding that the Alliance lacked standing).

[162] All. for Hippocratic Med., https://allianceforhippocraticmedicine.org/ [https://perma.cc/67M4-RNEF].

[163] Alliance for Hippocratic Medicine, *Upholding and Promoting the Fundamental Principles of Hippocratic Medicine*, 88 Linacre Q. 321, 321 (2021).

[164] All. for Hippocratic Med. v. FDA, 78 F.4th 210, 222 (5th Cir. 2023), *rev'd and remanded*, 602 U.S. 367 (2024).

foundational requirement: "Properly authenticated clinical practice guidelines are relevant… *if introduced through a witness who can lay a proper foundation.*"[165]

Some states have taken a more realistic approach to guidelines. For example, Illinois holds that guidelines promulgated by medical specialty societies, health insurers, and other health organizations have significant evidentiary value, yet are not complete answers to the applicable standard of care.[166] Still, as of April 2024, "most states have not officially made provisions for practice guidelines."[167]

States may have taken a cue from a leading torts treatise that explains the logical limits of guidelines:

> Courtroom use of standards prescribed in advance to establish limits on liability of defendants presents some inherent problems. As a means of limiting a patient's rights, standards might have the most legitimacy if they were generated by governmental agencies with public representatives. But such standards are likely to be politically driven, for example, by cost-cutting motives, and may not reflect good assessment of responsible medical care. On the other hand, if standards-in-advance are generated purely by medical professionals, perhaps with an eye to potential liability, then medical professionals and not the public processes of courts or legislatures would be deciding the patient's rights.[168]

The Restatement seems to indirectly acknowledge these flaws when it states that more case law development is needed to determine what represents authoritative and material guidelines.[169] But launching a new rule without case law support on the speculative hope that eventually, it could be made workable through trial and error, is inimical to the Restatement process.

The linchpin for allowing hearsay evidence is that certain classes of evidence are trustworthy.[170] Thus, Federal Rule of Evidence § 803(18) properly looks to the reliability of the guidelines. In the case of practice guidelines, that is particularly important because many guidelines have inherent bias and conflicts of interest that are not readily apparent on the face of the guideline.[171]

D. Claims in Support of Asymmetry Also Fail

Claims in support of the second aspect of § 6(b), that its asymmetry is appropriate because some guidelines are over-competent or that a case might involve alternative methods of treatment, also do not suffice. Not all guidelines are over-competent and not all cases involve alternative methods of treatment. As already noted, there is an inherent inconsistency in the over-competent argument.[172] Nor does it follow from the possibility of different views about the method of treatment in a given case that the use of practice guidelines as standard of care evidence should be restricted in all cases to just defendant providers. While differing views might be a reason a defendant provider might want to use a particular practice guideline, practice guidelines are not irrebuttable for either side. If a plaintiff presents a practice guideline about one method of treatment, the defendant would be able to rebut with a practice guideline about the method that she followed. The possibility that in some cases there may be differing methods of care does not require that plaintiffs be banned from also using them in an inculpatory manner.

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[165]Frakes v. Cardiology Consultants, P.C., No. 01-A-01-9702-CV-00069, 1997 WL 536949, at *6 (Tenn. Ct. App. Aug. 29, 1997) (Koch, Jr., J., concurring) (emphasis added).

[166]*See* Robert John Kane & Lawrence E. Singer, Illinois Practice Series: The Law of Medical Practice in Illinois § 33:3 & n.14 (3d ed. 2024).

[167]Dan B. Dobbs et al., The Law of Torts § 295 (2d ed. Supp. 2024).

[168]*Id.*

[169]Medical Malpractice Practice Guidelines, *supra* note 3, § 6, Reporters' Note, cmt. *f* ("Accordingly, additional case-law development will be needed to refine what constitutes appropriate expertise, relevance, and perspective in various situations—and also how current various guidelines need to be, in order to be utilized.").

[170]*See* Fed. R. Evid. 803 notes of advisory committee on proposed rules.

[171]*See* discussion *supra* Part II.B.

[172]*See* discussion *supra* Part IV.B.

The asymmetry aspect of § 6(b) would be nothing short of an anomaly. American jurisprudence is based on the premise that justice is blind.[173] A foundational rule of evidence is that all relevant evidence is admissible by either party.[174] And while many types of evidence are excluded, hearsay being a prime example, the exclusions apply equally to all parties. To overcome this bedrock principle of evenhandedness requires strong policy justifications. Examples of the types of exceptions tolerated include bad character evidence and rape-shield laws but, even there, the one-sided exclusions are for the purpose of maintaining fundamental fairness.[175] That justification does not exist in the case of practice guidelines.

E. Other Conceptual Flaws Exist in the Proposal

There are also other conceptual flaws as well. There is an inherent inconsistency in the rule's treatment of the conclusive effect of practice guidelines. On the one hand, the Restatement states that practice guidelines are not conclusive but may support a no-liability finding, yet the comments and Reporters' Note make clear that the rule is intended to authorize the use of practice guidelines by defendants to provide "stand alone" evidence of a standard of care that would "obviate the need for expert testimony."[176] That would be conclusory.

Finally, § 6(a) would directly contradict the rationale underlying the learned treatise exception to the rule against hearsay. As noted by the Advisory Committee of the Federal Rules of Evidence in its explanation for the learned treatise exception:

> The writers have generally favored the admissibility of learned treatises, [citations omitted] … but the great weight of authority has been that learned treatises are not admissible as substantive evidence though usable in the cross-examination of experts. The foundation of the minority view is that the hearsay objection must be regarded as unimpressive when directed against treatises since a high standard of accuracy is engendered by various factors: the treatise is written primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy, with the reputation of the writer at stake. 6 Wigmore §1692. Sound as this position may be with respect to trustworthiness, there is, nevertheless, an additional difficulty in the likelihood that the treatise will be misunderstood and misapplied without expert assistance and supervision… .
>
> The [learned treatise] rule avoids the danger of misunderstanding and misapplication by limiting the use of treatises as substantive evidence to situations in which an expert is on the stand and available to explain and assist in the application of the treatise if declared. The limitation upon receiving the publication itself physically in evidence, contained in the last sentence, is designed to further this policy.[177]

There is nothing in the over fifty-year history of practice guideline use under that rule which would necessitate changing that rule, and especially changing it to favor only defendants.

In sum, the scant rationale provided for § 6(b) does not survive critical analysis nor does it support the wholesale change in the law that § 6(b) represents. Absent sound reasoning and principles, § 6(b) should not be adopted.

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[173]Travis W. Franklin, *The State of Race and Punishment in America: Is Justice Really Blind?*, 59 J. Crim. Just. 18, 18 (2018).

[174]*See* Fed. R. Evid. 402.

[175]*See* Regan Kreitzer LaTesta, *Rape Shield Statutes and the Admissibility of Evidence Tending to Show a Motive to Fabricate*, 46 Clev. St. L. Rev. 489, 490, 509 (1998).

[176]Medical Malpractice, *supra* note 17, § 6, Reporters' Note, cmt. *f.*

[177]Fed. R. Evid. 803, notes of advisory committee on exception 18.

V. The Restatement's Approach to Practice Guidelines Violates Foundational Principles of the Civil Justice System

A basic premise of civil justice is that for every wrong there is a remedy.[178] For far too long, medical malpractice plaintiffs were denied justice at the hands of the "locality rule." As confirmed by the Restatement, that rule has now been swept aside in favor of a national standard of care.[179] Nonetheless, decades of tort-reform legislation has created substantial barriers to justice and caps on damages, making medical malpractice litigation the most arduous litigation possible.[180] Still, there are basic foundational principles that adhere: justice is blind,[181] parties have a right to cross-examination,[182] parties cannot set their own standard of care[183] and procedures should not unduly delay the quest for justice.[184]

A. The Rule Denies Equal Justice

Justice is supposed to be blind; it bides no favor and suffers no inequality. All who seek justice are treated evenhandedly, regardless of class, race, wealth or power. Neither evidence nor substantive rules are supposed to tilt the scales for or against either party. But § 6(b) would violate this fundamental principle.

Practice guidelines are indisputably hearsay documents. Any party can use them under the "learned treatise" exception as either exculpating or inculpating evidence when they are established as reliable by an expert's admission on cross-examination or by another expert's testimony.[185] That rule treats all parties equally; it affords no special weight to evidence when proffered by defendants. But, under § 6(b), when practice guidelines are relied on by defendants, they would *ipso facto* be transformed into non-hearsay prima facie evidence. Since that evidence "can, standing alone, provide sufficient evidence of compliance with a standard of care to obviate the need for expert testimony concerning the standard of care,"[186] it would give special weight to guidelines offered by defendants and could lead to unjust results. That is incompatible with the principle of equal justice.

B. The Rule Could Eviscerate Plaintiff's Right to Cross-Examination

As envisioned by § 6(b), the rule would "obviate the need for expert testimony concerning the standard of care."[187] Such stand-alone evidence would necessarily be self-authenticating. And while the Restatement notes that ordinarily a sponsoring expert witness will be necessary,[188] it is clearly anticipated that when practice guidelines are offered by defendants, they may be deemed self-authenticating so that, without any further evidence, explanation or sponsoring witness, they may be sufficient to defeat the plaintiff's claim.[189] That would allow the introduction of potentially dispositive evidence without any opportunity for cross-examination, an astonishing proposition that is inconsistent with fundamental trial fairness.

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[178] *See* Marbury v. Madison, 5 U.S. (1 Cranch) 137, 163 (1803) ("The very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury.").

[179] Medical Malpractice, *supra* note 17, § 5 cmts. *c* & *m* ("[T]his reasonable provider standard is assessed on a national, rather than local, basis, with some variation in the standard based on relevant factors and circumstances…. [T]his Section rejects the Second Restatement's 'locality rule' in favor of a 'national' standard.").

[180] *See* Daniels & Martin, *supra* note 24, at 1052.

[181] Franklin, *supra* note 173, at 18.

[182] *See* 5 John Henry Wigmore, Wigmore on Evidence: Evidence in Trials at Common Law §1367 (4th ed. Supp. V 2024).

[183] *See* Williams v. Lawrence + Mem'l Hosp., Inc., 273 A.3d 235, 240, 237 n.6 (Conn. App. Ct. 2022).

[184] Fed. R. Civ. P. 1.

[185] Fed. R. Evid. 803, notes of advisory committee on exception 18.

[186] Medical Malpractice Practice Guidelines, *supra* note 3, § 6, Reporters' Note, cmt. *f.*

[187] *Id.*

[188] *Id.* § 6 cmt. *f* ("some expert testimony will usually be needed …").

[189] *Id.* § 6, Reporters' Note, cmt. *f* (This section "addresses … whether practice guidelines can, standing alone, provide sufficient evidence of compliance with a standard of care to obviate the need for expert testimony concerning the standard of care.").

The critical role that cross-examination plays in the quest for justice has been lost in the § 6(b) proposal. In the words of John Henry Wigmore, cross-examination is "beyond any doubt the greatest legal engine ever invented for the discovery of truth."[190] One of the primary objectives of the rules of evidence is to place important safeguards around hearsay evidence to protect the rights of litigants to test evidence by cross-examination.[191] In the case of practice guidelines, those safeguards have heightened significance because of the lack of standards or regulatory framework for the sound, objective development or updating of practice guidelines.[192] There is no requirement for disclosure of bias, motive, funding sources, conflicts of interest, or any other aspect of the process by which the guideline was created, the exact type of information that would go to credibility, authenticity, and reliability. Nor is there any requirement that guidelines be updated to keep abreast of medical developments. But standalone guidelines that are not subject to cross-examination would leave it to trial counsel to explain meaning and import. It does not take much imagination to see what mischief could ensue.

The concept that practice guidelines could be self-authenticating also seems to run afoul of the principle underlying the Federal Rules of Evidence § 201, which prevents judicial notice of facts unless they are not subject to "reasonable dispute" because they are established by either common knowledge or "sources whose accuracy cannot be reasonably questioned."[193] That same "not reasonably questioned" standard should underly the reliability and trustworthiness of practice guidelines used as litigation evidence. It is present in the learned treatise hearsay exception, either by way of expert admission during cross-examination or through a sponsoring witness, but lacking in § 6(b), and there is nothing in § 6(b) that will cure or offset that defect.

C. The Rule Would Impermissibly Allow the Medical Profession to Set Its Own Variable Standards of Care for Litigation Purposes

§ 6(b) could have another far-reaching effect. It would enable medical entities, or like-minded individuals, to devise medical standards of care, thus affording the medical profession opportunities to enact its own standard of care to justify practices that would otherwise be deemed substandard. And, as discussed below, those standards could resurrect locality rules.

A fundamental principle of tort law is that parties are not entitled to set the standards by which they are to be judged. As famously observed by Judge Learned Hand, "a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages."[194] That principle is most often found in connection with customary practices.[195] The same principle applies with respect to practice guidelines. The medical profession can never set the medical standard of care, because, in doing so, it would be setting its own standard of care. Thus, in *Adams*, the court held that a medical or scientific community cannot set a "litigation standard" for when its members are sued:

> If the CAP and ASC can define what constitutes admissible expert testimony in their members' professional negligence cases, then there is no apparent reason why other groups whose members face lawsuits cannot do the same. For example, why couldn't pharmaceutical companies adopt guidelines setting high standards of proof for establishing that a plaintiff's injury was caused by a given drug and justify doing so based on their experience with the complex nature of pharmacology and their expertise in the field? Why couldn't an association of prison guards and wardens presume

[190] Wigmore, *supra* note 182, §1367.

[191] *See generally* Fed. R. Evid. 802 (stating that hearsay evidence is inadmissible unless it falls into a certain category of exception).

[192] *See* discussion *supra* Part II.B.

[193] Fed. R. Evid. 201(b).

[194] The T.J. Hooper, 60 F.2d 737, 740 (2d Cir. 1932).

[195] *See* Restatement (Third) of Torts: Liability for Physical & Emotional Harm, *supra* note 132, §13 cmt. *b* ("[C]ompliance with custom does not … conclusively show that the actor was free of negligence… . [P]ossibly, the entire community or industry has lagged: all members of the group to which the actor belongs may have been inattentive to new developments or may have been pursuing self-interest in a way that has encouraged the neglect of a reasonable precaution.").

> to define the meaning of "deliberate indifference" or the requirements for admission of evidence in custodial litigation? They can't because courts do not allow interested groups to set evidentiary or other litigation standards.[196]

Many other professions already have practice guidelines, and there is a multitude of industry and trade group standards or guidelines.[197] Many of the groups that promulgated those guidelines and standards would be deemed "authoritative" under the § 6(b) definition. Under current law, those guidelines and standards are available to both plaintiff and defendants to use both inculpatorily and exculpatorily.[198] But if § 6(b) were adopted, what would stop any of those entities from claiming, by analogy, that their guidelines or standards should also be prima facie evidence available only to members of the organizations? If professional guidelines issued by "authoritative" organizations are so inherently reliable in the field of medicine that they do not need expert testimony to support them, why stop with medical guidelines? Would not defendants in many other professions, trades or industries welcome the opportunity to declare their own standards and create rules that would only be available to their members?

D. The Restatement's Attempt to Limit Admissible Guidelines to those Derived from Authoritative Sources Provides a Meaningless Qualification that Will Likely Increase the Cost of and Delay Medical-Malpractice Litigation

Purportedly, the new rule would not allow defendants to use all practice guidelines. To weed out substandard guidelines, the rule is limited to "authoritative" guidelines.[199] But how would authoritativeness be determined? A comment in the Restatement suggests that "authoritative status might be shown primarily through evidence that the organization or entity issuing the guideline has appropriate expertise and integrity and speaks with authority in a relevant portion of the medical-provider community."[200] Other potentially relevant considerations include "(1) the body issued the guideline after a period of careful, open deliberation, and (2) the guideline is designed to guide medical care in the best interest of patients."[201]

These factors provide no real guidance to courts. It would seem to permit county medical associations to reinstate local customs through promulgation of a guideline, despite the modern rejection of that standard in the courts[202] and in the very same Restatement.[203] Despite the multiple references to national standards in § 5 and its comments, no similar restriction is placed on practice guidelines in § 6(b).

Beyond the prospect for reinstating local guidelines, read literally § 6(b) would authorize defendants to introduce any relevant practice guideline that came from an "authoritative" entity.[204] And it assigns the

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[196] Adams v. Lab'y Corp. of Am., 760 F.3d 1322, 1334 (11th Cir. 2014).

[197] *See, e.g.*, Certified Fin. Planner Bd. of Standards, Inc., Practice Standards Reference Guide: Reference Guide to the Practice Standards for the Financial Planning Process (2020) (providing guidance for certified financial planners); The Mass. Bd. of Registration of Architects & the Mass. Bd. of Registration of Pro. Eng'rs & Land Surveyors, Professional Practice: A Guide to the Practice of Architecture, Engineering, and Land Surveying in Massachusetts (2023) (assisting architects professional engineers, and professional land surveyors in Massachusetts understand their professional responsibilities); Int'l Fin. Corp., Environmental, Health, and Safety General Guidelines (2007) (discussing general and industry-specific expectations for international industry practices relating to environmental, occupational, and community health).

[198] *See* Fed. R. Evid. 803(18).

[199] Medical Malpractice Practice Guidelines, *supra* note 3, § 6 cmt. *f* ("[T]he guideline must be 'authoritative.' Many areas of medical practice have multiple and even conflicting guidelines, and not all would meet this test.").

[200] *Id.*

[201] *Id.*

[202] *See, e.g.*, Darling v. Charleston Cmty. Mem'l Hosp., 211 N.E.2d 253, 257 (Ill. 1965) ("[C]ustom should never [sic] be conclusive."); Palmer v. Biloxi Reg'l Med. Ctr., Inc., 564 So. 2d 1346, 1354 (Miss. 1990) ("Mississippi physicians are bound by nationally-recognized standards of care…"); Travers v. District of Columbia, 672 A.2d 566, 568 (D.C. 1996) ("[T]he applicable standard is a national standard, not just a local custom."); Norris v. Fritz, 270 P.3d 79, 87 (Mont. 2012) ("A medical malpractice plaintiff must establish that a physician's conduct breached a national standard of care.").

[203] *See* Medical Malpractice, *supra* note 17, § 5(a), cmts. *c* & *m.*

[204] *Id.* § 6(b).

determination of whether a practice guideline is authoritative to a judge.[205] Unlike Federal Rule of Evidence § 803(18), where authoritativeness is either admitted during cross-examination or established by a sponsoring expert witness,[206] under § 6(b) where authoritativeness is defined by the promulgating entity, when defendants offer so-called "stand-alone" guidelines, it could potentially trigger "authoritativeness" hearings, that would be similar to a *Daubert* hearing.[207] Those hearings require the judge to play the role of a gatekeeper on the admission of scientific evidence by assuring its reliability through a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and … whether that reasoning or methodology properly can be applied to the facts in issue."[208] Where the parties dispute the expert testimony's admissibility, "the district court must hold an in limine hearing (a so-called *Daubert* hearing) to consider the conflicting evidence and make findings about the soundness and reliability of the methodology employed by the scientific experts."[209] These hearings drain judicial resources.[210] As observed by the Fifth Circuit:.

> We would be remiss if we did not note that we are troubled by the amount of judicial resources that were devoted to the *Daubert* hearing. In a case capable of being tried start to finish in a day and one half, not only the court but the lawyers were engaged for the better part of five days in a hearing to determine the reliability of testimony and potential prejudice of exhibits involving a well-known test that is applied in a quite straightforward manner.[211]

In fact, *Daubert* hearings often become a "lengthy process, involving a 'complex mini-trial.'"[212] One court detailed the "overwhelm[ing]" nature of the hearings; it required more than "500 docket entries, and there are literally boxes of reports, depositions, and affidavits submitted in support of the parties' respective Motions to exclude experts," along with a request to stay the trial date that, "if granted in every case, could cripple the trial calendar."[213]

A hearing on whether a particular set of guidelines constitute authoritative guidance, given the outsized stakes involved in their admissibility, will generate, at a minimum, evidence about the sponsoring organization; the qualifications, potential biases, and apparent conflicts of interest among those who drafted the guidelines; the age of the guidelines and medical developments since the guidelines were promulgated; and expert opinion about the reliability and practical use of the guidelines. State court judges, who usually preside over medical malpractice cases, often lack the resources to handle such hearings. The result is a level of complexity, difficulty, delay, and cost that cannot be justified.

VI. As a Change in the Law, if at All Appropriate, § 6(b) is for the Legislative Process, Not a Restatement

When changes are proposed in Restatements, they are supposed to be accretional; proposals that would produce "wild swings" in the law or "major innovations of matters of public policy" are inappropriate.[214] Proposing to change the character of documents based on which party offers them, making the rule one-

[205] *See id.* §6 cmt. *f* ("Authoritativeness is best determined by the judge, based on local evidence law, rather than by the factfinder, as is true for other evidentiary rulings.").

[206] Fed. R. Evid.803 (18).

[207] *See* Daubert v. Merrell Dow Pharms., Inc.,509 U.S. 579, 592–93 (1993).

[208] *Id.*

[209] Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1318 n.10 (9th Cir. 1995), *on remand from* 509 U.S. 579.

[210] *See* Christine P. Bartholomew, *Death by* Daubert*: The Continued Attack on Private Antitrust*, 35 Cardozo L. Rev. 2147, 2189 (2014).

[211] United States v. Katz, 178 F.3d 368, 371 (5th Cir. 1999).

[212] Bartholomew, *supra* note 210, at 2189–90 (quoting Allapattah Servs., Inc. v. Exxon Corp., 61 F. Supp. 2d 1335, 1342 (S.D. Fla. 1999)).

[213] Minner v. Am. Mortg. & Guar. Co., 791 A.2d 826, 845 (Del. Super. Ct. 2000).

[214] The American Law Institute, Capturing the Voice of The American Law Institute: A Handbook for ALI Reporters and Those Who Review Their Work 6 (rev. ed. 2015).

sided, limiting cross-examination, and tilting the scales of justice, would unquestionably be major innovations that would embark into uncharted jurisprudence, as there is no case in any jurisdiction that has ever held that practice guidelines are admissible as self-authenticating, stand-alone substantive evidence or that they should only be available to defendants.

The rule also appears to be based on an unstated premise that the medical profession needs a safe harbor from malpractice litigation. But empirical evidence strongly suggests that a considerable safe harbor already exists. Given the difficulties in prevailing as a plaintiff in a medical malpractice lawsuit, including win rates that are less than half of other torts, extreme expenses, and frequently capped damages,[215] many meritorious cases are turned down because of the disincentives to reaching a compensatory and profitable result are too great.[216] Indeed, most potential plaintiffs do not sue.[217] The Institute of Medicine estimated that around one million or more injuries each year were the product of medical errors.[218] A subsequent study concluded that deaths due to medical errors alone numbered 195,000 per year.[219] In fact, the "evidence is quite clear that while many patients are injured, few ever sue."[220] But, whether an additional safe harbor is needed is a matter for the legislative process, not a Restatement. As noted by Rosoff, treating practice guidelines as establishing the applicable standard of care "would be a substantial departure from existing law and would, presumably, require legislative action."[221]

Rosoff's comment is based on the fundamental principle of separation of powers.[222] The Restatement's proposal concerning practice guidelines justifies itself on the basis of policy arguments.[223] However, policy judgments that bring about such extraordinary change as the Restatement proposes, belong in the legislative realm, not within the judicial sphere. As the United States Supreme Court has declared, "[p]olicy arguments are properly addressed to Congress, not this Court. It is Congress's job to enact policy and it is this Court's job to follow the policy Congress has prescribed."[224] Although the

[215] *See* sources cited *supra* note 24 and accompanying text.

[216] *See* sources cited *supra* note 151.

[217] *See* Tom Baker, The Medical Malpractice Myth 37 (2005) (describing studies indicating more occasions of medical malpractice than medical-malpractice lawsuits); David A. Hyman & Charles Silver, *Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid*, 59 Vand. L. Rev. 1085, 1089–92 (2006) (citing studies showing significant underclaiming of medical malpractice); Douglas A. Kysar et al., *Medical Malpractice Myths and Realities: Why an Insurance Crisis Is Not a Lawsuit Crisis*, 39 Loy. L.A. L. Rev. 785, 791 (2006) (finding that the medical malpractice cases are underutilized); Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 Tex. L. Rev. 1595, 1608 (2002) ("[O]nly a tiny fraction of patients injured due to negligence file a claim.").

[218] *See* Inst. of Med., *supra* note 58, at 1 (explaining that two studies, from Colorado/Utah and New York, respectively supported that 2.9 and 3.7 percent of hospitalizations resulted in adverse events and further noting that U.S. hospital admissions totaled 33.6 million in 1997).

[219] *Medical Liability: New Ideals for Making the System Work Better for Patients: Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions*, 109th Cong. 72 (2006) (statement of Neil Vidmar, Russell M. Robinson II Professor of Law, Chair, Duke Law School).

[220] Hyman & Silver, *supra* note 217, at 1089.

[221] Rosoff, *supra* note 101, at 339.

[222] The Kansas Supreme Court has provided a commonly understood definition of separation of powers: "The basic meaning of the separation of powers doctrine is that the whole power of one department should not be exercised by the same hands which possess the whole power of either of the other departments." Kansas v. Ponce, 907 P.2d 876, 879 (Kan. 1995). Although the United States Constitution contains no explicit language concerning the separation of powers, the constitutional structure of government makes it a fundamental part of our government. *See* Cong. Rsch. Serv., *Separation of Powers Under the Constitution*, Const. Annotated, https://constitution.congress.gov/browse/essay/intro.7-2/ALDE_00000031/ (last visited Dec. 2, 2024). State constitutions often are explicit about separation of powers, including it within the state declaration of rights, such as in Md. Const. Declaration of Rights art. 8 ("That the Legislative, Executive and Judicial powers of Government ought to be forever separate and distinct from each other; and no person exercising the functions of one of said Departments shall assume or discharge the duties of any other."), or as a stand-alone requirement. *See, e.g.*, Fla. Const. art. 2, § 3 ("No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided herein.").

[223] Medical Malpractice, *supra* note 17, § 6 cmt. *f.*

[224] SAS Inst., Inc. v. Iancu, 584 U.S. 357, 368 (2018).

Supreme Court is not a common law court, save in admiralty cases, state courts, which are common law courts, uniformly adopt the same position.[225] § 6(b) oversteps this foundational restriction.

Conclusion

The Restatement has failed to make the case for the creation of a special new rule that would allow defendants to use practice guidelines as stand-alone prima facie evidence of the medical standard of care. In the more than half a century of experience with practice guidelines, no court has ever gone so far. There is already a proven system in place, Federal Rule of Evidence § 803(18), that evenhandedly allows both the inculpatory and exculpatory use of practice guidelines. In the absence of any sound reason or policy, or case law support to change that system, § 6(b) should not be adopted.

[225] *See, e.g.*, Borgelt v. Austin Firefighters Ass'n, 692 S.W.3d 288, 301 (Tex. 2024) ("Courts … must also rigorously distinguish between policy conflicts and legal questions. Under our Constitution, policy choices belong to the other branches."); Teig v. Chavez, 8 N.W.3d 484, 494 (Iowa 2024) (declaring that party's argument was a "policy consideration best left to the legislative branch"); Mathews v. Becerra, 455 P.3d 277, 298 (Cal. 2019) ("[O]ur role is not to supplant the Legislature's policymaking role."); Campaign for Fiscal Equity, Inc. v. New York, 861 N.E.2d 50, 58 (N.Y. 2006) (explaining that an "abiding 'respect for the separation of powers upon which our system of government is based'" means courts "cannot 'intrude upon the policy-making and discretionary decisions that are reserved to the legislative and executive branches'"); *Ex parte* Ankrom, 152 So.3d 397, 420 (Ala. 2013) ("[P]ublic-policy arguments should be directed to the legislature, not to this Court."); Falco Lime, Inc. v. Mayor of Vicksburg, 836 So.2d 711, 725 (Miss. 2002) (citation omitted) ("Our Constitution provides that if there is a public policy issue to be addressed, it is for the Legislature, not this Court."); Flynn v. Dep't of Admin., 576 N.W.2d 245, 252 (Wis. 1998) ("This court has long held that it is the province of the legislature, not the courts, to determine public policy.").

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