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OF SWORDS AND SHIELDS: THE ROLE OF CLINICAL PRACTICE GUIDELINES IN MEDICAL MALPRACTICE LITIGATION

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INTRODUCTION

For several decades, state legislatures and courts have struggled with the question of how to rationalize the system of tort liability as it relates to medical malpractice. It has become commonplace to speak of the costs of malpractice litigation as having reached “crisis” levels, with profound impacts on physicians’ professional lives, the quality and quantity of health care delivered in this country, and the nation’s fisc. Indeed, both the direct and the indirect costs of malpractice

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litigation take a heavy toll on litigants and their insurers. Direct costs accrue in the form of litigation expenses and damages paid by malpractice liability insurers to successful plaintiffs.¹ Indirect costs arise in the form of "defensive medicine," that is, "physicians' ordering of tests and procedures . . . primarily [for the purpose of reducing] their exposure to malpractice risk."² Researchers have encountered difficulties in ascertaining the precise magnitude of these costs,³ but there is general agreement that they are significant. According to one estimate, the cost of defensive medicine is nearly \$7 billion, and the total cost of the medical malpractice system (including damage awards, malpractice insurance premiums, and defensive medicine) is over \$22 billion per year.⁴

Not all of this cost is socially inefficient. To be sure, it is desirable to have in place a medical malpractice system that channels reasonable compensation to the victims of medical negligence, even if it involves some transaction costs in the form of litigation expenses. However, there is little doubt that a portion of these costs are "excessive" in the sense that they are unrelated to this goal. Defensive medicine costs are "excessive" if they are incurred to pay for health services that contribute nothing to the health and well-being of the patients for which they are ordered. Litigation expenses may be "excessive" in two ways: First, the costs associated with achieving the "correct" outcome in a malpractice case⁵ may be higher than necessary (for example, because too much discovery was conducted or

¹ See Michael Daly, *Attacking Defensive Medicine Through the Utilization of Practice Parameters: Panacea or Placebo for the Health Care Reform Movement?*, 16 J. LEGAL MED. 101, 104 (1995) (reporting that 60¢ to 70¢ of every dollar paid to plaintiffs in malpractice damage awards goes to pay for litigation expenses).

² OFFICE OF TECHNOLOGY ASSESSMENT, 98TH CONG., IMPACT OF LEGAL REFORMS ON MEDICAL MALPRACTICE COSTS 6 (1993) (citation omitted).

³ It is difficult to separate out medical services that are ordered by physicians primarily or solely out of fear of liability from those ordered out of medical necessity. See Daly, *supra* note 1, at 105 (noting an "inability to separate liability-induced clinical practices from fee-for-service-induced practices").

⁴ OFFICE OF TECHNOLOGY ASSESSMENT, 103D CONG., DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE 155 (1994) [hereinafter OTA REPORT]. The figures cited are adjusted from the figures in 1984 dollars given in the Office of Technology Assessment Report. See also Deborah W. Garnick et al., *Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims?*, 266 JAMA 2856, 2856 (1991) (summarizing the various economic and social costs of the current malpractice system). *But cf.* OTA REPORT, *supra*, at 47-48, 74, 154-56 (noting the methodological difficulties of measuring the cost of defensive medicine).

⁵ By "correct" outcome in a malpractice case, I mean one that accurately reflects the true presence or absence of negligence on the part of the defendant.

an excessive number of high-priced medical experts was employed). Second, all costs incurred in cases in which an "incorrect" result is reached are socially inefficient. That is, an award of damages to a plaintiff who was not, in fact, the victim of medical negligence is an "excessive" cost of the medical malpractice system. The expense of litigation that does not result in compensation for an authentic malpractice victim is also inefficient. Efforts to reduce costs in the medical malpractice system should thus be aimed at three targets: discouraging defensive medicine, lowering the costs of producing accurate outcomes, and decreasing the incidence of incorrect outcomes.

In the last ten years, there has been increasing attention paid to the possibility of using clinical practice guidelines ("CPGs") to accomplish these goals. CPGs are consensus statements developed by various bodies—public and private—about what constitutes appropriate treatment for a specific condition, set of symptoms, or preventive care goal. The Institute of Medicine has defined CPGs as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."⁶ Because they derive from the consensus of experts, CPGs are thought to represent the prevailing standard of care in the medical profession. It is not surprising, then, that would-be tort reformers have suggested using CPGs as evidence of the legal standard of care in medical malpractice cases.⁷

At first blush, this proposal is attractive. The reformers point out that at present, the medical malpractice system is pervaded by uncertainty: uncertainty as to what constitutes the legal standard of care, uncertainty as to what evidence will be sufficient to prove a breach of that standard, and uncertainty as to the magnitude of the damages a jury will award if it is convinced by that evidence. This uncertainty is manifested in physicians' pursuit of defensive

⁶ COMMITTEE ON CLINICAL PRACTICE GUIDELINES, INSTITUTE OF MEDICINE, GUIDELINES FOR CLINICAL PRACTICE 2 (Marilyn J. Field & Kathleen N. Lohr eds., 1992) (internal quotation marks omitted). For a description of the process of guideline development, see Steven H. Woolf, *Practice Guidelines, a New Reality in Medicine: II. Methods of Developing Guidelines*, 152 ARCHIVES INTERNAL MED. 946 (1992).

⁷ See, e.g., Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, LAW & CONTEMP. PROBS., Spring 1991, at 91; Richard E. Leahy, Comment, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CAL. L. REV. 1483 (1989); see also ME. REV. STAT. ANN. tit. 24, §§ 2971-2979 (West 2000).

medicine.⁸ Unsure about exactly what is required of them, and averse to the risk of being sued, physicians protect themselves by ordering tests and other services that may be medically unnecessary but that will create a “paper trail” that they can later invoke in defense of the care rendered. If physicians knew *ex ante* that the standard of care to which they had a legal duty to conform was inscribed in black and white in a compendium of CPGs, it is argued, two benefits would be reaped. Physicians would operate under less uncertainty, and consequently would practice medicine less defensively. Additionally, physicians would have an incentive to comply with CPGs, which represent our best estimate of what constitutes good quality care.

This Article attempts to evaluate these arguments in light of the existing empirical evidence concerning the use of CPGs in medical practice and as the legal standard of care. It is proposed that while there may be certain efficiencies associated with the use of CPGs as the legal standard of care, their use is deeply problematic. The argument proceeds as follows: Courts, state legislatures, and academic commentators have suggested a variety of ways in which CPGs could be incorporated into malpractice litigation.⁹ While empirical evidence indicates that CPGs currently are being used both as exculpatory evidence (by physician defendants) and as inculpatory evidence (by plaintiffs), statutory reforms enacted to date provide for the one-way, “shield-only” use of CPGs.¹⁰ Indeed, there are good reasons to disallow their inculpatory use. Chief among these is that CPGs do not, in fact, appear to represent prevailing medical practice in most instances. But permitting 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 law¹¹ 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. Because of the problems associated with the inculpatory use of CPGs, the best course of action

⁸ Daniel W. Shuman, *The Psychology of Deterrence in Tort Law*, 42 U. KAN. L. REV. 115, 124 (1993).

⁹ *Infra* Part I.D.

¹⁰ See, e.g., FLA. STAT. ANN. § 408.02 (West, Supp. 1998); KY. REV. STAT. ANN. § 342.035(8) (Michie 1997); ME. REV. STAT. ANN. tit. 24, §§ 2971-2979 (West 2000).

¹¹ See FED. R. EVID. 402 (setting out the bedrock rule of evidence that presumes all relevant evidence, unless otherwise excluded, will be admitted).

is to restrict their use by both plaintiffs and defendants.

This Article proceeds in four parts. Part I provides background information about the evolution and purpose of CPGs, the standard of care in medical malpractice cases, current uses of CPGs in malpractice litigation, and reform proposals. Part II presents arguments against the use of CPGs to prove that the defendant physician breached the standard of care. Part III discusses the problems with allowing the one-way exculpatory use of CPGs by defendants. Part IV presents some concluding thoughts on the role CPGs should play in malpractice litigation in the future.

I. BACKGROUND

A. *Evolution and Purpose of Clinical Practice Guidelines*

CPGs have been a part of medical practice for more than half a century.¹² Interest in the possibilities of using CPGs to improve medical practice grew in the 1970s and 1980s after health services researchers discovered wide variations in care processes between different geographic locations within the United States.¹³ Practice variation is thought to imply an overuse of medical procedures in some geographic areas, and/or an underuse in other areas, that is attributable to physicians' uncertainty regarding appropriate indications for particular treatments.¹⁴ In response to these empirical findings, health economists such as Alain Enthoven began advocating the use of cost-effectiveness analysis to root out socially inefficient medical practices.¹⁵ Cost-effectiveness analysis and a related method

¹² R. Dale Walker et al., *Medical Practice Guidelines*, 161 W.J. MED. 39, 39 (1994) (citing Steven H. Woolf, *Practice Guidelines: A New Reality in Medicine: I. Recent Developments*, 150 ARCHIVES INTERNAL MED. 1811 (1990)).

¹³ See, e.g., James M. Perrin et al., *Variations in Rates of Hospitalization of Children in Three Urban Communities*, 320 NEW ENG. J. MED. 1183 (1989) (studying Boston, Rochester, and New Haven); John Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCIENCE 1102 (1973) (studying Vermont); John E. Wennberg et al., *Are Hospital Services Rationed in New Haven or Over-Utilized in Boston?*, 329 LANCET 1185 (1987) (studying New Haven and Boston).

¹⁴ Walker, *supra* note 12, at 40.

¹⁵ See J. Rosser Matthews, *Practice Guidelines and Tort Reform: The Legal System Confronts the Technocratic Wish*, 24 J. HEALTH POL., POLY & L. 275, 279-82 (1999) (discussing Enthoven's work regarding carotid endarterectomies); Lori Rinella, Comment, *The Use of Medical Practice Guidelines in Medical Malpractice Litigation—Should Practice Guidelines Define the Standard of Care?*, 64 UMKC L. REV. 337, 341 (1995) (noting that practice guidelines may reduce waste and abuse).

of evaluating clinical interventions, outcomes research,¹⁶ have produced a large body of findings concerning the efficacy of various health services, upon which clinical practice guidelines can be based.

A number of different parties have involved themselves in composing and disseminating CPGs. The promulgators can be grouped into three categories: professional societies, government bodies, and health care payers (that is, HMOs and insurance companies). The American Medical Association ("AMA") and more than fifty physician specialty boards have been involved in the development of CPGs.¹⁷ CPGs developed by professional medical societies are regarded as highly authoritative,¹⁸ due to both physicians' expertise and the fact that, unlike insurers, physicians' financial incentives traditionally have been aligned with providing top-quality care to their patients. Guidelines developed by professional societies tend to be broad and flexible in nature, leaving substantial room for physicians to exercise clinical judgment. The AMA refers to its CPGs as "parameters" to connote that the guidelines are meant merely to identify "floors" and "ceilings" of appropriate care, defining a range of acceptable practices from which physicians can select according to their training and judgment.¹⁹

Medical professional societies have two motivations for developing CPGs. First, they seek to reduce the incidence of avoidable medical injuries and improve the quality of care by reducing overuse of certain services. The AMA has stated:

In essence, it is hoped that practice parameters will enable physicians to provide high-quality medical care more effectively and efficiently, thereby responding to society's need to control health care expenditures without sacrificing the quality of care. It is expected that practice parameters will help physicians reduce the amount of unnecessary or inappropriate care for patients [and] reduce the incidence of avoidable injuries caused by substandard care and the amount of defensive

¹⁶ Outcomes research is similar to cost-effectiveness analysis in that it examines the relative efficacy of different treatments in achieving desired clinical outcomes, but outcomes research does not focus on the comparative evaluation of the *costs* of different interventions. Megan L. Sheetz, Note, *Toward Controlled Clinical Care Through Clinical Practice Guidelines: The Legal Liability for Developers and Issuers of Clinical Pathways*, 63 BROOK. L. REV. 1341, 1349-50 (1997).

¹⁷ See Walker, *supra* note 12, at 40.

¹⁸ See Leahy, *supra* note 7, at 1510-13 (noting that CPGs developed by professional medical societies are highly regarded within the medical profession).

¹⁹ Havighurst, *supra* note 7, at 91.

medicine²⁰

In addition, medical professionals have developed their own guidelines as a means of defending themselves against competing guidelines promulgated by health care payers. The payers' guidelines, which are influenced by insurers' cost-consciousness, are frequently more restrictive and perceived to pose a threat to physicians' autonomy.²¹

The federal and state governments have recently joined the professional societies' efforts to develop CPGs. In 1989, Congress created the Agency for Health Care Policy and Research ("AHCPR"), now renamed the Agency for Healthcare Research and Quality ("AHRQ"), to "enhance the quality, appropriateness, and effectiveness of health care services" through, among other things, "the development and periodic review and updating of . . . clinically relevant guidelines."²² In the past decade, AHCPR/AHRQ has become a major force in the creation and dissemination of guidelines in a wide range of areas. Although not as active as the federal government, several states also have ongoing projects to develop CPGs as part of statewide medical quality improvement programs and initiatives to reduce malpractice costs.²³

Managed care organizations and traditional health insurers have developed their own guidelines for appropriate care. While guidelines created by professional and government bodies usually serve merely to educate physicians in the hope that they will choose to change their practice behavior, guidelines created by health care payers are often used for utilization review and physician profiling purposes. Utilization review is the evaluation by a third-party payer of a physician's treatment orders in order to make decisions about whether medical care will be paid for by the insurer. Physician profiling is a payer's analysis of a physician's practice patterns for purposes of judging whether the physician is practicing cost-efficient

²⁰ Edward B. Hirshfeld, *From the Office of the General Counsel: Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886, 2887 (1991) (citations omitted).

²¹ *See* Stephen M. Merz, *Clinical Practice Guidelines: Policy Issues and Legal Implications*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 306, 308 (1993) (noting that peer review organizations may refuse payment based on these guidelines); Rinella, *supra* note 15, at 341 ("Physicians want their own guidelines to determine review and payment criteria to defend against unmerited payment denial by third party payers.")

²² Merz, *supra* note 21, at 307 (citations and internal quotation marks omitted).

²³ *See id.* at 307 (noting the efforts made by ten states as of 1989).

care.²⁴ Compliance with CPGs clearly assumes added importance when the physician knows that his patient may not receive coverage for the services he requests on the patient's behalf if those services are not indicated by the relevant practice guideline. Compliance with CPGs may even be an explicit or implicit requirement of a physician's participation in an HMO.²⁵

While guidelines developed by professional medical societies are focused primarily on achieving the best medical outcomes, guidelines developed by health care payers are heavily influenced by cost-control concerns.²⁶ Thus, payer-developed guidelines should be viewed as less authoritative than those developed by economically disinterested researchers and clinicians.

Recent years have seen the issuance of CPGs by malpractice liability insurers as well as health insurers. "Liability insurance carriers are also financially motivated, but their goal is to profit by controlling malpractice losses through the promulgation and enforcement of specific clinical standards."²⁷ Because malpractice suits are best avoided by ensuring good clinical outcomes, malpractice insurers have more incentive than health insurers to adopt CPGs that emphasize top-quality care over low-cost care. These guidelines thus fall somewhere between payer guidelines and professional societies' guidelines on the continuum of authoritativeness.²⁸ Like health insurers, many liability insurers have taken specific steps to enforce compliance with their guidelines. For example, the Utah Medical

²⁴ See William Trail & Brad A. Allen, *Government Created Medical Practice Guidelines*, 10 J.L. & HEALTH 231, 236 (1995-96) (explaining physician profiling).

²⁵ See Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 374 (1995).

²⁶ See John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEG. MED. 421, 437 (1994) ("[S]ome payers use parameters, indeed develop them, as a method to maximize profits under the guise of reducing inefficient or unnecessary services."); Daniel W. Shuman, *The Standard of Care in Medical Malpractice Claims, Clinical Practice Guidelines, and Managed Care: Towards a Therapeutic Harmony?*, 34 CAL. W. L. REV. 99, 103 (1997) ("Although clinical practice guidelines were initially driven by concerns with the quality of care, currently their use by managed care plans is often driven by concerns with the cost of care."). For a summary of empirical findings concerning the effect of CPGs on medical costs, see Steven H. Woolf, *Practice Guidelines: A New Reality in Medicine: III. Impact on Patient Care*, 153 ARCHIVES INTERNAL MED. 2646, 2649 (1993).

²⁷ Marshall B. Kapp, *'Cookbook' Medicine: A Legal Perspective*, 150 ARCHIVES INTERNAL MED. 496, 497 (1990).

²⁸ *But see* Woolf, *supra* note 26, at 2652 (noting that because liability insurers' guidelines are designed to minimize malpractice claims, "the recommendations may reflect legal more than scientific evidence").

Insurance Association and a Colorado insurer require compliance with their obstetrical guidelines as a condition of malpractice coverage.²⁹ Other insurers raise or lower physicians' malpractice insurance premium rates depending upon their willingness to comply with the CPGs.

The combined efforts of professional organizations, federal and state governments, and health care and liability insurers have produced a staggering number of CPGs. A 1994 review estimated that more than 1600 different CPGs had been created over the years.³⁰ As noted above, these guidelines vary widely in quality.³¹ They also vary in scope. Some CPGs are narrowly drawn descriptions of clinical procedures that leave little room for discretion on the part of the physician, while others are vague recommendations as to how complex medical problems might be approached.³² Some clinical problems are quite amenable to governance by a rigid algorithm. For example, the administration of anesthesia "can be handled in essentially the same way for a wide spectrum of patients."³³ In contrast, a problem like clinical depression requires a large amount of clinical judgment, and the guidelines for that condition are correspondingly general.³⁴

The overall picture of CPGs is thus characterized by tremendous diversity—in the parties creating the guidelines, their motivations, the intended purposes of the guidelines, the type of evidence upon which the guidelines are based, the procedures through which the guidelines are developed, the scope of the guidelines, the specificity of the recommendations, and physicians' perceived need to comply

²⁹ INSTITUTE OF MEDICINE, *MEDICAL PROFESSIONAL LIABILITY AND THE DELIVERY OF OBSTETRICAL CARE* 118 (1989).

³⁰ See Ayres, *supra* note 26, at 421.

³¹ See Mark Kadzielski et al., *Peer Review and Practice Guidelines Under Health Care Reform*, 16 WHITTIER L. REV. 157, 161 (1995) ("[T]here exists [sic] good guidelines which are valid and have potential use, as well as bad guidelines which may be equated with 'junk science.'").

³² *Compare Activities During the Examination*, QUALITY DETERMINANTS OF MAMMOGRAPHY: CLINICAL PRACTICE GUIDELINE NO. 13 (Agency for Healthcare Research and Quality, Rockville, Md.), Oct. 1994 (giving detailed instructions for the performance of mammograms), with *Effects of Cardiac Rehabilitation Exercise Training*, CARDIAC REHABILITATION: CLINICAL PRACTICE GUIDELINE NO. 17 (Agency for Healthcare Research and Quality, Rockville, Md.), Oct. 1995 (offering only general advice for cardiac rehabilitation).

³³ Sheetz, *supra* note 16, at 1346-47 (quoting Hirshfeld, *supra* note 20, at 2886); see also Ayres, *supra* note 26, at 427 (observing that anesthesiology guidelines "concern highly specific aspects of patient care in a controlled environment").

³⁴ *Infra* note 179 and accompanying text.

with the guidelines. Tort reformers who propose to use CPGs as the standard of care in medical malpractice cases therefore have many questions to answer regarding which guidelines will be applied in a particular case and why. "Practice parameters that address the same clinical problem, but have different applications, goals, and recommendations will present a problem for courts."³⁵ Guidelines that were developed with a particular goal in mind—for example, cost control, or providing the highest quality of care that is technologically possible—may not be easily transferable to the litigation setting.

While many of the promulgators of guidelines have discussed the possibility that their guidelines might be used by litigants in malpractice cases, this does not appear to have been their intention. One review article in a medical journal comments:

The good news is that the guidelines are not standards of care, meaning mandatory requirements for practitioners. Rather, they are rudimentary road maps outlining options in the diagnosis and treatment of particular conditions.

....

... [L]itigators can inappropriately use the guidelines as a defined recipe (i.e., a standard of care) that, if not followed, provides a basis for a lawsuit.³⁶

For these reasons, the fact that CPGs may usefully guide the practice of medicine does not necessarily imply that they also should guide the practice of medical malpractice law. In order to understand how CPGs might or might not be appropriate decision tools in malpractice cases, it is necessary to understand their relation to the legal standard of care in medical malpractice suits as established at common law. The following sub-Part provides a brief review of this standard.

B. *The Standard of Care in Medical Malpractice Cases*

Medical malpractice claims are adjudicated under a negligence standard. The plaintiff must prove four elements: (1) that the defendant physician owed a duty of care; (2) that the defendant breached this duty; (3) that the breach was the proximate cause of the plaintiff's injuries; and (4) that the plaintiff actually incurred damages

³⁵ Hirshfeld, *supra* note 20, at 2888.

³⁶ A. John Rush, *Clinical Practice Guidelines: Good News, Bad News, or No News?*, 50 ARCHIVES GEN. PSYCHIATRY 483, 486 (1993).

as a result of the physician's conduct.³⁷ The physician's duty is defined by the legal standard of care. While the standard of care in medical negligence cases has changed somewhat over time, the basic standard—as in nonmedical negligence cases—is “reasonable and ordinary care.” More specifically, a physician must exercise that degree of care which would be exercised by a physician in good standing in the same medical specialty in a similar community in like circumstances.³⁸

Until the middle of the twentieth century, state courts adhered to a “locality rule,” which held physicians to the standard of care determined by other physicians in the same locality.³⁹ The justification for this rule was that “disparities in medical knowledge and equipment between rural and urban communities resulting from differences in communication, transportation, and economic resources” made it unfair to hold rural practitioners to the same standard as urban physicians.⁴⁰ It was difficult for plaintiffs to prevail under the locality rule because courts required the expert witnesses called to testify as to the standard of care to be from the same locality as the defendant physician. Physicians working in the same town typically refused to give testimony that would incriminate a colleague, so plaintiffs were left without available experts to support their claims. Additionally, the focus on localities produced wide variations in the legal standards of care (and case outcomes) across geographic areas.⁴¹ These problems led most states to reject the locality rule.

Many state courts considered replacing the locality rule with a national standard of care. Among the arguments offered in favor of such a standard were that advancements in communication and transportation made possible the mass dissemination of new breakthroughs in medical care, so that there was no longer any justification for holding a “backwoods” physician to a lesser standard than a physician in a state-of-the-art urban hospital.⁴² Most courts

³⁷ RICHARD A. EPSTEIN, *CASES AND MATERIALS ON TORTS* 166 (6th ed. 1995).

³⁸ 61 AM. JUR. 2D *Physicians, Surgeons & Other Healers* § 205 (1981).

³⁹ Sam A. McConkey, *Simplifying the Law in Medical Malpractice: The Use of Practice Guidelines as the Standard of Care in Medical Malpractice Litigation*, 97 W. VA. L. REV. 491, 498 (1995).

⁴⁰ See Troyen Brennan, *Overview of Legal Issues*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 319, 321 (1993).

⁴¹ McConkey, *supra* note 39, at 498.

⁴² See, e.g., *Shilkret v. Annapolis Emergency Hosp. Ass'n*, 349 A.2d 245, 248-52 (Md. 1975) (“[R]ecognizing the significant developments which have occurred in the training and practice of medicine... a majority of American courts have now

accepted the argument that medical knowledge had become more easily accessible to rural practitioners, so that they might reasonably be expected to keep pace of the latest developments in care. However, these courts hesitated to adopt a flat national standard of care because they were cognizant that the physical and financial resources available to physicians in different localities still varied considerably. The result was that most states opted for an intermediate standard of care called the "similar community" rule. As set forth in the classic case of *Hall v. Hilbun*, this rule requires that the physician

use his or her knowledge [to] treat... each patient, with such reasonable diligence, skill, competence, and prudence as are practiced by minimally competent physicians *in the same specialty* or general field of practice throughout the United States, who have available to them *the same general facilities, services, equipment, and options*.⁴³

This standard not only requires that physicians maintain a level of competence comparable to others in their field, but also acknowledges that resource constraints (for example, the lack of a CT scanner) may prevent a rural physician from being able to deliver the state-of-the-art care she knows is practiced at resource-rich urban hospitals.

The court's use of the words "as are practiced" in the above rule signifies that the legal standard of care is centered upon prevailing medical practice—that is, on *custom*.⁴⁴ In tort law generally, a defendant's compliance with custom is not dispositive of a negligence claim. Medical malpractice law, however, has evolved somewhat differently. In other kinds of negligence cases, the Supreme Court has declared, "What usually is done may be evidence of what ought to be done, but what ought to be done is set by the standard of reasonable prudence, whether it is usually complied with or not."⁴⁵ In

abandoned the strict locality rule as being too narrow.").

⁴³ 466 So. 2d 856, 873 (Miss. 1985) (emphasis added), *quoted in* Brennan, *supra* note 40, at 321; *see also* 61 AM. JUR. 2D *Physicians, Surgeons & Other Healers* § 205 (1981) ("[T]he standard . . . is the average standard of the profession.").

⁴⁴ "Custom" can be defined as "an unconscious collective agreement on how an activity should be carried out" that "develops over time when a group of actors, acting independently of, and often in competition with, each other, reach the same decisions regarding the manner in which their activity should be conducted." James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1384-85 (1994).

⁴⁵ *Tex. & Pac. Ry. v. Behymer*, 189 U.S. 468, 470 (1903).

the case of *The T.J. Hooper*,⁴⁶ Judge Learned Hand agreed that compliance with custom is a factor to be taken into account in determining whether the defendant has been negligent, but does not constitute absolute proof of non-negligence. He famously observed that an entire industry “may have unduly lagged in the adoption of new and available devices.”⁴⁷ Thus, industry custom may depart from the common law negligence standard of reasonable care and “[c]ourts must in the end say what is required.”⁴⁸

The *Restatement (Second) of Torts* embodies this judicial determination.⁴⁹ It notes that custom is relevant evidence of non-negligence because it reflects a shared judgment about the optimal level of precaution-taking, arrived at by a weighing of the risk reduction associated with additional precautions against the costs of those precautions.⁵⁰ Custom, however, is not controlling on the issue of negligence because “[c]ustoms which are entirely reasonable under the ordinary circumstances which give rise to them may become quite unreasonable in the light of a single fact in the particular case.”⁵¹ Additionally, some customs may be unreasonable in all cases. An industry may adhere to a custom that carries clearly excessive risk out of a desire to save time, effort, or money.⁵² As the *Restatement* says, it is the task of courts to recognize this as negligence; otherwise, “[i]f the only test is to be what has always been done, no one will ever have any great incentive to make any progress in the direction of safety.”⁵³

The most current discussion draft for the forthcoming *Restatement (Third) of Torts* adheres to this philosophy, drawing a distinction between “ordinary care” and “reasonable care.”⁵⁴ That draft acknowledges, however, that this general rule has been modified by the courts in negligence cases involving *professional* customs, including

⁴⁶ 60 F.2d 737 (2d Cir. 1932).

⁴⁷ *Id.* at 740.

⁴⁸ *Id.*

⁴⁹ *See* RESTATEMENT (SECOND) OF TORTS § 295A (1965) (“In determining whether conduct is negligent, the customs of the community, or of others under like circumstances, are factors to be taken into account, but are not controlling where a reasonable man would not follow them.”).

⁵⁰ *Id.* § 295A cmt. b; *cf.* *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (holding that there can be no general rule of what constitutes negligent behavior and that the court must evaluate the probability of loss in comparison to the cost of a precaution in determining whether an action was negligent).

⁵¹ RESTATEMENT (SECOND) OF TORTS, § 295A cmt. c (1965).

⁵² *See id.* (providing examples illustrating why custom is not always controlling).

⁵³ *Id.*

⁵⁴ RESTATEMENT (THIRD) OF TORTS § 11 cmt. a (Discussion Draft 1999).

medical malpractice cases. The draft observes that in such cases, "professional customs tend to establish the negligence standard."⁵⁵ The defendant's departure from custom may serve as conclusive evidence of negligence. At the very least, courts are likely to dismiss a case if the plaintiff has not come forward with any evidence of the defendant's noncompliance with custom.⁵⁶ Although courts have been reluctant to view a defendant's compliance with custom as conclusive evidence of non-negligence, it is still fairly unusual for a court to strike down a professional custom as falling short of the standard of reasonable care.⁵⁷

One such exceptional case is the much discussed 1974 Washington case of *Helling v. Carey*.⁵⁸ The plaintiff brought suit against her ophthalmologists after suffering severe vision impairment due to glaucoma. She had been under the ophthalmologists' care for nine years and during that time had complained several times about her deteriorating vision. The defendants never performed an eye-pressure test to determine whether she might be afflicted with glaucoma. Uncontroverted evidence was presented at trial showing that the professional custom among ophthalmologists was not to perform glaucoma tests on patients under the age of forty because glaucoma was extremely rare in that age group. The defendants prevailed in the lower courts, but the Washington Supreme Court reversed, holding that in this case customary practice did not constitute reasonable care.⁵⁹ Because the glaucoma test was so inexpensive and easy to administer, and could so dramatically reduce the risk of vision damage due to glaucoma, the ophthalmology

⁵⁵ *Id.* at § 11 cmt. c reporter's note (citing cases); see also *Quintana v. United Blood Servs.*, 811 P.2d 424, 427 (Colo. Ct. App. 1991) ("Accordingly, in a medical malpractice case, the conduct of the physician is measured against the accepted or customary medical practices of similarly trained and similarly situated physicians, rather than standards of reasonableness determined by judges and juries." (citation omitted)), *aff'd* 827 P.2d 509 (Colo. 1992); *Henderson & Siliciano*, *supra* note 44, at 1384 ("Unlike some areas of negligence law where the jury's wisdom or the legislature's fiat define the standard of care, courts in medical malpractice cases have traditionally looked to the customary practices of the medical profession as the benchmark of acceptable behavior." (citations omitted)).

⁵⁶ See FRANK A. MCCLELLAN, *MEDICAL MALPRACTICE: LAW, TACTICS, AND ETHICS* 33 (1994).

⁵⁷ See RICHARD A. EPSTEIN, *TORTS* 140 (1999) ("In medical matters, virtually all courts treat conformity with practice within the profession as meeting the standard of the reasonable physician.").

⁵⁸ 519 P.2d 981 (Wash. 1974).

⁵⁹ See *id.* at 983 (holding that the court is not bound "by the standards of the ophthalmology profession").

profession was negligent in failing to adopt the test as a routine practice. Citing then-Judge Hand's opinion in *The T.J. Hooper*,⁶⁰ the court made the aggressive statement that under these facts, "it is the duty of the courts to say what is required to protect patients."⁶¹

This decision was considered "radical" even by the judges who handed it down.⁶² Associate Justice Utter observed in his concurring opinion that the standard adopted by the court approached a strict liability rule. While the majority couched its ruling in negligence terms, Utter's position was that it was "illogical" for a court to supplant the judgment of medical professionals as to what constitutes reasonable care, and what the court was really doing was "imposing liability, because, in choosing between an innocent plaintiff and a doctor, who acted reasonably according to his specialty but who could have prevented . . . this disease . . . the plaintiff should not have to bear the risk of loss."⁶³ The physician, who was insured, was in a better position to shoulder the loss.⁶⁴

Whether viewed through the lens of negligence law or as a strict liability case, *Helling* represented a substantial departure from traditional medical malpractice jurisprudence. The implications for physicians were not lost on professional societies and malpractice insurers. Their intensive lobbying led the Washington state legislature to enact a statute designed to overturn *Helling* and reinstate the previous, custom-based, standard of care.⁶⁵ The Washington courts, however, subsequently have construed the law as not undermining *Helling*.⁶⁶ Thus, Washington remains atypical in its approach to professional malpractice: A physician in Washington is afforded little protection from tort liability by complying with the customary practices of her colleagues.

⁶⁰ 60 F.2d 737 (2d Cir. 1932).

⁶¹ *Helling*, 519 P.2d at 983.

⁶² McCLELLAN, *supra* note 56, at 36.

⁶³ *Helling*, 519 P.2d at 984 (Utter, J., concurring).

⁶⁴ *Id.* at 985.

⁶⁵ See WASH. REV. CODE. § 7.70.040 (1975) (providing that a health care provider is negligent only if she failed to exercise that degree of care, skill, and learning expected of a reasonably prudent provider in the same specialty, in the state of Washington, acting in similar circumstances).

⁶⁶ See Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 WIS. L. REV. 1193, 1214 (citing *Harris v. Groth*, 663 P.2d 113 (Wash. 1983) (holding that a health care provider must exercise the degree of care, skill, and learning possessed, as opposed to that demonstrated, by the average practitioner); *Gates v. Jensen*, 595 P.2d 919 (Wash. 1979) (same); *Brown v. Dahl*, 705 P.2d 781 (Wash. Ct. App. 1985) (same)).

Given that most states deem custom to constitute the standard of care in medical malpractice cases, the question naturally arises as to how litigants may establish what the relevant custom is in a particular set of circumstances. For professional malpractice cases, the testimony of an expert witness in the same field as the defendant is required. Such experts often base their opinions entirely on their own experience and observations. They may, however, base their opinions partly on written industry codes and standards that have been promulgated either by governmental bodies or by voluntary associations within the industry. This practice is clearly relevant to the question of what role clinical practice guidelines, which are a type of written industry standard, might play in malpractice litigation.

The state courts vary in their approaches to the admissibility of industry codes and standards.⁶⁷ A large number of cases support the view that such codes and standards are admissible, probative evidence on the issue of the defendant's duty. Since such codes are believed to be "objective standards representing a consensus of opinion carrying the approval of a significant segment of an industry," they are deemed to "contain the elements of trustworthiness and necessity which justify an exception to the hearsay rule."⁶⁸ Courts that admit written industry standards generally require an expert to testify as to the standards' acceptance in the industry.⁶⁹ Moreover, compliance or noncompliance with the written standards is not viewed as *conclusive* evidence of negligence, or the absence thereof, only as *some* evidence of it.⁷⁰ The rationale is that while the standards indicate the prevailing thinking in the industry about the appropriate level of precautions, and in some cases may codify industry custom,⁷¹ they do not rise to the

⁶⁷ See Daniel E. Feld, Annotation, *Admissibility in Evidence, on Issue of Negligence, of Codes or Standards of Safety Issued or Sponsored by Governmental Body or by Voluntary Association*, 58 A.L.R.3d 148 § 2(a), at 155 (1974) (summarizing the varying approaches to the admissibility of safety codes or standards).

⁶⁸ *Id.*; see also *id.* § 3, at 157-59 (collecting cases).

⁶⁹ *Id.* § 2(a), at 155.

⁷⁰ *Id.* § 2(b), at 157.

⁷¹ The discussion draft of the *Restatement (Third)* recognizes that written safety codes and standards may have been written to reflect prevailing custom or may have gained such widespread acceptance and compliance as to have established a new custom, but implicitly acknowledges the possibility that in some cases such codes may *not* represent current custom. See RESTATEMENT (THIRD) OF TORTS § 11 cmt. e (Discussion Draft 1999) ("Insofar as . . . the code . . . is shown to be the equivalent of custom, evidence concerning the code or recommendation should be treated in accordance with this section.").

level of substantive law.⁷² Violating an industry safety standard, therefore, is not the same thing as violating a statute, which may give rise to an inference of per se negligence. A few courts have declined to afford written industry standards even this degree of weight; they have opted to make such standards inadmissible even when expert authentication is proffered.⁷³

The specific views of the state courts toward the admissibility and weight of clinical practice guidelines as evidence of the standard of care in medical malpractice cases will be discussed shortly. Before proceeding to that discussion, it is interesting to consider a related issue: whether a physician may offer as a defense to a negligence claim the fact that he complied with the decision of an HMO or other insurer regarding medically necessary and appropriate care in a particular case. The answer appears to be no. In the case of *Wickline v. California*,⁷⁴ a California court held that a physician may not abdicate his duty to adhere to the professional standard of care merely because an insurer has declined to cover the medical services required to satisfy that standard. The case involved a patient covered by the California state Medicaid program ("Medi-Cal"). Following vascular surgery on her leg, the patient developed complications that led her treating physicians to decide that she required a longer hospital stay than was typically authorized by Medi-Cal. However, Medi-Cal denied their request for an extension of her stay. The patient was discharged and subsequently developed additional complications that necessitated the amputation of her leg. The patient sued Medi-Cal for negligently requiring the physician to discharge her despite her medical need for additional hospital days.⁷⁵

The jury found in favor of the patient and the State appealed. The appellate court found for Medi-Cal on the narrow ground that the physician in charge, after receiving word of Medi-Cal's decision, ultimately had decided that it would not violate the standard of care or the patient's best interest to discharge her promptly. This judgment was uncontested at trial. Medi-Cal was not negligent

⁷² Feld, *supra* note 67, §2(b); see also RESTATEMENT (THIRD) OF TORTS § 11 cmt. c (Discussion Draft 1999) ("[B]ecause it is issued by a private body, the actor's compliance with or departure from the code does not call into play the rules relating to violation of and compliance with public enactments . . .").

⁷³ See RESTATEMENT (THIRD) OF TORTS § 11 cmt. e, reporter's note (Discussion Draft 1999) (collecting cases).

⁷⁴ 239 Cal. Rptr. 810 (Ct. App. 1986).

⁷⁵ See *id.* at 812-17.

because it did not coerce this decision or override the medical judgment of the physician.⁷⁶

Although the physicians involved in the decision were not named as defendants in the case, the appellate court seized the opportunity to issue a warning to physicians: The duty to ensure that a patient receives appropriate care rests squarely with the physician, regardless of the coverage decisions of the patient's insurer. The court admonished,

the physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient's care. He cannot point to the health care payor as the liability scapegoat when the consequences of his own determinative medical decisions go sour.⁷⁷

Thus, one cannot look to health care payers to set either the medical or the legal standard of care for medical practice. The *Wickline* decision bears on the debate over the role of CPGs in malpractice litigation because it suggests that compliance with guidelines issued by HMOs or other insurers may not constitute a valid affirmative defense for a physician whose management of the patient resulted in injury.⁷⁸

With these basic principles and precedents of medical malpractice law in mind, it is now appropriate to turn to an examination of the current uses of CPGs in malpractice litigation.

C. Roles of CPGs in Malpractice Litigation

This sub-Part addresses four questions relating to the current uses of CPGs: First, what are the rules governing their admissibility in evidence? Secondly, what weight do courts give CPGs on the issue of negligence? Thirdly, how (and how frequently) are CPGs currently being used? Finally, what effect has the use of CPGs had on medical

⁷⁶ See *id.* at 819-20 ("Medi-Cal did not override the medical judgment of [the] treating physicians . . . [t]herefore, there can be no viable cause of action against it for the consequences of that discharge decision.").

⁷⁷ *Id.* at 819.

⁷⁸ Although *Wickline* dealt specifically with an insurer decision issued contemporaneously with the patient's care, the reasoning underlying the decision would seem to apply with equal force to an insurer coverage decision issued ex ante in the form of a practice guideline. Both kinds of insurer decisions raise the same issues: the financial incentives insurers face to stint on care and the physician's duty to serve as an advocate of his patient's best interest, which arises from the nature of the physician-patient relationship.

malpractice litigation?

CPGs, like other kinds of evidence, are subject to the admissibility requirements of the Federal Rules of Evidence and applicable state and local evidence rules. In order to be admissible on a particular point, CPGs must satisfy the evidentiary requirements of relevance, authenticity, and reliability. Evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."⁷⁹ CPGs will be considered relevant evidence of the standard of care only if they actually represent the legal standard of care for a particular medical condition or procedure *and* that medical condition or procedure was applicable to the particular clinical interaction at issue.⁸⁰ The authenticity of the guidelines is established by having an expert testify that the guidelines are accurate representations of what they purport to be.

Establishing the reliability of the guidelines requires addressing their status as hearsay evidence.⁸¹ Because they are out-of-court statements, CPGs will be considered inadmissible hearsay unless the party offering them can demonstrate that they fall within one of the exceptions to the hearsay rule. The most commonly invoked exception is the learned treatise rule, which provides for the admissibility of "statements contained in public treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art" when "established as a reliable authority" by the testimony of an expert witness or by judicial notice.⁸² However, there exists some

⁷⁹ FED. R. EVID. 401.

⁸⁰ See Gary W. Kuc, *Practice Parameters as a Shield Against Physician Liability*, 10 J. CONTEMP. HEALTH L. & POL'Y 439, 462-63 (1994) (noting that "the key issue [is] whether the practice parameters apply to the facts of the case rather than whether [they] set forth valid standards of care").

⁸¹ See FED. R. EVID. 801-805. The Federal Rules define "hearsay" as "a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted." *Id.* Rule 801(c). Hearsay is inadmissible evidence, *see id.* Rule 802, unless it falls within one of a number of specific exceptions, *see id.* Rule 803, 804.

⁸² *Id.* Rule 803(18). There are some limitations imposed on the use of learned treatise evidence: It may be read into evidence but may not be used as an exhibit. See THOMAS A. MAUET & WARREN D. WOLFSON, TRIAL EVIDENCE 226 (1997) (discussing the use of such a treatise on direct examination). Moreover, some states' rules of evidence (though not the Federal Rules) stipulate that it may only be admitted if called to the attention of the expert on cross-examination. In such states, the expert would not be permitted to base her testimony on direct examination of the CPGs. See Kuc, *supra* note 80, at 463-64 (discussing limitations upon the "learned treatises" exception).

controversy over whether CPGs qualify as learned treatises. The court in the Kentucky case of *Davenport v. Ephraim McDowell Memorial Hospital*⁸³ refused to consider the proffered professional society CPGs a learned treatise, though it admitted the guidelines anyway. Whether a CPG will be deemed a learned treatise turns on its authoritativeness, which depends on which body issued it. A learned treatise

must have been written primarily by professionals in the field for fellow professionals. It must have been subject to scrutiny and exposure for inaccuracy by some kind of peer review process, with the reputation of the writer at stake. It is "reliable" for purposes of the rule when it is recognized as authoritative in the relevant discipline. The literature and its author, not just the journal they appear in, must be established as authoritative.⁸⁴

Some commentators have suggested that CPGs meet the requirements for learned treatises because they usually appear in peer-reviewed journals,⁸⁵ but the above definition suggests that the offeror must show more than this.⁸⁶ He must also show that the body promulgating the guidelines is a well-respected medical authority and that the process through which the guidelines were developed and updated was sound.

While there are cases in which courts have spurned efforts to get CPGs admitted as learned treatises, there appears to be a trend towards admitting them, subject to the satisfaction of the above requirements. Courts are increasingly willing to allow the use of all kinds of professional standards as learned treatises⁸⁷ and to entertain expert testimony that essentially amounts to a review of the scientific literature.⁸⁸ The 1993 Supreme Court decision in *Daubert v. Merrell*

⁸³ 769 S.W.2d 56 (Ky. Ct. App. 1988), cited in Peter D. Jacobson, *Legal and Policy Considerations in Using Clinical Practice Guidelines*, 80 AM. J. CARDIOLOGY 74H, 75H (1997).

⁸⁴ MAUET & WOLFSON, *supra* note 82, at 225-26.

⁸⁵ See Troyen A. Brennan, *Practice Guidelines and Malpractice Litigation: Collision or Cohesion?*, 16 J. HEALTH POL., POL'Y & L. 67, 75 (1991) ("Since practice guidelines are relevant and since they usually appear in peer-reviewed journals or other accepted authorities, it seems very likely that a plaintiff's or defendant's expert will be able to testify citing such practice guidelines . . .").

⁸⁶ Cf. Franklin M. Zweig & Hazel A. Witte, *Assisting Judges in Screening Medical Practice Guidelines for Health Care Litigation*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 342, 349 (1993) (observing that peer review is merely one of several indicators judges may apply in evaluating the reliability of scientific evidence).

⁸⁷ See Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL., POL'Y & L. 289, 293 (1996) (discussing the use of guidelines during the pre-trial stages of litigation).

⁸⁸ Brennan, *supra* note 85, at 75.

Dow Pharmaceuticals, Inc.,⁸⁹ however, may affect this trend. *Daubert* created a new analytical framework for the judicial evaluation of the reliability and authoritative nature of proffered scientific evidence. It is perhaps too early to judge the impact of *Daubert* on the admissibility of CPGs, but one possible effect may be that judges will more closely scrutinize the procedures through which the guidelines were developed⁹⁰ and the credentials and motivations of the organization that promulgated the guidelines.

Assuming that a court is willing to admit CPGs as evidence of the standard of care, what weight will it give this evidence? The prevailing practice is to admit CPGs in connection with expert testimony, but not to give them determinative weight.⁹¹ Thus, CPGs constitute *some* evidence of the legal standard of care, but are thrown into the pot along with other kinds of evidence—for example, opposing expert testimony based on the expert's own experience and observation. The jury is free to decide which evidence is most persuasive.⁹² "Thus, under the current majority of state law, practice guidelines have the same effect as any other learned treatise: a tool for expert witnesses."⁹³ However, many courts have gone so far as to recognize CPGs offered by the plaintiff as establishing a rebuttable presumption of the standard of care, shifting the burden of proof to the defendant. The defendant then may rebut the presumption by showing that the guidelines were not applicable to the particular facts of the case.⁹⁴

⁸⁹ 509 U.S. 579 (1993). In *Daubert*, the Supreme Court altered its approach to the admissibility of scientific evidence. Previously, under the rule announced in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), *overruled by Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993), scientific evidence was admitted only if the scientific principle underlying it had gained "general acceptance" in the scientific community. *Daubert* shifted the responsibility for admission from the scientific community to the trial judge, imposing upon judges a duty to serve as gatekeepers and evaluate scientific evidence based on a range of factors. General acceptance continues to be a relevant consideration, but attention is also paid to whether the evidence was derived from a rigorous application of the scientific method. *Daubert* is only binding on the federal courts, but many states have opted to follow its approach. MAUET & WOLFSON, *supra* note 82, at 277.

⁹⁰ See Zweig & Witte, *supra* note 86, at 349 (noting that "[s]ince validity and reliability—the strength of evidence—are a fundamental element [sic] in clinical practice guidelines, judges' duty to screen may require them to appraise the strength of guidelines evidence").

⁹¹ Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, L. & CONTEMP. PROBS., Winter & Spring 1991, at 119, 131 & n.53.

⁹² Rinella, *supra* note 15, at 351.

⁹³ McConkey, *supra* note 39, at 516.

⁹⁴ See Kapp, *supra* note 27, at 498 (noting that defendants have been able to meet this burden of proof in many cases).

How are CPGs currently being used: as inculpatory evidence offered by plaintiffs to show that the physician deviated from the standard of care, or as exculpatory evidence offered by defendants to show compliance with the standard? The available empirical evidence is limited, but suggests that the guidelines are being used both ways. The most reliable study on this topic is that performed by Andrew Hyams, of the Harvard School of Public Health, and his colleagues, who reviewed records at two professional liability insurance companies and interviewed 578 personal injury attorneys rather than relying on published judicial opinions.⁹⁵ The researchers concluded that the use of CPGs in malpractice litigation is a “two-way street.”⁹⁶

The study determined that, overall, CPGs are used in malpractice cases infrequently, though their use may be increasing.⁹⁷ Forty-eight percent of the personal injury attorneys surveyed reported having had at least one case per year in which CPGs had played a role, but only 36% had had one case per year in which they played an “important” role.⁹⁸ Only 17 of the 259 insurance claims reviewed, or 6.6%, involved the use of practice guidelines.⁹⁹ Of these 17, 12 were cases in which the guidelines had been used for inculpatory purposes, 4 were cases of exculpatory use, and 1 was indeterminable.¹⁰⁰ Thus, in this sample, the guidelines were used as inculpatory evidence at three times the rate of their exculpatory use. The guidelines most often used were those issued by professional societies, individual hospitals, and the Joint Commission for Accreditation of Health Care Organizations.¹⁰¹ Other research has indicated that guidelines promulgated by health care payers do not carry the same weight in litigation as guidelines issued by these organizations.¹⁰²

⁹⁵ See Andrew L. Hyams et al., *Practice Guidelines and Malpractice Litigation: A Two-Way Street*, 122 ANNALS INTERNAL MED. 450, 451-52 (1995) (noting that published judicial opinions represent less than one percent of all suits brought).

⁹⁶ See Hyams et al., *supra* note 87, at 291 (noting that CPGs have been used “as potentially compelling evidence to support either side’s case”).

⁹⁷ See Hyams et al., *supra* note 95, at 453 (reporting that 178 of the 578 attorneys surveyed believed guideline use to be increasing, while only 7 thought it was decreasing).

⁹⁸ *Id.*

⁹⁹ *Id.* at 452.

¹⁰⁰ *Id.*

¹⁰¹ See *id.* at 453 (“The leading sources of guidelines were the American College of Obstetricians and Gynecologists (28.4%), hospital procedures and protocols (22.7%), the Joint Commission for Accreditation of Health Care Organizations (6.8%) and the American Medical Association (6.8%).”).

¹⁰² See Leonard Berlin, *Standard of Care*, 170 AM. J. RADIOLOGY 275, 277 (1998)

Hyams's survey of attorneys suggests that while the use of CPGs in litigation is relatively rare, CPGs do have some impact on the kinds of malpractice cases that are brought and their eventual outcomes. Twenty-seven percent of attorneys surveyed indicated that a CPG had influenced their decision to settle a case and 22% believed that a guideline had influenced a trier of fact in a case in the past year.¹⁰³ Moreover, 26% of plaintiffs' attorneys reported that CPGs had influenced, at least once in the previous year, their decision not to take a case, and 31% said that a guideline influenced their decision to bring a case.¹⁰⁴ Based on this evidence, the researchers speculated that the use of guidelines may help plaintiffs' attorneys (and presumably also judges) separate out frivolous malpractice claims from meritorious ones.¹⁰⁵ By making it easier to determine whether the facts of a particular case indicate a deviation from the standard of care and to prove that issue in a trial, CPGs also may encourage more plaintiffs and their attorneys to press forward with meritorious cases.¹⁰⁶ Since empirical research has demonstrated that the number of malpractice claims brought represents only a tiny fraction of the actual number of instances of medical malpractice,¹⁰⁷ this result would be desirable from the standpoint of compensation.

Building on this empirical evidence, which suggests that CPGs may perform useful functions in litigation but are currently used only infrequently, tort reformers have offered a range of proposals for increasing the role of CPGs in malpractice cases. The next sub-Part examines these reform efforts and the problems associated with each.

(citing *Levine v. Rosen*, 616 A.2d 623 (Pa. 1992)).

¹⁰³ Hyams et al., *supra* note 95, at 453.

¹⁰⁴ *Id.*

¹⁰⁵ *See id.* at 454 ("When physicians comply with guidelines, the exculpatory value of those guidelines will likely dissuade plaintiffs' attorneys from bringing cases.")

¹⁰⁶ *See id.* ("When physicians fail to comply, plaintiff's [sic] attorneys will use the guidelines as evidence of negligence."); *see also* Garnick et al., *supra* note 4, at 2858 ("If guidelines serve to define malpractice more precisely, some meritorious cases that are not currently pursued will be identifiable.")

¹⁰⁷ *See* PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE 69 (1993) (citing a Harvard Medical Practice Study, which found that in 1984, in New York State, only 1 malpractice claim was filed for every 7 medical injuries to patients resulting from negligence). A large proportion of these lawsuits—around 85%—represented claims by persons who did not actually suffer an injury due to negligence. *See* Brennan, *supra* note 85, at 69. When individual malpractice claims were matched to medical records, the researchers found that only 1% to 2% of patients who actually suffered a negligent injury filed a lawsuit. WEILER ET AL., *supra*, at 72-73.

D. Tort Reform Proposals Involving CPGs

Proposals advanced to date for giving CPGs a greater role in medical malpractice litigation can be grouped into three categories. One group of reformers advocates requiring physicians and/or patients to enter into contracts *ex ante* to recognize a set of guidelines as constituting a binding standard of care. A second group has proposed that courts take judicial notice of CPGs as the standard of care, with deviations therefrom conclusively establishing negligence. A third group, by far the most influential, urges that compliance with CPGs should constitute an affirmative defense for physicians, but that deviations from CPGs should not be used as inculpatory evidence. These three approaches are each reviewed in turn.

1. The Contract Model

One of the most notable trends in American medicine in the last fifteen years is the increasing prominence of contracting in the provision of health care. With the rise of managed care, the typical physician's practice has evolved into a nexus of contracts between the physician and multiple managed care organizations. Patients select and contract with a health plan and then choose from among a restricted number of physicians who have contracts with the plan. Thus, physicians and patients contract formally with health plans and informally with each other. Physicians and health plans also contract with liability insurers to insure against risks incident to their relationships with patients.

Tort reformers have seized upon the possibility of using this web of contracts as a vehicle for incorporating CPGs into medical practice. The idea of this contract model of reform is that the parties to these contracts could agree *ex ante* that a certain set of practice guidelines will define the parameters of their relationship. Thus, the contract between a malpractice insurer and a physician might state that coverage for a particular dispute will only be forthcoming if the physician's conduct complied with the relevant CPG. Alternatively, the insurer might grade the premiums it charges the physician according to the physician's stated willingness, at the time of contracting, to comply with a range of CPGs.¹⁰⁸ The contract between

¹⁰⁸ This reform has already been adopted in some states, including Utah and Colorado, for practice areas such as obstetrics, anesthesia, and breast cancer diagnosis. Kapp, *supra* note 27, at 497.

a physician and an HMO might also make the physician's participation in the plan conditional upon her continued compliance with CPGs adopted by the HMO.

Going a step further, physicians might even enter into written contracts with patients at the time of rendering care (for example, before performing a surgery or screening the patient for cancer), adopting a particular set of guidelines as the legal standard of care should any dispute arise in the future.¹⁰⁹ HMOs might do the same with their insureds when an individual signs on with a particular plan. This proposal recognizes that guidelines differ in the extent to which they are driven by cost and quality of care concerns, and asserts that the inclusion of CPGs in physician-patient or HMO-patient contracts would serve "as a potential vehicle for finally enfranchising consumers to choose the style of medical care that best suits their preferences and their pocketbooks."¹¹⁰

The proposal for including CPGs in contracts between patients and physicians, or between patients and managed care organizations, is certainly the most controversial in the contract model of reform. The proposal suffers from the same weaknesses as many other recent health care proposals based on the idea of "consumer choice": the problems of imperfect information, imperfect rationality, and imperfect freedom of choice. The idea that an individual consumer with no medical training could competently compare the clinical practice guidelines adopted by different health plans and physicians, accurately gauging their medical appropriateness and cost-effectiveness, borders on the absurd. Proponents of the contract model respond to this objection by suggesting that only those CPGs that have been "certified" by the federal government as meeting minimum standards should be used.¹¹¹ This might eliminate the lowest-quality guidelines, but would still leave a range of CPGs for consumers to evaluate and choose among. Most consumers simply do not have the requisite information and training to be able to perform this task.

Even if consumers could obtain and comprehend this

¹⁰⁹ See Havighurst, *supra* note 7, at 108 ("Instead of defining the obligations of health care professionals in universal terms, the law might contemplate that the physician's duty in a given malpractice case might be found in the contract between the physician and the patient.").

¹¹⁰ *Id.* at 113.

¹¹¹ See *id.* at 114-16 (noting that federal certification would "give greater reliability and credibility to consumers' economizing choices").

information, this proposal would still be vulnerable to a consumer rationality critique. Consumer choice theory assumes that consumers will choose the affordable bundle of goods and services that maximizes their utility.¹¹² This, in turn, is based on an assumption that individuals are rational utility maximizers. There is a considerable body of literature questioning this premise. Consumers may have tastes for health care products that do not actually maximize their utility.¹¹³ For example, with regard to tastes for different health plans, consumers may prefer to stay in their current plan simply because it is what they are used to, regardless of the fact that an objective analysis would reveal that another plan would serve their needs better. Choice experiments also suggest that decision utilities may be extremely myopic, focusing on the utility associated with transactions rather than with long-term outcomes.¹¹⁴ Consumers also may be unable to predict the results of their choices,¹¹⁵ may “overweight outcomes that are considered certain, relative to outcomes that are merely probable,”¹¹⁶ and may display inconsistent preferences by disregarding components that the alternatives have in common and focusing on the ways in which they differ.¹¹⁷ As a result of such dynamics, consumers may not act as rational utility maximizers and a competitive marketplace in which consumers act on their preferences may not actually make people better off.

Finally, the contract model of reform fails to acknowledge the limited range of consumers’ choices in health care. Consumers who are fortunate enough to have employer-sponsored health insurance (if they are given a choice of health plans at all) typically are

¹¹² See generally KENNETH J. ARROW, *Uncertainty and the Welfare Economics of Medical Care*, in *ESSAYS IN THE THEORY OF RISK-BEARING* 177-210 (1971) (applying consumer choice theory to the demand for health insurance).

¹¹³ See Thomas Rice, *Can Markets Give Us the Health System We Want?*, 22 *J. HEALTH POL., POLY & L.* 383, 404-11 (1997) (disputing the applicability of the core assumptions of consumer choice theory to the health care market).

¹¹⁴ See Daniel Kahneman, *New Challenges to the Rationality Assumption*, 150 *J. INSTITUTIONAL & THEORETICAL ECON.* 18, 18 (1994) (“[P]eople are myopic in their decisions, may lack skill in predicting their future tastes, and can be led to erroneous choices by fallible memory and incorrect evaluation of past experiences.”).

¹¹⁵ Rice, *supra* note 113, at 407.

¹¹⁶ Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 *ECONOMETRICA* 263, 265 (1979).

¹¹⁷ See *id.* at 271 (“This approach to the choice problems may produce inconsistent preferences, because a pair of prospects can be decomposed into common and distinctive components in more than one way, and different decompositions sometimes lead to different preferences.”).

presented with only two or three plan options. The sometimes-large differences in premium rates among plans may restrict the range of choices even further for workers whose budgets are tight. Consumers in the individual insurance market also face a very restricted range of choices among health plans, because individual-plan premiums are so exorbitant that most individuals are lucky if they can find a single plan whose rates they can afford to pay. The HMO choices available to individuals who receive their coverage through Medicaid and Medicare vary widely from state to state and locality to locality.¹¹⁸ Once in a health plan, individuals must choose a primary physician from among the limited number with whom their health plan has contracts, and may be given very little information about the different physicians.

For all of these reasons, the idea that consumers could, in a voluntary and informed fashion, enter into *ex ante* contracts with managed care organizations or physicians accepting a particular set of CPGs as the legal standard of care that will govern their relationship is extremely problematic. The informational asymmetries are less of a concern in the contracting between physicians and managed care plans and between physicians and liability insurers, although those bargaining relationships, too, are unequal. Physicians may have little choice but to contract with a particular managed care organization, and accept its CPGs, if that HMO controls a significant market share in the physician's area. There may be a limited number of liability insurers willing to take the physician on as an insured, particularly if the physician has had malpractice problems in the past. In addition, the physician may reside in a state in which all the liability insurers have adopted the same set of CPGs,¹¹⁹ leaving the physician with no choice at all. These realities depart significantly from contract model reformers' vision of a "pluralistic" market in which contracting parties choose the best set of guidelines from among many competing options.¹²⁰

¹¹⁸ State Medicaid rules may severely restrict recipients' ability to choose among managed care plans. Medicare beneficiaries in urban areas may have a wide array of HMOs from which to choose, but those in rural areas may find that only one HMO serves their area, or none at all.

¹¹⁹ This is the situation in Utah, where the Utah Medical Insurance Association has adopted obstetrical standards, modeled on those of the American College of Obstetricians and Gynecologists, that are mandatory for all insured physicians. *See* Kapp, *supra* note 27, at 497 (noting the incentives for, and examples of, private insurers setting standards).

¹²⁰ *See* Havighurst, *supra* note 7, at 113 (envisioning "a range of meaningful, well-

2. The Judicial Notice Model

The second model of reform that has emerged from the academic commentary on CPGs proposes that courts take judicial notice of CPGs as representing the legal standard of care.¹²¹ Judicial notice is the acceptance by the court of certain facts without requiring the party who bears the burden of proof to produce evidence proving those facts.¹²² Under this model, with the help of an impartial, court-retained medical expert, the bench would identify a set of guidelines that is both authoritative and applicable to the conduct at issue in the litigation, and adopt the CPGs as the standard of care. At trial, the plaintiff would thus be relieved of the burden of establishing the physician's duty. The proof at trial would focus on the other three elements of a negligence claim: whether the physician breached the standard of care, whether the plaintiff suffered an injury, and whether the physician's negligence was the proximate cause of that injury.¹²³ Substantiating breach of duty requires proof that the physician deviated from the procedures outlined in the practice guidelines. In this way, the judicial notice approach resembles the doctrine of per se negligence, which holds that violations of certain safety statutes constitute negligence as a matter of law.¹²⁴

considered options . . . developed in a pluralistic environment").

¹²¹ Hall, *supra* note 91, at 129-31; Leahy, *supra* note 7, at 1522; Rinella, *supra* note 15, at 352.

¹²² See Rinella, *supra* note 15, at 352 (outlining the theory of judicial notice in medical malpractice litigation). Judicial notice is governed by Rule 201 of the Federal Rules of Evidence, which provides that "[a] judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned." FED. R. EVID. 201 (b).

¹²³ *Elba Wood Prods., Inc. v. Brackin*, 356 So. 2d 119, 122 (Ala. 1978).

¹²⁴ See, e.g., *Martin v. Herzog*, 126 N.E. 814, 815 (N.Y. 1920) (holding that the defendant's failure to install headlights on his buggy as required by statute "is more than some evidence of negligence. It is negligence in itself."). While most state courts hold that violation of a safety statute is conclusive proof on the negligence issue, precluding rebuttal by other evidence, a minority have held that such violation only creates a presumption of negligence, or constitutes evidence of negligence. See DAN B. DOBBS, *TORTS AND COMPENSATION* 141 (2d ed. 1993) (citing California, Michigan, and Washington as examples). The per se negligence rule has not previously been applied to industry standards or other forms of private regulation. Accordingly, bringing CPGs within the ambit of the rule would represent a significant extension of the rule. See Brennan, *supra* note 85, at 77 (differentiating practice guidelines and per se negligence); Edward B. Hirshfeld, *Practice Parameters and the Malpractice Liability of Physicians*, 263 JAMA 1556, 1560 (1990) (discussing the evidentiary weight of the guidelines and the concern that they might be used as a form of per se negligence).

Proponents of this view assert that the standard of care should remain a jury question where no reliable CPGs have been established, but that where authoritative guidelines do exist, "allowing a jury to undermine that standard is not only bad policy, but can lead to irrational results."¹²⁵ Among their strongest arguments are that:

First, practice guidelines are prospectively determined. As a result, they will be much more objective and reliable than a jury's assessment of the opinion of a hired expert considering a case retrospectively.

... [R]etrospective evaluations by hired experts, in view of undesirable outcomes, may often cause a jury to focus on *perfect* care rather than customary or reasonable care. . . .

Second, practice guidelines represent well-considered opinions of expert panels, based upon reviews of the best available data, as to how physicians should approach certain clinical problems. The prospective deliberations and consensus of such a panel are much more likely to be impartial and reliable than jury decisions based upon the testimony of individual experts paid to render an opinion after the fact.¹²⁶

There are several responses that might be made to such arguments. First, as is discussed in greater depth in Part II of this Article, CPGs themselves may represent an ideal of optimal care, rather than prevailing medical custom. Thus, using CPGs as the judicially-noticed standard of care may involve no less a "focus on perfect care" than using jury determinations of the standard.

Secondly, while practice guidelines do "represent well-considered opinions of expert panels," their application to any particular case does not. A determination as to the applicability of the guidelines to the case at hand will be made by the judge. Proponents of the judicial notice model argue that judges are better situated to make this determination than juries because they "have more experience with medical malpractice cases and the standard of care concept" and because they are more likely to ask appropriate questions of experts.¹²⁷ Judges certainly are more sophisticated than juries in matters of law, but their experience on the bench does not provide them with any medical expertise that could be parlayed into a determination of whether a particular set of CPGs fit a particular clinical situation.¹²⁸ Judges would retain an impartial medical expert to render an opinion

¹²⁵ Leahy, *supra* note 7, at 1500.

¹²⁶ *Id.* at 1506.

¹²⁷ *Id.* at 1527.

¹²⁸ *See id.* at 1505 ("Judges obviously lack the requisite medical expertise to identify and critically evaluate the data relevant to such decisions [as the standard of care].").

on this issue, and base their decision on her opinion. The question then becomes whether reliance on a single "impartial" expert opinion is preferable to evaluating competing opinions offered by two or more experts hired by the litigants. This issue is taken up in greater depth in Part III of this Article, but for the moment it might briefly be noted that our adversarial system is grounded in the assumption that the truth is more likely to emerge from the clash of opposing sides than from a report by an "impartial" investigator.

A third problem with the judicial notice model is that, as even its advocates acknowledge, it would only be practicable where there has emerged a single set of guidelines that medical practitioners recognize as authoritative and controlling. This limitation arises from the requirement of Rule 201 of the Federal Rules of Evidence that the fact to be judicially noticed must be "not subject to reasonable dispute" because it is established by either common knowledge or "sources whose accuracy cannot be reasonably questioned."¹²⁹ Given that there currently exist over 1600 different practice guidelines, it seems unlikely that only a single set could reasonably be claimed to apply in any given case. Additionally, the American Medical Association has taken the position that the "state of the art" with respect to CPGs is not advanced enough to move to the judicial notice model.¹³⁰ There are too many issues yet to be resolved with respect to the content of CPGs, the evidence underlying them, and the auspices and procedures under which they are developed to afford them this degree of weight in legal proceedings. The science of guideline development has not progressed to the point where we have produced documents "whose accuracy cannot reasonably be questioned." As a result, proposals for judicial notice are premature at best.

3. The Maine Model

The third major model of tort reform involving CPGs involves the creation of an affirmative defense¹³¹ for physicians who can demonstrate compliance with applicable practice guidelines. This

¹²⁹ FED. R. EVID. 201(b).

¹³⁰ See Ed Hirshfeld, *Use of Practice Parameters as Standards of Care and in Health Care Reform: A View from the American Medical Association*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 322, 323 (1993) (explaining the AMA position that CPGs should only be evidence for the standard of care); Rosoff, *supra* note 25, at 384.

¹³¹ An affirmative defense is a "defendant's assertion raising new facts and arguments that, if true, will defeat the plaintiff's or prosecution's claim, even if all allegations in the complaint are true." BLACK'S LAW DICTIONARY 430 (7th ed. 1999).

approach has become known as the "Maine model" because that state adopted it as a statutory demonstration project in 1990.¹³² This approach might also be thought of as creating a "one-way street" for practice guidelines as it permits their exculpatory use by defendants but not their inculpatory use by plaintiffs.

The Maine statute limits the malpractice liability of physicians in four specialty areas who voluntarily agree to follow established CPGs adopted pursuant to the project.¹³³ The State adopted twenty practice guidelines in anesthesiology, emergency medicine, obstetrics and gynecology, and radiology. Physicians who follow the guidelines when the clinical situation so mandates may invoke their compliance as an absolute affirmative defense against medical malpractice claims accruing between January 1, 1992 and December 31, 1996.¹³⁴ The statute further provides that plaintiffs are completely precluded from introducing CPGs as evidence at trial, whether the defendant physician is participating in the demonstration project or not.¹³⁵ The plaintiff may, however, challenge whether a CPG introduced by the physician is applicable to the clinical situation at issue and whether the physician did, in fact, comply with the guideline.¹³⁶ Maine's approach has been emulated by Florida¹³⁷ and Kentucky.¹³⁸

¹³² ME. REV. STAT. ANN. tit. 24, §§ 2971-2979 (West 2000). For a detailed discussion of the Maine project, see Jennifer Begel, *Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation*, 47 ME. L. REV. 69 (1995).

¹³³ See Rinella, *supra* note 15, at 342-43 (outlining the structure of the Maine demonstration project).

¹³⁴ *See id.* at 343.

¹³⁵ *See* ME. REV. STAT. ANN. tit. 24, § 2977 (West 2000) (setting out the admissibility of the practice parameters as evidence).

¹³⁶ *See id.* § 2975(2) (delegating the burden of proof for compliance with parameters).

¹³⁷ *See* FLA. STAT. ANN. § 408.02 (West Supp. 1998) (setting out the statutory practice parameter guidelines). For a summary of Florida's project, see Trail & Allen, *supra* note 24, at 245-47 (noting that Florida's project contains the same basic structure as the Maine Project, the only critical difference being the admissibility of the guidelines by the plaintiff). Importantly, unlike the Maine statute, the Florida statute does not restrict a plaintiff's ability to introduce CPGs into evidence. *See id.* at 246 (noting the absence of a provision limiting a plaintiff's use of the guidelines in litigation). Guidelines offered by a plaintiff in Florida provide evidence of the standard of care, but do not conclusively establish it. Noncompliance with CPGs does not create a prima facie case of negligence. *Id.* at 247.

¹³⁸ *See* KY. REV. STAT. ANN. § 342.035(8) (Michie 1997) (authorizing the commissioner to develop practice parameters). While Maine's law provides physicians with an absolute affirmative defense, Kentucky's law provides only a *presumption* that a physician who complied with the relevant CPG met the legal standard of care. *See id.* at § 342.035(8) (b) (authorizing a presumption of legal compliance where the guidelines

"One-way street" reforms, like the other models of reform discussed earlier, seek to clarify the standard of care in medical malpractice claims and simplify litigation. The statutory language and academic commentary surrounding Maine-model reforms, however, place unique emphasis on a second motive: inducing greater physician compliance with CPGs.¹³⁹ It is thought that providing physicians with a safe harbor in malpractice litigation will give them strong incentives to comply with practice guidelines. This will result in societal gains in the form of higher quality care and reduced defensive medicine.

The empirical evidence reported to date suggests that the program has not succeeded in achieving these goals.¹⁴⁰ A study of outcomes in obstetrics and gynecology found neither appreciable improvements in rates of three pregnancy-related conditions (failure to progress, fetal distress, and prolonged pregnancy) nor any significant declines in caesarean section rates attributable to the demonstration project.¹⁴¹ A survey of Maine physicians conducted as part of the study revealed that only a small percentage of the physicians believed that the CPGs had had an effect on caesarean section rates, defensive medicine practices, or malpractice risk.¹⁴² Studies published as of December 1997 indicate that CPG compliance has been invoked as an affirmative defense in only one case in Maine since the adoption of the demonstration project,¹⁴³ so the impact of the project on litigation costs and litigation outcomes is uncertain at best.

In addition to these efficacy concerns, Maine-model reforms also raise fundamental questions of fairness. The effect of this model is to

have been complied with).

¹³⁹ See Rinella, *supra* note 15, at 342-43 (outlining the structure of the Maine demonstration project); Trail & Allen, *supra* note 24, at 251, 254 (discussing the general benefits of the guidelines and the goals at which they are aimed).

¹⁴⁰ It must be remembered, however, that the project is limited in scope, involving CPGs which affect only four specialties and only certain areas within those specialties. By one estimate, the guidelines affect only about three to four percent of medical practice in Maine. See Gordon H. Smith, *A Case Study in Progress: Practice Guidelines and the Affirmative Defense in Maine*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 355, 361 (1993) (assessing the results of the demonstration project).

¹⁴¹ See Ronald D. Deprez, *The Affirmative Defense—Does It Have an Impact on Physician Compliance?*, 22 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 567, 567-68 (1996) (outlining the preliminary results of the demonstration project).

¹⁴² See *id.* at 568.

¹⁴³ See Matthews, *supra* note 15, at 300 (stressing the difficulty in establishing practice guidelines as a legal standard).

situate the plaintiff and the defendant in a malpractice case differently with respect to the evidence each may use to build her case. There are several objections that may be raised to this anomalous one-way use of relevant, probative evidence. These concerns are set forth in Part III.

4. Future Directions for Reform

The three reform models described above all proceed from the premise that CPGs should figure more prominently in malpractice litigation, and the models should employ a variety of mechanisms to achieve that goal. The contract-model and judicial-notice-model reforms assume that it is legitimate and valuable for the use of CPGs in litigation to be a two-way street. Maine-model reformers recognize that there may be persuasive reasons not to allow the inculpatory use of CPGs, but contend that we should still allow their one-way, exculpatory use. The remainder of this Article takes issue with these assertions. It is argued, first, that indeed there are very compelling reasons not to permit the inculpatory use of CPGs, at least in the way the reformers envision; and, second, that permitting this evidence to be used only by defendants requires a strong policy justification, which is lacking. As a consequence, it is untenable to argue that CPGs should assume a more prominent role in litigation *either* as a two-way street *or* as a one-way street.

II. THE INCULPATORY USE OF CPGs: LEAVING CUSTOM BEHIND

Those who favor the increased inculpatory use of CPGs provide an impressive array of policy reasons to do so: to reduce uncertainty, to reduce defensive medicine, to weed out unmeritorious claims, to promote compliance with CPGs, and to improve the quality of care. What is notably absent from these reformers' accounts, however, is an examination of exactly what CPGs are supposed to represent. Specifically, do CPGs represent prevailing medical custom, or do they represent an ideal standard of care toward which the medical profession should strive? If the latter, is it appropriate to use the tort law—the legal standard of care—to *pull up* the medical standard of care? I will argue that the answer to both questions is no.

A. *The Relationship Between CPGs and Prevailing Medical Practice*

1. Are CPGs Meant to Represent Custom?

A review of the medical and legal literature on practice guidelines leaves one highly uncertain as to whether CPGs are meant to represent current medical custom or an ideal standard of care. One appeals court characterized the well-established guidelines promulgated by the American College of Obstetricians and Gynecologists ("ACOG") merely as "the *minimal* accepted standards for [the physician's] specialty."¹⁴⁴ Academic commentators, too, have described CPGs as a "minimum" or "quality *baseline*," stressing that they should be "realistic" and embody "conduct with which the medical profession is capable of complying ordinarily."¹⁴⁵ Under this view, CPGs do represent prevailing custom.

In contrast, a District of Columbia court of appeals held that the standards of the American Association of Anesthesiology were not necessarily "mandatory" because they were "emerging" and "encouraged."¹⁴⁶ Other courts and commentators have suggested that CPGs represent an ideal of care that may or may not be possible to implement. The North Dakota District Court, for example, noted that geographic and resource constraints facing rural hospitals may make it infeasible to adhere to the ACOG guidelines in some areas of the country.¹⁴⁷ Clark Havighurst has commented that most guidelines will "rarely even purport to be probative of custom as such."¹⁴⁸

Some commentators have distinguished between newly minted and well-established guidelines, arguing that some, but not all, CPGs represent prevailing medical custom. With respect to guidelines that advocate the use of new high-tech equipment, for example,

¹⁴⁴ *Jewett v. Our Lady of Mercy Hosp.*, 612 N.E.2d 724, 726-27 (Ohio Ct. App. 1992) (emphasis added).

¹⁴⁵ Kapp, *supra* note 27, at 498 (emphasis added); see also Ray Fish & Melvin Ehrhardt, *The Standard of Care*, 12 J. EMERGENCY MED. 545, 547 (1994) ("The fact that a proposed standard has been published by a credible medical society probably does indicate that to follow the proposed standard would be acceptable practice However, published recommendations are not generally regarded as standards of care until they are widely accepted by physicians.").

¹⁴⁶ *Washington v. Wash. Hosp. Ctr.*, 579 A.2d 177, 182 (D.C. 1990).

¹⁴⁷ See *Anderson v. United States*, 731 F. Supp. 391 (D.N.D. 1990), *quoted in* Berlin, *supra* note 102, at 277; see also Ayres, *supra* note 26, at 429 (suggesting that guidelines developed by physicians who practice at university medical centers may not be appropriate for rural physicians).

¹⁴⁸ Havighurst, *supra* note 7, at 101.

[a] guideline becomes a standard of care when the device behind the guideline is available and readily usable as a practical matter by members of other medical specialties who have cause and reason to consider its use.

....

... Before ... mandate [of a standard of care] by law, ... the profession must recognize the matriculation of the idea to the guideline to the standard.¹⁴⁹

Such suggestions build from a typology established by David M. Eddy, who is considered the father of the clinical practice guideline movement. Eddy described three different types of CPGs: "standards," "guidelines," and "options."¹⁵⁰ A "standard" is based on solid empirical evidence about the effects and outcomes of the medical intervention at issue and on virtual unanimity among patients as to the overall desirability of the outcomes. If only some of the important outcomes of an intervention are known, and what is known about the outcomes is preferred by an appreciable but not unanimous majority of patients, then a CPG concerning that intervention is described as a "guideline." If there is significant uncertainty about either the outcomes of the intervention or their desirability to patients, the CPG should be regarded merely as an "option."

According to Eddy, standards are intended to apply very rigidly. Deviations from a standard "will be rare and difficult to justify" and "should trigger thoughts of malpractice."¹⁵¹ Guidelines "should be followed in *most* cases," but may be tailored to fit individual cases. "Deviation from a guideline by itself does not imply malpractice."¹⁵² Options are merely informational. They "leave practitioners free to choose any course."¹⁵³ Thus, under Eddy's typology, a standard should be viewed as a minimum standard of care and as representing prevailing medical custom. In contrast, guidelines and options may or may not represent custom, and may or may not represent a true ideal. They represent our best guesses, at different levels of certainty, about what the ideal standard of care is. Not everyone agrees with these

¹⁴⁹ William H. Ginsburg, *When Does a Guideline Become a Standard? The New American Society of Anesthesiologists Guidelines Give Us a Clue*, 22 ANNALS EMERGENCY MED. 1891, 1895 (1993).

¹⁵⁰ David M. Eddy, *Designing a Practice Policy: Standards, Guidelines, and Options*, 263 JAMA 3077, 3081 (1990).

¹⁵¹ *Id.* at 3077.

¹⁵² *Id.*

¹⁵³ *Id.*

guesses, so not all physicians follow the guidelines. Noncompliance should not be penalized because we are not yet certain that we have guessed correctly.

Even Eddy's assumption that "standards" represent custom can be questioned, for it does not account for the fact that the diffusion of new standards into medical practice takes time. First, the guidelines must be disseminated to medical professionals through such vehicles as publication in medical journals or mailings to hospitals. Following dissemination, an interval of time is required for physicians to read and evaluate the guidelines and to change their practice patterns in order to fit them. Thus, the mere fact that a standard has been published does not mean that it represents custom. "Over time, if the guideline is widely adopted and followed by the medical community, it will increasingly become a statement of the customary practice. In the interim, however, the guideline may reflect just the opposite, a statement of what the profession at large does not currently do."¹⁵⁴

Overall, judicial and academic statements of what CPGs are meant to represent are characterized by confusion and overgeneralization. There exists little agreement as to whether CPGs represent a minimum baseline, a not-yet-attained ideal, or a customary practice that lies somewhere between these two extremes. Moreover, most commentators tend to lump all guidelines together rather than acknowledge the varying levels of empirical certainty that undergird them. Finally, even those—such as Eddy—who do recognize finer distinctions among CPGs tell us little about the amount of time and effort that must be expended before new CPGs can be considered firmly entrenched in custom.

This confusion in the literature may be explained in part by the near-absence of any reference to empirical studies of compliance with CPGs. Legal commentators consistently speculate about whether or not CPGs represent custom without examining the actual evidence on this point. What does this evidence show?

2. The Compliance Gap

Estimates of the percentage of physicians who comply with well-established CPGs in their specialties vary from study to study¹⁵⁵ and

¹⁵⁴ Rosoff, *supra* note 25, at 380.

¹⁵⁵ It is somewhat difficult to compare the results of compliance studies because different measures of compliance are used in each of them. Some studies examine medical outcomes—for example, the rates of adverse medical events or other key

from guideline to guideline. The results of several of the major compliance studies may be summarized as follows:

- The average compliance rate with eleven different CPGs created by the National Institutes of Health was just 57%, even after an informational conference was held in an effort to boost compliance.¹⁵⁶
- Only 6% of physicians who were aware of hypertension guidelines referred to them “very often,” whereas nearly 40% said they used the guidelines “very little” or “not at all.” About two-thirds of physicians’ hypertension treatment practices conformed to the guidelines, both before and after the guidelines were released.¹⁵⁷
- Only 13% of patients at a university internal medicine practice received the annual mammogram prescribed by well-known CPGs.¹⁵⁸
- Compliance with various of the National Cancer Institute’s guidelines on staging and radiation therapy for certain types of cancer ranged from 27% to 67%.¹⁵⁹
- Contrary to diabetes guideline recommendations, 84% of Medicare patients with diabetes did not receive recommended tests, 54% had not seen an ophthalmologist, and 45% had not undergone cholesterol screening.¹⁶⁰
- Sixty-four percent of physicians complied with a CPG on chest pain, a result that prompted the study authors to conclude that “this was a successfully implemented guideline.”¹⁶¹

markers of poor-quality care—while others survey or observe physicians directly to see if their practice patterns conform to prescribed procedures. I have focused on the latter group of studies because their measure of compliance is more direct and reliable.

¹⁵⁶ Jacqueline Kosecoff et al., *Effects of the National Institutes of Health Consensus Development Program on Physician Practice*, 258 JAMA 2708 (1987).

¹⁵⁷ Martha N. Hill et al., *Awareness, Use, and Impact of the 1984 Joint National Committee Consensus Report on High Blood Pressure*, 78 AM. J. PUB. HEALTH 1190, 1191 (1988), cited in Woolf, *supra* note 26, at 2648.

¹⁵⁸ Stephen J. McPhee et al., *Performance of Cancer Screening in a University General Internal Medicine Practice*, 1 J. GEN. INTERNAL MED. 275, 277 (1986).

¹⁵⁹ Leslie G. Ford et al., *Effects of Patient Management Guidelines on Physician Practice Patterns: The Community Hospital Oncology Program Experience*, 5 J. CLINICAL ONCOLOGY 504, 507 (1987), cited in Woolf, *supra* note 26, at 2648.

¹⁶⁰ Jonathan P. Weiner et al., *Variation in Office-Based Quality: A Claims-Based Profile of Care Provided to Medicare Patients with Diabetes*, 273 JAMA 1503, 1505 (1995), cited in Roger J. Zoorob & Michael D. Hagen, *Guidelines on the Care of Diabetic Nephropathy, Retinopathy and Foot Disease*, 56 AM. FAM. PHYSICIAN 2021, 2026 (1997).

¹⁶¹ A. Gray Ellrodt et al., *Measuring and Improving Physician Compliance with Clinical*

- Fewer than 50% of patients recovering from heart attacks received the beta-blocker drugs recommended by the American College of Cardiology guidelines.¹⁶²
- About 60% of physicians were aware of national guidelines on preventive care and high blood pressure one year after the guidelines were released.¹⁶³
- Physicians disagreed with about 12% of published guidelines on preventive services.¹⁶⁴
- Only 3% of Canadian physicians tested could correctly identify the appropriate actions recommended by guidelines on caesarean sections in eight scenarios. The average score for individual scenarios was only 67% correct.¹⁶⁵

These results can be synthesized into two primary findings. First, overall compliance with CPGs is fairly low. A meta-analysis of 23 compliance studies published in the 1980-1991 period determined that the average compliance rate across 143 sets of guidelines was only 54.5%.¹⁶⁶ Compliance may be suboptimal for a variety of reasons: Physicians may not be aware of the guidelines, they may disagree with them on their face, they may feel the guidelines do not apply to a

Practice Guidelines: A Controlled Interventional Trial, 122 ANNALS INTERNAL MED. 277, 280 (1995).

¹⁶² Donald A. Brand et al., *Cardiologists' Practices Compared with Practice Guidelines: Use of Beta-Blockade After Acute Myocardial Infarction*, 26 J. AM. C. CARDIOLOGY 1432, 1434 (1995). The "target" compliance rate in this study was 75%, see *id.* at 1435, suggesting that the authors did not believe the guidelines represented prevailing medical custom.

¹⁶³ Hill et al., *supra* note 157, at 1190 (indicating that the guidelines codified, rather than changed, practice behavior among the physicians in the sample); see also K.C. Stange et al., *Physician Agreement with U.S. Preventive Services Task Force Recommendations*, 34 J. FAM. PRAC. 409, 414 (1992) (reporting further that 39% of surveyed practicing physicians had never heard of the guidelines set forth by the United States Preventive Services Task force).

¹⁶⁴ Stange et al., *supra* note 163, at 413 (noting that physician disagreement with recommendations was associated with older age, not having completed a residency, male sex, less prior exposure to the guidelines, and greater perception of their impracticability).

¹⁶⁵ Jonathan Lomas et al., *Do Practice Guidelines Guide Practice? The Effect of a Consensus Statement on the Practice of Physicians*, 321 NEW ENG. J. MED. 1306, 1308 (1989).

¹⁶⁶ Roberto Grilli & Jonathan Lomas, *Evaluating the Message: The Relationship Between Compliance Rate and the Subject of a Practice Guideline*, 32 MED. CARE 202, 202 (1994). Compliance was highest in the areas of cardiology and oncology (around 63% and 62%, respectively). See *id.* at 208 (comparing this with preventive care, dental care, and gynecology). The more complex the procedure the lower the compliance. See *id.* at 203 (defining high complexity as occurring when a practitioner with average skills working in an average setting perceives a procedure to be difficult or as requiring specific resources for its implementation).

particular case, or they may be unable to adhere to the prescribed procedures because of resource constraints.

The second finding is that compliance is substantially lower when the CPG is disseminated unaccompanied by any targeted efforts by hospitals, health insurers, or liability insurers to induce compliance. Interventions such as educational seminars,¹⁶⁷ feedback, and audits¹⁶⁸ may boost compliance substantially. Even more effective may be financial incentives, such as liability insurers' offers to reduce malpractice insurance premiums if physicians agree to follow CPGs.¹⁶⁹ Most guidelines, however, are not implemented using these means. They are published in leading journals, and hospitals and physicians are expected to conform their practice to the new state of the art. It is therefore unsurprising that compliance rates for most guidelines are not higher.

Based on this review of the empirical literature, it might be said that a *preponderance*, or *slim majority*, of physicians comply with well-publicized clinical practice guidelines. For most guidelines, however, compliance is no higher than this. Is this sufficient to conclude that the guidelines represent medical *custom*? "Custom" is a slippery concept, but it arguably represents something more entrenched and more prevalent than just a majority approach. *Black's Law Dictionary* defines "custom and usage" as "[g]eneral rules and practices that have become generally adopted through unvarying habit and common use."¹⁷⁰ This definition suggests a level of adherence to the practice far exceeding fifty percent.

If CPGs do not, in fact, represent custom, are they a proper basis for the standard of care in malpractice cases? That is, should tort law

¹⁶⁷ See Bernard S. Linn, *Continuing Medical Education: Impact on Emergency Room Burn Care*, 244 JAMA 565, 569 (1980) (revealing that patients who received an educational intervention complied more frequently with medical regimens and had fewer early complications in their burns).

¹⁶⁸ See Woolf, *supra* note 26, at 2647 (considering guidelines as a form of continuing medical education). But see Harold I. Goldberg et al., *A Randomized Controlled Trial of CQI Teams and Academic Detailing: Can They Alter Compliance with Guidelines?*, 24 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 130, 135 (1998) (finding that education and feedback sessions with physicians did not improve compliance with national guidelines for the treatment of hypertension and depression).

¹⁶⁹ See Walker et al., *supra* note 12, at 41 (noting that in Massachusetts, insurers that offered a twenty percent premium reduction for anesthesiologists who complied with CPGs saw the number of lawsuits related to hypoxia during anesthesia drop from six per year to zero, over a three-year period).

¹⁷⁰ BLACK'S LAW DICTIONARY 390 (7th ed. 1999).

rely on professional custom in these cases or should it strive to hold physicians to some higher ideal of good medical practice?

B. *The Consequences of Preferring CPGs to Custom*

This sub-Part first responds to common arguments against reliance on custom in medical malpractice litigation. It then argues that the use of custom serves an important signaling role in tort law: It reduces the uncertainty facing actors about what level of precaution is legally required of them. This, in turn, increases the deterrent value of the tort law. Finally, this sub-Part argues that judicial deviation from custom in malpractice cases represents an imprudent use of the tort law to engineer the practice of medicine. The implication of these arguments is that to the extent that CPGs are not representative of medical custom, their role in setting the standard of care in malpractice cases should be minimal.

1. The Case Against Custom

Two arguments are commonly advanced in favor of abandoning or reducing our reliance on medical custom to establish the standard of care. The first, and perhaps more compelling, argument is that there exists such heterogeneity of opinion among physicians as to proper care that it cannot be said that a single custom truly exists. The highly differentiated nature of medical problems and the differing rates at which physicians are willing to accept new technologies and treatment modalities into their practice are cited as sources of this heterogeneity.¹⁷¹ The wide variation observable in practice patterns across the country is said to constitute evidence of the lack of consensus.¹⁷² An unfortunate implication of this diversity of practice and opinion is that it necessitates the use of medical experts in litigation to cull a single standard from the cacophony of opinion. This gives rise to a battle of the experts in which hired guns clash with opposing opinions, neither of which is any more

¹⁷¹ See Henderson & Siliciano, *supra* note 44, at 1390-91 (discussing the impediments to the formation of a stable concept of custom).

¹⁷² Practice pattern variations, however, are not necessarily indicative of differing opinions as to what constitutes good-quality care. Such variations may instead be the product of resource constraints—that is, physicians may agree on what ought to be done, but physicians in poor and rural areas may not have the wherewithal to adhere to the agreed-upon standard. The “similar communities” rule for the standard of care in malpractice law represents an acknowledgment of this reality. *Hall v. Hilbun*, 466 So. 2d 856, 872 (Miss. 1985).

empirically supportable than the other.¹⁷³

There are two responses to this argument. The first, which is discussed in greater depth later in this Article, is that departure from custom in favor of greater reliance on CPGs will ameliorate neither the heterogeneity problem nor the “battle of the experts” problem. It is true that there exists a diversity of opinion among physicians as to the proper standard of care, but it is equally true that there exists a diversity of opinion among *guideline promulgators*. The fact there are currently 1600 different CPGs in existence attests to this fact. Litigants would probably need to use expert witnesses to select among these guidelines and to convince the trier of fact that their chosen guideline represents the true standard of care; thus, the “battle of the experts” would not be eliminated, but rather *supplemented* with an additional “battle of the guidelines.”¹⁷⁴ Additionally, existing medical malpractice law already takes into account the fact that there exist diverse schools of opinion regarding proper care. The law provides that if a physician’s conduct deviates from the majority approach to treatment in a particular clinical situation but conforms to a “respectable minority” approach, it will not be deemed negligent.¹⁷⁵ Rather than inferring from a diversity of opinion that no custom exists, this approach concludes that, in some circumstances, more than one custom may exist. This is an eminently reasonable way to deal with the heterogeneity problem.

The second argument commonly advanced against reliance on custom is that much medical custom is wasteful and should not be encouraged by the courts. Clark Havighurst has argued:

With respect to medical care, however, custom is a poor guide to what is economically justified. Customary medical practices have evolved in the United States under systems of paying for medical care that create economic incentives for both physicians and patients to overutilize services, spending more on marginal benefits than they are in any sense worth. For the tort system to enforce adherence to practice norms arising spontaneously under an incentive system fraught with moral hazard is to convert an inefficiency that may be acceptable as a necessary

¹⁷³ See Havighurst, *supra* note 7, at 96 (noting that experts are “not impartial . . . they are selected by the parties with a view to the positions they will take and their skill in persuading juries”).

¹⁷⁴ Rosoff, *supra* note 25, at 386.

¹⁷⁵ See *id.* at 388 (suggesting that courts should use an acceptable, rather than the best, guideline); see generally EPSTEIN, *supra* note 57, at 142 (discussing the difficulties in deciding “which [medical] custom prevails when there is an honest division of opinion over the proper course of treatment”).

cost of financial protection into a mandatory burden on society.¹⁷⁶

One might quarrel with Havighurst's characterization of medical custom. While it was undoubtedly true in the past that physicians had significant financial incentives to oversupply care, because of the nature of the historically predominant fee-for-service reimbursement system, this may no longer be true in the age of managed care.¹⁷⁷ To the extent that defensive medicine is still practiced, however, Havighurst's characterization may have some continuing relevance. He may be correct in thinking that using medical custom will encourage overprovision of care, a socially inefficient outcome. Using CPGs, however, would also result in inefficiency and overprovision, for a different reason. The problem with CPGs is not that the standard of care they embody is itself inefficient, although it may be. The problem is, rather, that a shift from reliance on custom to reliance on CPGs will increase the amount of uncertainty physicians have about the legal standard of care, and this uncertainty itself creates inefficiency.

2. CPGs, Custom, and Uncertainty

At first blush, it might seem that a switch to a CPG-based standard of care would *reduce* the amount of uncertainty physicians currently face as to what is required of them.¹⁷⁸ This argument rests on two assumptions, however: (1) that CPGs are clear and specific enough to let a physician know exactly what to do in a given clinical encounter; and (2) that there is a single dominant CPG to which the physician knows he must adhere. Neither of these assumptions are certain at this point in time.

A large proportion of the current guidelines are extremely vague.

¹⁷⁶ Havighurst, *supra* note 7, at 97-98 (footnotes omitted).

¹⁷⁷ "Moral hazard" results from the fee-for-service system because physicians receive additional income for every marginal service they render. Historically, efforts by insurers to audit physician charges to ensure that the services rendered were "medically necessary" have been minimal. The advent of managed care, however, has both decimated the number of physicians who operated on a fee-for-service basis and dramatically increased the use of utilization review, or audits for medical necessity. Physicians operating under managed care contracts render care on a capitated basis: They receive a flat monthly or annual payment from the insurer in exchange for providing a comprehensive range of services. The amount of income they receive per patient does not vary with the amount of services actually rendered, so the moral hazard problem is eliminated (and may actually be inverted, since capitation provides incentives to *undersupply* care).

¹⁷⁸ Kapp, *supra* note 27, at 498; Rinella, *supra* note 15, at 352.

Indeed, vague guidelines are necessary for more complex medical situations in order to allow physicians sufficient latitude to exercise clinical judgment. The AHRQ guidelines on depression are a classic example. The guidelines state, “[t]he specific medication choice is based on side-effect profiles, history of prior response, family history of response, type of depression, concurrent general medical or psychiatric illnesses, and concurrently prescribed medications.”¹⁷⁹ Consider as a second example the National Institutes of Health’s guideline on coronary-artery bypass surgery: “A reasonable diagnostic workup of a patient with angina pectoris [prior to considering bypass surgery] . . . should be done as efficiently as possible to provide definitive information on which clinical decisions can be based. Unnecessary and redundant procedures should be avoided.”¹⁸⁰ What would be more informative to a physician trying to determine what standard of care is legally required of her: these CPGs or her knowledge of the customary practice among her colleagues and those who trained her? Certainly most physicians would choose the latter.

CPGs may also be vague in a second way: They may not state clearly whether they are, in Eddy’s terminology, “standards,” “guidelines,” or “options.”¹⁸¹ The myriad CPG promulgators in the United States have, as yet, failed to adopt a common vocabulary to indicate the strength of the empirical foundations of a given CPG and the extent to which it is legally binding.¹⁸² Consequently, CPGs do not clearly signal physicians whether compliance is mandatory or merely suggested—that is, whether the CPG represents a firmly entrenched medical standard of care or merely an educated guess at what constitutes good quality care.

In addition to the vagueness problem, there is also the problem of

¹⁷⁹ *Depression in Primary Care*, TREATMENT OF MAJOR DEPRESSION: CLINICAL PRACTICE GUIDELINE NO. 5 (Agency for Healthcare Research and Quality, Rockville, Md.), Apr. 1993; see also Kadzielski et al., *supra* note 31, at 163 (“Such a guideline is really of little or no help at all. . . . A guideline such as this would be difficult to introduce as justification in a court of law for one physician’s decision to prescribe an antidepressant medication.”).

¹⁸⁰ National Institutes of Health, *Consensus-Development Conference Statement: Coronary-Artery Bypass Surgery: Scientific and Clinical Aspects*, 304 NEW ENG. J. MED. 680, 681 (1981), quoted in Mark R. Chassin, *Standards of Care in Medicine*, 25 INQUIRY 437, 439 (1988).

¹⁸¹ *Supra* notes 150-53 and accompanying text.

¹⁸² See Hirshfeld, *supra* note 20, at 2887 (“Without these common understandings, a court confronted with a practice parameter would have to inquire into the process used for its development, the meaning of its format, and the meaning of its terminology in order to understand the limits of its use.”).

multiplicity. There are 1600 sets of guidelines in existence.¹⁸³ For any given medical condition or intervention, there may be a dozen or more competing guidelines. For example, the American Cancer Society's guidelines for breast cancer detection recommend "a mammogram every year" after age 50, while the American College of Obstetricians and Gynecologists' guidelines just recommend "regular" mammograms.¹⁸⁴ How is a physician to know which guideline to follow? As Arnold Rosoff has commented, "a pluralistic system allowing alternative, conflicting guidelines is inherently untidy and undoubtedly would complicate matters by inviting controversy over which guideline should be regarded as authoritative, or more authoritative."¹⁸⁵

Given these problems of vagueness and multiplicity, it is not unreasonable to argue that the level of uncertainty physicians have about the legal standard of care might actually be increased, rather than decreased, by a shift from custom to CPGs as the basis for that standard. What are the implications of increased uncertainty for the efficiency of the tort law?

It is an established principle in the law-and-economics literature that where there exists uncertainty surrounding the standard of care, a negligence regime will overdeter risky conduct, resulting in inefficiency. As rational economic actors, potential defendants conduct a cost-benefit analysis to determine what level of precaution to take in the conduct of their affairs. Where this analysis is performed under conditions of uncertainty,

defendants do not face a simple choice between actions certain to lead to liability and actions bearing no risk of liability at all. Instead, each possible action is accompanied by an associated probability that a defendant will be tried, found liable, and made to pay damages or a fine

. . . To the extent that defendants are influenced by the fear of liability, their behavior will be influenced by this distribution of probabilities, rather than simply by the nominal legal standard.¹⁸⁶

¹⁸³ See Ayres, *supra* note 26, at 421.

¹⁸⁴ Levine v. Rosen, 616 A.2d 623, 628 (Pa. 1992).

¹⁸⁵ Rosoff, *supra* note 25, at 386. For an example of the way in which the multiple guidelines for mammograms have created confusion over the legal standard of care, see *Kramer v. Milner*, 639 N.E.2d 157 (Ill. App. Ct. 1994).

¹⁸⁶ John E. Calfee & Richard Craswell, *Some Effects of Uncertainty on Compliance with Legal Standards*, 70 VA. L. REV. 965, 969-70 (1984). For some standard criticisms of economic analysis of tort law, see Shuman, *supra* note 8, at 137-39.

Empirical research has confirmed that physicians do alter their behavior in response to the perceived threat of malpractice litigation.¹⁸⁷ They will take precautions (such as ordering additional diagnostic tests and other services) to the extent that they believe it will appreciably reduce their risk of being sued.

It is not desirable, however, to have physicians take every conceivable precaution to prevent adverse medical outcomes. Standard economic analysis assumes that while the cost of each marginal precaution is constant, the benefits of marginal precautions decline.¹⁸⁸ The result is that at some point, the marginal costs of additional precautions outweigh their benefits. Taking precautions beyond this point constitutes inefficient overdeterrence of risky behavior. Thus, the goal of the tort law is to encourage risk-taking and precaution-taking at the equilibrium level where marginal cost equals marginal benefit.¹⁸⁹

Deterrence theory assumes that actors are cognizant of the likelihood of tort sanctions for negligent behavior and choose to take necessary precautions to avoid those sanctions.¹⁹⁰ Research in the criminal law context has revealed that three factors influence the likelihood that an actor will engage in proscribed conduct: the swiftness, certainty, and severity of punishment.¹⁹¹ Of these, certainty is believed to be by far the most important motivation.¹⁹² Applied to malpractice liability,¹⁹³ this research suggests that physicians' precaution-taking behavior will be influenced by physicians' perceived likelihood of having an unfavorable judgment levied against them. This likelihood can be viewed as the product of several correlated¹⁹⁴

¹⁸⁷ WEILER ET AL., *supra* note 107, at 132.

¹⁸⁸ For an excellent presentation of this efficiency analysis, see EPSTEIN, *supra* note 57, at 91-93.

¹⁸⁹ This idea was famously expressed by Judge Learned Hand in *United States v. Carroll Towing Co.*, as follows: "[I]f the probability be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P; i.e., whether $B < PL$." 159 F.2d 169, 173 (2d Cir. 1947).

¹⁹⁰ Shuman, *supra* note 8, at 116.

¹⁹¹ *Id.* at 121.

¹⁹² *See id.* (stating that empirical research is conclusive regarding the relationship between certainty and deterrence).

¹⁹³ Daniel Shuman notes that there are reasons to question the applicability of the criminal law research to the civil context, but adopts this extension nonetheless. *Id.* at 121 & n.32.

¹⁹⁴ The probabilities are correlated because the more egregious the physician's deviation from the standard of care, the more likely an injury is to result, and the more grievous the injury, the more likely the patient is to file and win a lawsuit.

probabilities: the probability that the physician's conduct will fall below the legal standard of care, the probability that an injury will result, the probability that the patient will file a malpractice suit, and the probability that the suit will be resolved in the plaintiff's favor.¹⁹⁵

Uncertainty as to any of these probabilities will lead the actor to err on the side of taking excessive precautions. This is because the costs of undercompliance and overcompliance with the standard of care are asymmetrical.¹⁹⁶ Undercompliance exposes the actor to the risk of expensive litigation, while overcompliance subjects him only to the additional cost of the extra precautions taken.¹⁹⁷ The attractiveness of reduced exposure to liability will be highest where the amount the actor would expect to pay, if found liable, is high. Thus, the incentive to overcomply will be greatest within activities in which the equilibrium level of care still involves a significant risk of costly accidents.¹⁹⁸ Medicine would certainly seem to fall into this category, as adverse outcomes frequently result even from good-quality care. According to this analysis, if a physician is uncertain about the legal standard of care for a particular clinical situation—that is, if he is uninformed as to where the law has fixed the equilibrium point for precaution-taking—he will oversupply precautionary medical services such as diagnostic tests. This overdeterrence is manifested in the practice of defensive medicine.

Since the substitution of CPGs for custom as the legal standard of care would increase the level of uncertainty physicians have about the standard of care, we would expect to see an attendant *increase* in defensive medicine rather than a decrease. A CPG-based standard of care would make the tort law less efficient.

¹⁹⁵ [The tort law] cannot enable [a man] to predict with certainty whether a given act under given circumstances will make him liable, because an act will rarely have that effect unless followed by damage, and for the most part, if not always, the consequences of an act are not known, but only guessed at as more or less probable.

O.W. HOLMES, JR., *THE COMMON LAW* 79 (Boston, Little Brown & Co. 1881).

¹⁹⁶ See EPSTEIN, *supra* note 57, at 98 (describing how an actor would choose to spend one hundred dollars in extra precautions to insure against a one thousand dollar risk in the presence of an uncertain standard); Calfee & Craswell, *supra* note 186, at 966-67.

¹⁹⁷ Under fee-for-service medicine, the insurer, rather than the physician, pays these additional costs. This incentivizes doctors to overcomply, unlike other economic actors who must bear the costs of additional precautions themselves.

¹⁹⁸ Calfee & Craswell, *supra* note 186, at 981.

3. Tort Law As an Engineering Tool

The foregoing discussion suggests that one function of the tort system—perhaps even the dominant function¹⁹⁹—is to bring about the efficient level of safety. But a shift from custom to CPGs as the basis of the standard of care does not further the efficiency function. In addition, such a shift would ill-serve other functions of the tort law. Tort law in the medical malpractice realm serves a compensation function for patients injured by physician conduct that falls *below* customary medical practice. Grounding the legal standard of care in CPGs is not tailored to furthering this goal because in most cases it sets the threshold of liability *above* custom.²⁰⁰ In such a regime, tort law overcompensates injured parties and serves as a tool of social engineering by *pulling up* the medical standard of care towards some ideal. Co-opting the tort law in this fashion is imprudent and unfair.

As discussed in sub-Part I.B, for most industries, the courts have shown little reluctance to engage in judicial inflation of the customary standard of care. They have uncoupled the negligence standard from the blameworthiness standard. Blameworthiness, Oliver Wendell Holmes wrote, is “determined by the existing average standards of the community”—that is, by custom.²⁰¹ But in the name of incentivizing people to make progress in the direction of safety, Holmes felt it legitimate to hold some defendants liable notwithstanding the fact that they were not “blameworthy.”²⁰² This uncoupling of the negligence standard from custom has not, however, taken hold in the context of medical malpractice. The courts have shown far greater reluctance to impose their vision of safe and socially optimal practice upon medical professionals, and for good reason. As Richard Epstein has eloquently explained:

Physicians and other health care providers operate under multiple constraints: the glare of publicity when things go wrong; the censure of their colleagues; peer review; revocation of hospital privileges; a referral network; licensing; and the pressure to do a good job when a life is on the line. Perfection is the social aspiration, but not a legal requirement; an honest effort in conformity with customary standards is all that can be

¹⁹⁹ Richard A. Posner, *A Theory of Negligence*, 1 J. LEG. STUD. 29, 33 (1972).

²⁰⁰ As was discussed earlier, some CPGs—those devised by health care payers—may prescribe care that is less than what doctors would ordinarily do. More commonly, however, CPGs represent *optimal* care, and customary practice falls short of their prescriptions.

²⁰¹ HOLMES, *supra* note 195, at 125.

²⁰² *Id.* at 125-26.

demanded of physicians. Innovation and medical advance are surely desired, but these are fostered by wise institutional practices, and imaginative medical research. Even if medical standards "lagged" behind our deepest aspirations, the law could not bring it up to speed by altering the rules governing medical malpractice actions.²⁰³

This passage suggests that there is a fundamental distinction between what the tort law is trying to achieve and what health care reformers are trying to achieve. While medical malpractice law has traditionally aimed to deter conduct that falls below the customary standard of care and compensate persons injured as a result of such conduct,²⁰⁴ reformers who advocate the use of CPGs in litigation have another motive: to raise the quality of care above existing customary practice. It is clear from the academic commentary on tort reform that proponents of CPGs view their use in litigation as a lever to compel physicians to comply with guidelines.²⁰⁵

Wielding the tort law as a club in this fashion raises fairness concerns vis-à-vis physician-defendants. When courts begin to leave custom behind and craft new standards of care, a serious notice problem is created. Physicians have come to expect, based on decades of malpractice jurisprudence, that their actions will be judged against the standards of prevailing medical practice. To hold that a medical custom is facially unreasonable, such that compliance with it will not excuse a physician from liability, violates these expectations. It is unfair to penalize physicians for noncompliance with a standard of which they have been given inadequate notice. This was the concern of the Washington state legislature in overturning by statute the decision in *Helling v. Carey*.²⁰⁶

More fundamentally, wielding the tort law as an instrument of social engineering is imprudent because it is an inefficient way of bringing about improvements in the quality of medical care. There are still some who dispute that greater compliance with CPGs will

²⁰³ EPSTEIN, *supra* note 57, at 140-41.

²⁰⁴ See generally Shuman, *supra* note 8, at 118-19 (discussing the deterrence and compensation functions of tort law).

²⁰⁵ See Hyams et al., *supra* note 95, at 450 ("Reformers believe that guidelines [will] reduce litigation by encouraging compliance with the standard of care . . ."); Trail & Allen, *supra* note 24, at 251 (noting that doctors will be more willing to comply with the guidelines because doing so will give them an affirmative defense in malpractice litigation).

²⁰⁶ 519 P.2d 981 (Wash. 1974) (holding that reasonable prudence required that the doctor administer a routine pressure test of glaucoma to the patient even though professional standards did not require the doctor to do so).

improve the quality of care, but even if that premise is accepted, it does not necessarily follow that the tort law is the means that should be employed to induce greater compliance. Changing behavior on a mass scale through litigation involves heavy administrative costs. Among the sources of expense are: the direct costs of litigation, including attorneys' fees and the costs of discovery and juries; the long period of time that it may take to achieve a change in the legal regime through litigation; and the possibility of having to litigate the same issues on a repeated basis against different noncomplying defendants.²⁰⁷

Where possible, it is economically preferable to avoid these litigation costs by attempting to change behavior through private channels. Possible means of doing so include contract, the enforcement of social norms through self-help,²⁰⁸ and educative persuasion. Of these, the last holds the greatest promise for increasing compliance with CPGs. There has already evolved a substantial commitment, on the part of institutional health care providers and academic researchers, to piloting various educational, training, and monitoring programs to encourage physicians to learn about and follow CPGs.²⁰⁹ While not uniformly successful, such initiatives are far less expensive than enforcing compliance through litigation. There is no empirical evidence directly comparing the effectiveness of litigation and education in inducing compliance, but it is reasonable to posit that education may be more effective in the long run because education may actually persuade physicians that following the guidelines represents good quality care, rather than merely showing them that compliance is a necessary evil in order to avoid being sued. If physicians genuinely believe in the legitimacy of the guidelines, they will be more likely to make them a consistent part of their practice.

A final consideration counseling against a judicial departure from reliance on custom to establish the standard of care is institutional competence. Are judges and juries competent to determine what the appropriate standard of care is in medical encounters? Richard

²⁰⁷ See GUIDO CALABRESI, *THE COSTS OF ACCIDENTS* 286-87 (1970) (noting the costliness of the tort system's reliance on juries and individual case-by-case determinations).

²⁰⁸ See, e.g., Robert C. Ellickson, *A Critique of Economic and Sociological Theories of Social Control*, 16 J. LEGAL STUD. 67, 68 (1987) (describing the main method of private dispute resolution among ranchers in Shasta County, California).

²⁰⁹ See *supra* notes 167-68 and accompanying text (discussing interventions which may boost compliance with CPGs).

Posner has argued that courts are only able to determine optimal levels of precaution-taking in "simple cases."²¹⁰ The factual complexity of most medical conditions and treatments takes malpractice cases out of this category. Loosening the malpractice standard from its anchor in custom would greater expose it to the varying winds of untrained guesses about what constitutes appropriate care.

Advocates may respond that rather than providing judges and juries unbridled discretion to select a standard of care, reform merely contemplates allowing them to base their decisions on the CPG standard, which represents the consensus of top experts in the relevant medical specialty. Surely there is no institutional competence problem with that. This argument would be persuasive if there existed only a single set of CPGs for each medical condition and intervention. In a "pluralistic" guideline environment,²¹¹ however, courts must choose which set of guidelines to adopt in a particular case. It is not at all clear that judges have the expertise to be able to evaluate the strengths and weaknesses of competing guidelines. While courts could employ their own independent medical experts to assist in this determination, arguably it is preferable to allow the market to select a governing standard of medical practice—that is, to rely on custom.

I have argued that since CPGs do not represent current medical custom, and it would be ill-advised to depart from custom as the standard of care in malpractice cases, CPGs should not be afforded substantial weight as inculpatory evidence. Many of those who agree that it is premature, at best, to allow plaintiffs to wield CPGs as a sword in malpractice litigation have suggested that this does not mean that we should preclude physician-defendants from using them as a shield. Arguably, Maine-model reforms address many of the problems raised above. The multiplicity problem, for example, is dealt with by granting physicians an affirmative defense whenever they have complied with *any* authoritative guideline. As the next Part discusses, however, the one-way exculpatory use of CPGs raises problems of its own.

²¹⁰ RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 161 (3d ed. 1986).

²¹¹ Havighurst, *supra* note 7, at 113.

III. THE EXCULPATORY USE OF CPGs: ASYMMETRY AND ANOMALY

A. *One-Way Streets in the Law*

Permitting the introduction of certain evidence by one party to a lawsuit but not by the other party is an anomaly in the law.²¹² The most fundamental rule of the Federal Rules of Evidence is that all evidence that is relevant is admissible unless specifically excluded.²¹³ There are many types of evidence that are excluded under the Rules, but typically these exclusions apply equally to both parties. This reflects a general preference in American law for symmetry, or evenhandedness, in the application of legal rules. As Barbara Flagg and Katherine Goldwasser have observed, "Law would not be law as we know it without the requirement of evenhandedness; justice as we envision her is blindfolded, so as not to see who stands before her."²¹⁴ There are exceptions to the rule of symmetry, but they are few and far between, and each is justified by an important policy concern. Arguably, no such policy justification exists for the one-way use of clinical practice guidelines evidence in medical malpractice cases.

1. Character Evidence

Perhaps the best-known exception to the rule that if evidence is admissible, it is admissible by either party to a dispute, is character evidence in criminal cases. Rule 404(a)(1) states that "[e]vidence of a person's character or a trait of character is not admissible [by the prosecution] for the purpose of proving action in conformity therewith on a particular occasion," but may be offered by the accused to prove his own *good* character.²¹⁵ The prosecution may only offer character evidence in rebuttal if the defendant has chosen to introduce character evidence. This one-way street is justified by the basic tenet of criminal law that a defendant should be tried only on the instant charge, not for prior bad acts. We have good reason to

²¹² See Begel, *supra* note 132, at 97 ("No other area of law comes to mind in which plaintiffs would be prohibited from using relevant evidence regarding standards, guidelines, or usual and customary practices in similar circumstances."); Adam Kargman, Note, *Three Maelstroms and One Tweak: Federal Rules of Evidence 413 to 415 and Their Arizona Counterpart*, 41 ARIZ. L. REV. 963, 964 (1999) (discussing the Federal Rules of Evidence in sexual assault cases).

²¹³ FED. R. EVID. 402.

²¹⁴ Barbara Flagg & Katherine Goldwasser, *Fighting for Truth, Justice, and the Asymmetrical Way*, 76 WASH. U. L.Q. 105, 105 (1998).

²¹⁵ FED. R. EVID. 404(a)(1).

fear that if jurors hear evidence of the accused's rotten character and prior transgressions, they will become inflamed and cast a verdict based on character, rather than on the evidence before them relating to the present charge.²¹⁶ Thus, character evidence is viewed as almost always more prejudicial than probative when offered, which under Rule 403²¹⁷ merits its exclusion. In contrast, character evidence offered to impeach a prosecution witness may sometimes be more probative than prejudicial. It makes sense to allow an asymmetry in the Rules of Evidence to correct this asymmetry inherent in the circumstances.²¹⁸ Richard Friedman explains:

The accused is simply in a different situation from any other potential witness—for either the prosecution or the defense—in a criminal case. . . . The accused's conduct is necessarily the central issue in the case, and even without character impeachment evidence, the prosecution will do its best to put him in a bad light by trying to show that he committed the crime charged. If the prosecution witness is a mere observer, however, the defense may not have any comparable mudslinging opportunity—unless character impeachment evidence is allowed.²¹⁹

While there is a great danger that the jury will convict the defendant based on character evidence, there is no significant danger that the jury will use character impeachment evidence offered by the defense against a prosecution witness for an improper purpose—that is, to draw conclusions about the witness's propensities unrelated to her testimony. “Because the witness is only an observer, her non-testimonial propensities are not material and are unlikely to affect the jury's result.”²²⁰ Therefore, it does not substantially burden the prosecution or jeopardize the fairness or accuracy of the trial to admit character evidence against prosecution witnesses but prohibit the

²¹⁶ See *Michelson v. United States*, 335 U.S. 469, 475-76 (1948) (noting that prior bad acts are excluded, not because they are irrelevant, but because there is a risk that they will “overpersuade” a jury); Kargman, *supra* note 212, at 963 (discussing the tradition of disfavoring character evidence on behalf of the defendant).

²¹⁷ Rule 403 provides that “[a]lthough relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.” FED. R. EVID. 403.

²¹⁸ See Richard D. Friedman, Comment, *Character Impeachment Evidence: The Asymmetrical Interaction Between Personality and Situation*, 43 DUKE L.J. 816, 830 (1994) (averring that this asymmetry simply responds to different situations with different results, each promoting the truth-determination process).

²¹⁹ *Id.* at 830-31.

²²⁰ *Id.* at 827 n.35.

prosecutor from introducing such evidence against the defendant. This asymmetry in the Rules of Evidence has a solid justification and little prejudicial impact.

2. Evidence of Past Sexual Conduct

A second instance of asymmetry in the Federal Rules is the treatment of evidence of past sexual conduct in rape cases. In 1994, as part of the Violent Crime Control and Law Enforcement Act, Congress adopted Rules 413, 414, and 415, which allow evidence of prior sexual assaults and child molestations by a defendant to be admitted and "considered for its bearing on any matter to which it is relevant."²²¹ The treatment of the defendant in these Rules stands in stark contrast to the treatment of victims of sexual misconduct in Rule 412. That Rule provides that evidence of a victim's past sexual behavior or "sexual predisposition" is inadmissible in any civil or criminal proceeding involving alleged sexual misconduct except for certain narrow purposes.²²² As one commentator has put it, Rules 412 through 415 collectively provide that "plaintiffs and prosecutors can 'dirty up' defendants, but defendants cannot do the same to plaintiffs."²²³

An extremely important social policy underlies Rule 412: protecting victims of sex crimes from harassment, embarrassment, sexual stereotyping, and invasions of privacy. In the absence of such protection, rape victims would be put through devastating cross-examination at trial, and such an ordeal not only amounts to secondary victimization but also deters victims from reporting and testifying against sex offenders.²²⁴ It is also argued that Rules 413 through 415 are justified by the high rate of recidivism among sex offenders, which makes evidence concerning their past sexual conduct particularly relevant to the adjudication of a sex offense charge against them.²²⁵ Finally, like the asymmetry concerning other

²²¹ FED. R. EVID. 413(a), 414(a). Rules 413 and 414 are addressed to criminal cases. Rule 415 applies the same rule to civil cases. *Id.* Rule 415(a).

²²² *Id.* Rule 412(a). The exceptions are set forth in subsection (b), and include such purposes as proving that a person other than the accused was the source of semen or other physical evidence. *Id.* Rule 412(b).

²²³ Kargman, *supra* note 212, at 971.

²²⁴ *See* MAUET & WOLFSON, *supra* note 82, at 254 (discussing the policy purpose behind Rule 412).

²²⁵ *But see* Kargman, *supra* note 212, at 973-74 (disputing that rates of recidivism among sex offenders, as measured by the number of rearrests, are higher than among other criminals).

kinds of character evidence, the asymmetry on sexual history evidence is thought to be justified as a corrective measure for an inherent asymmetry in the criminal trial itself. Rape trials are viewed as stacked against the victim because of societal views toward women and sexuality:

Rules 412 and 415 can be used to cleanse the fact finding process of biases that have reinforced the asymmetry of power and powerlessness in matters of sex. Both of these rules assist the trier of fact in focusing on the behavior of the alleged perpetrator, rather than indulging in stereotypic beliefs that women cannot be believed when making claims of sexual misconduct. The result is a potentially powerful tool to combat long-held stereotypes that have infected sexual misconduct cases: that the victim either invited the treatment, or deserved it, or is not to be believed without sufficient corroboration.²²⁶

While there seems little doubt that the Rules' asymmetry regarding sexual history evidence imposes a substantial burden on the defense in rape cases, policy considerations are believed to outweigh this burden.

3. Other Asymmetrical Rules of Evidence

There are two other instances of asymmetry in the Federal Rules that are worthy of mention. Rule 410 provides that a prosecutor may not introduce evidence that the defendant offered to plead guilty or nolo contendere to the charges against her.²²⁷ The prosecutor also may not introduce any statements made by the defendant in the course of plea discussions that did not result in a plea of guilty or that resulted in a guilty plea that the defendant later withdrew.²²⁸ The Rule does not specifically provide that a *defendant* may introduce statements made by the prosecutor in the course of plea discussions, but this is implied from the fact that the Rule states only that plea evidence is not "admissible against the defendant."²²⁹ The Rule thus embodies an asymmetry.

This asymmetry is, however, both insignificant and well justified. It is insignificant because there are few circumstances in which a defendant who has withdrawn her guilty plea, or decided not to enter such a plea, would wish to introduce any statements made by the

²²⁶ Jane Harris Aiken, *Sexual Character Evidence in Civil Actions: Refining the Propensity Rule*, 1997 WIS. L. REV. 1221, 1262-63 (citation omitted).

²²⁷ FED. R. EVID. 410(1)-(2).

²²⁸ *Id.* Rule 410(3).

²²⁹ *Id.* Rule 410.

prosecutor during the aborted plea discussions. One might envision a situation in which the defendant would want to introduce the prosecutor's statements during plea discussions for the purpose of later holding her to an oral promise made in the negotiations, but this would only occur where the defendant has actually entered a guilty plea and thus would not be covered by Rule 410. The asymmetry in Rule 410 is also justified by the state's strong interest in encouraging plea negotiations. In the absence of Rule 410, criminal defendants would be extremely reluctant to enter into plea discussions and make incriminating statements therein, for fear that their statements would be used against them at a subsequent trial should the negotiations fail. There are no such concerns that would motivate the two-way exclusion of plea statements—that is, the exclusion of the prosecutor's statements as well as the defendant's.

A final instance of asymmetry in the Federal Rules is Rule 801(d)(2), the party admissions exception to the hearsay rule. Rule 801(d)(2) provides that an out-of-court statement is admissible if the statement is made by a party and offered against her.²⁴⁹ Thus, a plaintiff may use the defendant's own incriminating statement against her at trial. This Rule constitutes an asymmetry in the law because the defendant is not allowed to introduce her own statements against the plaintiff. There are, however, two considerations justifying the asymmetry. First, if one takes another view of the Rule, it is not asymmetrical at all: both plaintiffs and defendants may offer statements made by the other party against that party. The Rule does not grant special evidentiary privileges to one party and not the other. Secondly, there are valid reasons for admitting party admissions against the declarant:

The most persuasive explanation is that the admissions doctrine expresses the philosophy of the adversary system, in which each party is responsible for making or breaking, winning or losing, his own lawsuit—by his conduct both in and out of court. And a series of somewhat related reasons points in the same direction: The hearsay doctrine is designed to protect parties against uncross-examined statements, but a party can hardly complain that he has not had a chance to cross-examine himself; admissions are a kind of conduct, amounting to behavior by a party which provide circumstantial evidence of what they assert; admissions give rise to estoppel notions and should be usable against a party for similar reasons; and a common sense of fairness suggests that one should simply not be allowed to complain that his words are proved

²⁴⁹ *Id.* Rule 801(d)(2).

against him.²³¹

More fundamentally, where the party admission consists of an incriminating statement, there is much less reason to be skeptical of the truth of the statement than there is with most hearsay evidence. People generally do not make false statements against their pecuniary or penal interest.²³² Thus, particularly where the statement is an incriminating one, it makes sense to have a rule of evidence permitting one party to introduce the other party's statement into evidence against her, but prohibiting the declarant party from introducing her own statement even if she feels it somehow works in her favor to do so.

The foregoing examples illustrate that asymmetries in the Federal Rules are few in number and uniformly backed by a strong policy or epistemological justification. To adopt a Maine-model approach to the admissibility of CPGs in medical malpractice suits would run against the current of the law of evidence and would require a valid justification of its own. Arguably, no such justification exists.

B. *Possible Justifications for One-Way Admissibility*

There are two arguments that Maine-model reformers might put forward in favor of the one-way use of CPGs, but ultimately neither is persuasive. The first argument is that the need to protect physicians from the threat of a huge damages award justifies permitting physicians to use compliance with CPGs as an affirmative defense in malpractice cases while barring plaintiffs from using noncompliance with CPGs to prove negligence. The costs of malpractice litigation—to both physicians and society—are so large, the argument goes, that we must provide physicians with a safe harbor against frivolous suits. Moreover, according to law-and-economics theory, reducing the uncertainty surrounding malpractice litigation by providing that the physician will be “off the hook” if he can prove compliance with a relevant CPG will produce a more optimal level of precaution-taking by physicians and thereby strengthen the deterrent function of tort

²³¹ CHRISTOPHER B. MUELLER & LAIRD C. KIRKPATRICK, EVIDENCE UNDER THE RULES 212 (3d ed. 1996) (citations omitted).

²³² See MAUET & WOLFSON, *supra* note 82, at 199 (“The hearsay exception is based on the assumption that people do not make statements damaging to themselves unless they believe for good reason that their statements are true.”). Rule 804 grants rights to introduce this evidence to both parties and includes the statements of non-party witnesses as well as party admissions against interest. FED. R. EVID. 804.

law.

There are several problems with this argument. First, it is debatable whether there is a greater social need to insulate physicians from tort liability than there is to protect other groups of defendants. The costs of malpractice litigation, both direct and indirect, are certainly high, but this can also be said of the costs of tort litigation in a variety of other industries. Secondly, even if one does accept the argument that physicians deserve special protection from tort suits, there are more direct ways of going about limiting their liability. For examples of possible strategies, it is useful to look at the rules for products liability set forth in the new *Restatement (Third) of Torts: Products Liability*.²³³ There, the American Law Institute carved out special liability rules for blood products, prescription drugs, vaccines, and medical devices because it felt that these products are so vitally important to the nation's welfare that their manufacturers must be encouraged to innovate and bring new products to market without fear of being sued.²³⁴ The *Restatement* modifies the traditional negligence standard for product design defects for these medical products, making it much more difficult for plaintiffs to win suits against the manufacturers, in order to provide this extra measure of protection. This is an approach to providing safe harbors that does not violate the spirit of the Federal Rules by introducing an asymmetry into the law of evidence.

A third problem is that if the guideline invoked by the physician in her affirmative defense is a minimalist CPG created by a health care payer, or merely an "option," to use Eddy's language,²³⁵ unsupported by sound scientific evidence and a high degree of medical certainty, then compliance with the guideline may not constitute non-negligence as the law of medical malpractice has traditionally conceived of it. Permitting an affirmative defense based on compliance with such guidelines would not only weed out frivolous lawsuits, it would weed out some meritorious suits as well. This is undesirable from the standpoint of compensation. Thus, the argument that physicians deserve special protection from malpractice litigation does not adequately justify the imposition of a special evidentiary disability on malpractice plaintiffs. There are fairer and more precise ways to protect physicians.

²³³ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 2, 6, 19(c) (1998).

²³⁴ See generally George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087 (2000).

²³⁵ *Supra* notes 150-53 and accompanying text.

The second argument that Maine-model reformers might advance in favor of the one-way use of CPGs is that this affirmative defense would dramatically reduce the battle of the experts we presently see in malpractice suits.²³⁶ This argument should be taken seriously, as there is no doubt that the existing level of reliance on expert opinion in malpractice cases has produced undesirable results. Expert witnessing has become a profession in and of itself, with "hired guns" available for rent to the highest bidder.²³⁷ The sometimes-enormous fees paid to medical experts create reason to doubt their objectivity. Even if experts maintain the highest level of scientific integrity and offer genuine and thoughtful opinions, there is some doubt as to whether lay juries are able to evaluate competently the competing opinions of more than one expert. They may not understand the complicated information conveyed to them at trial.²³⁸ They also may not know how to choose between two seemingly well-qualified experts who have reached opposite conclusions. There is some evidence that jurors may choose to believe one expert over the other on the basis of factors irrelevant to the scientific merit of their opinion, such as the expert's appearance, tone, and demeanor.²³⁹

Maine-model reformers are right to point out the shortcomings of reliance on expert opinions. They are overly optimistic, however, in their estimation of how far CPGs can go toward ameliorating the battle of the experts. Experts will still be used, and required, for at least three functions in a tort system that bases the standard of care on CPGs. First, because litigants may invoke any one of a number of competing sets of guidelines in a given case, expert opinion will be needed to ascertain whether the proffered guidelines do in fact represent the appropriate standard of care. This will require proof that the organization that promulgated the guideline is composed of qualified experts who are not motivated by the need to economize in the provision of medical care, that the guidelines were developed through a process characterized by scientific rigor and consensus

²³⁶ See Smith, *supra* note 140, at 358 (optimistically reporting in 1993 that the 1990 Maine project had "stopped the battle of the experts," even though no malpractice suits had yet been brought invoking the project's CPG-based affirmative defense).

²³⁷ For a collection of news stories and reports discussing this phenomenon, see Leahy, *supra* note 7, at 1497 n.63.

²³⁸ See Trail & Allen, *supra* note 24, at 242 ("While jurors endeavor to remain objective and evaluate the conflicting testimony provided by the expert witnesses, it is unrealistic to expect laymen to comprehend intricate and detailed medical procedures and related information.").

²³⁹ Leahy, *supra* note 7, at 1497 & n.64.

decisionmaking, that the guidelines are up-to-date, and that other sets of guidelines are not superior to the set selected.²⁴⁰ Thus, in the pluralistic environment of CPGs, the battle of the experts would not be eliminated, but rather supplemented by a “battle of the guidelines.”²⁴¹

Second, experts will need to testify that the guidelines selected are applicable to the particular clinical interaction at issue. The expert must examine the clinical encounter itself and offer an opinion as to whether the guidelines apply to that patient, exhibiting those symptoms, requiring that particular intervention, in that particular care setting. The more broadly stated and flexible the guidelines are, the more extensive this factual inquiry by the expert will have to be. For example, if the guidelines use language calling for a particular procedure where “relevant complications exist” or where “the [physician] has a hunch that [the] procedure may be helpful,” as the AMA recommends that CPGs should, then “the statement will lose any semblance of a guiding standard and the case will degenerate into a conventional battle of the experts.”²⁴²

Third, an expert will be needed to testify as to the physician’s compliance or noncompliance with the relevant guideline. Did the physician follow the prescribed procedures, and if not, did she have a valid justification for her deviation in this patient’s case? This function of the expert recognizes that CPGs address the disease or the intervention, rather than the particular patient. They set forth general rules and procedures that may not be applicable to a given patient due to that patient’s unique set of symptoms, medical history, other present medical problems, or preferences for treatment.²⁴³ While the use of professional experts to render opinions certainly is not unproblematic, the great virtue of experts is their ability to apply a body of knowledge and expertise to the facts of a particular case. An

²⁴⁰ See Begel, *supra* note 132, at 88 (“[D]efense experts may be necessary to explain the guidelines and justify their admissibility as conclusive evidence of a standard of care.”); Garnick et al., *supra* note 4, at 2859 (listing other issues regarding practice guidelines that will still require expert medical testimony).

²⁴¹ Rosoff, *supra* note 25, at 386.

²⁴² Hall, *supra* note 91, at 132-33.

²⁴³ See Hirshfeld, *supra* note 20, at 2889 (“A given patient may have physical characteristics or complicating medical problems that were not anticipated by the parameter authors, and it may be appropriate to depart from the recommendations or standards of the parameter.”); Woolf, *supra* note 26, at 2651 (“The patient’s medical history, comorbid illnesses, and personal circumstances may mean that the individual is better served by options other than those advocated in the guideline.”).

expert can tell the factfinder how other competent physicians would have dealt with this particular patient. CPGs can only tell the factfinder how physicians should deal with the symptoms presented in a hypothetical patient. The decision trees embodied in CPGs do not and cannot account for every individual-level contingency that might affect a physician's decision. The Office of Technology Assessment has estimated that even for garden-variety medical problems, there may be over *ten billion* pathways for diagnosing the condition.²⁴⁴ Since CPGs are, at best, rudimentary summaries of the most common pathways, there is much about a doctor's decisionmaking that is not captured and requires expert explanation. As the former General Counsel of the AMA has put it, "Working with uncertainty is where medicine becomes an art as well as a science, and it is not feasible to expect practice parameters to capture and express the art of medicine."²⁴⁵ It would be impossible to use CPGs as the standard of care without employing some medical expert to interpret the guidelines and verify their applicability to the plaintiff's case.

The limited empirical evidence collected to date confirms that the use of CPGs in malpractice suits does not significantly reduce reliance on expert witnesses. A survey of 578 attorneys who litigate malpractice claims found that only 4.7% felt that the use of a guideline decreased the need for an expert; about 12% felt that the use of a guideline actually increased the need for an expert; and the remainder felt that it had no effect.²⁴⁶ In summary, because experts will still be required to fulfill several functions in malpractice trials, it is wishful thinking to assert that reliance on CPGs to establish the standard of care will end the battle of the experts.²⁴⁷

C. Constitutional Issues

It has thus far been argued that permitting the one-way use of CPGs in malpractice suits would be ill-advised from the standpoint of the law of evidence. It would constitute an anomalous deviation from the general rule that if evidence is relevant and probative, it is

²⁴⁴ OTA REPORT, *supra* note 4, at 143.

²⁴⁵ Hirshfeld, *supra* note 20, at 2888.

²⁴⁶ Hyams et al., *supra* note 95, at 453. The researchers concluded that "our results diminish the hope that guidelines will effectively eliminate the battle of the experts in malpractice litigation." *Id.* at 454 (citation omitted).

²⁴⁷ See Kadzielski et al., *supra* note 31, at 170 ("[T]he application of guidelines as affirmative defenses will not change the role of plaintiffs' expert witness in malpractice litigation.").

probative both ways and should be admissible by both parties to the litigation.²⁴⁸ While there are examples of this type of asymmetry in the Federal Rules of Evidence, they are all backed by an important policy justification. Neither of the justifications offered by Maine-model reformers—protecting doctors from malpractice litigation or eliminating the battle of the experts—justifies the asymmetry they propose.

Some commentators also have argued that the one-way use of CPGs in malpractice litigation raises constitutional concerns. Both an equal protection problem and a due process problem have been posited. The equal protection argument might be formulated in two different ways. One could argue that Maine-model systems create an impermissible distinction between civil plaintiffs and civil defendants. Alternatively, one could argue—as Jennifer Begel has done—that Maine-model systems unconstitutionally burden medical malpractice plaintiffs more than other kinds of plaintiffs.²⁴⁹ While the first formulation may seem the more intuitive description of the classification, it is likely that courts would choose to frame the classification in terms of a distinction between malpractice litigants and other civil litigants. Maine's one-way admissibility standard has not been challenged on constitutional grounds, so we cannot be sure how the classification would be described. Other aspects of Maine's demonstration project, however, such as its prelitigation notice requirements and its requirement that plaintiffs submit their claims to a prelitigation screening panel, have been the subject of equal protection challenges.²⁵⁰ These equal protection claims were couched in terms of a distinction between malpractice litigants and other litigants.²⁵¹ The courts in Maine and elsewhere have held that rational basis review is the appropriate standard of scrutiny for such classifications, as neither a fundamental right nor a suspect or quasi-

²⁴⁸ See FED. R. EVID. 402 ("All relevant evidence is admissible.").

²⁴⁹ See Begel, *supra* note 132, at 94-98 (arguing that the Maine system should be struck down under the rational basis standard).

²⁵⁰ See *Houk v. Furman*, 613 F. Supp. 1022 (D. Me. 1985) (discussing Maine's prelitigation notice requirement); *Irish v. Gimbel*, 691 A.2d 664, 673 (Me. 1997) (holding that Maine's mandatory screening panel process for medical malpractice actions does not violate equal protection).

²⁵¹ See *Houk*, 613 F. Supp. at 1028-34 (denying plaintiff's assertion that the notice requirement "impermissibly distinguishes between medical malpractice plaintiffs and plaintiffs in other tort actions"); *Irish*, 691 A.2d at 673 (rejecting plaintiffs' argument that the screening process created "an arbitrary distinction between medical malpractice victims and all other tort victims").

suspect class is involved.²⁵² Begel appears to believe that the same analytical framework would be applied in a suit challenging the evidentiary provisions of the Maine statute.²⁵³

Because prelitigation notice requirements and prelitigation screening requirements facially affect both parties to malpractice litigation, it is unsurprising that the courts have chosen to view the classification as malpractice litigants versus other litigants. A closer parallel to a one-way admissibility rule for CPGs in malpractice cases might be Federal Rules of Evidence 412 through 415, the rape shield laws. Like the shield-only CPG rule, the rape shield rules permit one party to the litigation to introduce a certain kind of seemingly probative evidence while denying the other party the right to introduce the same kind of evidence.²⁵⁴ The rape shield laws have been challenged on equal protection grounds, and despite the fact that they appear to set up a classification between prosecutors and criminal defendants, courts uniformly have analyzed the classification as one between sexual offense defendants and other criminal defendants.²⁵⁵ Finding that sexual offense defendants are not a suspect class and that the rules do not impinge upon a fundamental right,²⁵⁶ the courts have applied a rational basis standard of scrutiny and have implicitly upheld the classification embodied in Rules 412 through 415. If these rules, which significantly burden a criminal defendant, withstand constitutional scrutiny, then a fortiori, it is highly likely that a similar evidentiary rule burdening a *civil* defendant would be upheld. After all, criminal defendants receive a much higher level of constitutional protection, under the Fifth and Sixth

²⁵² See *Houk*, 613 F. Supp. at 1028 (“The plaintiff points to no special circumstances . . . which would warrant a departure from the general rule requiring application of the rational relationship test.”); *Irish*, 691 A.2d at 673 (“We have held that medical malpractice plaintiffs are not a suspect class and do not possess a fundamental right to pursue their causes of action. Therefore, we apply the rational relationship test” (citation omitted)).

²⁵³ See Begel, *supra* note 132, at 95 (“A survey of the jurisdictions in which equal protection challenges to tort reform measures in the medical malpractice arena have been addressed suggests that the classification in the Maine legislation would be tested according to the rational basis standard.”).

²⁵⁴ See *supra* Part III.A.2 (justifying the asymmetry in rape shield evidence rules).

²⁵⁵ See, e.g., *United States v. Mound*, 149 F.3d 799, 801 (8th Cir. 1998) (finding that Rule 413 does not violate a fundamental right and that sex-offense defendants are not a “suspect class”); *United States v. Enjady*, 134 F.3d 1427, 1433-34 (10th Cir. 1998) (“Rule 413 does not violate . . . a defendant’s fundamental right to a fair trial. Thus, the rational basis test applies and a strong presumption of validity attaches to the evidentiary classification made in enacting Rule 413.”).

²⁵⁶ *Mound*, 149 F.3d at 801; *Enjady*, 134 F.3d at 1433-34.

Amendments, than do civil defendants.²⁵⁷

Thus, it would appear that, regardless of how the classification is framed, a one-way admissibility rule for CPG evidence would trigger only rational basis review and would survive an equal protection challenge. Begel disputes this, arguing that Maine's evidentiary classification would fail to satisfy even a rational basis analysis.²⁵⁸ This argument, however, is unpersuasive. Under the rational basis test, a legislative classification will be upheld as long as it bears a rational relationship to some legitimate state interest. The threshold for legitimacy of the interest is very low, and it is likely that a court would deem the Maine classification's expressed statutory purpose—encouraging physicians to participate in the demonstration project (that is, to comply with CPGs) in order to increase the quality of medical care rendered in Maine—to be sufficient.²⁵⁹

In addition to an equal protection problem, one might argue that the one-way use of CPGs in malpractice litigation raises a question of due process. Begel has commented:

Certainly the right to a jury trial and access to the judicial process are meaningless if the procedures afforded fail to give the litigants a complete opportunity to have their claims tried fairly and impartially. Allowing evidence to be used only by one party and not by the other,

²⁵⁷ The Sixth Amendment to the Constitution guarantees a criminal defendant certain fair trial rights not enjoyed by the prosecution, while the Fifth Amendment lets the accused choose not to testify at trial. In contrast, civil litigants in federal court share equally the protections of the Fifth Amendment's Due Process Clause.

Green v. Bock Laundry Mach. Co., 490 U.S. 504, 510 (1989). In *Green*, the Supreme Court held that Federal Rule of Evidence 609(a)(1), which provides that evidence that a witness has been convicted of a felony, "shall" be admitted for the purpose of attacking the witness's credibility "only if" the court determines that the probativeness of the evidence outweighs its prejudice "to the defendant," did not apply to witnesses in civil cases. *Green*, 490 U.S. at 527.

²⁵⁸ See Begel, *supra* note 132, at 96-98 ("Even assuming a Maine court would apply the lowest level of scrutiny, the rational basis test, to the guidelines legislation, the fact that it denies plaintiffs [sic] use of relevant evidence regarding compliance with guidelines would likely render at least that aspect of the legislation unconstitutional.")

²⁵⁹ In reference to this point, Begel merely states conclusorily that "[s]uch enticement would not, and should not, be deemed by any court to justify the disparate treatment of medical malpractice litigants under this provision of the legislation." *Id.* at 98. The Maine courts, however, previously have found the purpose of "assuring the continued availability of affordable health care" to be a legitimate objective justifying a related classification between malpractice litigants and other litigants, *Houk v. Furman*, 613 F. Supp. 1022, 1034 (D. Me. 1985), and this purpose seems sufficiently similar to the goal of assuring good quality health care that a court would also deem the latter to be legitimate.

without any sufficient articulable justification, would seem to make the proceedings constitutionally suspect. The problem is exacerbated by the fact that admissibility of the evidence could reasonably be predicted to alter the outcome of any given case.²⁶⁰

The AMA has taken the opposite position, that no due process problem is created by the one-way defensive use of CPGs. It has argued that nonmutual collateral estoppel²⁶¹ and other asymmetries in the law show that due process does not "require that both parties always have the benefit of the same legal presumptions or even the same evidence."²⁶² This may be so, but Begel is right to note that the key issue is whether or not a sufficient justification exists for the asymmetry.²⁶³ If there is no legitimate basis for the distinction between parties, so that the distinction is arbitrary and irrational, it will not survive a due process challenge. Thus, the legal analysis for a due process claim concerning the one-way use of CPGs essentially boils down to the same question as the analysis for an equal protection claim: Does the differential treatment of the parties have a rational basis? The answer is likely to be the same: yes. States' interests in reducing malpractice litigation costs and encouraging physicians to comply with practice guidelines would probably be deemed sufficient.

Thus, it would appear that the shield-only use of CPGs in malpractice litigation does not impose an unconstitutional burden upon plaintiffs under either an equal protection or a due process theory. This does not mean, however, that such use of CPGs is good policy. Moreover, even if it is not unconstitutional, a Maine-model policy violates the spirit of the Federal Rules of Evidence by upsetting the presumption that the law should treat litigants evenhandedly.

CONCLUSION

This Article has argued that increased reliance on clinical practice guidelines to establish the standard of care in medical malpractice

²⁶⁰ Begel, *supra* note 132, at 100-01.

²⁶¹ Nonmutual collateral estoppel refers to the ability of one party to invoke a previous judgment adverse to the other party as a means of precluding the other party from relitigating the same issue in the instant suit. See *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331 (1979) (permitting *offensive* nonmutual collateral estoppel); *Blonder-Tongue Lab. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971) (allowing *defensive* nonmutual collateral estoppel).

²⁶² Hirshfeld, *supra* note 20, at 2890.

²⁶³ See Begel, *supra* note 132, at 93 ("[T]he validity of the provision would depend, if presented to a court, on whether the disparate treatment of the parties amounted to a violation of the State or Federal constitutions.").

cases would be undesirable whether the guidelines are used in an inculpatory or an exculpatory fashion. Among the reasons for disallowing the inculpatory use of CPGs is that CPGs do not appear to represent custom in most instances. Compliance with most guidelines is presently quite low, so that the guidelines cannot be said to embody prevailing medical practice. Departing from custom as the anchor of the standard of care, and relying on the prescriptions of CPGs instead, could undermine the deterrent function of tort law by increasing the amount of uncertainty physicians face in determining what the law requires of them.

Permitting physicians to use CPGs as an affirmative defense in malpractice, while denying plaintiffs the right to use this evidence to prove their own case, is also problematic. Restricting access to relevant evidence on a key element of a legal claim to one party to the litigation is an anomaly in the law and requires strong justification, which is lacking in the case of CPGs. The need to protect physicians from frivolous lawsuits does not constitute a persuasive justification, and, contrary to their proponents' claims, Maine-model reforms do not significantly reduce the problems associated with reliance upon expert witnesses in malpractice cases. The shield-only use of CPGs is unfair to plaintiffs, although this unfairness does not appear to rise to the level of a constitutional violation.

Moreover, while Maine-model reforms may seem to benefit physicians by giving them a safe harbor, this shelter comes at a price. Compliance with CPGs may be technically voluntary under a Maine-model system—that is, physicians can choose whether or not they wish to take advantage of the affirmative defense—but the practical effect of such policies may be to make compliance with CPGs mandatory. Physicians may come to feel as though they have to comply with the guidelines, under penalty of exposure to a crippling damages award. The fact that some malpractice insurers have begun to require compliance with CPGs as a condition of coverage or of affordable premiums is testimony to the reality of this effect. This is not to say that more widespread physician compliance with CPGs created by reputable, authoritative professional societies would be socially undesirable. To the contrary, there is every indication that it would improve the quality of care rendered in this country. Physicians, however, may view mandatory compliance with prescribed guidelines as a very significant infringement upon their professional autonomy, and it should be noted that physicians' ability to invoke CPGs defensively under a Maine-model system may come at the cost of this

loss of freedom.

Because of these problems with both the inculpatory and the exculpatory uses of CPGs, the best course of action, at least at this point in time, is to restrict their use by both plaintiffs and defendants. CPGs should not be used to replace expert testimony as to the customary standard of care. This does not mean, however, that there is *no* role for CPGs in malpractice litigation. It might be desirable for experts to use them to lend credence to their own opinions. That is, an expert could offer an independent opinion as to prevailing medical practice in the relevant specialty, community, and clinical situation. Then, if there exists an authoritative set of practice guidelines that essentially prescribes the same standard of care, the expert could invoke the guidelines to say, "Not only is this what physicians *actually do*, this is also what Professional Society X says is the *optimal* thing to do in this situation." This use of CPGs would retain custom as the standard of care and experts as the means of explaining current custom to the jury, while allowing both parties to use the edicts of professional societies as supporting evidence that the custom itself is reasonable. The advantage of this type of system is twofold: (1) because it retains custom as the relevant standard, it does not create an uncertainty or notice problem for physicians; and (2) because it uses experts rather than written guidelines to determine the standard of care in a particular case, it is a patient-centered rather than a disease-centered approach. An expert can review a particular plaintiff's medical charts and ascertain what was medically required *in the plaintiff's case*; CPGs can only tell the court what is required in a *typical* case where the patient presents a certain medical condition or set of symptoms.

Such a system would represent a sounder, less radical alternative to the reforms proposed by advocates of the judicial notice model and the Maine model. Though well-intentioned, those reformers fail to appreciate the fact that we are still in the technological adolescence of the clinical practice guidelines movement. We have yet to resolve basic issues such as which set of guidelines is *the* authoritative prescription for a particular medical problem, what procedures should be used to create guidelines, what institutions, goals, and values should drive their development, and how we can ensure that guidelines are disseminated and adopted by physicians. It would be foolhardy to make CPGs the centerpiece of malpractice litigation before the science of creating and implementing them on a wide scale has fully evolved.