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ADMINISTRATIVE LAW APPROACHES TO MEDICAL MALPRACTICE REFORM

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I. INTRODUCTION

The United States has just witnessed its third crisis in the availability and affordability of medical liability insurance in thirty years.[1] Many physicians and other providers delivered health-care services with no liability insurance or stopped providing services altogether.[2] Physicians and other health-care providers, as well as medical liability insurers, are calling for reforms.[3] Before Congress is the Bush Administration's proposal advanced as a cornerstone of the Administration's health policy, to modify state tort law by federal law.[4]

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1. *See* William M. Sage, *The Forgotten Third: Liability Insurance and The Medical Malpractice Crisis*, HEALTH AFF., July/Aug. 2004, at 10. *See generally* Kenneth E. Thorpe, *The Medical Malpractice 'Crisis': Recent Trends and the Impact of State Tort Reforms*, HEALTH AFF., Jan. 21, 2004, at W4-20, *available at* http://www.healthaffairs.org.

2. *See, e.g.*, Joseph B. Treaster, *Rise in Insurance Forces Hospitals to Shutter Wards*, N.Y. TIMES, Aug. 25, 2002, § 1, at 1; Susan Warner, *Practicing Without a Net*, N.Y. TIMES, June 2, 2002, § 14NJ, at 1.

3. American Medical Association, *Medical Liability Reform*, *available at* http://www.ama-assn.org/ama/pub/category/9255.html ("AMA has designated medical liability reform as its number one priority."); American Hospital Association, *Health Care Liability Reform*, *available at* http://www.hospitalconnect.com/aha/key_issues/hpl/; MARKET CONDITIONS WORKING GROUP, NAT'L ASS'N OF INS COMM'RS, MEDICAL MALPRACTICE INSURANCE: A STUDY OF MARKET CONDITIONS (Sept. 9, 2003) (Draft Report presented to the National Association of Insurance Commissioners), *available at* http://www.wsma.org/NAIC_medmal_study.pdf (last visited Sept. 1, 2004); *see also Harming Patient Access to Care: The Impact of Excessive Litigation: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 107th Cong. (2002).

4. Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2004, H.R. 4280, 108th Cong. (2004); Pregnancy and Trauma Care Access Protection Act of 2004, S. 2207, 108th Cong. (2004); Healthy Mothers and Healthy Babies Access to Care Act of 2003, S. 2061, 108th Cong. (2004); Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2003, H.R. 5, 108th Cong. (2003); Patients First Act of 2003, S. 11, 108th Cong. (2003).

This proposal calls for the imposition of a cap on non-economic damages as well as other measures aimed at reducing the frequency and severity of medical malpractice claims. States are adopting similar reforms as well.[5]

The latter half of the Twentieth Century witnessed an explosive expansion in tort liability generally.[6] One consequence of this explosion in tort law has been a call for the reform of the state common law tort system and curtailment of expanding tort liability.[7] Of note, a substantial body of analysis, much of it empirical, defends the performance of the common law tort system in handling tort claims during this period.[8] Like other areas of tort law, liability for medical malpractice expanded with changes in rules governing the standard of care and a greater willingness of medical specialists to testify in medical malpractice cases.[9] Subsequently, there have been three crises in the availability and affordability of medical liability insurance that have made medical liability insurance unduly expensive and often unavailable, which in

5. *See* Am. Med. Ass'n, Medical Liability Reform—NOW!: A Compendium of Facts Supporting Medical Liability Reform and Debunking Arguments Against Reform 23–35 (2004), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/450/mlrnowjune112004.pdf; Health Policy Studies Div., Nat'l Governors Ass'n, Issue Brief: Addressing the Medical Malpractice Insurance Crisis (Dec. 5, 2002), *available at* http://www.nga.org/center/divisions/1,1188,C_ISSUE_BRIEF^D_4703,00.html.

6. *See generally* PETER W. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1988); TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE (Peter H. Schuck ed., 1991); Kenneth S. Abraham & Lance Liebman, *Private Insurance, Social Insurance, and Tort Reform: Toward a New Vision of Compensation for Illness and Injury*, 93 COLUM. L. REV. 75 (1993).

7. *See* Adam D. Glassman, *The Imposition of Federal Caps in Medical Malpractice Liability Actions: Will They Cure the Current Crisis in Health Care?*, 37 AKRON L. REV. 417 (2004); Peter Charles Choharis, *A Comprehensive Market Strategy for Tort Reform*, 12 YALE J. ON REG. 435 (1995); STEPHEN J. CARROLL & NICHOLAS PACE, ASSESSING THE EFFECTS OF TORT REFORMS (1987); *see generally* American Tort Reform Association, *available at* http://www.atra.org; American Tort Reform Foundation, *available at* http://www.atrafoundation.org; Doctors for Medical Liability Reform, *available at* http://www.protectpatientsnow.org.

8. *See, e.g.*, Deborah Jones Merritt & Kathryn Ann Barry, *Is the Tort System in Crisis? New Empirical Evidence*, 60 OHIO ST. L.J. 315 (1999); Deborah R. Hensler, *The Real World of Tort Litigation, in* EVERYDAY PRACTICES AND TROUBLE CASES 155 (Austin Sarat et al. eds., 1998); Marc Galanter, *Real World Torts: An Antidote to Anecdote*, 55 MD. L. REV. 1093 (1996); Deborah R. Hensler, *Reading the Tort Litigation Tea Leaves: What's Going on in the Civil Liability System?*, JUST. SYS. J., Spring 1993, at 139; Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—And Why Not?*, 140 U. PA. L. REV. 1147 (1992); Marc S. Galanter, *The Day After the Litigation Explosion*, 46 MD. L. REV. 3 (1986).

9. *See* Matt Clark et al., *Malpractice: MD's Revolt*, NEWSWEEK, June 9, 1975, at 58, 65; J. S. Boyden, Jr., *Editorial: On the Independence of Expert Witnesses*, J. LEGAL MED., July/August 1976, at 3.

turn has disrupted the ability of physicians and other providers to deliver medical care.[10]

The major critique of the state common law tort system with respect to malpractice is that the processes of imposing liability for medical injury and compensating medical injury are inefficient and, more important, result in inconsistent and irrational outcomes.[11] Specifically, it is argued that jury decisions and awards in malpractice cases are inconsistent and irrational and often based on unsound science,[12] a major critique of tort litigation generally. [13] Further, many meritorious claims are neither filed nor compensated.[14] To the extent that such eventualities make it more difficult for medical liability insurers to predict the outcome of claims, they infuse a degree of uncertainty into underwriting that necessarily makes liability insurance less affordable or even available.[15]

10. Thorpe, *supra* note 1, at W4-20.

11. *See* Symposium, *Medical Malpractice: External Influences and Control*, 60 L. & CONTEMP. PROBS. 1 (1997); Symposium, *Medical Malpractice: Lessons for Reform*, 54 L. & CONTEMP. PROBS. 1 (1991); Symposium, *Medical Malpractice: Can the Private Sector Find Relief?*, 49 L. & CONTEMP. PROBS. 1 (1986).

12. *See, e.g.*, Dennis J. Devine et al., *Jury Decision Making: 45 Years of Empirical Research on Deliberating Groups*, 7 PSYCHOL. PUB. POL'Y & L. 622 (2001); Symposium: *The American Civil Jury: Illusion and Reality*, 48 DEPAUL L. REV. 197 (1998); Christopher E. Smith, *Imagery, Politics, and Jury Reform*, 28 AKRON L. REV. 77 (1994); Jody Weisberg Menon, *Adversarial Medical and Scientific Testimony and Lay Jurors: A Proposal for Medical Malpractice Reform*, 21 AM. J.L. & MED. 281 (1995).

13. *See, e.g.*, David L. Faigman, LEGAL ALCHEMY: THE USE AND MISUSE OF SCIENCE IN THE LAW (1999); Peter W. Huber, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURT ROOM (1993); Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637 (1993); Joelle Anne Moreno, *Beyond the Polemic Against Junk Science: Navigating the Oceans that Divide Science and Law with Justice Breyer at the Helm*, 81 B.U. L. REV. 1033 (2001); A. Dan Tarlock, *Who Owns Science*?, 10 PENN ST. ENVTL. L. REV. 135 (2002); David L. Faigman, *Mapping the Labyrinth of Scientific Evidence*, 46 HASTINGS L.J. 555 (1995); Jeff L. Lewin, *Calabresi's Revenge? Junk Science in the Work of Peter Huber*, 21 HOFSTRA L. REV. 183 (1992); Jean Macchiaroli Eggen, *Toxic Torts, Causation, and Scientific Evidence After Daubert*, 55 U. PITT. L. REV. 889 (1994); Gary Edmond & David Mercer, *Trashing "Junk Science"*, 1998 STAN. TECH. L. REV. 3 (1998); Vicki Christian, Comment, *Admissibility of Scientific Expert Testimony: Is Bad Science Making Law*?, 18 N. KY. L. REV. 21 (1990).

14. *See* Troyen A. Brennan et al., *Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation*, 335 NEW ENG. J. MED. 1963, 1963 (1996). *See also* PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION (1993).

15. *See* U.S. GEN. ACCOUNTING OFFICE, PUB. NO. GAO-03-702, MEDICAL MALPRACTICE INSURANCE: MULTIPLE FACTORS HAVE CONTRIBUTED TO INCREASED PREMIUM RATES 15–16 (2003); MEDICAL MALPRACTICE INSURANCE REPORT: A STUDY OF MARKET CONDITIONS, *supra* note 3; *see generally* FRANK A. SLOAN ET AL., INSURING MEDICAL MALPRACTICE (1991); Ralph A. Winter, *Perspective on the Insurance Crisis: The Liability Crisis and the Dynamics of Competitive Insurance Markets*, 5 YALE J. ON REG. 455 (1988).

As a result of these crises, medical malpractice has become yet another area of state tort law that has been attacked as inadequate to meet the twin ostensible aims of tort: compensation of tort victims and punishment of tortfeasors.[16] Most early reforms of malpractice focused on controlling claim frequency or severity through damage caps and other measures.[17] Since the 1970s, particularly in academic circles, there has been considerable interest in medical malpractice reform and a plethora of proposals for malpractice reform that went beyond reducing frequency and severity of malpractice claims.[18] Such reforms included various no-fault compensation schemes,[19] alternative dispute resolution methods for adjudicating claims,[20] and enterprise liability for health plans.[21] These later proposals explicitly try to improve the malpractice adjudication or compensation system from the perspective of claimants and to address negligent medical practice more directly.

Yet, despite the hue and cry over medical malpractice and the widespread concern that medical malpractice law has failed, there has been little exploration of administrative approaches to provide systems of adjudication and compensation that are more efficient and fair to address the crisis. Following the crisis of the mid-1980s, the American Medical Association and the Professional Insurers of America Association (PIAA) floated proposals for administrative, fault-based systems at the state level.[22] However, these

16. *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS §§ 46–52 (5th ed. 1984).

17. Randall R. Bovbjerg, *Legislation on Medical Malpractice: Further Developments and a Preliminary Report Card*, 22 U.C. DAVIS L. REV 499, 522–27, (1989); PATRICIA M. DANZON, MEDICAL MALPRACTICE: THEORY, EVIDENCE, AND PUBLIC POLICY 158–173 (1985).

18. *See* Eleanor D. Kinney, *Malpractice Reform in the 1990s: Past Disappointments, Future Success?*, 20 J. HEALTH POL. POL'Y & L. 99 (1995).

19. *See, e.g.*, Randall R. Bovbjerg & Frank A. Sloan, *No-Fault for Medical Injury: Theory and Evidence*, 67 U. CIN. L. REV. 53 (1998); Randall R. Bovbjerg et al., *Administrative Performance of "No-Fault" Compensation for Medical Injury*, 60 LAW & CONTEMP. PROBS. 71 (1997); Barbara A. Brill, Comment, *An Experiment in Patient Injury Compensation: Is Utah the Place?*, 1996 UTAH L. REV. 987 (1996). *See also* Jeffrey O'Connell & James F. Neale, *HMO's, Cost Containment, and Early Offers: New Malpractice Threats and a Proposed Reform*, 14 J. CONTEMP. HEALTH L. & POL'Y 287, 295–96 (1998).

20. ELEANOR D. KINNEY, PROTECTING AMERICAN HEALTH CARE CONSUMERS (2002); Eleanor D. Kinney, *Tapping and Resolving Consumer Concerns About Health Care*, 26 AM. J.L. & MED. 335, 348–68 (2000); Thomas B. Metzloff, *The Unrealized Potential of Malpractice Arbitration*, 31 WAKE FOREST L. REV. 203 (1996); Neil Vidmar & Jeffrey Rice, *Jury-Determined Settlements and Summary Jury Trials: Observations About Alternative Dispute Resolution in an Adversary Culture*, 19 FLA. ST. U. L. REV. 89 (1991).

21. *See* William M. Sage, *Enterprise Liability and the Emerging Managed Health Care System*, 60 LAW & CONTEMP. PROBS. 159 (1997); Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Choice of the Responsible Enterprise*, 20 AM. J.L. & MED. 29 (1994).

22. COMM. TO STUDY ALTERNATIVES TO THE PRESENT SYS., PHYSICIAN INSURERS ASS'N OF AM., A COMPREHENSIVE REVIEW OF ALTERNATIVES TO THE PRESENT SYSTEM OF

proposals received little attention when they were made and subsequently. It is quite curious that reformers now are not looking to administrative law as they have in the past when tort law has failed. Administrative law has had much to offer in the past in curing deficiencies in tort law.[23] It has much to offer today. This article explores the potential contributions of administrative law to the reform of the adjudication and compensation of medical malpractice claims.

II. THE TORT OF NEGLIGENCE AND ITS DISCONTENTS

The conventional medical malpractice claim, based on negligence, contains four elements.[24] First is the duty on the part of the defendant not to expose the plaintiff to a reasonably foreseeable risk of injury. Second is the breach of that duty by the defendant's violation of the applicable standard of care. Third, the defendant's breach of the duty must be the cause of the plaintiff's injury. Finally, the plaintiff must have suffered actual damage to a legally protected interest. To establish a prima facia case of negligence, the plaintiff must present evidence that the defendant had a duty not to expose the plaintiff to a reasonably foreseeable risk of injury, that the defendant breached that duty as defined by the applicable standard of care, that the breach caused the damage, and that there was actual damage.

A. Problems with Proving Elements of the Prima Facia Case in Medical Malpractice

According to *Restatement (Third) of Torts, Tentative Draft*, a person is negligent when that "person does not exercise reasonable care under all the circumstances."[25] Making this determination is difficult particularly because the application of this rule is contextual. It is also the quintessential example of a mixed question of law and fact, in which both the court and jury have different roles to play in determining the issue and their roles overlap in many respects.[26] The most important factual issue in this mixed question of law and fact is the tortfeasor's foreseeability of the injury as well as whether the tortfeasor breached the standard of care. The most important question of law is what is the applicable standard of care?

RESOLVING MEDICAL LIABILITY CLAIMS (1989); Kirk B. Johnson et al., *A Fault-Based Administrative Alternative for Resolving Medical Malpractice Claims*, 42 VAND. L. REV. 1365 (1989).

23. *See infra notes* 49–52 and accompanying text.

24. BLACK'S LAW DICTIONARY 1061–62 (8th ed. 2004). *See also* KEETON ET AL., *supra* note 16, § 30, at 164; KENNETH S. ABRAHAM, THE FORMS AND FUNCTIONS OF TORT LAW 70–79 (1997).

25. RESTATEMENT (THIRD) OF TORTS: NEGLIGENCE § 3 (Tentative Draft No. 1, 2001).

26. KEETON ET AL., *supra* note 16, § 37, at 235.

1. Foreseeability of Injury

The tort of negligence has always wrestled with how to address the issue foreseeability of the risk of injury. In most cases where the relationship between the tortfeasor and victim is fairly common—such as a treating physician and patient—existence of a duty to foresee injury is fairly straightforward. The analysis then proceeds to whether the tortfeasor breached the duty of care—whether he acted as a reasonable person would have in like or similar circumstances.

Duty itself becomes an issue when the relationship between the tortfeasor and victim is more unusual and attenuated, raising the question of whether the tortfeasor could have foreseen the injury as a matter of law, an issue that the judge would decide in a negligence case. Specific issues include: 1) whether an individual has a duty to an injured party if the risk of injury was not really foreseeable but occurred, and 2) what is the standard for foreseeability particularly when the risk of injury was small and/or the actual injury is unusual. Another related question is whether, as a matter of fact, an injury can be considered "caused" by another's conduct if the injury was unusual or occurred in an attenuated and remote manner even though there was a physical chain of connecting events following the defendant's conduct that gave rise to the injury.

Causation has been a point of debate since the early twentieth century, in particular since Judge Cardozo's landmark decision in *Palsgraf v. Long Island Railroad Co.*,[27] which imposed liability on a defendant railroad for an injury caused in an unusual way.[28] There was fierce debate over this issue during the drafting the *Restatement (Second) of Torts* in the 1950s and 1960s[29] Even today, as the American Law Institute prepares the *Restatement (Third) of Torts*,[30] there has been vigorous debate as to whether foreseeability in negligence law is a question of duty, which is a matter of law; a question of

27. 162 N.E. 99 (1928). *See also* William Prosser, *Palsgraf Revisited*, 52 MICH. L. REV. 1 (1953); ROBERT E. KEETON, LEGAL CAUSE IN THE LAW OF TORTS 78–80 (1963).

28. *See, e.g.*, Leon Green, *Foreseeability in Negligence Law*, 61 COLUM. L. REV. 1401 (1961) [hereinafter *Foreseeability*]; Leon Green, *The Causal Relation Issue in Negligence Law*, 60 MICH. L. REV. 543 (1962) [hereinafter *The Causal Relation Issue*]; Heidi M. Hurd and Michael S. Moore, *Negligence in the Air*, 3 THEORETICAL INQUIRIES L. 333 (2002); John C. P. Goldberg & Benjamin C. Zipursky, *The Restatement (Third) and the Place of Duty in Negligence Law*, 54 VAND. L. REV. 657 (2001); Richard W. Wright, *Once More into the Bramble Bush: Duty, Causal Contribution, and the Extent of Legal Responsibility*, 54 VAND. L. REV. 1071 (2001); ABRAHAM, *supra* note 24, at 118–29.

29. RESTATEMENT (SECOND) OF TORTS §§ 291–293 (1965). *See, e.g.*, *Foreseeability*, *supra* note 28; *The Causal Relation Issue*, *supra* note 28; Prosser, *supra* note 27; KEETON ET AL., *supra* note 16.

30. RESTATEMENT (THIRD) OF TORTS: NEGLIGENCE § 3 (Tentative Draft No. 1, 2001).

breach, which is a mixed question of law and fact; or a question of proximate cause, which is a question of fact. [31]

Another dimension of foreseeability is the degree to which lay perceptions of foreseeability are, on one hand, scientific fact, or culturally determined and/or socially constructed, on the other hand. At first glance, foreseeability with respect to each element of the negligence case appears to be a straightforward question. The standard of care, in malpractice cases, is a matter of medical opinion and scientific fact, while the issue of foreseeability is based on common and shared human experience. Furthermore, the standard of care asks, "what would other similarly trained physicians do in similar circumstances," and its establishment is based on expert testimony. Similarly, determinations of causation are based either on lay perceptions of foreseeability or causation informed, where necessary, by expert opinion.

Therein lies the basis for the conclusion that foreseeability is culturally determined and even socially constructed. Proof of foreseeability of the risk, factors in the causation of the risk to occur, or breach of the standard of care are not based completely on scientific fact, to the extent that scientific facts inform the issues. Intuitive and other considerations are always implicated whether the judge or jury is making the determination. This characteristic of the proof of the elements of negligence as culturally determined and/or socially constructed effectively gives the judge and jury, as law interpreters and fact-finders, much latitude in their evaluation and acceptance of scientific evidence and other culturally or socially important factors. This phenomenon may explain the debate over whether juries in medical malpractice and other tort cases are rational when assessing science and/or awarding damages.[32]

31. *See, e.g.*, James R. Adams, *From Babel to Reason: An Examination of the Duty Issue*, 31 MCGEORGE L. REV. 25 (1999); Benjamin C. Zipursky, *Rights, Wrongs, and Recourse in the Law of Torts*, 51 VAND. L. REV. 1 (1998).

32. *See, e.g.*, Shari Seidman Diamond et al., *Juror Judgments About Liability And Damages: Sources of Variability and Ways to Increase Consistency*, 48 DEPAUL L. REV. 301 (1998); Michael J. Saks et al., *Reducing Variability in Civil Jury Awards*, 21 LAW & HUM. BEHAV. 243 (1997); David Baldus et al., *Improving Judicial Oversight of Jury Damage Assessments: A Proposal for the Comparative Additur/Remittitur Review of Awards for Nonpecuniary Harms and Punitive Damages*, 80 IOWA L. REV. 1109 (1995); Mark Geistfeld, *Placing a Price on Pain and Suffering: A Method For Helping Juries Determine Tort Damages For Nonmonetary Injuries*, 83 CAL. L. REV. 773 (1995); Frank A. Sloan & Chee Ruey Hsieh, *Variability in Medical Malpractice Payments: Is the Compensation Fair?*, 24 LAW & SOC'Y REV. 997 (1990). *But see, e.g.*, Neil Vidmar et al., *Jury Awards for Medical Malpractice and Post-Verdict Adjustments of Those Awards*, 48 DEPAUL L. REV. 265 (1999); Neil Vidmar, *The Performance of the American Civil Jury: An Empirical Perspective*, 40 ARIZ. L. REV. 849 (1998); Neil Vidmar, *Pap and Circumstance: What Jury Verdict Statistics Can Tell Us About Jury Behavior and the Tort System*, 28 SUFFOLK U. L. REV. 1205 (1994); Neil Vidmar, *Empirical Evidence on the Deep Pockets Hypothesis: Jury Awards for Pain and Suffering in Medical Malpractice Cases*, 43 DUKE L.J. 217 (1993). *See also* Brian J. Ostrom et al., *A Step Above Anecdote: A Profile of the Civil Jury in the 1990s*, 79 JUDICATURE 233 (1996).

2. The Standard of Care

The determination of the standard of care in medical malpractice cases, in most jurisdictions,[33] is what a reasonable physician in the same specialty would do in like or similar circumstances.[34] In medical malpractices cases, the determination of this standard is ceded to the medical profession. As a practical matter, the standard is set in individual malpractice cases through expert testimony of what one or more experts believe to be the relevant standard of care.[35] That expert is not required to substantiate his or her opinion of the standard of care with references to outside sources such as medical textbooks by acknowledged experts or medical practice guidelines and other medical standards of care by medical specialty societies, voluntary health organizations, or other medical professional groups.

Currently, the medical standard of care in a medical malpractice case is really a matter of public policy on science, even though in malpractice cases, due to the role of the jury and reliance on expert witnesses, its establishment is based on culturally determined perceptions or social constructs. As a matter of science policy, the standard of medical care in a community or a specialty really could and should be established by reference to more valid and verifiable expert authority in medical malpractice litigation. Reliance on the oral testimony of individual physicians is really an inefficient and unreliable way of getting information about the standard of care and its application to the fact-finders.

Today, with the evolution of evidence-based medicine,[36] the standard of care is becoming a matter of a consensus of medical science based on

33. *See* David M. Epstein, Annotation, *Medical Malpractice: Physician's Admission of Negligence as Establishing Standard of Care and Breach of that Standard*, 42 A.L.R.5TH 1 (1996); James O. Pearson, Jr., Annotation, *Modern Status of "Locality Rule" in Malpractice Action Against Physician Who is Not a Specialist*, 99 A.L.R.3D 1133 (1980); James Duff, Jr., Annotation, *Malpractice Testimony: Competency of Physician or Surgeon from One Locality to Testify, in Malpractice Case, as to Standard of Care Required of Defendant Practicing in Another Locality*, 37 A.L.R.3D 420 (1971).

34. *See* 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, 346 (1995); John C. Drapp III, Comment, *The National Standard of Care in Medical Malpractice Actions: Does Small Area Analysis Make It Another Legal Fiction?*, 6 QUINNIPIAC HEALTH L.J. 95, 97 (2003); Sam A. McConkey IV, Comment, *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, 496 (1995).

35. Philip G. Peters, Jr., *Empirical Evidence and Malpractice Litigation*, 37 WAKE FOREST L. REV. 757, 758 (2002).

36. *See, e.g.*, DAVID L. KATZ, CLINICAL EPIDEMIOLOGY & EVIDENCE-BASED MEDICINE: FUNDAMENTAL PRINCIPLES OF CLINICAL REASONING & RESEARCH (2001); DAVID L. SACKETT ET AL., EVIDENCE-BASED MEDICINE: HOW TO PRACTICE AND TEACH EBM (2d ed. 2000);

empirical evidence. Specifically, since the 1980s, three developments have driven the expanded and increasingly sophisticated

> use of medical standards of care in the delivery of health-care services in the United States today: (1) the standard-setting movement of the 1980s, with leadership from medical specialties and pressure from third-party payers; (2) the rise of managed care in the late 1990s, with health plans and providers delivering care in integrated delivery systems with computerized patient records systems; and (3) advances in the theory and science of defining, measuring, and improving the quality of medical care.[37]

The medical profession has clearly embraced medical practical guidelines, based on empirically derived medical evidence and developed in transparent and inclusive processes to be a conclusive consensus of experts on what is the standard of care from a medical perspective in treating a particular medical condition. Today there are thousands of medical standards of care used in nearly all clinical settings to guide medical practice and to asses the quality of care. Clearly, from the perspective of the medical profession the standard of care is a carefully considered matter of scientific fact supported by empirical evidence.

Yet, in tort litigation, the standard of care is much more haphazardly determined. In an individual case, it can be set by reference to applicable standards of care as though the unsubstantiated opinion of one practitioner with minimal credentials. There is vocal criticism that medical experts are not acknowledged or established as experts in their field and that their testimony does not comport with the best science available.[38] While the Supreme Court has attempted to improve judicial gatekeeping on the admissibility of expert testimony under the Federal Rules of Evidence,[39] apparently these decisions have not had a major impact on the use of expert testimony in medical malpractice cases.[40] In sum, it is clear that the current methodology for determining the standard of care and its breach in medical malpractice lawsuits has not kept up with the state of the art in modern medicine.

DANIEL J. FRIEDLAND ET AL., EVIDENCE-BASED MEDICINE: A FRAMEWORK FOR CLINICAL PRACTICE (1998).

37. Eleanor D. Kinney, *The Brave New World of Medical Standards of Care*, 29 J.L. MED. & ETHICS 323 (2001).

38. *See Special Issue: Evidence: Its Meanings in Health Care and in Law*, 26 J. HEALTH POL., POL'Y & L. 191 (2001).

39. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993); Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997); Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999).

40. *See* Daniel W. Shuman, *Expertise in Law, Medicine, and Health Care*, 26 J. HEALTH POL. POL'Y & L. 267 (2001).

3. The Measure of Damages

The determination of damages in medical malpractice cases is likewise established primarily through expert testimony of economists.[41] However, critics argue that damage awards are inconsistent in similar cases without justification or rationale especially when juries are making determinations.[42] Of note, empirical information suggests that jury damage awards are not as erratic as critiques suggest and are generally consistent with other legal decision makers.[43] However, medical science can also be brought to bear in assessing the severity and duration of injury and can be harnessed to determine the appropriate level of compensation for particular injuries of various severities and durations in a democratic manner.

III. ADMINISTRATIVE LAW APPROACHES TO THE RESOLUTION OF TORT CLAIMS

For the determination and proof of each element of the tort of medical malpractice, administrative law offers helpful approaches for reform. Outlined below are administrative law approaches to reform that might well be applied to the adjudication of the elements of the prima facia case and also the defenses in a medical malpractice claim.

A. Theoretical Issues

Important theoretical issues arise when administrative law approaches are used to resolve any public policy issue. Specifically, under administrative law theory, the state should establish public adjudication systems only for regulatory or benefactory programs that benefit the public generally. The legislature should not intervene where a problem involves individuals in their private affairs. State courts wrestled with this distinction in the early Twentieth Century when they sought to improve the adjudication and compensation of injuries on the job with administrative workers compensation schemes.[44] In many states, there were challenges to these schemes on grounds that they inappropriately replaced common law tort remedies.[45]

41. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 32, at 188–89 (5th ed. 1984).

42. *See supra* notes 11–13 and accompanying text.

43. *See* Roselle L. Wissler et al., *Decisionmaking About General Damages: A Comparison of Jurors, Judges, and Lawyers*, 98 MICH. L. REV. 751, 770 (1999); Neil Vidmar & Jeffrey J. Rice, *Assessments of Noneconomic Damage Awards in Medical Negligence: A Comparison of Jurors with Legal Professionals*, 78 IOWA L. REV. 883, 896 (1993).

44. ARTHUR LARSON, THE LAW OF WORKMEN'S COMPENSATION § 42.23, at 7–651 (1987).

45. *See* Ives v. S. Buffalo Ry. Co., 94 N.E. 431 (1911) (invalidating New York State's original workers' compensation statute). *But see* N.Y. Cent. R.R. Co. v. White, 243 U.S. 188 (1917) (upholding the amended New York workers' compensation statute). *See also* Helfrick v. Dahlstrom Metallic Door Co., 176 N.E. 141 (1931).

In its 1932 decision, *Crowell v. Benson*,[46] the United States Supreme Court recognized this public-private distinction with respect to a federally sponsored workers' compensation program with adjudication of claims by the agency. In concluding that adjudications could proceed before the administrative agency rather than an Article III court, the Court decided on grounds that judicial review was available to review the administrative decisions. Since *Crowell v. Benson*, the Supreme Court has become much more comfortable in drawing the line of public law to include threats to health and safety of individuals and the population.[47]

Indeed, public administrative law has been an important source of reform concepts when tort law has failed. When automobile accidents and insurance therefore became problematic in the 1950s and 1960s, reformers looked to statutory no-fault compensation plans to adjudicate and compensate auto accident claims.[48] As part of the debate over statutory compensation schemes for auto accidents, Guido Calabresi wrote his famous critique of the tort system as an inefficient means for minimizing the cost of accidents—one of the most persistent condemnations of the common law tort system even today.[49] More recently, in so-called mass tort litigation, courts have used administrative law approaches to adjudicate claims for injury and damage. For example, in asbestos litigation, a special master of the federal district court, functioning much like an administrative agency, adjudicates and compensates individual damage claims.[50]

In the 1960s, administrative law took on a greater role in regulating risks to heath and safety. In the 1960s and 1970s, in response to public concerns about environmental pollutions and industrial technology, Congress enacted

46. 285 U.S. 22 (1932). *See* Joshua I. Schwartz, *Nonacquiescence,* Crowell v. Benson, *and Administrative Adjudication*, 77 GEO. L.J. 1815 (1989); John Dickinson, Crowell v. Benson*: Judicial Review of Administrative Determinations of Questions of "Constitutional Fact*," 80 U. PA. L. REV. 1055 (1932); *Judicial Review of Administrative Findings*—Crowell v. Benson, 41 YALE L.J. 1037 (1932).

47. *See, e.g.*, Clinton v. City of New York, 524 U.S. 417 (1998); Fed. Mar. Comm'n v. S.C. State Ports Auth., 535 U.S. 743 (2002); Printz v. United States, 521 U.S. 898 (1997); Reno v. Flores, 507 U.S. 292 (1993); Thomas v. Union Carbide Agric. Prods. Co., 473 U.S. 568 (1985); Atlas Roofing Co. v. OSHRC, 430 U.S. 442 (1977).

48. *See* ROBERT E. KEETON & JEFFREY O'CONNELL, BASIC PROTECTION FOR THE TRAFFIC VICTIM: A BLUEPRINT FOR REFORMING AUTOMOBILE INSURANCE (1965); WALTER J. BLUM & HARRY KALVEN, JR., PUBLIC LAW PERSPECTIVES ON A PRIVATE LAW PROBLEM: AUTO COMPENSATION PLANS (1965).

49. GUIDO CALABRESI, THE COST OF ACCIDENTS (1970).

50. *See* Steven Kazan, *Asbestos Litigation & Tort Law: Trends, Ethics, & Solutions: Legislative Attempts to Address Asbestos Litigation*, 31 PEPP. L. REV. 227 (2003); Francis E. McGovern, *The Tragedy of the Asbestos Commons*, 88 VA. L. REV. 1721 (2002); STEPHEN J. CARROLL ET AL., ASBESTOS LITIGATION COSTS AND COMPENSATION: AN INTERIM REPORT (2002), *available at* http://www.rand.org/publications; *see also Asbestos Litigation Crisis: Hearings Before the Senate Committee on the Judiciary*, 108th Cong. (2003).

numerous statutes to regulate risk to health and safety from a wide variety of sources and activities in the environment and the workplace.[51] The regulatory programs under these statutes raised a host of complex scientific issues the accurate resolution of which was crucial for effective and publicly accepted regulation. By the 1970s, making decisions about scientific issues in a democratic manner was a central mission of administrative law.[52]

As administrative law has matured, it has moved beyond concerns about whether a matter is sufficiently public to be handled by public law and therefore administrative agencies—particularly when matters of human health and safety are involved. Mature administrative law is now much more concerned with crafting effective procedures for policy-making and dispute resolution. For example, it is concerned with assuring that scientific and technical information used to solve public law problems, such as threats to human health and safety, are accurate and reconciled in a way that results in sound and fair policies and decisions.

One of the greatest contributions of administrative law is the recognition that policy-making processes, rather than adjudication, are best for determining many factual issues based on physical or social sciences. Often, facts involving

51. *See, e.g.*, Endangered Species Conservation Act of 1969, Pub. L. No. 91-135, §§ 1–5, 83 Stat. 275, 275–278 (codified as amended at 16 U.S.C. § 1531); National Environmental Policy Act of 1969, Pub. L. No. 91-190, 83 Stat. 852 (codified as amended at 42 U.S.C. § 4321); Clean Air Act Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676 (codified as amended at 42 U.S.C. § 7401); Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (codified as amended at 29 U.S.C. § 651); Federal Insecticide, Fungicide, and Rodenticide Act of 1972, Pub. L. No. 92-516, § 2(b), 86 Stat. 973 (codified as amended at 7 U.S.C. § 136); Noise Control Act of 1972, Pub. L. No. 92-574, 86 Stat. 1234 (codified as amended at 42 U.S.C. § 4901); Federal Water Pollution Control Act of 1972, Pub. L. No. 92-240, §§ 1–3, 86 Stat. 47 (codified as amended at 33 U.S.C. § 1251); Safe Drinking Water Act of 1974, Pub. L. No. 93-523, 88 Stat. 1660 (codified as amended at 42 U.S.C. § 201); Toxic Substances Control Act of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (codified as amended at 15 U.S.C. § 2601); Federal Mine Safety and Health Amendments Act of 1977, Pub. L. No. 95-164, 91 Stat. 1290 (codified as amended at 30 U.S.C. § 801); Safe Drinking Water Amendments of 1977, Pub. L. No. 95-190, 91 Stat. 1393 (codified as amended at 42 U.S.C. § 201); Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685, Pub. L. No. 95-190 § 326(b), 91 Stat. 1404, 1405 (codified as amended at 42 U.S.C. § 7401); Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, 86 Stat. 816 (codified as amended at 33 U.S.C. § 1251); National Ocean Pollution Research and Development and Monitoring Planning Act of 1978, Pub. L. No. 95-273, 92 Stat. 228 (codified as amended at 33 U.S.C. § 1701); Port and Tanker Safety Act of 1978, Pub. L. No. 95-474, 92 Stat. 1471 (codified as amended at 33 U.S.C. § 1221); Comprehensive Environmental Response, Compensation, and Liability Act of 1980, Pub. L. No. 96-510, 94 Stat. 2767 (codified as amended at 42 U.S.C. § 9601); *see also* CASS R. SUNSTEIN, RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT 18 (Table 1.2) (2002).

52. *See* Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403 (1983); David L. Bazelon, *Coping With Technology Through the Legal Process*, 62 CORNELL L. REV. 817 (1977); Arthur Kantrowitz, *Controlling Technology Democratically*, 63 AM. SCIENTIST 505 (1975).

physical or social science do not vary in the cases of individual regulated parties. Further adjudicative proceedings are established through expert testimony. Variations in the knowledge and experience of experts tend to result in variations in the determination of scientific facts that may not be accurate.

Further, administrative law theory recognizes that such facts can be determined in a systematic manner marshaling relevant empirical information and are not adduced solely by the descriptive observation of individual fact-finders or expert witnesses. An example of this phenomenon, which is particularly apt in the case of tort, is the use of scientific methods in risk analysis by regulatory agencies.[53] These concepts and how they could be used to improve medical malpractice adjudication and compensation are explained in detail below.

B. The Concept of "Legislative Facts" and its Application to Malpractice

The late Professor Kenneth Culp Davis articulated the concept of "legislative facts" in the 1940s.[54] According to Professor Davis, "[l]egislative facts do not usually concern the immediate parties but are the general facts which help the tribunal decide questions of law and policy and discretion." [55] Legislative facts are distinguished from "adjudicative facts," which Professor Davis describes as "[f]acts pertaining to the parties and their businesses and activities."[56]

Policy-making processes, such as notice-and-comment rulemaking under § 553 of the Federal Administrative Procedures Act[57] are most appropriate for determining legislative facts. These processes enable decision makers to marshal all relevant scientific information in its original format, e.g., published articles, peer-reviewed empirical research, governmental studies and reports, as well as commentary of acknowledged experts. In addition, interested parties can put information before the decision maker.

Furthermore, how scientific facts should be used in applying legal standards are, in the words of Professor Lon Fuller, "polycentric" issues, involving multiple considerations many of which are really policy or even moral judgments.[58] Adjudication is not a good decision-making process for determining these kinds of polycentric issues, according to Professor Fuller. Adjudication does not flush out all the important considerations needed to

53. *See infra* text accompanying notes 104–117.

54. Kenneth Culp Davis, *An Approach to the Problems of Evidence in the Administrative Process*, 55 HARV. L. REV. 364 (1942).

55. 2 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE § 12.3, at 413 (2d ed. 1979).

56. *Id.*

57. 5 U.S.C. § 553 (2000).

58. Lon L. Fuller, *The Forms and Limits of Adjudication*, 92 HARV. L. REV. 353, 394–404 (1978).

make sound determinations of legislative fact. One reason for this phenomenon is that the placement of facts before the decision maker is generally in the control of the parties and not the decision makers. Further, the information must generally be relevant to the dispute at issue and thus information that addresses broader policy concerns may not get before the decision maker.

In sum, legislative facts ideally should not be established in an adjudicative proceeding that does not permit the consideration of all the factors that are considered in determining questions of law, policy, and discretion. Rather, legislative facts should be developed in a legislative-type process such as a legislative hearing in which the conveners can marshal all relevant information in a systematic fashion from all interested and affected parties.

1. Use of Legislative Facts in Adjudication

This important distinction in the nature of factual determinations and the appropriate process for making these determinations has become well-developed in administrative law. Administrative law theory prefers informal policy-making processes for determining legislative facts.[59] Indeed, current administrative law theory eschews using trial-type proceedings in rulemaking because it contributes little to the accurate determination of legislative facts.[60]

Furthermore, in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*,[61] the United States Supreme Court made it very clear that an agency could determine an important scientific fact, i.e., the environmental risks posed by nuclear waste, in an informal rulemaking proceeding and then subsequently use that fact in making a decision in an adjudicative proceeding.

Currently, many agencies routinely determine legislative factual issues in policy-making processes independently of the adjudication in which they may be raised.[62] Further, when issues involving legislative facts arise in adjudicative hearings, the administrative law doctrine of "official notice" is available to permit admission of legislative facts into evidence without preparing a foundation with an expert witness.[63]

59. *See* 3 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE § 14.4, at 23 (2d ed. 1980).

60. *See* Procedures for the Adoption of Rules of General Applicability (Recommendation No. 72–5), 38 Fed. Reg. 19,782, 19,782 (July 23, 1973). *See also* United States v. Fla. E. Coast Ry. Co., 410 U.S. 224 (1973).

61. 435 U.S. 519 (1978). *See* Antonin Scalia, Vermont Yankee*: The APA, the D.C. Circuit, and the Supreme Court*, 1978 SUP. CT. REV. 345 (1978).

62. *See* David L. Faigman, *To Have and Have Not: Assessing the Value of Social Science to the Law as Science and Policy*, 38 EMORY L.J. 1005, 1072–77 (1989).

63. ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW § 8.4.8, at 229–34 (2d ed. 2001).

A great example of how an agency recently used a policy-making process to establish legislative facts that were relevant in its adjudicative proceedings is the promulgation of its medical-vocational guidelines used in determining disability for Social Security programs as a legislative rule by the Social Security Administration (SSA).[64] SSA promulgated these regulations in the 1980s in order to bring more consistency to the determination of qualification for disability benefits at a time when demand for benefits was growing dramatically and SSA had great concerns about inequities resulting from inconsistent testimony of vocational experts about the existence of jobs in the national economy.[65] The Social Security Act provides that a claimant,

> not only [be] unable to do his previous work but [must be unable], considering his age, education, and work experience, [to] engage in any other kind of substantial gainful work which exists in the national economy, regardless of whether such work exists in the immediate area in which he lives, or whether a specific job vacancy exists for him, or whether he would be hired if he applied for work.[66]

The medical-vocational guidelines are basically decision trees to be followed in determining whether jobs exist in the national economy for individuals with specific characteristics with respect to degree of impairment, age, education, and work experience.[67] The guidelines commence with the recognition that there are certain impairments that are so severe that no one with the impairment could pursue any gainful work.[68] If the claimant has such an impairment, disability is determined with no further adjudication.

The guidelines then delineate the elements of the statutory elements that are relevant in determining whether a claimant is qualified for benefits. These elements include whether the claimant retains the ability to perform either his former work or some less demanding employment, and if not, whether the claimant retains the capacity to pursue less demanding work elsewhere.[69] To address this second element, the regulation requires an assessment of the claimant's present job qualifications according to the following relevant

64. Rules for Adjudicating Disability Claims in Which Vocational Factors Must be Considered, 43 Fed. Reg. 55,349 (Nov. 18, 1978) (codified at 20 C.F.R. pt. 404, subpt. P (2004)).

65. *See* Robert L. Burgdorf, Jr., *"Substantially Limited" Protection from Disability Discrimination: The Special Treatment Model and Misconstructions of the Definition of Disability*, 42 VILL. L. REV. 409 (1997).

66. 42 U.S.C. § 423(d)(2)(A) (2000). The Social Security Act authorizes two disability programs: the Social Security Disability Insurance (SSDI) program, 42 U.S.C. §§ 401–434 (2000), *id.* at § 423 (schedule of benefits), and Supplemental Security Income (SSI) program, *id.* at § 404. The federal government contracts with states to determine disability under both programs. *Id.* at § 423. The definitions of disability for the SSI program are those used for the SSDI program. *Id*. at § 416.

67. 20 C.F.R. pt. 404, subpt. P.

68. *See id.* at § 404.1520(d) (referring to impairments listed at pt. 404, subpt. P, app. 1).

69. *See id.* at § 404.1520(e)–(f).

factors: physical ability, age, education, and work experience.[70] Then a determination occurs of whether jobs exist in the national economy that a person with the claimant's qualifications could perform.[71] The decision maker matches the claimant's specific characteristics regarding degree of impairment, age, education and work experience, all matters of adjudicative fact, with the factors in the guidelines. The decision maker then follows the decision trees to determine whether a suitable job in the national economy, a matter of legislative fact, exists for the claimant.[72] These guidelines eliminate the need to call vocational experts to establish the existence of suitable jobs in the national economy.

The medical-vocational guidelines have withstood legal challenge,[73] as well as widespread criticism.[74] In *Sullivan v. Zebley*, the United States Supreme Court delineated the dimensions of their use but did not invalidate the guidelines.[75] These guidelines are now an accepted part of Social Security disability determinations. To gain this acceptance, they have had to function relatively effectively and fairly. One reason for their success may be the specificity in addressing most conceivable variations that claimants exhibit with respect to physical ability, age, education and work experience. The experience with these guidelines has much to offer malpractice litigation, particularly with respect to defining and applying the applicable standard of care and also in determining damages.

2. Using Legislative Facts to Establish the Standard of Care

The concept of legislative fact can make an important contribution to the establishment of the standard of care in medical malpractice cases. As discussed above,[76] the standard of care for diagnosis and treatment of a disease or injury is really a quintessential matter of legislative fact. Also as discussed above,[77] the establishment of the standard of care in medical malpractice cases involves the testimony of often only one physician who testifies, based on

70. *Id.* at § 404.1520(g).

71. *Id.* at §§ 404.1520(f), .1566 to .1569.

72. *See* 20 C.F.R. pt. 404, subpt. P, app. 2 (2004).

73. *See* Heckler v. Campbell, 461 U.S. 458 (1983); Bowen v. Yuckert, 482 U.S. 137 (1987).

74. *See generally* Mark S. Smith, Heckler v. Campbell *and the Grid: Are Disability Claimants Entitled to Examples of Suitable Jobs?*, 9 AM. J.L. & MED. 501 (1984); John J. Capowski, *Accuracy and Consistency in Categorical Decision-Making: A Study of Social Security's Medical-Vocational Guidelines—Two Birds with One Stone or Pigeon-Holing Claimants?*, 42 MD. L. REV. 329 (1983).

75. 493 U.S. 521 (1990). *See* Richard P. Weishaupt & Robert E. Rains, Sullivan v. Zebley*: New Disability Standards for Indigent Children to Obtain Government Benefits*, 35 ST. LOUIS U. L.J. 539 (1991).

76. *See supra* text accompanying notes 54–75.

77. *See supra* text accompanying notes 33–40.

anecdotal experience, as to what is the applicable standard of care in a given case.

Recognition that standard-setting is a matter of legislative fact permits greater policing and possibly even elimination of expert testimony to establish the standard of care—thus addressing a persistent complaint about current malpractice litigation.[78] The standard of care for the diagnosis and treatment of disease and injury is a legislative fact in that it can be established without reference to particular individuals. This is not to say that there is not variation in the course of disease or injury in specific individuals, but again, these variations generally depend on factors particular to classes of human beings and not on factors that, as a rule, exist in only one individual. In the latter case, individual variation would be an adjudicative fact, but to the extent that specific variations are predictable across human beings, their determination would be a matter of legislative fact. If the variation were not unique to the claimant, how the physician should have addressed the variation could be included in a medical practice guideline and determined as a legislative fact.

Medical practice guidelines are "systematically developed statements of recommendation for patient management to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[79] Another definition is "[s]tandardized specifications for care developed by a formal process that incorporates the best scientific evidence of effectiveness with expert opinion."[80] They are among an array of medical standards of care used for various purposes in the delivery of health care.[81] Since their emergence on a widespread basis in the 1980s, medical practice guidelines have become increasingly widespread and sophisticated. The guidelines have moved from statements of procedures that constitute good quality care to detailed decision trees that guide steps in care depending on patient-specific variables.[82] Now medical practice guidelines, medical standards of care and the theoretical foundation of evidence-based medicine are well-accepted in medical circles.[83] They are also now widely accessible through the National Guideline Clearinghouse™ (NGC™), which is a public resource for evidence-

78. *See supra* text accompanying notes 54–75.

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

80. Lucian L. Leape, *Practice Guidelines and Standards: An Overview*, 16 QUALITY REV. BULL. 42, 43 (1990).

81. *Id. See also* Cynthia D. Mulrow & Kathleen N. Lohr, *Proof and Policy from Medical Research Evidence*, 26 J. HEALTH POL. POL'Y & L. 249, 260 (2001).

82. Kinney, *supra* note 37, at 325.

83. *See, e.g.*, Mulrow & Lohr, *supra* note 81, at 261; Carter L. Williams, Note, *Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?*, 61 WASH. & LEE L. REV. 479 (2004).

based clinical practice guidelines within the Agency for Healthcare Research and Quality (AHRQ) of the Department of Health and Human Services (DHHS).[84]

When medical specialty societies began developing and publishing medical practice guidelines on a widespread basis in the 1980s, scholars and other reformers immediately recognized their potential for rationalizing the standard of care in medical malpractice adjudication.[85] Further, there have been proposals to use these various standards of care to better manage the establishment of the standard of care in medical malpractice cases.[86] The state of Maine established a demonstration to test the use of medical practice guidelines only as an affirmative defense for physicians in malpractice cases.[87] Notably, however, guidelines were not often used in this manner during course

84. AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEP'T OF HEALTH & HUM. SERVS., NATIONAL GUIDELINE CLEARINGHOUSE, http://www.guideline.gov (last visited Oct. 4, 2004).

85. *See generally* Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. 327 (2001); Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645 (2001); E. Haavi Morreim, *From the Clinics to the Courts: The Role Evidence Should Play in Litigating Medical Care*, 26 J. HEALTH POL. POL'Y & L. 409 (2001); Jodi M. Finder, *The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?*, 10 HEALTH MATRIX 67, 91 (2000); 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 (1997); 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 (1997); 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 (1995); John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421 (1994); Troyen A. Brennan, *Practice Guidelines and Malpractice Litigation: Collision or Cohesion?*, 16 J. HEALTH POL. POL'Y & L. 67 (1991); Edward B. Hirshfeld, *Practice Parameters and the Malpractice Liability of Physicians*, 263 JAMA 1556 (1990); 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); Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 LAW & CONTEMP. PROBS. 119 (1991); Eleanor D. Kinney & Marilyn M. Wilder, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U.C. DAVIS L. REV. 421 (1989).

86. *See* Ralph Peeples et al., *The Process of Managing Medical Malpractice Cases: The Role of Standard of Care*, 37 WAKE FOREST L. REV. 877 (2002); Deborah W. Garnick et al., *Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims?*, 266 JAMA 2856 (1991); *see also* CLARK C. HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM (1995); Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 LAW & CONTEMP. PROBS. 87 (1991); Clark C. Havighurst, *Practice Guidelines for Medical Care: The Policy Rationale*, 34 ST. LOUIS U. L.J. 777 (1990).

87. ME. REV. STAT. ANN. tit. 24, §§ 2971–79 (West Supp. 1993–1994).

of the demonstration.[88] Some states have also permitted use of medical practice guidelines as an affirmative defense in malpractice cases while others permit both sides to introduce guidelines into evidence.[89]

As a practical matter, it appears the medical practice guidelines or other medical standards of care have been used to prove the standard of care in medical malpractice cases. However, they may not have lived up to their potential. In addition to data on the Maine demonstration,[90] a 1996 empirical study of fifty-four cases that mentioned societies or agencies that issue practice guidelines reported that only twenty-eight had used medical practice guidelines in proving the standard of care.[91] Perhaps this is because medical practice guidelines are not specific enough to delineate all the circumstances that could go wrong in the course of a medical procedure or the treatment of a disease or injury.

One approach to improving the usefulness of medical practice guidelines in the establishment of the standard of care is to develop standards that are specifically targeted at setting the standard of care in malpractice cases. This is not a new concept. In the past, theorists interested in establishing no-fault compensation schemes for malpractice have identified circumstances in which medical treatment falls below the standard of care and should be compensated without further consideration fault.[92] The most prominent theory of late is accelerated compensation events, developed by Bovbjerg and Tancredi.[93]

88. Jennifer Begel, *Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation*, 47 ME. L. REV. 69 (1995); *Maine Doctors Test Lawsuit Preventive*, N.Y. TIMES, Aug. 19, 1994, at A23; U.S. GEN. ACCOUNTING OFFICE, PUB. NO. HRD-94-8, MEDICAL MALPRACTICE: MAINE'S USE OF PRACTICE GUIDELINES TO REDUCE COSTS (1993), *available at* http://161.203.16.4/t2pbat5/150172.pdf.

89. *See, e.g.*, tit. 24, §§ 2971–79; MINN. STAT. ANN. § 145.65 (West 2000); FLA. STAT. ANN. § 408.02 (West 2004); MD. CODE ANN., HEALTH-GEN. § 19-1602 (West 2000) (repealed 1999); *see generally* Gary W. Kuc, Comment, *Practice Parameters as a Shield Against Physician Liability*, 10 J. CONTEMP. HEALTH L. & POL'Y 439 (1993); Andrew L. Hyams et al., *Practice Guidelines and Malpractice Litigation: A Two Way Street*, 122 ANNALS INTERNAL MED. 450, 454 (1995).

90. *See supra* text accompanying notes 87–88.

91. Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & L. 289, 295–296 (1996).

92. *See* COMM'N ON MED. PROF'L LIAB., AM. BAR ASS'N, DESIGNATED COMPENSABLE EVENT SYSTEM: A FEASIBILITY STUDY 9–10 (1979).

93. *See* Laurence R. Tancredi & Randall R. Bovbjerg, *Rethinking Responsibility for Patient Injury: Accelerated-Compensation Events, A Malpractice and Quality Reform Ripe for a Test*, 54 LAW & CONTEMP. PROBS. 147 (1991); Randall R. Bovbjerg et al., *Obstetrics and Malpractice: Evidence on the Performance of a Selective No-Fault System*, 265 JAMA 2836 (1991); Walter Wadlington, *Medical Injury Compensation: A Time for Testing New Approaches*, 265 JAMA 2861 (1991); Laurence R. Tancredi & Randall R. Bovbjerg, *Advancing the Epidemiology of Injury and Methods of Quality Control: ACEs as an Outcomes-Based System for Quality Improvement*, 18 QUALITY REV. BULL. 201 (1992).

They propose an "avoidable event" approach to compensation reform, developed independently by experts and contained in lists of events that are deemed avoidable through better systems of care. These lists of compensable events, which are really based on medical practice guidelines, have been explored primarily in the development of no-fault reform.[94] More recently, a forum of stakeholders has established a list, in a consensus process, of events that should "never" happen in the provision of care.[95] All of these events schemes could be developed further to apply to all malpractice adjudication.

The policy-making process should also be designed to identify all the variables that would influence the application of the guideline so that variations and responses thereto can be incorporated into the guideline. Such variables would include the array of remedies for the medical condition in question and the reasons for selecting specific remedies, important patient variations, important geographic variables, and also different approaches based on recognized differences in the medical training of schools of physicians, e.g., allopathy, homeopathy and osteopathy. It is important that the guidelines are specific enough to address most common patient variations in their application. For example, if there is a known complication among a subset of patients, the complication should be addressed in the guideline, the patient variables that precipitate the complication should be identified, and the recommended approaches for addressing the complication should be specified. If the medical practice guideline is too general and does not address known variations in its application, then the application of the guideline to specific plaintiffs will inevitably be decided by adjudicative facts that are particular to the patient even though similar facts might well occur with many other similarly situated patients.

Finally, it is critical that the process for developing such a medical standard of care, whether the sponsor is a state, the federal government, or another appropriate authority, be credible. To be credible, the process must be transparent and must involve appropriate and well-respected expert advisors, medical specialty societies, voluntary health organizations and other individuals and organizations that the public recognizes have an appropriate role in establishing medical standards.[96] The policy-making process must also

94. David M. Studdert & Troyen A. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, 286 JAMA 217 (2001); David M. Studdert & Troyen A. Brennan, *Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States*, 27 AM. J.L. & MED. 225 (2001); Bovbjerg et al., *supra* note 93; Tancredi & Bovbjerg, *supra* note 93.

95. *See* NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE: A CONSENSUS REPORT (2002).

96. Eleanor D. Kinney, *Behind the Veil Where the Action Is: Private Policy Making and American Health Care*, 51 ADMIN. L. REV. 145, 193 (1999); *see also* KINNEY, *supra* note 20, at 109–126.

garner all available empirical research, as it is critical that it reflects the latest clinical and health services research rather than simply the opinions of specific physicians, however notable. In addition, the process should also reflect the concept of "appropriateness" of services in that the potential health benefits of the service exceed the potential harms or risks by a margin.[97]

3. Using Legislative Facts to Establish Damages and Compensation

Administrative agencies have become quite systematic in their measurement of damages. Most public compensation programs administered by agencies, such as the Social Security Disability Insurance program, [98] Department of Labor Workers' Compensation programs,[99] and Veterans Disability programs,[100] award benefits pursuant to predetermined schedules based on specific types and degrees of injury or illness. These schedules permit the award of compensation through consultation with the relevant schedules and without litigation in most cases.

Several scholars have suggested scheduling damages in medical malpractice cases as a means of bringing rationality and consistency to injury compensation in medical malpractice.[101] While it is beyond the scope of this

97. *See* Mulrow and Lohr, *supra* note 81, at 259.

98. 42 U.S.C. §§ 401–434 (2000).

99. *See, e.g.*, Longshore and Harbor Workers' Compensation Act, Pub. L. No. 104-324, 110 Stat. 3933 (1996) (codified as amended at 33 U.S.C. §§ 901–950 (2000)); Family and Medical Leave Act of 1993, Pub. L. No 103-3, 107 Stat. 6 (codified as amended at 29 U.S.C. §§ 2601–2654 (2000)) (providing compensation for many federal workers, including postal workers, peace corps workers and volunteers, and civil officers or employees in any branch of government); Federal Mine Health and Safety Act of 1969, Pub. L. No. 91-173, 83 Stat. 742 (1969) (codified as amended at 30 U.S.C. §§ 901–945 (2000)) (providing compensation for victims of Black Lung Disease); National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10 to 300aa-23 (2000)); Energy Employees Occupational Illness Compensation Program Act of 2000, Pub. L. No. 106-398, 114 Stat. 1654 (codified as amended at 42 U.S.C. §§ 7384–7385o (2000)); Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (codified as amended at 29 U.S.C. §§651–78 (2000)); Radiation Exposure Compensation Act Amendments of 2000, Pub. L. No. 106-245, 114 Stat. 501 (codified as amended at 42 U.S.C. § 2011 (2000)); DIV. OF LONGSHORE AND HARBOR WORKERS' COMP. (DLHWC), U.S. DEP'T OF LABOR, PROCEDURE MANUAL ch. 3-301, § 8, *available at* http://www.dol.gov/esa/owcp/dlhwc/lspm/lspm3-301.htm (calculation procedure for compensating loss of wage-earning capacity); The Workers' Comp Service Center, *at* http://www.workerscompensation.com/minnesota/htdocs/index.php3?SCREEN=department&sid=&department=3104 (providing detailed fee schedules for Minnesota and information about other states' workers' compensation programs).

100. 38 U.S.C. §§ 5301, 5307 (2000).

101. *See, e.g.*, James F. Blumstein et al., *Beyond Tort Reform: Developing Better Tools for Assessing Damages for Personal Injury*, 8 YALE J. ON REG. 171 (1991); Randall R. Bovbjerg et al., *Valuing Life and Limb in Tort: Scheduling "Pain and Suffering,"* 83 NW. U. L. REV. 908 (1989); Michael J. Saks et al., *Reducing Variability in Civil Jury Awards*, 21 LAW & HUM. BEHAV. 243 (1997); Shari Seidman Diamond et al., *Juror Judgments about Liability and*

article to analyze these proposed schemes in great detail, it is important to emphasize that they address the exact same issues as statutory compensation schemes—the nature, severity, and permanency of the injury. The level of compensation for injuries of a specific nature, severity, and permanency are all issues that can be independently determined without reference to specific individuals. As such, they are legislative facts.

As legislative facts, states or even the federal government could establish the nature, severity and permanency of medical injuries as well as associated compensation levels in a policy-making process. Already, the Severity of Injury Scale developed by the National Association of Insurance Commissioners, which ranges from one (emotional injury only) to nine (death), is widely used as a measure of the severity and duration of disability in the insurance industry.[102]

How these facts are determined is important because process is the major force that accords credibility to the determination of legislative facts. Sponsoring authorities, such as states, should constitute expert panels composed of representatives from interested parties, including former malpractice litigants, to develop schedules of injury compensation for purposes of compensating malpractice claims. Appropriate interests represented include physicians, insurers, disability and long-term care professionals, and financial experts. To assure transparency and credibility, the meetings of the panel should be regular, public, and offer an opportunity for other interested parties to present views and information to the panel. The reports of the panel should also be available to the public, who will have an opportunity to comment on drafts that will be incorporated into final products. This type of process is very typical of administrative policy-making processes.

It is also important that compensation schedules be empirically grounded. Such a condition presumes that the schedule will be based on empirical research of what existing statutory compensation schemes pay and the experience of claimants with respect to needs met and other benefits under these schemes. The empirical research should also address the levels of compensation under existing accident and disability compensation schemes to gain political support for the adoption of compensation schedules for malpractice. Finally, should compensation schedules be implemented, it is critical that they be evaluated empirically. Administrative agencies have great experience in the design and implementation of empirical studies for the evaluation of government programs, including demonstrations of innovative approaches to public problems.

Damages: Sources of Variability and Ways to Increase Consistency, 48 DEPAUL L. REV. 301, 320–322 (1998).

102. NAT'L ASS'N OF INS. COMM'RS, MALPRACTICE CLAIMS: FINAL COMPILATION 304–06 (M. Patricia Sowka ed., 1980).

The remaining argument against using damage schedules is that they do not allow the unique characteristics of specific individuals to justify variation from the common schedules. Such differences could easily be accommodated in much the same way as the concept of special damages in tort law addresses such exigencies. Specifically, special damages would be available when the plaintiff sustains a special type of damage unique to him or her.[103] The definition of the circumstances or the rules for determining eligibility for special damages would clearly have to be quite tight to resist pressures to obtain special damages in unwarranted circumstances where the claimant did not incur truly unique damage.

B. Risk Analysis in the Regulation of Risks to Health and Safety and its Application to Malpractice

Modern regulation targeted to reduce or eliminate risks to human health and safety began with public health regulation in the nineteenth century. It accelerated after World War II and the concurrent period of great confidence in the contributions of technology to human well-being. Specifically, in the 1960s concerns emerged as to the degree to which various technology-based activities posed risks to human health and safety. The emergence of the environmental movement is exemplary of this development. By the end of the 1960s, a sea change occurred in the public attitudes toward technology from relatively unquestioned acceptance of technology to concerns about its risks to human health and safety.

During the 1960s and 1970s, the U.S. Congress enacted a host of new statutes establishing new regulatory programs to reduce the risks to human health and safety in the environment, the workplace and other settings.[104] In response to this substantial increase in federal regulation of health and safety risks, the business community and political conservatives sought to roll back the scope of these new regulatory programs. Immediately after his inauguration, Republican President Ronald Regan adopted Executive Order 12,291, with Executive Order 12,498, following.[105] These executive orders required cost-benefit analysis for major rules promulgated by federal administrative agencies as well as a regulatory impact analysis for major rules.

The debate over risk analysis, which was so divisive during the 1980s, has largely been resolved in the U.S. The federal government sponsored many high-level studies of risk analysis by expert panels during this period to clarify

103. DAN B. DOBBS, LAW OF REMEDIES: DAMAGES-EQUITY-RESTITUTION § 3.3(4), at 226–29 (2d ed. 1993).

104. *See supra* notes 51–52 and accompanying text.

105. *See* Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 19, 1981); Exec. Order No. 12,498, 50 Fed. Reg. 1036 (Jan. 8, 1985).

the role of risk analysis in federal regulation.[106] Now there is wide acceptance of the concept that risk-benefit analysis is an appropriate component of regulation. All presidents after Reagan, including Democratic President Bill Clinton, issued executive orders requiring cost-benefit analysis in major rulemaking proceedings.

In conjunction with these developments, various types of risk-benefit analysis have evolved to address different conceptions of proper approaches to such analysis. In addition, scholars and policy-makers in administrative law and policy science have paid considerable attention to improvement of the regulation of risks to health and safety. Scholars have analyzed whether risks are defined and measured correctly. [107] In more recent years, scholarship has critiqued the assumptions and associated techniques used in regulatory risk analysis to determine if a particular regulatory intervention is appropriate.[108]

1. Methods of Risk Analysis

Risk analysis is the balancing of the risks of an enterprise and the benefits to be obtained from the enterprise.[109] Over the years, epidemiologists, toxicologists, and other physical and social scientists have developed methods

106. *See, e.g.*, COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994); CARNEGIE COMM'N ON SCIENCE, TECH., & GOV'T, RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING (1993); COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

107. *See, e.g.*, COMM. ON RISK CHARACTERIZATION, NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY (Paul C. Stern & Harvey V. Fineberg eds., 1996); STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993); IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (1992); THOMAS O. MCGARITY, REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY (1991); EUGENE BARDACH & ROBERT A. KAGAN, GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS (1982); MICHAEL S. BARAM ET AL., ALTERNATIVES TO REGULATION: MANAGING RISKS TO HEALTH, SAFETY AND THE ENVIRONMENT (1982); *see also* Kenneth J. Arrow et al., *Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?*, 272 SCIENCE 221 (1996); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 92 COLUM. L. REV. 261 (1991); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988).

108. *See, e.g.*, SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH (2003); CASS R. SUNSTEIN, THE COST-BENEFIT STATE (2002); JULIAN MORRIS, RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE (2000); RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (John D. Graham & Jonathan Baert Weiner, eds., 1995).

109. *See* CONG. RESEARCH SERV., HOUSE SUBCOMM. ON SCIENCE, RESEARCH, & TECH., 98TH CONG., A REVIEW OF RISK ASSESSMENT METHODOLOGIES 63–68 (Comm. Print 1983).

for analyzing risk.[110] It involves an assessment of the nature of a risk, the population exposed to the risk, and the selection of one or more common measures of the risk, such as deaths, injuries, or variations thereof. Also, an extensive body of mathematical and epidemiological techniques has been developed to estimate and calculate risk as well as its magnitude and probability.[111] In addition, methods have been developed to address the phenomena of uncertainty and variability—factors which are an inherent part of risk.[112]

A major concern of scholars and other observers is that inaccurate public perception of risk dominates risk-benefit analysis resulting in questionable regulatory policy.[113] In the last twenty-five years, there has also been an extraordinary body of empirical research on risk perception that suggests public perceptions of particular risks and their comparative importance are quite inaccurate.[114] This research indicates that the most important determinants of public perception of risk are qualitative factors grounded in cultural and psychological factors. For example, qualitative variables such the voluntariness or familiarity of the risk will shape public perception of risk and, specifically, minimize risk in public perceptions in ways that are not warranted by empirical evidence of risk. This research confirms the observation that the concept of risk itself is a sociological construct.[115] The upshot has been the development of analytical approaches to the assessment of risk that endeavor to quantify the probability of risk of injury from specific activities.

2. Use of Risk Analysis in Determining Foreseeability and Causation in Malpractice Adjudication

The real potential contribution of regulatory risk analysis to tort is its methods for marshaling scientific and empirically tested information and methodologies to ascertain the nature of a particular risk and its harm, as well as the probability the risk of injury will occur and to what magnitude. These methods of risk analysis assess risk in a more systematic fashion than does tort law, as discussed above,[116] and remains a controversial issue among tort scholars, policy-makers and practitioners. Specifically, the elements of duty

110. *See* RICHARD WILSON & EDMUND A. C. CROUCH, RISK-BENEFIT ANALYSIS (2001).

111. *Id.* at 25–80.

112. *Id.* at 80–97.

113. *See, e.g.*, *id.*; SUNSTEIN, *supra* note 51; BREYER, *supra* note 107.

114. *See, e.g.*, RISK, MEDIA, AND STIGMA: UNDERSTANDING PUBLIC CHALLENGES TO MODERN SCIENCE AND TECHNOLOGY (James Flynn et al. eds., 2001); PAUL SLOVIC, THE PERCEPTION OF RISK (2000); Paul Slovic, *Perception of Risk*, 236 SCIENCE 280 (1987).

115. *See, e.g.*, RISK AND SOCIOCULTURAL THEORY: NEW DIRECTIONS AND PERSPECTIVES (Deborah Lupton ed., 1999); SHELDON KRIMSKY AND DOMINIC GOLDING, SOCIAL THEORIES OF RISK (1992).

116. *See supra* notes 44–53, 98–103 and accompanying text.

and causation both call for a determination of the foreseeability of the probability and magnitude of the risk, and, as discussed above, foreseeability has proven to be both a theoretical and empirical problem in the resolution of negligence cases.[117]

Furthermore, under administrative law theory, many of the issues associated with the foreseeability and particularity of the risk of injury are legislative facts that can be determined independently of the circumstances of the parties.[118] From this perspective, it is unnecessary to inquire whether there was a duty to foresee a risk as a matter of law in negligence cases because the risk was so remote and improbable. This kind of determination in administrative law would be a legislative fact and would be highly dependent on scientific notions of causation and probability.[119] To the extent that foreseeability of the risk of injury is a matter of breach of the standard of care or causation, much of the determination can be based on such legislative facts developed in epidemiological studies.[120] As such, these approaches are consistent with the evidence-based medicine movement that informs the development of medical practice guidelines and other medical standards of care.[121]

The most important potential contribution that modern regulatory risk analysis can make is the identification of the qualitative and often irrational factors that inform public perceptions of risk. This latter effort, grounded on important empirical research on the fundamental irrationality of public perceptions of risks,[122] demonstrates that such public perceptions may well influence juries and even judges in their decision making in negligence cases. Just as regulators have to respond to public perception of a particular risk, adjudicators of medical malpractice claims must recognize the issues associated with public perceptions of risk and take steps to ensure that decision makers, i.e., jury members, have accurate information about the probabilities and characteristics of the risk at issue. At the very least, courts should recognize that empirical evidence on public perception of risk are also essentially legislative facts that can be established through expert testimony at trial or other sources of legislative facts such as empirical research. Such information could do much to guide decision makers, including juries, in making more accurate assessments of relevant risks.

In assessing the risk of injury in medical malpractice cases, decision makers in malpractice adjudication should insist on more rigor in the analysis

117. *See supra* notes 28–29 and accompanying text.
118. *See supra* text accompanying notes 54–103.
119. *Id.*
120. *See supra* text accompanying notes 79–97.
121. *See supra* text accompanying notes 36–40.
122. *See supra* note 32 and accompanying text.

of the risk of injury to the victim. They should appreciate that much of the issue of foreseeability of risk involves legislative facts that are not particular to the individual. To the extent that relevant government-sponsored studies of particular risks are available, they should be available and introduced into evidence to clarify the risk analysis in the tort lawsuit.

IV. CONCLUSION

This article does not suggest that the resolution of medical malpractice claims should be moved to a state agency, such as a state health department, or a federal agency, such as the U.S. Department of Health and Human Services. Regarding transfer to a federal agency, tort law has traditionally been located within the province of state law. Sovereign states have managed tort law with little interference from the federal courts, except in the case of diversity jurisdiction where the federal courts have deferred to prevailing state law.[123] Likewise, Congress has been reluctant to interfere directly in state tort law. Only when it has perceived that there are threats to the health and safety of the population has Congress intervened and established a regulatory program.[124] Also, Congress has been willing to establish statutory injury compensation schemes for groups of workers with specific injuries as well as groups of workers with specific conditions such as brown lung disease and workers, such as longshoremen, working in nationwide industries.[125]

This article assumes that, in all likelihood, the adjudication and compensation of medical malpractice claims will remain in state courts under state law. Indeed, there are many reasons it is desirable to leave the adjudication of malpractice claims with state trial judges. First, these judges are established and have experience in the adjudication of medical issues and tort law. Second, the depth and sophistication of administrative law judges across states is inconsistent. Some states have central panels of well-paid and knowledgeable administrative law judges, while others use administrative law judges on a less systematic basis and often hire outside lawyers or use internal

123. *See* Erie R.R. Co. v. Tompkins, 304 U.S. 64 (1938); *see also* Joan E. Schaffner, *Federal Circuit "Choice of Law":* Erie *Through the Looking Glass*, 81 IOWA L. REV. 1173 (1996); William A. Braverman, Note, *Janus Was Not a god of Justice: Realignment of Parties in Diversity Jurisdiction*, 68 N.Y.U. L. REV. 1072 (1993).

124. *See generally* Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559 (1997); Perry H. Apelbaum & Samara T. Ryder, *The Third Wave of Federal Tort Reform: Protecting the Public or Pushing the Constitutional Envelope?*, 8 CORNELL J.L. & PUB. POL'Y 591 (1999); Valerie Watnick, *Federal Preemption of Tort Claims Under FIFRA: The Erosion of a Defense*, 36 U. MICH. J.L. REFORM 419 (2003); M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 PACE L. REV. 103 (2000); Michael A. Walker, Note, *CERCLA's Natural Resource Damage Provisions: A Loophole for Private Landowners?*, 9 ADMIN. L.J. AM. U. 425 (1995).

125. *See supra* notes 98–100 and accompanying text.

staff to adjudicate disputes.[126] Given the realities of state budgets, [127] it is unlikely that states would be willing to add major responsibilities to a central panel of ALJs or to develop the requisite ALJ corps to adjudicate malpractice claims.

However, it is not necessary to lodge adjudication of malpractice claims in an administrative agency to take advantage of fact-finding and analysis techniques used by administrative agencies of the type described above. These administrative law approaches can be enacted by statute or court rule and used in the resolution of conventional state tort causes of action. Whatever the venue, administrative law, in particular its concept of legislative facts and techniques of risk analysis, can contribute much to the expeditious and just adjudication and compensation of medical malpractice claims in the United States.

126. *See* Allen C. Hoberg, *Ten Years Later: The Progress of State Central Panels*, 21 J. NAT'L. ASS'N. ADMIN. L. JUDGES 235 (2001); Allen Hoberg, *Administrative Hearings: State Central Panels in the* 1990s, 46 ADMIN. L. REV. 75 (1994), *reprinted in* 14 J. NAT'L. ASS'N. ADMIN. L. JUDGES 107 (1994); *see also* Phyllis E. Bernard, *The Administrative Law Judge as a Bridge between Law and Culture*, 23 J. NAT'L. ASS'N. ADMIN. L. JUDGES 1 (2003).

127. *See* NAT'L GOVERNORS ASS'N, THE FISCAL SURVEY OF STATES: JUNE 2001, (2001), *available at* http://www.nasbo.org/Publications/PDFs/FSJUN2001.pdf; NAT'L GOVERNORS ASS'N, STATES FACE UNPRECEDENTED BUDGET SHORTFALLS, (Dec. 10, 2001), *available at* http://www.nga.org/nga/newsRoom/1,1169,C_PRESS_RELEASE^D_2945,00.html; MARK M. ZANDI, THE OUTLOOK FOR STATE TAX REVENUES (2001), *available at* http://www.nga.org/cda/files/TaxRevenues.pdf; NAT'L GOVERNORS ASS'N, STATES' BUDGET FORECAST CLOUDY, (Dec. 18, 2000), *available at* http://www.nga.org/nga/newsRoom/1,1169,C_PRESS_RELEASE^D_624,00.html.