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MEDICAL ERRORS: CAUSES, CURES, AND CAPITALISM

KEITH MYERS, M.D., J.D.¹

He that will not apply new remedies must expect new evils.

-Benjamin Franklin

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I. INTRODUCTION

Expenditures for healthcare consumed over thirteen percent of the United States gross domestic product in 1998, totaling over \$1.1 trillion dollars.² A recent Institute of Medicine (IOM) report estimated that the number of deaths attributable to medical

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²See, *Healthcare Costs Grow in Relation to U.S. Economy, HCFA Report Shows*, MED. INDUSTRY TODAY, Jan. 12, 2000, § Providers (citing Health Care Financing Administration (HCFA) data, (which reported a 5.6 percent rise in healthcare costs for 1998, matching overall U.S. economic growth).

errors in the U.S. was as high as 98,000.³ This number represented hospital deaths only.⁴ Undoubtedly, additional deaths and injuries occurred in the outpatient setting.⁵ Whether the IOM estimate was exaggerated or not, the larger issue is whether the overall healthcare industry is operating at an acceptable error rate.⁶ If the error rate is unacceptably high, then what should it be?⁷ Are there legal impediments to detecting, reporting, analyzing, and improving error rates?⁸

This article explores the causes of medical error, the medical profession's responses to errors, and how the legal system responds to medical error through litigation and legislation. Part II discusses the definition of "medical error," the frequency and pervasiveness of the problem, and the causes at the individual and system level. Part III considers how the culture of medicine has largely failed to address medical errors as a systems-based problem, and how the legal culture discourages admitting errors due to the threat of litigation. Focusing on systems, data must be collected and analyzed, and legal guidelines developed to encourage error reporting and develop standards, preferably at the state level. Part IV examines how both the legal and medical cultures might be reformed in order to reduce the rate of medical error, which would promote the ultimate goal of better quality healthcare. Legal barriers against error reporting need to be removed and liability theories re-evaluated, with appropriate legislation to foster these changes. Part V discusses the role of economic incentives which promoted the current state of affairs, and how these forces might effectively be employed to shape medical, legal, and legislative responses to medical error. It is clear that if medical error rates are unacceptably high, new approaches by doctors, lawyers, patients, and legislators are needed.

II. ERROR CLASSIFICATION

A. *What is Medical Error?*

A Jehovah's witness is given a blood products infusion to reduce her risk of bleeding.⁹ A seven-year-old-boy dies after receiving the wrong medication from an

³INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A BETTER HEALTH CARE SYSTEM* 31 (Linda T. Kohn et al., eds., 2000) [hereinafter IOM REPORT].

⁴*See id.*

⁵*See e.g.*, Eric J. Thomas et al., *Costs of Medical Injuries in Utah and Colorado*, 36 INQUIRY 255 (1999) (describing costs of adverse events, including outpatients).

⁶*See* Clement J. McDonald et al., *Deaths Due to Medical Errors are Exaggerated in Institute of Medicine Report*, 284 JAMA 93 (2000); Lucian L. Leape, *Institute of Medicine Medical Errors Figures are Not Exaggerated*, 284 JAMA 95 (2000).

⁷*See e.g.*, Thomas Bodenheimer, *The American Health Care System — The Movement for Improved Quality in Health Care*, 340 NEW ENG. J. MED. 488, 490-92 (1999) (suggesting "six sigma" quality goal, an error tolerance level of less than 3.4 errors per million events).

⁸*See* Bryan A. Liang, *Promoting Patient Safety Through Reducing Medical Error: A Paradigm of Cooperation Between Patient, Physician, and Attorney*, 24 S. ILL. U. L.J. 541, 549-57 (2000) [hereinafter Liang, *Promoting Patient Safety*].

⁹*See* Gregory S. Loeben, *To Disclose or Not to Disclose? A Case of Medical Mistake*, 2 MED. CROSSFIRE 80 (2000).

unlabelled cup on an operating room tray.¹⁰ In the first case, the patient is unharmed and unaware that her caregivers have violated her religion-based treatment refusal.¹¹ In the second case, a child is dead, and a family is devastated.¹² Are these medical errors? It seems intuitively clear that the second case is, but what about the first?

The term “error” suggests an unintentional act or omission.¹³ By logical extension, the term “medical error” suggests an unintentional act that is related to the practice of medicine.¹⁴ Patient death or injury is thus not required to meet this definition. Rather, it is sufficient that patient safety is inadvertently threatened, whether actual or potential, or that a patient’s refusal for service is not obeyed.¹⁵ Note that patient errors might also be included in this definition if, for example, a patient commits a mistake with medication that proper education could have prevented.¹⁶

Excluded from this definition of medical error are willful, reckless, and intentional acts or omissions, because these are outside the scope of “inadvertent.”¹⁷ Even though a reckless act or omission may be unintentional, it falls so far outside of the realm of a reasonable standard of due care that it is not mere negligence.¹⁸ Rather, recklessness implies an indifference equivalent to willful behavior.¹⁹ Examples of such recklessness might include a surgeon who operates while intoxicated, or a doctor who treats a condition for which he is not trained despite the availability of referral for more appropriate care.²⁰ *Res ipsa loquitor*, however, is a policy-based legal doctrine which creates an inference of negligence (in many jurisdictions), and is reasonably viewed as within the definition of medical error.²¹

¹⁰See Rebecca Voelker, “*Treat Systems Not Errors*,” *Experts Say*, 276 JAMA 1537, 1538 (1996).

¹¹See Loeben, *supra* note 9, at 80.

¹²See Voelker, *supra* note 10, at 1537-38.

¹³Webster’s Third New Int’l Dictionary 771 (1971) defines error as:

1a: an act or condition of often ignorant or imprudent deviation from a code or behavior... b: ...an unintentional deviation from truth or accuracy... c: an act that through ignorance, deficiency, or accident departs from or fails to achieve what should be done... 3: something produced by mistake... 6: a deficiency or imperfection in structure or function: DEFECT.

¹⁴See Liang, *Promoting Patient Safety*, *supra* note 8, at 542.

¹⁵See *id.*

¹⁶See *id.*

¹⁷See *id.*

¹⁸See *id.* Conduct on this level also includes intentional torts such as battery, and criminal acts. Liang, *supra* note 8.

¹⁹BLACK’S LAW DICTIONARY 1270 (6th ed. 1990).

²⁰See *e.g.*, *Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996) (finding physician negligent for performing operation he was not trained to do).

²¹See *e.g.*, *Ybarra v. Spagnard*, 154 P.2d 687 (Cal. 1944) (allowing an inference of negligence).

B. The Scope of the Problem

A recent report by the Institute of Medicine (IOM) estimated that between 44,000 and 98,000 patients die each year in the U.S. from medical errors.²² The IOM arrived at this number by extrapolation from previous studies in New York, Utah and Colorado.²³ Other prior studies also showed a substantial risk of death from medical error.²⁴

The IOM report has been criticized for its methodological flaws, and for possibly overestimating the actual number of deaths caused by medical error.²⁵ Alternatively, the IOM report has been criticized for study design flaws that may have resulted in an underestimate of deaths.²⁶ Of note is that the IOM report's number of deaths estimate was derived solely from data on hospitalized patients.²⁷ Certainly, outpatients also die from medical error, though the number of deaths is uncertain.²⁸

Adverse events and outcomes occur in the absence of medical error, and it may be important to make methodological or semantic distinctions between adverse events and medical errors.²⁹ Regardless of these technical concerns and of the criticism of the IOM report, medical errors do occur at some rate. The major premise of this discussion is that this rate is too high.³⁰ Further, there is a subgroup of errors causing patient harm which is preventable.³¹ For example, in the Utah and Colorado study the cost of preventable adverse events was nearly half of the total

²²See IOM Report, *supra* note 3, at 31.

²³See *id.* at 30-31 (citing Troyen A Brennan *et al.*, *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study*, 324 *ENG. J. MED.* 370 (1991), and Eric J. Thomas *et al.*, *Cost of Medical Injuries in Utah and Colorado*, 36 *INQUIRY* 255 (1999)).

²⁴See *e.g.*, David C. Classen *et al.*, *Adverse Drug Events in Hospitalized Patients*, 277 *JAMA* 301 (1997)(finding that adverse drug events caused an almost two-fold increased risk of death); David P. Phillips *et al.*, *Increase in U.S. Medication-Error Deaths Between 1983 and 1993*, 351 *LANCET* 643 (1998) (finding 2.57-fold increase in medication deaths).

²⁵See *e.g.*, Troyen A. Brennan, *The Institute of Medicine Report on Medical Errors—Could it Do Harm?*, 342 *N. ENG. J. MED.* 1123 (2000)(arguing that hospital care is actually becoming safer, distinguishing terms adverse event and error, and criticizing IOM methodology); Clement J. McDonald *et al.*, *Deaths Due to Medical Errors are Exaggerated in Institute of Medicine Report*, 284 *JAMA* 93 (2000) (criticizing IOM methodology).

²⁶See Lucian L. Leape, *Institute of Medicine Figures are Not Exaggerated*, 284 *JAMA* 95 (2000) (arguing that IOM report may have underestimated number of deaths).

²⁷See IOM Report, *supra* note 3, at 29-31.

²⁸See *supra* note 23. Comprehensive estimates for overall outpatient deaths due to medical error are not available. Medication error seems to be the most studied outpatient medical error.

²⁹See Brennan, *supra* note 25, at 1123-25.

³⁰See Bodenheimer, *supra* note 7, at 488 (1999) (discussing healthcare quality, comparison with other industries, and organizations for monitoring quality).

³¹See *id.* at 488-89.

costs attributable to adverse events.³² The physician's credo *primum non nocerum* ("first do no harm"), thus suggests that it is incumbent upon medical doctors to lead the effort to reduce medical errors.³³

C. Errors Occur at the Level of the Individual

If medical error creates potential harm to a patient, when does it occur during the delivery of healthcare? The answer is that it can occur at any stage of medical care.³⁴ Despite the complexity of healthcare as a "system," actual delivery of care operates at the individual level.³⁵ Thus, the common denominator for all healthcare is a one-on-one interaction between a provider and a patient.³⁶ It is this interpersonal dynamic which exposes or creates error potential at various stages, such as examination, testing, diagnostic theorizing, or treatment, to name a few.³⁷ Since healthcare is delivered at the human level, medical errors are ultimately attributable to a person and not to an institution or system.³⁸ This fact does not mean that *legal* liability for errors rests solely at the individual level, for clearly organizations and hospitals may be found liable for medical errors.³⁹

If the endpoint or baseline source for all medical error is at the provider-patient level, then what can be done about it? Both sides of the care delivery equation, patients and providers, want to reduce medical error rates to the lowest feasible level.⁴⁰ A reduction in medical error rates would be cost-effective through more efficient resource allocation, and the quality of care would improve.⁴¹ However, there are undoubtedly members of the plaintiff bar who fear economic harm if medical error rates are substantially reduced.⁴² This latter group has an incentive to maintain the *status quo*, or to allow error rates to increase, in order to flourish.⁴³ Therefore, it is not so straightforward to claim that reducing errors is a universal goal.

³²See *id.*

³³See Liang, *Promoting Patient Safety*, *supra* note 8, at 563.

³⁴See IOM Report, *supra* note 3, at 35-36.

³⁵See CHARLES VINCENT & BAS DE MOL, *SAFETY IN MEDICINE* 233 (2000).

³⁶See *id.*

³⁷See IOM Report, *supra* note 3, at 35-36. Author's note: A "computer error" might be blamed for a medical mistake by an automatic dose delivery machine. Even here, though, error would likely be traceable to the human who designed, built, or programmed the machine, or entered incorrect patient data.

³⁸See Liang, *supra* note 8, at 542.

³⁹See *e.g.*, *Jones v. Chicago HMO Ltd. of Illinois*, 730 N.E. 2d 278 (Ill. 2000) (holding HMO potentially liable for doctor's negligence because HMO assigned excessive number of patients to the doctor).

⁴⁰See Bodenheimer, *supra* note 7, at 490-92.

⁴¹See *id.*

⁴²See Jeffrey Ghannam, *Goal to Reduce Medical Errors is Fraught With Difficulties*, 86 A.B.A. J. 88 (2000).

⁴³See *id.*

D. System Errors

Although errors are committed by individuals and affect only one patient at a time, the provider-patient interaction does not occur in a vacuum.⁴⁴ This interaction is influenced by the environment, an external force which increases or decreases the chance for inevitable human error.⁴⁵ This outside force, in the context of a medical errors discussion, is labeled a *system*.⁴⁶ A system may be defined as, "a complex unity formed of many often diverse parts subject to a common plan or serving a common purpose."⁴⁷ Alternatively, a system is defined as "an organized or established procedure or method or the set of materials or appliances used to carry it out."⁴⁸

A *healthcare system* may thus be viewed as an environmental force which is complex, establishes procedures and methods, and serves a common purpose. Because this force exerts an influence on the patient-provider encounter, it is necessary to examine whether the healthcare system promotes or can prevent medical errors.⁴⁹ One caveat is required: Systems exist in many forms and sizes.⁵⁰ In the medical context, for example, a system may be a single doctor's office, an operating room, or a large network of hospitals.⁵¹

Regardless of the size or complexity of a system, research has consistently shown human error can be accounted for, measured, and reduced through proper organization and methodology.⁵² Medical systems are often compared with other industries, particularly aviation and nuclear energy.⁵³ Research shows systems in these other industries, through proper design and monitoring, share the potential to reduce the likelihood of mishap caused by human error.⁵⁴ For example, aircraft

⁴⁴See IOM Report, *supra* note 3, at 49-52.

⁴⁵See *id.* See also Robert E. Anderson *et al.*, *The Sensitivity and Specificity of Clinical Diagnostics During Five Decades: Toward an Understanding of Necessary Fallibility*, 261 JAMA 1610, 1614 (1989).

⁴⁶See IOM Report, *supra* note 3, at 52.

⁴⁷See WEBSTER'S DICTIONARY, *supra* note 13, at 2322.

⁴⁸See *id.*

⁴⁹See VINCENT & DE MOL, *supra* note 35, at 66-67. See also Liang, *Promoting Patient Safety*, *supra* note 8, at 544-45; and, Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851, 1853 (1994).

⁵⁰See IOM Report, *supra* note 3, at 52.

⁵¹See *id.* For example, the Veterans Administration's entire network of hospitals can be viewed as a single system. Within this larger system are smaller systems at the hospital and sub-hospital levels.

⁵²See Leape, *supra* note 49, at 1854. See also Liang, *Promoting Patient Safety*, *supra* note 8, at 544-45; Lucian L. Leape, *Promoting Patient Safety by Preventing Medical Error*, 280 JAMA 1444, 1445 (1998) [hereinafter *Preventing Medical Error*].

⁵³See Leape, *supra* note 49, at 1854. See also Liang, *Promoting Patient Safety*, *supra* note 8, at 544-45.

⁵⁴See Leape, *Preventing Medical Error*, *supra* note 52, at 1444-45.

manufacturers assume human error will occur, so the planes are designed with automatic and redundant features that effectively buffer or absorb pilot error.⁵⁵

Individual and system errors may be distinguished by labeling them as “active” and “latent,” respectively.⁵⁶ Active errors occur at the individual operator level, and usually have more immediate effects.⁵⁷ Latent errors are system-based potential errors: Potential meaning that they trigger or promote error.⁵⁸ Latent errors are removed from individual control, and because they are unrecognized in a complex system, pose a greater threat to safety.⁵⁹ A latent error in a complex system can promote multiple active errors before someone recognizes the system’s flaw.⁶⁰ Unfortunately, for the patient who is injured or killed prior to that moment of flaw recognition, any system fixes come too late.

III. MEDICAL AND LEGAL INFLUENCES

A. *Pathology of the Medical Culture*

Physicians are taught to be compulsive and to attend to detail, which is an inarguably desirable feature of their training.⁶¹ They are also taught that mistakes are caused by individual failure.⁶² My personal experience as a medical student and internal medicine resident was entirely consistent with these observations.⁶³ The medical culture persists in propagating the myth that the appropriate standard of medical care is error free.⁶⁴ Any failure to uphold this standard is viewed as an individual failure, and the doctor alone is viewed as culpable.⁶⁵

Rather than admit that perfection is an unrealistic standard, medical training and practice persist in demanding error free practice.⁶⁶ This fosters what one commentator labels the “shame and blame” mentality of the medical culture toward medical error.⁶⁷ Physicians are taught to feel shame for any mistake, and to accept

⁵⁵See Leape, *supra* note 49, at 1855.

⁵⁶See IOM Report, *supra* note 3, at 55-56.

⁵⁷See *id.*

⁵⁸See David W. Bates & Atul A. Gawande, *Error in Medicine: What Have We Learned?*, 132 ANN. INT. MED. 763 (2000).

⁵⁹See IOM Report, *supra* note 3, at 55-56.

⁶⁰See *id.*

⁶¹See Liang, *Promoting Patient Safety*, *supra* note 8, at 545.

⁶²See Bates & Gawande, *supra* note 58, at 763.

⁶³M.D., University of Miami, 1987; residency, University of Hawaii, 1987-1990; Board Certified, Internal Medicine, 1990.

⁶⁴See Leape, *supra* note 49, at 1852.

⁶⁵See Bates & Gawande, *supra* note 58, at 763.

⁶⁶See Leape, *supra* note 49, at 1852.

⁶⁷See Liang, *Promoting Patient Safety*, *supra* note 8, at 545.

the entire blame.⁶⁸ In some instances this approach may be entirely appropriate. Some who attend medical school or enter residency training are simply not up to the job. Others, upon clearing the hurdles of training, commit overt malpractice and deserve to be blamed and punished. However, unyielding reliance on the reactive shame and blame approach, rather than attempting some degree of a proactive systems based approach, has been criticized for failing to adequately self-regulate the medical profession⁶⁹ or reduce error rates.⁷⁰ Further, the reactive approach probably has little or no effect on latent errors, because these are not consistently admitted or reported.⁷¹

In clinical terms, the medical culture's traditional focus on individual culpability for error is pathological in the sense that such a mentality flatly ignores a reality that doctors are themselves clearly aware of: Humans make mistakes, and this includes doctors! If a patient so adamantly denied this reality despite objective evidence to the contrary, his doctor would diagnose him as having insane delusions. Also, the provider's fear of blame and guilt for errors provides a disincentive to be forthright.⁷² The fear of being sued is a major deterrent to admitting or reporting errors.⁷³ Loss of hospital privileges or insurance contracts, or sanctioning by medical boards provide additional disincentives to admit error.⁷⁴ Thus, while no physician can objectively deny that errors happen to them or their colleagues, the culture of medicine exists in a state of suspended disbelief.⁷⁵

Although personal accountability is a desirable norm for any professional, the medical culture has traditionally overemphasized individual culpability at the expense of failure to truly explore the alternative explanations or mechanisms which promote error.⁷⁶ Not until fairly recently has the medical culture realized that systems play a substantial, if not preeminent, role in promoting medical errors.⁷⁷ This is a step in the right direction. The sad irony of the traditional approach is that it ignores fundamental medical diagnostics and treatment philosophy. Diseases are the underlying cause of symptoms, so find and fix the former to cure the latter. How many more patients must die due to faulty systems before the *primum non nocerum* clause is triggered?

⁶⁸See *id.*

⁶⁹See Joan Vogel & Richard Delgado, *To Tell the Truth: Physicians' Duty to Disclose Medical Mistakes*, 28 UCLA L. REV. 52, 58-59 (1980).

⁷⁰See Voelker, *supra* note 10, at 1537-38.

⁷¹See *id.*

⁷²See Jonathan R. Cohen, *Apology and Organizations: Exploring an Example From Medical Practice*, 5 FORDHAM URB. L.J. 1447, 1467 (2000); see *id.*; Leape, *supra* note 49, at 1852; Voelker, *supra* note 10, at 1537.

⁷³See Jeffrey Ghannam, *Goal to Reduce Medical Errors is Fraught With Difficulty*, 86 A.B.A. J. 88 (2000); David Orentlicher, *Medical Malpractice: Treating the Causes Instead of the Symptoms*, 28 MED CARE 247, 247-49 (2000).

⁷⁴See Leape *et al.*, *Preventing Medical Error*, *supra* note 52, at 1444.

⁷⁵See *id.*

⁷⁶See VINCENT & DE MOL, *supra* note 35, at 70.

⁷⁷See Voelker, *supra* note 10, at 1537-38 and, Leape, *supra* note 49, at 1852.

B. Legal Disincentives Error Reporting

Similar to the way the environmental forces of systems influence the endpoint provider-patient error rate, the medical profession's perceived "wall of silence"⁷⁸ does not arise in isolation from factors external to medicine.⁷⁹ Aside from shame or guilt, physicians are reluctant to admit errors because of the perceived threat of litigation or other sanctions.⁸⁰ Whether this threat is real or imaginary, the legal culture is a contributing cause of physicians' reluctance to admit errors.⁸¹ Traditional malpractice claims for negligence, and the discoverability of voluntarily reported error data are the two primary sources of this reluctance.⁸² This section explores these roadblocks to error reporting or error-rate reduction attempts.

The concept of medical malpractice was described in Sir William Blackstone's *Commentaries on the Laws of England* in 1768.⁸³ In the United States, medical malpractice claims were uncommon until the mid-1800s.⁸⁴ The rise in claims in that era paralleled the development of more standardized medical practice and education, and the use of innovative techniques by physicians.⁸⁵ In response to the threat of suits, many physicians could purchase malpractice insurance by the end of the nineteenth century.⁸⁶ Ironically, as innovation and standardization improved medical knowledge and quality, there arose identifiable "standards" of care which plaintiffs could allege were breached as the basis for a negligence claim.⁸⁷ Also, the presence of liability insurance made physicians more desirable targets for plaintiff's lawyers, a feature which persists in the current malpractice system.⁸⁸

⁷⁸See Vogel & Delgado, *supra* note 69, at 52-54.

⁷⁹See Lawrence Gostin, *A Public Health Approach to Reducing Error: Medical Malpractice as a Barrier*, 283 JAMA 1742 (2000).

⁸⁰See *id.* at 1742-43; Liang, *Promoting Patient Safety*, *supra* note 8, at 555-59. Other sanctions affect government contracts, hospital privileges, or medical licensure. See Gostin, *supra* note 79, at 1742-43.

⁸¹See Jeffrey Ghannam, *supra* note 73, at 88.

⁸²See *id.*

⁸³See James C. Mohr, *American Medical Malpractice Litigation in Historical Perspective*, 283 JAMA 1731, 1732 (2000) (citing WILLIAM BLACKSTONE, 3 COMMENTARIES ON THE LAWS OF ENGLAND 122 (1768), where Blackstone used the term *mala praxis* to describe neglect or unskilled practice as breaking a patient's trust and causing injury). See also Roger N. Braden & Jennifer L. Lawrence, *Medical Malpractice: Understanding the Evolution-Breaking the Revolution*, 25 N. KY. L. REV. 675, 693 (1998) (citing *Cross v. Guthery*, 2 Root 90 (Conn. 1794) as the earliest U.S. case of medical malpractice).

⁸⁴See Mohr, *supra* note 83, at 1731-43. According to Mohr, the social factors which promoted the rise of malpractice litigation included Americans' less religiously fatalistic attitude about personal health, and the lack of government or self-regulation of medical practice. See *id.*

⁸⁵See *id.* at 1735-37.

⁸⁶See *id.* at 1736-37.

⁸⁷See *id.*

⁸⁸See Mohr, *supra* note 83, at 1731-43.

Two major goals of medical malpractice litigation are to compensate negligently injured patients, and to deter negligent behavior.⁸⁹ Unfortunately, the present legal system is a very inefficient and inaccurate means of promoting these goals.⁹⁰ Only a small percentage of injured patients actually attempt to sue their doctors.⁹¹ Many victims of medical negligence simply fail to realize that they were wrongfully injured, and fail to seek legal redress.⁹² Conversely, other patients who have adverse or suboptimal outcomes not caused by negligence file suit against their providers.⁹³

The legal system's failure to consistently promote and enforce the injury-compensation and deterrence policies of medical negligence actions has thus failed to provide clear guidance to the medical community.⁹⁴ One message is that if a doctor is negligent, he probably won't be sued.⁹⁵ The concurrent message is that providing non-negligent care is not clearly a shield from patients at least attempting to sue.⁹⁶ Therefore, negligent practitioners are neither effectively punished nor deterred, and the more careful physicians are randomly punished in spite of their diligence.⁹⁷

As a result of the apparent randomness of negligence liability, doctors are faced with a disincentive to report medical errors.⁹⁸ Additionally, the threat of litigation promotes defensive medical practices.⁹⁹ Extra tests, procedures, and therapies are recommended by doctors in an attempt to avoid gaps where plaintiffs' lawyers may

⁸⁹See Troyen A. Brennan, *Medical Malpractice Reform-The Long View*, 11 J. CLIN. ANES. 265 (1999). A third social function of the tort system is to provide corrective justice, but this is "impossible to measure." See *id.*

⁹⁰See *id.* at 265.

⁹¹See Orentlicher, *supra* note 73, at 248. Indigent patients are the least likely to sue, though they are the patients most in need of compensation for injury. See *id.*

⁹²See Vogel & Delgado, *supra* note 69, at 56-57. With the prevalence of personal injury attorney advertising, patients today are probably more aware of their legal counseling options.

⁹³See e.g., Orentlicher, *supra* note 73, at 248 (stating that "most lawsuits are filed in the absence of negligence." However, this is probably a reflection of patients', rather than attorneys', misperception of whether negligence occurred. Thus, even diligent pre-suit screening by attorneys does not adequately prevent such claims); Paul Weiler, *The Case for No-Fault Medical Liability*, 52 MD. L. REV. 908, 913 (1993) (claiming lawyers have difficulty deciding whether to file a claim).

⁹⁴See Bryan A. Liang, *The Legal System and Patient Safety: Charting a Divergent Course*, 91 ANESTHESIOLOGY 609 (1999) [hereinafter Liang, *The Legal System and Patient Safety*].

⁹⁵See e.g., Weiler, *supra* note 93, at 912-13 (finding only one-in-three likelihood of malpractice claims being paid to victims of serious injury caused by negligence).

⁹⁶See Liang, *The Legal System and Patient Safety*, *supra* note 94, at 609.

⁹⁷There is also undoubtedly what I would call a "hassle factor" threshold. This is the point where a non-negligent (from the physician's viewpoint) physician is willing to settle a claim for an amount of money that represents the value of closure and ending the personal distress of litigation.

⁹⁸See Leape *et al.*, *supra* note 52, at 1447.

⁹⁹See Weiler, *supra* note 93, at 916-17.

seek to establish a foothold.¹⁰⁰ These defensive practices are costly in both economic and human terms. One study estimated the cost of defensive medicine at \$18 billion annually.¹⁰¹ Aside from this economic waste, the mass effect of defensive medicine increases the risk of medical errors which result in patient injury.¹⁰² Thus, the legal system, or at least medicine's reaction to it, has a causative role in the medical error rate. Also, malpractice insurers seem satisfied with *the status quo*, because of the actuarial stability it provides, as long as the insurers retain their ability to refuse coverage of high risk doctors.¹⁰³

Reducing medical errors should result in higher quality and more cost-effective care. The first step toward this end is error disclosure, and therein lies the rub. Given the already unpredictable nature of the medical malpractice tort process, doctors are unwilling to voluntarily disclose their errors for fear of discovery by plaintiffs.¹⁰⁴ Admitting error so that it may be used against you is either foolish or masochistic. It's tantamount to giving aid and comfort to the enemy. Although state laws may immunize certain mandated quality assurance monitoring or peer review processes from liability, they do not always protect the *information* from discovery.¹⁰⁵ The information from these programs may be discoverable by plaintiffs under the traditional *Hickman v. Taylor* substantial need and undue hardship test.¹⁰⁶ Also, reporting the information to third parties, such as consultants, private and federal quality monitoring agencies, or in cases tried in federal courts, immunity may not apply.¹⁰⁷ Hence, absent better assurance that error disclosure will not be discovered by plaintiffs, the medical community remains reluctant to volunteer this information.¹⁰⁸

¹⁰⁰See *id.*, and, Liang, *The Legal System and Patient Safety*, *supra* note 94, at 610.

¹⁰¹See Weiler, *supra* note 93, at 916-17.

¹⁰²See Liang, *The Legal System and Patient Safety*, *supra* note 94, at 610.

¹⁰³See Brennan, *supra* note 89, at 266.

¹⁰⁴See Liang, *Promoting Patient Safety*, *supra* note 8, at 55-59.

¹⁰⁵See *e.g.*, FLA. STAT. § 395.0197(1) (2000) (requiring all licensed hospitals to establish an internal risk management program); MASS. ANN. LAWS ch.111, § 203(d) (West 2000)(same). These statutes provide for immunity of risk management data from discovery.

¹⁰⁶*Hickman v. Taylor*, 329 U.S. 495 (1947). Applies to attorney work product materials prepared in anticipation of litigation. See *id.* at 510-11. Alternatively, the information can sometimes be viewed as factual and thus not covered by the attorney-client privilege under *Upjohn v. United States*, 449 U.S. 383, 395-96 (1981). See Liang, *Promoting Patient Safety*, *supra* note 8, at 558-59. See also *Healthtrust v. Saunders*, 651 So.2d (Fla. 1995) (denying discovery in absence of showing need and undue hardship).

¹⁰⁷See Liang, *supra* note 8, at 55-59 and *nn.* 53-61.

¹⁰⁸See *supra* notes 90-98 and accompanying text.

IV. CURES FOR MEDICAL ERRORS

A. *Adopt a Systems Approach*

If medical errors are not being reduced by the traditional tort system,¹⁰⁹ and individual physicians are operating at a level of efficiency that still produces an unacceptable error rate,¹¹⁰ then a new model for error reduction is necessary.¹¹¹ This model, as previously mentioned, is the systems approach.¹¹² The medical community has become increasingly aware of the need for such an approach, through studies of human error psychology and by examining other high-risk industries.¹¹³

The medical profession, upon admitting its awareness of the systems-based influences and causes of medical error, is ethically compelled to pursue this approach if public opinion is to continue to grant physicians a foothold on the moral high ground.¹¹⁴ Despite obstacles, including the threat of litigation, the duty owed to patients is paramount.¹¹⁵ Besides, it would be foolish, and overtly self-destructive, if medicine waits until forces entirely outside of the profession dictate the terms of this endeavor. Medicine's limited remaining capacity to self-regulate would evaporate. If nothing else, a better approach to reducing errors, and a good faith effort to implement this approach, is a matter of self-preservation.

Ironically, the threat of litigation has already led to some progress by medicine to incorporate a systems-based approach. In response to the rising malpractice insurance costs of the 1980s, the field of anesthesiology became a pioneer in the application of the systems approach to medical error reduction.¹¹⁶ By assessing the systems in which anesthesiologists delivered care, and implementing technological advances, the mortality rate from anesthesia was reduced by over ten-fold.¹¹⁷ The anesthesiology field's success was attributable to improved information strategies, development of practice guidelines and standards, human factors evaluation, strong leadership, and a multidisciplinary approach.¹¹⁸ Extending this approach to other areas of medicine appears worthwhile, with adjustments and fine tuning for outpatient and individual provider settings.

¹⁰⁹See Bodenheimer, *supra* note 7, at 490-92.

¹¹⁰See Liang, *Promoting Patient Safety*, *supra* note 8, at 544-45.

¹¹¹See *id.*; IOM Report, *supra* note 3, at 56.

¹¹²*Id.* at 71-75; Leape, *supra* note 49, at 1854-55.

¹¹³See Bates & Gawande, *supra* note 58, at 765-66.

¹¹⁴See *id.*; Leape, *supra* note 49, at 1851.

¹¹⁵*Id.* at 1856; IOM Report, *supra* note 3, at 164.

¹¹⁶See IOM Report, *supra* note 3, at 164 (citing anesthesiology study where anesthesia mortality was reduced from one in 10,000 to 20,000 to less than one in 200,000 through the use of monitoring devices).

¹¹⁷See *id.* at 144-45.

¹¹⁸See Bodenheimer, *supra* note 7, at 491-92; Liang, *Promoting Patient Safety*, *supra* note 8, at 561-62; Leape, *supra* note 49, at 1856; IOM Report, *supra* note 3, at 173-74.

Leading medical and legal commentators have called for a systems approach to medicine which is modeled after those used in aviation and nuclear energy.¹¹⁹ These complex, high-risk industries have studied the causes of human error, and have implemented systems which reduce the influence of human imperfection.¹²⁰ The common feature in these systems is that they expect and anticipate human error, and thereby integrate their systems to accommodate this reality.¹²¹ Given the complexity and variety of settings for healthcare delivery, there is no one size fits all approach. However, with some innovative thinking,¹²² leadership, and grassroots commitment, medicine can address the systems flaws it now is beginning to acknowledge.¹²³

B. Collect the Data and Encourage Error Reporting

Medical error reduction could lessen the unpredictability of the tort system by increasing the overall quality of care. Less patients will be injured, shrinking the pool of potential plaintiffs. To effect this change, errors need to be studied, which can only happen if they are more comprehensively reported. The ideal error detection-prevention process should: 1) identify errors by individual providers practicing substandard care, 2) identify deficiencies which increase the risk of error by providers within a system, 3) establish methods to reduce errors in both contexts, and 4) provide legal safeguards and market incentives for voluntary error reporting.

Licensing of individual physicians occurs at the state level. In the 1889 decision *Dent v. West Virginia*,¹²⁴ the U.S. Supreme Court endorsed this system as proper to ensure that physicians had the “requisite qualifications” to practice medicine.¹²⁵ In 1986, the Health Care Quality Improvement Act established the National Practitioner Data Bank (NPDB).¹²⁶ The NPDB stores information about individual provider malpractice claims and decisions affecting clinical privileges.¹²⁷ This information is used for credentialing and licensing purposes, and is protected from discovery by plaintiffs’ attorneys.¹²⁸ Also, at the state level, statutes may require reporting of some adverse patient events.¹²⁹ Together with traditional tort liability, state laws, licensing boards, and the NPDB provide checks on physician errors. However, they are *post facto* reactive checks that do not systematically address error types and

¹¹⁹See IOM Report, *supra* note 3, at 159-66, 173-74.

¹²⁰See *id.* at 162-65.

¹²¹See *id.*

¹²²See Paul Plsek, *Innovative Thinking for the Improvement of Medical Systems*, 131 ANN. INT. MED. 438, 438-44 (1999).

¹²³See IOM Report, *supra* note 3, at 156-57, 167.

¹²⁴129 U.S. 114, 123 (1889).

¹²⁵See *id.*

¹²⁶42 U.S.C. §§ 11101 *et seq.* (1986).

¹²⁷See IOM Report, *supra* note 3, at 121-22.

¹²⁸See *id.* at 122.

¹²⁹See *e.g.*, FLA. STAT. § 458.351 (requiring physician reporting of “adverse incidents,” such as patient death or surgical complications).

causes, offering only the threat of punishment, which serves as a disincentive to voluntary error reporting.

A healthcare system can be virtually any level of complexity, but for the purposes of this analysis, the hospital will be considered as the standard example.¹³⁰ Though no two hospitals are identical, and each department in a hospital represents a system within a system, they share some common features. Hospitals are accredited for the most part by the private, not-for-profit Joint Commission on Accreditation of Healthcare Organizations (JCAHO).¹³¹ Though JCAHO is a private entity, Medicare¹³² and many states require JCAHO accreditation as a condition of facility licensure or certification.¹³³ JCAHO has a “sentinel event” policy which requires facilities to report certain bad outcomes.¹³⁴ Hospitals are also commonly required by state statute to have an internal risk management program to investigate adverse patient incidents, and develop quality control and improvement programs.¹³⁵ Thus, in the hospital context, there is at least some effort to identify and correct system errors.

A more sophisticated approach is needed for detecting errors in both office and hospital settings, though.¹³⁶ Many proposals exist for collecting and analyzing this data in a way that will provide meaningful insight into the causes of individual and systems-based errors. One suggestion is for a “patient safety center” under the auspices of the National Institutes of Health.¹³⁷ Under this proposal, error reporting by physicians and institutions would be mandatory, yet non-punitive unless errors are not reported as required.¹³⁸ The data would be reported to a neutral third party which lacks sanctioning ability, similar to the Aviation Safety Reporting System

¹³⁰For example, a large outpatient group practice has systems elements, such as practice protocols, nursing guidelines, or a central pharmacy, to name a few. Arguably, even a solo practitioner performs under a system, because he or she develops standardized approaches to common problems, approaches which may promote error if the approaches have latent defects.

¹³¹Managed care organizations such as HMOs are accredited by the National Committee on Quality Assurance (NCQA), a private organization. See www.ncqa.org.

¹³²42 U.S.C. §§ 1395X(e), 1395bb. (2000) JCAHO accreditation suffices for Medicare certification purposes.

¹³³See FLA. STAT. § 395.0161. For example, Florida allows JCAHO accreditation in lieu of state periodic inspection.

¹³⁴See Bryan A. Liang and Kristopher Storti, *Creating Problems as Part of the Solution: The JCAHO Sentinel Events Policy, Legal Issues and Patient Safety*, 33 AMER. J. HEALTH L. 263, 264 (2000).

¹³⁵See e.g., FLA. STAT. § 395.0197 (providing for, “a) the investigation and analysis of the frequency and causes of general categories of specific types of adverse incidents to patients.” and “b) the development of appropriate measures to minimize the risk of adverse incidents to patients. . .”).

¹³⁶See e.g., Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market*, 37 ARIZ. L. REV. 825, 861-62 (1995) (suggesting that medical license boards have little effect on error rates).

¹³⁷See Liang, *Promoting Patient Safety*, *supra* note 8, at 561-62.

¹³⁸See *id.* at 561-64.

(ASRS).¹³⁹ Other proposals include data collection by the National Patient Safety Foundation,¹⁴⁰ or a federally funded Center for Quality Improvement in Patient Safety.¹⁴¹

Assuming that a data collection center is established, one problem that the data collectors will have is deciding what data to gather.¹⁴² This is a technical issue beyond the scope of this paper.¹⁴³ It is sufficient to note that merely collecting the data is a daunting task, subject to abstraction and interpretation bias.¹⁴⁴

Another concern with mandatory error reporting is liability exposure. Threatening to punish reporting failures may have some coercive influence,¹⁴⁵ but does not efficiently promote the ultimate goal of simply obtaining the errors information for analysis and systems improvements. Fully anonymous reporting might provide raw data, but would not lead consistently to corrective measures at specific sites, because only widespread problems would be addressable. In the absence of anonymity then, what should be done to promote error disclosure information which is more useful to address problems at specific sites?

Granting liability immunity to those who provide error data is one solution.¹⁴⁶ Many states already grant immunity to peer review and utilization review organizations.¹⁴⁷ As noted earlier, such immunity does not extend to “administrative information,” such as certain safety data.¹⁴⁸ For example, in *State ex rel. United Hospital v. Bedell*,¹⁴⁹ the West Virginia Supreme Court held that a hospital’s incident report, made after a patient was injured in the hospital, was not immune from

¹³⁹*See id.* at 561-62. The ASRS collects data and provides it to NASA rather than the FAA. Bypassing the FAA, which has the authority to sanction pilots and carriers, promotes voluntary error reporting. *See id.*

¹⁴⁰*See* Bodenheimer, *supra* note 7, at 490. The National Patient Safety Foundation was established in 1997 by the American Medical Association, and focuses on systems’ relations to medical errors. *See id.*

¹⁴¹*See Remarks by the President on Medical Errors*, Feb. 22, 2000. (President Clinton proposed this center and a \$20 million start-up fund.) www.ahrq.gov last visited Sept. 19, 2000.

¹⁴²*See* UNDERSTANDING HEALTH OUTCOMES RESEARCH 214-217 (Robert L. Kane ed., 1997).

¹⁴³*See* Jost, *supra* note 136, at 851-54, for an in-depth discussion of these technical issues.

¹⁴⁴*See id.*

¹⁴⁵*See* Liang, *Promoting Patient Safety*, *supra* note 8, at 562-64.

¹⁴⁶*See id.* Professor Liang suggests federal legislation to protect “all safety analysis in continuous and ongoing safety programs.” He emphasizes that immunity is conditioned upon the provider’s making actual use of the collected data. *See id.*

¹⁴⁷*See e.g.*, FLA. STAT. §§ 766.101(1)-(7) (2000) (providing discovery and liability immunity to committee procedures and members, respectively); MASS. ANN. LAWS ch.111, § 203 (West 2000)(same).

¹⁴⁸*See* Liang, *Promoting Patient Safety*, *supra* note 8, at 556.

¹⁴⁹*State ex rel. United States Hospital v. Bedell*, 484 S.E.2d 199, 213 (D.C. W. Va. 1997).

discovery because it was not a document prepared in anticipation of litigation.¹⁵⁰ Other limitations on immunity may include the reports of peer review panels¹⁵¹ or information disclosed to third parties.¹⁵² If states wish to encourage error reporting, legislators may wish to extend immunity privileges to error data collecting activities. However, even if full immunity is not granted, some error data should be reportable without fear of litigation, such as when there has been no actual patient harm.¹⁵³

Instead of reporting medical errors directly to a national databank, I propose a different approach which is market-based and operates principally at the state level. A national databank would be unlikely to account for regional practice differences, and the solutions proposed would be aimed at a national lowest common denominator. It is preferable to collect data at the state level, where accountability and flexibility are more immediate.¹⁵⁴ This would allow a variety of approaches, and states which evolve desirable systems more rapidly than other states could serve as models.¹⁵⁵ State legislatures, insurers, regulators, and professional organizations could look to these leading states and incorporate reporting systems features most desirable for their own state. Market forces, such as funding decisions and insurance rates, would provide incentives not to be a laggard state. Similarly, states would also decide immunity issues for themselves. The data collected could still be passed on to a national databank, which could assess the data and make further recommendations.¹⁵⁶ Rather than being used as a justification for new federal legislation, these recommendations could be used by market actors to provide incentives for states to evolve their own data collection process. In this way, desirable market forces and state autonomy would be preserved.

Instead of creating yet another federal bureaucracy,¹⁵⁷ with all of the attendant inefficiencies, funding decisions for medical errors data collection and analysis, should occur using private resources at the state level. However, I do not suggest a state bureaucracy instead of a federal one. The data should be collected by a private company, which need not be confined to a state's borders. The private company

¹⁵⁰*See id.*

¹⁵¹*See* Bayfront Medical Center v. State, 741 So.2d 1226,1229 (Fla. Dist. Ct. App. 1999) (finding report of peer review process not privileged, though records of peer review process were) (*emphasis added*).

¹⁵²*See* Liang, *Promoting Patient Safety*, *supra* note 8, at 557. "Nonhospital information" is, for example, information generated by the use of an outside safety expert. *See id.*

¹⁵³*Cf.* Fred Rosner *et al.*, *Disclosure and Prevention of Medical Errors*, 160 ARCH. INT. MED. 2089-92 (2000)(emphasizing ethical duty of physicians to admit error).

¹⁵⁴Florida established a Health Information Systems Council consisting of "executive-level managers for the state's health-related entities." *See* FLA. STAT. § 381.90(1) (2001). Minnesota law established a "[h]ealth outcomes data" collection process. *See* MINN. STAT. ANN. § 62J.301(a) (West 1996).

¹⁵⁵*See e.g.*, Representative Jim Slatterly and Janet Murguia, *The Role of the States in Health Care Reform*, 3 KAN. J.L. & PUB. POL'Y. 156, 161 (1993-94) (concluding that states are better able to implement healthcare reform measures than the federal government).

¹⁵⁶*See supra* notes 134-38, and accompanying text.

¹⁵⁷*See id.*

could contract directly with providers, who would incorporate the cost of collecting data into the cost of doing business. The state could allow one or more such private entities to collect the data along specified parameters, and then report their findings directly to the state.¹⁵⁸ Such a system would be cost-effective through the avoidance of fines and sanctions for failing to report errors, and ultimately through actual error reduction which results in lower liability insurance and litigation costs. Any void in the market which presently exists for a private errors data collecting entity will be more efficiently filled by a private information technology company than by a new government bureaucracy, and market competition would promote efficiency and results.

C. Standards of Care and the Use of Practice Guidelines

If a systems approach is adopted, and data collected, there remains the problem of how best to use the information in order to reduce errors. It may appear obvious that errors will decrease by applying the best known practices to each patient.¹⁵⁹ However, medicine is less well suited for standardization than certain purely mechanical tasks, because of individual patient diversity and complexity.¹⁶⁰ Also, many medical problems can be successfully treated in more than one way, which suggests there is not always a ready applicable “best” method for a given patient or problem.¹⁶¹ In spite of these difficulties, some standardization of medicine is possible to reduce patient risk.¹⁶² Clinical practice guidelines (CPGs) have thus emerged, and are developed continuously, with an emphasis on scientific evidentiary support.¹⁶³ This section discusses how these guidelines affect the legal standard of care.

Traditionally, the legal standard for medical negligence was based on the local practice custom established by the medical community.¹⁶⁴ As medical knowledge

¹⁵⁸An existing element of the state government, such as the Department of Health, could receive the data reports. The state could follow the recommendations of the private analysts, or formulate its own recommendations. The state’s role would be mainly that of oversight, which would not require much, if any, additional manpower.

¹⁵⁹See Charles Marwick, *Will Evidence-Based Practice Help Span Gulf Between Medicine and Law?*, 283 JAMA 2775, 2776 (2000).

¹⁶⁰See *id.* at 2776. “Evidence-based medicine in practice defines the likelihood of something happening. It is never 100 percent. . . [t]he same evidence applied in one case may not apply in another. The circumstances of the individual patient may be different, or the circumstances may be the same, but patients may refuse one treatment in favor of another.”

¹⁶¹See Arnold J. Rosoff, *Legal Implications of Clinical Practice Guidelines in Emergency Medicine*, in LEGAL MEDICINE 1, 7 & n.11 (Cyril H. Wecht ed., 1995) (discussing “respectable minority” practice variations).

¹⁶²See IOM Report, *supra* note 3, at 32 (citing anesthesia’s success in reducing operative mortality through the use of practice guidelines) available at <http://books.rap.edu/books0309068371/html/>.

¹⁶³Examples include the American Medical Association’s CLINICAL PRACTICE GUIDELINES DIRECTORY (1999) and the National Guidelines Clearinghouse’s website, available at www.guideline.gov.

¹⁶⁴RESTATEMENT (SECOND) OF TORTS § 299A (1965). Adherence to custom may be considered by jury, but is not dispositive. See *id.*

and sophistication evolved, so did the legal standard in two main ways. First, a national standard of care applies to doctors practicing anywhere in the country, with some variation allowed to account for urban versus rural settings and resource availability.¹⁶⁵ Second, regardless of a particular community's customs, the objective standard of "skill and knowledge normally possessed by members of that profession in good standing in similar communities" applies.¹⁶⁶ This objective standard may at times serve as a basis to impugn an industry-wide practice as negligent. A striking example was the Washington Supreme Court's ruling in *Helling v. Carey*,¹⁶⁷ which declared that failure to screen a young patient for glaucoma was negligence, even though it was not usual practice for eye doctors to perform screening at that age.¹⁶⁸ Thus, the law has forced medical standards of care to evolve, because the standard of care is ultimately a legal, rather than a medical, question.¹⁶⁹

Perhaps partly as a response to the law, medicine at the dawn of the 21st century is attempting to systematize and objectify standards of care through the establishment of CPGs based on scientific evidence.¹⁷⁰ The Institute of Medicine defines CPGs as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."¹⁷¹ CPGs are generally developed by academic leaders and authoritative bodies for particular medical specialties.¹⁷² CPGs were initially promulgated as a quality improvement tool, but have also become cost-containment devices.¹⁷³ Whether used to improve quality or lower costs, or both, a strong emphasis on evidence based medicine (EBM) is stressed as an underpinning for all CPGs.¹⁷⁴ It is believed that a

¹⁶⁵See *Hall v. Hilbun*, 466 So.2d 856, 879 (Miss. 1985) (allowing out of state physician expert witnesses to testify regarding standard of care in Mississippi, so long as the experts were made familiar with the local "facilities, equipment, personnel and general medical resources available").

¹⁶⁶RESTATEMENT (SECOND) OF TORTS § 299A, cmt. g (1965).

¹⁶⁷519 P.2d 981 (Wash. 1974).

¹⁶⁸See *id.* at 984. The Washington Supreme Court subsequently held that the state legislature intended to abolish the *Helling* rule in WASH. REV. CODE § 4.24.290 (1975). See *Gates v. Jensen*, 579 P.2d 374, 376 (Wash. 1978) (re-imposing traditional standard of "that degree of skill, care, and learning possessed by other persons in the same profession").

¹⁶⁹See Rosoff, *supra* note 161, at n.11.

¹⁷⁰See AMA Clinical Practice Guidelines, *supra* note 163.

¹⁷¹INSTITUTE OF MEDICINE, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 8 (Marilyn J. Field & Kathleen N. Lohr eds., 1990).

¹⁷²For example, CPGs have been promulgated by the American Colleges of Cardiology, of Pediatrics, and of Obstetrics and Gynecology. See IOM Report, *supra* note 2, at 145-46.

¹⁷³See Rosoff, *supra* note 161, at 1-2; Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 370 (1995). See also FLA. STAT. ANN § 408.02 (West 200) (encouraging practice parameter development to improve resource utilization and decrease practice delivery variations).

¹⁷⁴See e.g., Gordon H. Guyatt *et al.*, *Evidence Based Medicine: Principles for Applying the User's Guide to Patient Care*, 284 JAMA 1290, 1295 (2000) (discussing need for evidence data gathering to improve practice guideline development).

strong scientific evidentiary basis for CPGs will promote broader applicability and acceptance by practitioners in a variety of clinical settings.¹⁷⁵

In theory, well designed and widely followed CPGs will reduce medical error through better overall practice quality.¹⁷⁶ However, the potential or actual use of CPGs as the legal standard of care in negligence actions has caused doctors to hesitate in accepting them.¹⁷⁷ One solution to reduce physician apprehension is to allow CPG use as purely exculpatory evidence in a malpractice suit.¹⁷⁸ Maine and Kentucky have enacted statutes which adopt this approach, at least to some degree.¹⁷⁹ Ironically, such an approach may serve to reduce already low compliance with CPGs, because plaintiffs would not be able to introduce evidence of noncompliance.¹⁸⁰ Thus, if CPGs are to function as effective error reduction mechanisms, they must be widely followed by doctors, so it may be important to allow plaintiffs to introduce evidence of CPG noncompliance.¹⁸¹ However, a catch-22 situation could result if the law encourages compliance with guidelines as a presumptive standard of care, since the more widespread the use of CPGs becomes, the more they can be used against providers, irrespective of the broader quality of care effects of a given CPG.¹⁸² In this respect, physician reluctance to accept CPGs is rational.

The goal of this discussion of CPGs is to emphasize caution by courts and legislators in adopting CPGs as legal standards of care. Medical errors will be

¹⁷⁵See *id.* But see John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421 (1999). Ayres states that “the strength of the scientific data and expert judgment should be made explicit in the guideline.” See *id.* at 427. Further, he argues that guidelines may be no more authoritative than text books or learned treatises, and that guidelines often address controlled environments, like operating rooms. Also guidelines may be biased toward academic practice settings, failing to account for differences between urban and rural settings, and that guidelines are often outdated by the time they are published. See *id.* at 427-32.

¹⁷⁶See IOM Report, *supra* note 2, at 135-36.

¹⁷⁷See Rosoff, *supra* note 161, at 2. Rosoff cites other reasons besides litigation concerns which impact physicians’ acceptance of CPGs, including the fact that “doctors have been wary of “cookbook medicine” and, in general, any attempt to reduce complex professional judgments to standardized formulas. . . [CPGs] would tend to undermine professional autonomy,” and physicians’ perception that “third party payers will use them to deny payment for care that doctors believe should be provided to their patients. . .” See *id.*

¹⁷⁸See Andrew L. Hyams *et al.*, *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL., POL’Y & LAW 289, 292 (1996).

¹⁷⁹See *e.g.*, ME. REV. STAT. ANN. Title 24, § 2975 (West 1999) (restricting use of practice parameter compliance evidence to affirmative defenses by doctors or their employers); KY. REV. STAT. ANN. § 342.035(8)(b) (Michie 1999) (creating presumption that standard of care met by adherence to practice guidelines).

¹⁸⁰See Hyams, *supra* note 178, at 292.

¹⁸¹See *id.* at 292-304.

¹⁸²See Wendy K. Mariner, *Outcomes Assessment in Health Care Reform: Promise and Limitations*, 20 AM. J.L. & MED. 37, 57 (1994) (expressing concern that guidelines “may inappropriately or inadvertently reduce the quality of care”) (*emphasis added*).

reduced by widespread application of what actually works best for a particular clinical scenario.¹⁸³ However, blind adherence to CPGs may actually promote medical errors.¹⁸⁴ CPGs must be developed with some inherent flexibility to allow for specific resource limitations, practice style differences, and individual patient variables and preferences.¹⁸⁵ A *per se* approach that CPG conformity is not malpractice may unfairly prevent recovery by a patient who is injured by a physician's negligent adherence to a CPG.¹⁸⁶ Conversely, overly rigid CPGs might expose a doctor to liability when the reasonable and prudent approach is to not follow a CPG.¹⁸⁷ A more workable legal approach is to incorporate CPGs as admissible evidence or as burden shifting devices in malpractice actions.¹⁸⁸

D. Enterprise Liability

If liability risks deter error reporting by physicians, perhaps the law can alleviate this concern. As individual practitioner liability laws have evolved, so has the law with respect to insurers and hospitals. Physicians have traditionally been the primary target of malpractice actions. Until the 1950s, hospitals were legally protected under the doctrine of charitable immunity,¹⁸⁹ and doctors were usually viewed as independent contractors rather than agents or employees of the hospital.¹⁹⁰ Insurers were also insulated by the system of fee-for-service retrospective payment, because they were not actively involved in patient treatment decisions.¹⁹¹ For various policy and economic reasons, the law began to accept hospital and insurer vicarious or direct liability theories to allow plaintiff recovery in malpractice cases.¹⁹² This section discusses these theories using the term "Enterprise Liability (EL)" to encompass hospitals, insurers, and managed care and health maintenance organizations (MCOs, HMOs).

¹⁸³See Rosoff, *supra* note 161, at 2.

¹⁸⁴See Ayres, *supra* note 175, at 442 (stating "[i]n some situations, adhering to guideline recommendations might increase the risk of an unfavorable clinical outcome.>").

¹⁸⁵See Rosoff, *supra* note 161, at 381 (describing "respectable minority" practice variations).

¹⁸⁶See *id.*

¹⁸⁷See *id.* at 425.

¹⁸⁸See *supra* note 179.

¹⁸⁹See generally *President of Georgetown College v. Hughes*, 130 F.2d 810 (D.C. Cir. 1942), considered the landmark case eliminating charitable immunity. See also Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 385 (1994) (discussing demise of charitable immunity doctrine).

¹⁹⁰See BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 237-38 (Bd. ed.1997).

¹⁹¹See Abraham and Weiler, *supra* note 189, at 394-96. Insurers became more active participants in healthcare decisions under prospective payment systems, such as diagnosis-related groups (DRGs), implemented by Medicare in Private insurers, especially managed care, have followed suit with prospective payment systems. See *id.*

¹⁹²See FURROW, *supra* note 190, at 238-44.

Enterprise liability is not a novel concept. Rather, it is derived from the theory of *respondeat superior*, a policy-based tort theory which shifts the risk of liability to a company for the acts of its workers acting within their scope of duty.¹⁹³ The policy is based on the assumption that it is better to have companies insure consumers and others against losses than for potential tort victims to self-insure.¹⁹⁴ The theory expanded to apply in the products liability context.¹⁹⁵ EL has been extended to the medical malpractice context, albeit less thoroughly.¹⁹⁶ Vicarious liability is straightforward when a provider is an employee of a health plan or hospital, but when the provider is an independent contractor, EL generally rests upon how much control the enterprise exerted in a particular clinical situation.¹⁹⁷ Thus, if a hospital or other entity directly controlled a clinical decision,¹⁹⁸ or owned and operated particular equipment,¹⁹⁹ a plaintiff may have a viable EL claim. Also, EL may apply where a patient reasonably perceives and relies upon an apparent agency relationship between the provider and enterprise.²⁰⁰

Besides vicarious liability, an enterprise may be directly liable for negligence. Mere cost-saving attempts are not negligent, as noted this year by the Supreme Court in *Pegram v. Hedrich*.²⁰¹ However, an institution may be directly liable for failure to follow established protocols to provide an acceptable standard of care. For example, the Illinois Supreme Court held in *Jones v. Chicago HMO*²⁰² that an HMO may be liable for enrolling too many patients with a single doctor.²⁰³ There is considerable jurisdictional variation in applying EL legal standards, though. State statutes may

¹⁹³See Abraham & Weiler, *supra* note 189, at 383-84.

¹⁹⁴See George I. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1535 (1987). See also Barry R. Furrow, *Enterprise Liability and Health Care Reform: Managing Care and Managing Risk*, in CROSS NATIONAL PERSPECTIVES ON HEALTH CARE REFORM 45, 47 (William R. Frey ed., 1995).

¹⁹⁵See Priest, *supra* note 194, at 1535 (citing *Greenman v. Yuba Power Products*, 377 P.2d 897 (Cal. 1963) as a landmark decision applying enterprise liability).

¹⁹⁶See Abraham & Weiler, *supra* note 189, at 383-84.

¹⁹⁷See FURROW, *supra* note 190, at 240-45.

¹⁹⁸See e.g., *Berel v. HCA Health Servs.*, 881 S.W.2d 21 (Tex. App. 1994) (controlling details of provider's practice decisions could create EL).

¹⁹⁹This is known as the "inherent function test." See FURROW, *supra* note 190, at 250-51 (citing *Beeck v. Tucson Gen. Hosp.*, 500 P.2d 1153 (Ariz. Ct. App. 1972) (finding hospital liable for x-ray equipment malfunction which injured patient, because hospital owned and maintained the equipment)).

²⁰⁰See e.g., *Petrovich v. Share Health Plan*, 719 N.E.2d 756, 775 (Ill. 1999) (finding HMO vicariously liable under apparent agency theory).

²⁰¹530 U.S. 211, 219 (2000).

²⁰²HMO, 730 N.E.2d 1119 (Ill. 2000).

²⁰³See *id.* at 1135.

govern whether an HMO or other insurance plan can be sued for negligence.²⁰⁴ Another means of finding an enterprise liable is under a negligence *per se* theory, where the institute violates a statute directly or by failing to establish and follow protocols required by statute. For example, in *Edwards v. Brandywine Hospital*,²⁰⁵ the court concluded that a violation of a Health Department standard could be *per se* negligence.²⁰⁶

Aside from state statutory preclusion of EL, another significant obstacle to plaintiffs is ERISA²⁰⁷ preemption, which allows certain health plans to avoid state law claims for decisions that “relate to” health care plan administration.²⁰⁸ Fortunately for some plaintiffs, and perhaps also for physicians who desire the risk-sharing of EL, some courts are excluding state law based tort claims from ERISA preemption. For example, the Tenth Circuit in *Pacificare of Oklahoma v. Burrage*²⁰⁹ held that a vicarious liability malpractice claim could be remanded to state court and was not preempted.²¹⁰ The Circuit Courts are divided with respect to state law tort claims and ERISA preemption.²¹¹ The Supreme Court did not directly address the state law claims issue from *Pacificare* and similar cases such as *Pegram v. Hedrich*.²¹² Thus, at least in some jurisdictions, health plans and other insurers face a

²⁰⁴This applies to direct or vicarious liability contexts. See e.g., CAL. HEALTH & SAFETY CODE § 1371.25 (Deering 2001) (allowing negligence actions against HMOs). But see N.J. STAT. ANN. § 26:2J-25 (West 1999) (prohibiting negligence claims against HMOs).

²⁰⁵652 A.2d 1382 (Pa. Super. Ct. 1995).

²⁰⁶See *id.* at 1386-87.

²⁰⁷The Employee Retirement Security Act of 1974, 29 U.S.C. § 1001 (2002). Note that hospital liability is generally not at issue in this context.

²⁰⁸ERISA, The Employee Retirement Security Act of 1974, 29 U.S.C. § 1001 (2002) *et seq.*, was intended by Congress to protect employees from health care plan abuses, but it has become a major weapon for health plans and insurers to limit their liability. See Larry J. Pittman, *ERISA's Preemption Clause and the Health Care Industry: An Abdication of Judicial Law-Creating Authority*, 46 FLA. L. REV. 355, 358-59 (1994). A detailed discussion of ERISA preemption is beyond the scope of this paper. Pittman's article provides an in-depth review of ERISA, and he points out how ERISA is being used to “thwart the development of the law” in the area of third party negligence. See *id.* at 356-59.

²⁰⁹59 F.3d 151 (10th Cir. 1995).

²¹⁰See *id.* at 153.

²¹¹*Pegram v. Hedrich*, 530 U.S. 211 (2000). The court describes the division among various District Courts on the issue. See *id.* at 153, *n.2*. See e.g., *Bauman v. U.S. Healthcare, Inc.*, 193 F.3d 151 (3d Cir. 1999) (allowing state court negligence action for prematurely discharging newborn from hospital). But see *McMahon v. Digital Equip. Corp.*, 162 F.3d 28, 38 (1st Cir. 1998) (finding negligence claim ERISA preempted); *Jass v. Prudential Health Care Plan*, 188 F.3d 1482, 1494 (7th Cir. 1996) (same). See generally Bryan A. Liang, *Patient Injury Incentives in Law*, 17 YALE L. & POL'Y REV. 1, 36-45 (1998) (discussing ERISA preemption and split among federal courts).

²¹²530 U.S. 211 (2000). The Court unanimously held that breach of fiduciary duty was not an ERISA-based cause of action. See *id.* at 214. In dictum, the Court did not foreclose the possibility of state law claims avoiding ERISA preemption, “[t]he eligibility decision and the treatment decision were inextricably mixed.” See *id.* at 229. The Court went on to state “[n]or have we reason to discuss the interaction of such a claim with state law causes of action.” See

lesser risk of state law tort liability, which allows them to avoid blame or shift it to the individual provider.²¹³ This risk avoidance tactic seems to lessen the incentive to reduce medical error through cooperative quality improvement efforts between plans and providers.

As noted earlier, the current tort system does not effectively or efficiently deter malpractice by individual providers.²¹⁴ If one accepts the premise that malpractice is causally related to the rate of medical errors, then reducing malpractice would reduce errors. To enhance the deterrence effect and efficiency of the tort system, it makes sense to extend the liability risk to the enterprises on the delivery side of health care.²¹⁵ Although moral and ethical considerations should prompt efforts to reduce negligence and the resultant errors which harm patients, economic motivation will create a more practical necessity for change.²¹⁶ Sharing liability with providers will force enterprises to foster an effective partnership with providers to reduce the costs of medical errors by improving healthcare quality at all levels.²¹⁷ Part of the enterprise's burden should ideally include informing patients with quality of care and error data, so that enterprises will face additional market pressure to improve care.²¹⁸

E. Alternatives to the Standard Negligence Approach

As noted in the preceding section, enterprise liability may encourage efforts to reduce medical errors by creating a shared risk-benefit between providers and hospitals and hospitals or insurers. Enterprise liability theory still operates under a standard negligence model, though, because it merely extends duty to the enterprise through a vicarious or direct mechanism. There are alternative liability theories which focus on other ways to reduce medical errors and their negative impacts or resultant liability risks. The theories this section discusses are: apology; no-fault; and strict liability.

id. at *n.*9. The Court may be asked to resolve the meaning of “inextricably mixed” in a future case. Does it mean a negligence claim must be preempted for any ERISA plan?

²¹³See Peter D. Jacobson & Scott D. Pomfret, *ERISA Litigation and Physician Autonomy*, 283 JAMA 921 (2000). The authors point out that ERISA-based plans cover 125 million Americans (citing Department of Labor estimates). See *id.* at 921.

²¹⁴See William M. Sage *et al.*, *Enterprise Liability for Medical Malpractice and Health Care Quality Improvement*, 20 AM. J.L. & MED. 1, 2-3 (1994).

²¹⁵See *id.* at 7.

²¹⁶See Stuart Speiser *et al.*, THE AMERICAN LAW OF TORTS §1:30 (1983).

²¹⁷See Sage, *supra* note 214, at 1-3.

²¹⁸See Priest, *supra* note 194, at 1537. “It is well accepted that the optimal level of accident prevention will be attained if incentives are created for both the provider and consumer to make additional safety investments up to the point at which the marginal costs of such investments equal their marginal benefits.” See *id.* But see Clark C. Havighurst, *Vicarious Liability: Relocating Responsibility for the Quality of Medical Care*, 26 AM. J.L. & MED. 7, 14-15 (2000). Havighurst suggests that “the market alone cannot provide appropriate incentives to maintain quality because consumers cannot, in most cases, reliably assess the value of the services they receive. The policy problem therefore, is to narrow the extent to which consumer ignorance allows providers to give less than optimal care. . .” See *id.*

It seems like an ethical no-brainer that physicians who err should inform the patient of this fact as soon as the doctor learns it, regardless of actual harm.²¹⁹ This is consistent with the highest form of professional ethics.²²⁰ However, there may be instances where error disclosure might harm the patient through adverse psychological effects.²²¹ If this is the learned and reasonable judgment of a physician, then it seems ethical to not disclose an error to certain patients.²²² Conversely, error disclosure could actually *increase* a patient's confidence in a provider.²²³ By admitting error, the physician exposes his own humanity, which a patient may not only empathize with but be reassured by, because they perceive their doctor as someone who is honest and will strive to protect the patient's interests.²²⁴ The default ethical position should be to disclose the error to the patient, unless it is clear that the patient will be harmed by the disclosure.²²⁵

Unfortunately, a doctor's decision to admit error and apologize for it is not, at least psychologically, just a straightforward ethical question. Doctors fear being sued if they admit errors.²²⁶ In some instances, there is actual patient harm from a medical error, and the doctor will settle a claim or lose in court, irrespective of whether the doctor admits any error. Most doctors probably agree that professional standards are maintained at higher levels by punishing certain negligent providers.

Are there situations where doctors can admit their errors without risking a lawsuit?²²⁷ Certainly, if a patient isn't harmed, then there may be no damages to

²¹⁹See Loeben, *supra* note 9, at 81 (stating "on one side are individuals who feel strongly that patients should be told."). In fact, it is conceivable that the primary doctor should honestly address errors made by nurses or other providers. *See id.* *See also* Vogel & Delgado, *supra* note 69, at 94 (concluding that physicians should have a *legal* duty to admit errors, "because the medical profession does not regulate itself effectively, discourages the reporting of malpractice to patients, and erects formal and informal barriers to patients' access to information.") (*emphasis added*).

²²⁰See Rosner *et al.*, *supra* note 153, at 2092 (concluding that "truth telling should not be the mark of the heroic physician but rather a distinguishing feature of all decent physicians.").

²²¹See Loeben, *supra* note 9, at 81.

²²²See *id.*

²²³See *id.* at 83 (stating "patients can understand and accept medical error much easier than they can understand and accept medical dishonesty.").

²²⁴See Steve S. Kramer & Ginny Hamm, *Risk Management: Extreme Honesty May be the Best Policy*, 131 ANNALS INTERNAL MED. 963 (1999) (citing study which showed 43 percent of families were motivated to sue in part because of a suspicion of a cover-up, betrayal of trust, or desire for revenge).

²²⁵See *id.* at 967.

²²⁶See Bates & Gawande, *supra* note 58, at 764-66. The authors point out that failure to admit error is ethically contradictory to physicians' "fierce ethic of individual responsibility." *See id.* at 764.

²²⁷See Cohen, *supra* note 72, at 1473-74. The Lexington VA Hospital experience has been positive in this respect, both economically and ethically. In addition, telling the truth may improve morale by allowing providers to do the "right thing." Besides morale boosting, apology may have positive effects on business goodwill and reputation. Cohen uses the

interest a plaintiff's attorney. However, the patient could fire the doctor, or somehow impugn the doctor's reputation, so the doctor may still have an economic incentive to remain silent. Perhaps, though, there is a human tendency to forgive that is being overlooked by doctors (or hospitals and insurers).²²⁸ It is doubtful that doctors are widely actually dishonest or are perceived as dishonest.²²⁹ Unfortunately, it is the medical culture itself which inhibits a more optimal level of honesty with respect to medical errors.²³⁰ Fortunately, medical leaders are realizing that admitting errors is one step toward fixing the overall problem, and is a better ethical approach.²³¹

Apology presents a cost-effective and ethical approach to medical errors in a context like a Veterans' Administration Hospital, partly because providers are insulated from individual liability.²³² In the private sector context, the applicability of apology may be limited to the enterprise's willingness to accept or share the liability risk with the individual provider.²³³ One approach that automatically imposes risk on the enterprise is a no-fault system of medical injury liability, which focuses on causation rather than duty.²³⁴ The proponents of various no-fault systems argue that such systems reduce administrative costs and improve compensation to injured patients.²³⁵ Florida already has a limited no-fault medical liability system,

example of Johnson & Johnson's behavior in response to the Tylenol poisoning scandal. *See id.* at 1474-76.

²²⁸But see Philip G. Peters, *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 196 (2000) (citing studies which show declining public confidence in medical practitioners).

²²⁹In my personal experience as a physician, patients seem quite willing to forgive mistakes, such as medication side effects, when I apologize to them and emphasize my willingness to continue to help them fix their problem. In another context, perhaps President Clinton could have avoided impeachment if he had been promptly honest and apologetic for his sexual indiscretions. In that context, though, unwillingness to be honest may reflect a more fundamental character trait, which is arguably selected by the political process.

²³⁰*See* Bates & Gawande, *supra* note 58, at 763; Leape *et al.*, *Preventing Medical Error*, *supra* note 51, at 1444.

²³¹*See* Leape *et al.*, *Preventing Medical Error*, *supra* note 52, at 1447.

²³²*See* Kraman & Hamm, *supra* note 224, at 965. VA providers do not pay malpractice premiums, and are not named individually in malpractice claims. They are reported to the National Practitioner Data Bank for actual malpractice payouts. *See id.* Malpractice insurers also contribute to physicians' reluctance to admit errors, but if the insurers realized a net savings from honest error admission, they would probably be more receptive to this approach. *See id.* at 965-67.

²³³*See id.*

²³⁴*See e.g.*, Abraham & Weiler, *supra* note 189, at 432-36 (promoting no-fault approach to medical malpractice); Randall R. Bovbjerg & Frank A. Sloan, *No-Fault for Medical Injury: Theory and Evidence*, 67 U. CIN. L. REV. 53, 99-120 (1998) (analyzing pros and cons of no-fault system); Paul C. Weiler, *supra* note 93, at 950 (1993) (favoring no-fault approach).

²³⁵*See e.g.*, Weiler, *supra* note 93, at 923-35 (discussing benefits of no-fault compensation to injured patients, and decreased administrative costs).

which applies to Workers' Compensation and brain-damaged newborns.²³⁶ Data indicates that administrative costs are lower and patients are compensated faster than in the traditional tort system, though overall costs are not lower.²³⁷

Strict liability has also been proposed as a method to reform the current malpractice system.²³⁸ Strict liability theory is a policy based cost-shifting mechanism which is applied to promote public safety through injury prevention.²³⁹ Strict liability has yet to be applied to medical services, but is applicable to certain medical devices under products liability laws.²⁴⁰ For example, in *Porter v. Rosenberg*,²⁴¹ Florida's Fourth District Court of Appeals acknowledged that strict liability applied to silicone breast implant manufacturers and distributors.²⁴² However, the surgeon in the case was not strictly liable for selecting and using the implant.²⁴³ The *Porter* court left open the possibility of strict liability for a service provider where the "essence of the transaction" between the patient and the provider was akin to a business-customer relationship.²⁴⁴

V. CAPITALISM

A. *The Entitlement Mentality*

This discussion of the causes and potential solutions to medical errors is incomplete without at least a brief analysis of the roles of patients as consumers, and the economic forces which have fostered and perpetuated the current healthcare market in the United States.²⁴⁵ As discussed in section II.C of this article, healthcare

²³⁶See Bovbjerg & Sloan, *supra* note 234, at 82-83 (citing FLA. STAT. §§ 766.305, 766.315, and describing a similar approach in Virginia).

²³⁷*See id.*

²³⁸See Barry Furrow, *Defective Medical Treatment: A Proposal For the Application of Strict Liability to Psychiatric Services*, 58 B.U. L. REV. 392, 434 (concluding strict liability should apply to "defective medical treatment" in a manner similar to products liability).

²³⁹*See id.* at 410-411.

²⁴⁰See FURROW, *supra* note 190, at 265-70. The RESTATEMENT (SECOND) OF TORTS § 402A (1965), provided the traditional rule of products liability. See DAVID W. ROBERTSON ET AL., CASES AND MATERIALS ON TORTS 558 (1998). There is now a RESTATEMENT (THIRD) OF TORTS (1997) devoted specifically to products liability. *See id.*

²⁴¹650 So.2d 79 (Fla. Dist. Ct. App. 1995).

²⁴²*See id.* at 81.

²⁴³*See id.* at 83. *See also* Tanuz v. Culberg, 921 P.2d 309, 316 (N.M. Ct. App. 1996) (concluding that public policy precluded strict liability against physician using jaw joint implants).

²⁴⁴*See Porter*, 650 So.2d at 83.

²⁴⁵A detailed discussion of either is beyond the scope of this article. *See generally* Weiler, *supra* note 93, at 950 (favoring no-fault); Bovbjerg & Sloan, *supra* note 234, at 99-120 (discussing pros and cons); Mark F. Grady, *Why Are People Negligent? Technology, Nondurable Precautions, and the Medical Malpractice Explosion*, 82 NW. L. REV. 293, 306-310 (1988) (discussing strict liability, effects of technology, and transaction costs).

delivery ultimately occurs at the individual patient level.²⁴⁶ Patients' perceptions, and their willingness or ability to pay for their own medical care influence the rate of medical errors.²⁴⁷ The law operates in this context to support, propagate, or even expand error rates.

At this point in our nation's history, universal healthcare is not a fundamental right.²⁴⁸ The U.S. Supreme Court has acknowledged a right to healthcare under the Eighth Amendment for prison inmates,²⁴⁹ and under the Fourteenth Amendment for confined mental patients,²⁵⁰ due to these groups' "special relationship" with the government. In other cases, the U.S. Supreme Court has expressly refused to grant healthcare the status of a fundamental right. In *Harris v. McRae*, the Court rejected a right to state funded abortions.²⁵¹ In *Youngberg v. Romeo*,²⁵² the Court stated that it was an "established principal" that "[a]s a general matter, a State is under no constitutional duty to provide substantive services within its border."²⁵³ The *Youngberg* Court did find a due process right to minimally adequate training to ensure safety and freedom from undue restraint for a severely retarded patient who was involuntarily committed.²⁵⁴ Thus, the U.S. Supreme Court has refused to grant constitutional right status to healthcare for the general population, suggesting a proper deference to the political process and legislature.

In every state, though, there already exists broad access to medical care through Medicaid²⁵⁵ and Medicare²⁵⁶ programs. Medicaid, a federally assisted state program, provides coverage to needy children and adults. Medicare, also federally funded, provides coverage for the disabled and for persons over age sixty-five. Thus, even though there is not an absolute *right* to healthcare, benefit programs already exist for those patients willing to declare and substantiate their need for assistance.

Patients not covered by Medicaid or Medicare rely upon employer provided insurance benefits, or must purchase their own coverage out-of-pocket. This still

²⁴⁶See *supra* notes 234-44 and accompanying text.

²⁴⁷See *supra* note 246.

²⁴⁸See e.g., Van M. Halley, *The Right to Health Care: Key Policy Issue or Useless Concept*, KAN. J.L. & PUB. POL'Y. 101, 120 (1993) (stating that absent a "special relationship" between the state and a patient, healthcare is not a constitutional right).

²⁴⁹See *Estelle v. Gamble*, 429 U.S. 97, 103-104 (1976) (stating it would be "cruel and unusual punishment" to deny prisoners adequate healthcare).

²⁵⁰See 457 U.S. 307, 324-25 (1982).

²⁵¹448 U.S. 297, 317-18 (1980).

²⁵²*Youngberg*, 457 U.S. at 320.

²⁵³See *id.* at 324-25.

²⁵⁴See *id.*

²⁵⁵42 U.S.C.S. § 1396 (2000) *et seq.* Established in 1965, Medicaid provides, "(1) medical assistance on behalf of families with dependent children. . . whose income and resources are insufficient to meet the costs of necessary services," and "(2) rehabilitation and other services to help such families attain or retain capability for independence or self care. . ."

²⁵⁶42 U.S.C.S. § 426 (2000) *et seq.* Also established in 1965, Medicare provides for healthcare for individuals over age 65, and disabled individuals. See *id.* at §§ 426(a)-(b).

leaves as many as forty-four million Americans without health insurance.²⁵⁷ Proponents of universal health insurance emphasize these uncovered millions when such plans are debated.²⁵⁸ What such proposals ignore, though, is the dynamic nature of this uninsured group. Most are young and between jobs, and many have simply chosen to not purchase insurance.²⁵⁹ Many of those between jobs could have elected to continue employer-sponsored coverage under the Consolidated Omnibus Budget Act of 1985 (COBRA) for at least eighteen months.²⁶⁰ In contrast, less than one percent of the elderly are without insurance.²⁶¹ Therefore, those who need insurance the most, the poor, disabled, and elderly, already have access to it through existing programs. It may be that younger people without insurance have simply accepted a certain risk in exchange for saving money not spent on insurance.

Even if universal healthcare attained legal right status, there would remain the fact that medical services must be paid for. This is where the entitlement mentality rears its ugly head, because too many patients insist upon a scope of services which they are unable or unwilling to pay for. Patients are too often not aware of the true costs of coverage and services, creating what one commentator describes as a “moral hazard.”²⁶² Instead of using health insurance for the usual insurance function as protection against unpredictable loss, people tend to “over-insure” themselves for healthcare.²⁶³ They do so in large part because the law promotes employer and government sponsored insurance.²⁶⁴ Patients are thereby encouraged to assume that their care is or should be paid for by their employers or the government.²⁶⁵

The economic reality, which such a mindset ignores, is that *neither* the government nor employers actually pay for healthcare. The government creates no wealth, it can only confiscate and redistribute it through what Frederic Bastiat

²⁵⁷See www.hhs.gov, the Department of Health and Human Services (HHS) website, testimony of Claude Earl Fox, M.D., Administrator of the Health Resources and Services Administration, before the Senate Committee on Health, Education, Labor, and Pensions, Subcommittee on Public Health, March 23, 2000. Website accessed Oct. 13, 2000. See also Geri Aston, *Uninsured Numbers Down; Struggle Goes On*, 43 AMER. MED. NEWS, Oct. 16, 2000, at 5 (citing U.S. Census Bureau figures which show 42.6 million uninsured Americans in 1999, down 1.7 million from 1998).

²⁵⁸See e.g., James E. Dalen, *Health Care in America: The Good, the Bad, and the Ugly*, 160 ARCH. INT. MED. 2573, 2575 (2000) (citing figure of 43 million uninsured Americans, and advocating employer mandated health insurance); Frank Davidoff, *The 28th Amendment*, 130 ANN. INT. MED. 692-94 (1999) (suggesting constitutional amendment to provide universal health insurance).

²⁵⁹See *supra* note 257, HHS website data (describing uninsured as commonly between ages 21 and 24, and workers who experienced “some unemployment”).

²⁶⁰29 U.S.C.S. §§ 1161, 1162(2) (2000).

²⁶¹See *supra* note 257.

²⁶²See Clark C. Havighurst, *American Health Care and the Law-We Need to Talk!*, 19 HEALTH AFFAIRS 84, 86-88 (2000).

²⁶³See *id.* at 88.

²⁶⁴See *id.* at 87-88.

²⁶⁵See *id.*

accurately labeled as “legal plunder.”²⁶⁶ The government does not pay for anything, the productive citizens do. Employers also do not pay for healthcare, because the costs are passed on to consumers through higher prices, and to employees through wages adjusted for the expense of insurance. Therefore, what those who claim is an entitlement to healthcare are really demanding is the property of their fellow citizens, and they must rely on the coercive power of the government to take it for them.²⁶⁷

Perhaps before patients insist upon an entitlement to the fruits of their fellow citizens’ labor, they should pause to consider the consequences of such a mentality. For example, a prominent feature of the 2000 presidential campaign was each candidate’s prescription drug plan for Medicare patients.²⁶⁸ The premises of such plans were flawed in at least two major ways. First, the vast majority of Medicare patients are over age sixty-five, a segment of the population which is wealthier on average than the younger people who will pay the lion’s share of the cost. Second, these proposals for prescription drugs create a disincentive for younger people to save for their retirement needs.²⁶⁹ Plans like these only reinforce the entitlement mentality by passing along costs to those who bear the burden of paying for others’ healthcare.²⁷⁰ Do the Medicare beneficiaries of such plans properly view their desire for prescription drugs as a burden on their children and neighbors?

The impact of the entitlement mentality on medical errors should be self-evident. At some point, freedom of choice is restricted by the strings attached to entitlement programs. For example, only certain doctors or hospitals will accept Medicare or Medicaid. The patient is thus less able to effectively provide the economic incentives to reduce medical error by seeking care from competing providers. Thus, shielding selected providers from full-fledged market competition reduces the threat that patients will shop elsewhere for a lower error-rate doctor or hospital. Without such an economic threat, providers have less incentive to improve quality through reduced error rates.

B. Contractual Freedom

Suppose the federal government, responding to “the high price of automobiles,” enacted legislation to provide universal automobile purchasing insurance. An insurance policy, provided by the government or the employer, allows each citizen to purchase a car from a participating auto maker. Each insured person purchases the car he or she wants, as long as the purchase is pre-approved.²⁷¹ This creates an

²⁶⁶See FREDERIC BASTIAT, *THE LAW* 10-13 (Dean Russell trans., Foundation for Economic Education, Inc., 1997) (1850).

²⁶⁷See *id.*

²⁶⁸See Michael Fumento, *Bribing the Elderly: Bush and Gore Push Free Drugs In Bid for Key Votes*, INVESTOR’S BUS. DAILY, Oct. 6, 2000, at A24.

²⁶⁹See *id.*

²⁷⁰See Robert J. Samuelson, *It’s More Than a Drug Problem*, NEWSWEEK, Sept. 25, 2000, at 37.

²⁷¹Analogous to the prospective payment system for healthcare. See generally, Abraham & Weiler, *supra* note 189, at 393-96 (describing prospective payment system). This analogy is perhaps tenuous with respect to emergency medical care, because people do not have the

incentive for each person to use the insurance and purchase the most expensive car allowed by the policy, regardless of need or ability to pay.²⁷² At some point, the program becomes too costly, and a limit is placed on car prices. It is illegal for the seller to exceed the price limits, or to allow any covered person to pay the seller directly for amounts that exceed coverage limits.²⁷³ Participating car sellers would then attempt to maximize profit by reducing production costs, motivated to improve quality only to the extent of the buyers' ability to choose between participating sellers.

It is hard to imagine Americans accepting such restrictions on their choice of what car they can buy, yet such a system already exists to limit individual choice for healthcare, arguably a more personal choice than choosing a car.²⁷⁴ The providers of healthcare, primarily doctors and hospitals, though private insurers may also be included here, are similarly restricted in their choices of what care to provide.²⁷⁵ Contractual freedom to choose either the care received or the care provided is restricted.²⁷⁶ If freedom to choose is restricted by non-market forces, then incentives to improve quality are reduced to the extent competition is discouraged. This translates into a suboptimal climate for medical error detection, admission, and reduction.²⁷⁷ Therefore, both patients and providers must have greater contractual freedom if market efficiencies are to affect medical error reduction.²⁷⁸

One example on the provider side of healthcare contracts is "without cause" termination clauses. Professor Liang calls for an end to these clauses in provider

same emergency need to purchase a car. However, the point is, that some thought must be given to healthcare ahead of time, because nearly everyone will eventually need medical care.

²⁷²See Havighurst, *supra* note 262, at 99 (describing healthcare costs, stating ". . .consumers do not regularly or systematically compare benefits to cost. . .").

²⁷³See *id.* at 89. "The rising costs of the public programs led eventually to regulation-like reforms. . ." of medical care. See *id.*

²⁷⁴See *id.* With respect to medicine, Havighurst states that, "Congress could not have foreseen how the infusion of so much money into the health care system, coupled with the moral hazard that accompanies any form of third-party payment, would forever alter not just the economics but also the culture of medical care." I disagree that this was not foreseeable. The effects of government financing and regulation are foreseeable when economic motivation is considered in terms of dynamic rather than static terms. I doubt that Congress *couldn't* have foreseen this. Medicare is properly viewed as a political strategy to influence voters, rather than a sound economic program.

²⁷⁵See *id.* at 89-92.

²⁷⁶See *id.* at 96. "Not only are many important aspects of health care transactions prescribed by explicit regulation, but today's health care contracts do not even attempt to specify in customized terms the desired character, quantity, and quality of the services that customers purchase." See *id.* Havighurst, *supra* note 262 at 96.

²⁷⁷See Liang, *Promoting Patient Safety*, *supra* note 7, at 565, (describing need to end "without cause" termination clauses in provider contracts in order to encourage provider participation in error reporting).

²⁷⁸See *id.* (discussing provider choice); Havighurst, *supra* note 262, at 97 (discussing consumer choice).

contracts with HMOs and other managed care entities.²⁷⁹ This will encourage physicians to report errors without fear of backlash.²⁸⁰ Unfortunately, Professor Liang's remedy is federal legislation, thus further entangling the government in our healthcare system.²⁸¹ This is like Socrates asking for more hemlock. Physicians should admit they are in their current situation precisely because they have lobbied for federal involvement in healthcare, and they helped get Medicare and Medicaid passed in the first place.²⁸² Now physicians lament the fact that the market has reacted to restrict their contractual freedom.²⁸³ A sounder approach by physicians to obtain contractual freedom is to reject these contracts up front, or argue in court that they should not be enforced for policy reasons.²⁸⁴ Otherwise the medical community is further abdicating its position as a market player to the federal government. The result can only be increased dependency on government for subsequent solutions.²⁸⁵

On the patient side of healthcare contracts, contractual freedom needs to be enhanced as well.²⁸⁶ As with physicians, though, patients are also to blame for the

²⁷⁹See Liang, *Promoting Patient Safety*, *supra* note 8, at 564.

²⁸⁰See *id.*

²⁸¹See *id.* Unsurprisingly, lawmakers have politicized the medical errors problem. See e.g., Chad Bowman, *Medical Errors Proposals Proliferate As Lawmakers Seek Reporting Systems*, 68 U.S. LAW WEEKLY 2643-44 (2000) (describing various legislative proposals by Republicans and Democrats in the House and Senate to require or promote medical errors reporting, such as the Medical Error Reduction Act, sponsored by Arlen Specter, (R-PA) and Tom Harkin (D-IA)). But see Michael Pretzer, *Congress Backs Away From Mandatory Medical Errors Reporting*, 77 MED. ECON. 25, 25-26 (2000) (describing successful lobbying efforts by physician and managed care organizations who opposed mandatory reporting).

²⁸²See PAUL J. FELDSTEIN, *THE POLITICS OF HEALTH LEGISLATION: AN ECONOMIC PERSPECTIVE*, 204-5, 243-45 (1988) (explaining how "economic self-interest" was used by physicians to affect legislation which benefited physicians).

²⁸³See Liang, *supra* note 8, at 564.

²⁸⁴The antitrust implications here are worth fighting on ethical grounds, but cannot be easily disregarded. See e.g., *American Medical Ass'n. v. United States*, 317 U.S. 519, 534-36 (1943) (finding Sherman Act violations and restraint of trade by medical organizations). Medical leaders should use the literature to voice how this process could occur in a non-collusive and ethical manner. The recent case of *Harper v. Healthsource of New Hampshire, Inc.*, 674 A.2d 962 (N.H. 1996), should provide some reassurance that courts are willing to view without cause termination clauses as counter to public policy. That is the decision of the *Harper* court, even in the absence of federal legislation. See *id.* The California Supreme Court also found a without cause contract termination clause invalid in *Potvin v. Metropolitan Life Insurance Co.*, 997 P.2d 1153, 1167-68 (Cal. 2000). The *Potvin* court found that the contract unfairly restricted the doctor's common law right to fair procedure, and impaired the doctor's ability to practice in a particular geographic area, because the insurer had such a large market share. See *id.* at 1167-68. The medical community should pursue the without cause contractual issue at the state rather than the federal level.

²⁸⁵Cf. Roger Pilon, *Freedom, Responsibility, and the Constitution: On Recovering Our Founding Principles*, 68 NOTRE DAME L. REV. 507, 546 (1993) (arguing that the law has evolved away from founding principles, and concluding, "the time has come to recover these principles and to take responsibility for our lives. . . for nothing less will free us as a people.").

²⁸⁶See Havighurst, *supra* note 262, at 97.

current restrictions on their choices.²⁸⁷ Clearly, not all patients have voted to involve the federal government in financing healthcare.²⁸⁸ However, the political process continues to operate under the premise that one group of voters, particularly the elderly with respect to healthcare, can organize to redistribute the wealth of other citizens to pay for the elders' healthcare.²⁸⁹ Politicians fall in line because their main goal is re-election.²⁹⁰ While it is true that this disparity cannot progress indefinitely,²⁹¹ the concept of medicine and other entitlement programs must be addressed realistically.²⁹² Either patients must accept greater responsibility for their family's healthcare, or they must accept choice limitations along with the money redistributed from others.²⁹³ The causal chain of events for the latter is less choice, less competition, and less pressure to improve quality and reduce medical errors.

It should be clear that neither providers nor patients can have their cake and eat it too, when the assertion is made that medical error reduction will be enhanced by contractual freedom. Doctors, patients, and politicians will continue to be motivated by their own self-interest.²⁹⁴ In general it is just such self-interest which enhances market efficiency.²⁹⁵ However, the redistribution mentality of healthcare thwarts this efficiency, because too few people are actually aware of what their own healthcare costs.²⁹⁶ Thus, there is less bargaining in the traditional contract sense.²⁹⁷ Both sides of the bargain need to acknowledge that by asking the government to get involved in healthcare financing, they have relinquished their bargaining power.²⁹⁸ Unless the provider-patient transaction occurs in a more arms-length fashion, without the

²⁸⁷See FELDSTEIN, *supra* note 282, at 242-45.

²⁸⁸Enough voters obviously did convince their representatives. *See id.* at 242-44. Feldstein describes this as the "Self-Interest Paradigm," where "individuals act according to self-interest, not necessarily the public interest," and "organized groups seek to achieve through legislation what they cannot achieve through the marketplace." *See id.* at 3.

²⁸⁹As Feldstein succinctly stated, "Legislation is a means of transferring wealth to those with political power from those without." *See id.* at 181.

²⁹⁰*See id.* at 3.

²⁹¹*See* FELDSTEIN, *supra* note 282, at 248-49 (describing a "self correcting element" to redistribution inequities). *See also id.* at 182 (criticizing Medicare as "designed to be both inequitable and inefficient.").

²⁹²*See* Havighurst, *supra* note 262, at 97.

²⁹³*See id.*

²⁹⁴*See* FELDSTEIN, *supra* note 282, at 3.

²⁹⁵*See* ADAM SMITH, THE WEALTH OF NATIONS, book IV, ch. II, at 421 (1776). "Every individual . . . generally, indeed neither intends to promote the public interest, nor knows how much he is promoting it . . . he intends only his own security." *See id.*, obtained Oct. 14, 2000, at the Adam Smith Institute website www.adamsmith.org.uk/policy/wisdom.

²⁹⁶*See* Havighurst, *supra* note 262, at 97.

²⁹⁷*See e.g.*, OLIVER WENDELL HOLMES, THE COMMON LAW 230 (Mark DeWolfe Howe ed., 1963) (stating . . . "it is the essence of a consideration, that, by terms of the agreement, it is given and accepted as the motive or inducement of the promise.") (1881).

²⁹⁸*See* Havighurst, *supra* note 262, at 97.

government middleman, contractual freedom, and thus its ability to lower medical error rates, will continue to be limited.²⁹⁹

C. *Economic Rationale*

Just as a systems approach should be taken with respect to the detection, analysis, and reduction of medical errors, a fundamental reassessment of the healthcare financing system is urgently needed.³⁰⁰ The market efficiencies of capitalism should be embraced, rather than restricted, by policy makers. Legislators, patients, providers, and even lawyers must acknowledge resource limitations, rather than make unsustainable promises through programs which pass costs along to taxpayers and succeeding generations.³⁰¹ Sooner, rather than later, the notion that “you get what you pay for” must be emphasized. If the system continues to tell patients that they get what *others* pay for, it will collapse of its own weight, because those who are actually paying will lose the incentive to be productive.

As noted earlier, healthcare is not a fundamental right, but most Americans have health insurance through their job or a government program.³⁰² Others elect to pay out-of-pocket for insurance or direct costs. Still others freely elect to forgo care or insurance. The minority of Americans left wanting for care or insurance will benefit from market solutions. For example, self-employed individuals and small businesses can form risk pool alliances which allow them to negotiate better insurance rates.³⁰³ Florida created just such a program in the Florida Health Care and Insurance Reform Act of 1993, which established community based health purchasing alliances.³⁰⁴ Another approach is to reconsider the purpose of health insurance, which is to prevent unpredictable costs.³⁰⁵ Many people can probably afford to trade-off between a higher deductible in exchange for lower premiums, as is done for home or auto insurance. Paying directly for certain small incidental costs would encourage true consumerism, while catastrophic losses would be avoided.

People should not be forced to buy what they don't want or need, yet that is exactly what is happening with many current policies through a one size fits all

²⁹⁹*See id.*

³⁰⁰*See e.g., Daniel J. Murphy, Medicare In Urgent Need of Reform as Population Ages, Costs Skyrocket, INVESTOR'S BUS. DAILY, Oct 23, 2000, at A26 (describing accelerating medical costs, especially those related to Medicare, which consumed \$213.6 billion, or 13.3 percent, of the federal budget in 1998. The high costs prompt the government to cut doctor reimbursements, which doctors respond to by cutting back on care).*

³⁰¹*See e.g., Editorial, Medicare: Gore's Hollow Attacks, INVESTOR'S BUS. DAILY, Oct. 2, 2000, at A24 (describing Medicare funding as needing to double by 2030, which does not even reflect planned prescription drug benefits. Also mentioned is the fact that the two-thirds of the elderly already have private drug insurance coverage, and that “the U.S. cohort with the highest median net worth - \$146,500 - is the 65 to 74-year old group”).*

³⁰²*See supra* notes 257-58.

³⁰³*See Mark A. Hall, The Role of Insurance Purchasing Cooperatives in Health Care Reform, 3 KAN. J.L. & PUB. POL'Y. 95, 98-99 (1993).*

³⁰⁴FLA. STAT. ANN. § 408.702(1) (1999).

³⁰⁵*See Havighurst, supra* note 262, at 88.

approach.³⁰⁶ Why should a fifty year old man have the same plan as a twenty-five year old woman? Employer sponsored plans could offer a greater menu of choices for a better custom fit for each employee. This allows employees flexibility to pay only for what they need or want. What the employee “saves” in benefits could thereby be realized as increased wages. Ideally, the tax code would equalize treatment for this variety of individual expenses, but a discussion of how this could be done is beyond the scope of this article.

The free market, and not the government, is the most efficient solution to increase access to healthcare, control costs, and improve quality through error reduction. A free market “gives people what they want instead of what a particular group thinks they ought to want.”³⁰⁷ As a critical corollary to this notion, the free market promotes individual responsibility by emphasizing that consumers get what they actually pay for. Government and the law play an important role in adjusting to and promoting competition, by enforcing contracts, and preventing fraud and deception.³⁰⁸ This creates an awareness by consumers, who in turn vote with their wallets when the market fails to meet their needs. In the recent case of *Pegram v. Herdrich*,³⁰⁹ the Supreme Court acknowledged that cost-control measures are necessary, and are influenced by market forces and negligence risks. Socialized medicine, on the other hand, will reduce market incentives to lower medical error rates, because consumer choice will be restricted. The economic incentives to produce a safer product will be blunted by reduced consumer choice and cost awareness.

Healthcare should remain a service, and not a right. Businesses who provide the service of healthcare, whether for profit or not, must still attend to the bottom line. That bottom line requires them to control costs while still offering a product that consumers demand. A business must face the threat that a competitor will create a more desirable product, either because it's cheaper, safer, or better in other ways. What the market will bear requires constant vigilance and adaptation by the business that wishes to remain viable. If what consumers ultimately desire is safer healthcare, then politicians, lawyers, insurers, and providers should honor that choice as promoting the essence of our liberties. Medical error rates will then fall as a necessary predicate for providers' market survival. The magic of capitalism's “invisible hand” will always create a niche for the able entrepreneur.³¹⁰

³⁰⁶See Havighurst, *supra* note 262, at 87-89.

³⁰⁷See MILTON FRIEDMAN, CAPITALISM AND FREEDOM 15 (1962).

³⁰⁸See F. A. HAYEK, THE ROAD TO SERFDOM 102 (1944).

³⁰⁹*Pegram*, 530 U.S. 211 (2000).

³¹⁰See ADAM SMITH, *supra* note 295, at 421, (describing how individuals intend only their own security when they interact with producers, but the result is an overall promotion of the public interest. “. . .and by directing that industry in such a manner as its produce may be of the greatest value, [the individual] intends only his own gain, and he is in this, as in many other cases, led by an *invisible hand* to promote an end which was never his intention.” (*emphasis added*)).