THE MEDICAL MALPRACTICE EPIDEMIC

> **epidemic** /épidémik/ *n. & adj.* ● *n.* **1** a widespread occurrence of a disease in a community at a particular time. **2** such a disease. **3** (foll. by *of*) a wide prevalence of something usu. undesirable. ● *adj.* in the nature of an epidemic (cf. ENDEMIC). □□ **epidemically** adv. [F *épidémique* f. *épidémie* f. LL *epdiemia* f Gk *epidēmia* prevalence of disease f. *epidēmios* (adj.) (as EPI-, dēmos the people)]
>
> ■ *n.* **1, 2** plague, pestilence, disease; outbreak, spread; scourge. 3 see *prevalence* (PREVALENT). ● *adj.* widespread, common, pandemic, rampant, rife, flourishing, mushrooming, nationwide, worldwide, international, universal, ubiquitous, general, prevalent; prevailing.
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> *Oxford American Dictionary and Thesaurus.* 2003. Oxford University Press. New York, NY.

I. INTRODUCTION

For over 40 years, study after study has confirmed the existence of a medical malpractice epidemic in the United States. Current research demonstrates that just under 200,000 people die every year in hospitals as result of medical mistakes.[1] It is roughly equivalent to two jumbo jets full of passengers colliding in midair each day of the year.[2] In the last four years, approximately twenty percent more people have died in hospitals from medical errors than the total of all U.S. battle deaths from all wars in the history of the United States[3]

The total national economic cost, including lost income, lost household production, disability and healthcare costs for these preventable adverse events approaches, if not, exceeds $60 billion per year.[4] Not included in this figure are the costs for pain, suffering, disfigurement or loss of enjoyment of life. And it does not in anyway account for the patients who survive the mistakes made. Rather than address the problem, politicians have spent hundreds of millions of dollars to misdirect analysis of the epidemic. Nonetheless, the epidemic continues. The topic is particularly relevant because recent legislative reforms do nothing to cure the epidemic. They do not even address it. The concept that limiting a patient's right to sue or that denying full recovery to those most injured will somehow reduce the number of errors that kill and injure patients does not comport with logic or history. Indeed logic and history show the opposite.[5]

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[1] *HealthGrades, Patient Safety In American Hospitals* 1 (July 2004), available at http://www.Healthgrades.com (last visited February 2, 2006); *see also*, *Health: Study: Hospital errors cause 195,000 deaths*. July 28, 2004, available at http://cnn.com.2004/HEALTH/07/28/health.mistakes.reut/index.html; *see also, HealthGrades, HealthGrades Quality Study: Third Annual Patient Safety in American Hospitals Study* (April 2006). *See also,* Healthgrades, Healthgrades Quality Study; Fourth Annual Patient Safety in American Hospitals Study (April 2007).

[2] Kohn, Linda T., *et al, To Err is Human: Building a Safer Health System* Washington D.C.: National Academy Press, 2000 at 1 *citing* Centers for Disease Control and Prevention (National Center for Health Statistics). "Births and Deaths: Preliminary Data for 1998." NATIONAL VITAL STATISTICS REPORTS. 47 (1999): 27. *See also*, Andrews, Lori B., *et al*, "An alternative strategy for studying adverse events in medical care." 349 THE LANCET 309-313 (1997); Chaundry, Sarwat I., M.D., *et al,* "Detection of Errors by Attending Physicians on a General Medicine Service' 18 J GEN INTERN MED 595-600 (2003), Schimmel, Elihu M., M.D., "The Hazards of Hospitalization" 60, No. 1 ANNALS OF INTERNAL MEDICINE 100-110 (1964).

[3] American Revolution (4,435); War of 1812 (2,260); Indian Wars (1,000); Mexican War (1,733); Civil War (214,938); Spanish-American War (385); World War I (53,402); World War II (291,557); Korean War (33,741); Viet Nam War (47,410); Gulf War (147); Iraq (2,543 as of February 19, 2007) equals 653,651. *See,* http://www.infoplease.com/ipa/a0004615.html and http://www.antiwar.com/casualties/index.php (last visited February 19, 2007). 195,000 x 4 = 780,000. 780,000 – 653,651 = 126,349. 126,349 ÷ 653,651 = 19.3%.

[4] *Supra* notes 2 and 3.

[5] *The Great Medical Malpractice Hoax:*
NPDB Data Continue To Show Medical Liability System Produce Rational Ooutcomes, Public Citizen, Congress Watch (January 2007)

II. CALIFORNIA MEDICAL INSURANCE FEASIBILITY STUDY

The Medical Insurance Feasibility Study, one of the first large hospital records' studies looking at hospital errors, was done in the 1970's[6]. The study was sponsored by the California Hospital Association and the California Medical Association in an effort to support their tort reform efforts. At the time, California was in the midst of a perceived medical malpractice insurance crisis. The idea behind the study was to test the feasibility of going to a no-fault system of compensation for injuries and death as a result of medical malpractice. The expectation was that the frequency and severity of malpractice would be shown to be a minor problem. They further expected to be able to show that the cost of a no-fault system would be substantially less than the premiums the doctors and hospitals were paying for medical malpractice insurance.[7]

The study revealed quite the opposite and the results were striking. The Medical Insurance Feasibility Study found that doctors and hospitals injured one out of every twenty hospitalized patients. Of those, one out of ten patients died from the injury. Extrapolated, that meant that in California in 1974 some 140,000 patients were injured, 14,000 of whom died as a result. The study also concluded that one out of every six of the medical injuries, over 23,000 cases, was the result of malpractice. The authors found that there was a positive correlation between the severity of the injury and malpractice. Four-fifths of the most seriously injured patients were injured by medical malpractice.[8]

The California Hospital Association and California Medical Association correctly concluded that a no-fault system was not the way to lower their malpractice insurance premiums. They shelved the study and moved their legislative initiatives in a different direction.[9] In 1975 the California legislature passed the Medical Injury Compensation Reform Act ("MICRA"). MICRA capped non-economic damages for pain and suffering at $250,000. There is no evidence to suggest that MICRA did anything to decrease the frequency or severity of medical injuries or medical malpractice in the state of California. Nor did it decrease the medical malpractice premiums for doctors and hospitals. Indeed, over the next 13 years the premiums continued to increase until California voters took matters into their own hands and passed Proposition 103, which changed the state's insurance laws. The insurance reform froze premiums, forced insurance companies to open their books and justify future increases. California voters got the right to elect their state insurance commissioner. After Proposition 103 passed, medical malpractice premiums began to decrease and stabilize.[10]

III. THE HARVARD MEDICAL PRACTICE STUDY

The next major study based upon hospital records of medical injuries caused by medical malpractice was the Harvard Medical Practice Study.[11] This study was conducted in the mid-80's during another medical malpractice insurance crisis. The Harvard Medical Practice Study was commissioned by the state of New York to evaluate

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[6] Mills, Don Harper, M.D., J.D.. "Medical Insurance Feasibility Study," 128 WEST J MED 360-365 (1978).

[7] Baker, Tom. *The Malpractice Myth*, Chicago: University of Chicago Press, 2005 at 25-27, *see generally*, Medical Insurance Feasibility Study, *supra* note 5.

[8] *Id*.

[9] *Id*.

[10] In fact, after the MICRA caps and until Proposition 103, thirteen years later, malpractice insurance premiums for California doctors increased by 450%. "Insurance reform required medical malpractice insurers to directly refund more that $135 million to policy holders." *See, How Insurance Reform Lowered Doctors' Medical Malpractice Rates in California and How Malpractice Caps failed* (2003) available at http://www.consumerwatchdog.org/mal-practice/rp/ 1008.pdf (last visited February 6, 2006).

[11] Harvard Medical Practice Study. *Patients, doctors, and lawyers: Medical Injury, Malpractice Litigation and Patient Compensation in New York: The report of the Harvard Medical Practice Study to The State of New York.* Cambridge: Harvard University, 1990.

medical injuries and also methods of compensating injured patients. The results of the study were published in three parts in the *New England Journal of Medicine* under special article status.[12]

The methodology of the Harvard Medical Practice Study is impressive. The Harvard researchers used a two-stage sampling process to create a weighted sample of 31,000 randomly selected records of hospitalized patients from a population of 2,671,863 non-psychiatric patients discharged from non-federal acute care hospitals in 1984. Each medical record was initially screened by two people, trained nurses or medical records administrators, using eighteen screening criteria. If the screeners agreed that a record met any of the criteria, then it was reviewed independently by two physicians, almost all of whom were board certified internists or surgeons. The physicians identified adverse events. The reviewers were asked to describe each adverse event and its relation to the medical care. They estimated the degree of disability that resulted. The reviewers were also asked to indicate whether each adverse event had been caused by a reasonably avoidable error. If yes, they classified the error and then indicated the specific type of error within the class. Finally, the physician reviewers were asked to determine if there was negligence.[13]

Part One of the Harvard Medical Practice Study "estimated the incidence of adverse events, defined as injuries caused by medical management, and the sub-group of such injuries that resulted from negligent or substandard care."[14] The results showed that adverse events occurred in 3.7 percent of the hospitalizations. 27.6 percent of the adverse events were due to negligence. The researchers found that 70.5 percent of the adverse events gave rise to a disability lasting less than six months. 2.6 percent caused permanent disability, 13.6 percent caused death. Like the California Medical Insurance Feasibility Study, the study also established that the percentage of adverse events attributable to negligence increased as the severity of the injury increased. The Harvard study concluded that of 2,671,863 patients, there were 98,609 adverse events, of which 27,179 involved negligence.[15]

Part Two of the Harvard Medical Practice Study analyzed the adverse events and their relation to error, negligence and disability. The authors found that drug complications were the most common type of adverse event (19%); wound infections were second (14%); and technical complications, third (13%). Forty-eight percent of the adverse events were associated with an operative procedure. However, adverse events during surgery were less likely to be caused by negligence (17%) than in non-surgical events (37%). The proportion of adverse events caused by negligence was highest for non-invasive therapeutic mishaps (77%); diagnostic mishaps (75%); and mishaps in the emergency room (70%).[16]

Part Three of the Harvard study looked at the other side of the equation. The Harvard researchers identified patients who had filed claims against healthcare providers in their sample. They compared those results with their findings based on their review of those records. The researchers then matched their results with statewide data on medical malpractice lawsuits. The Harvard study concluded that the vast majority of patients injured by medical negligence did not make a claim.[17]

IV. THE UTAH AND COLORADO STUDY

The Harvard Medical Practice Study stirred debate in at least some circles. As early as 1993, some healthcare safety experts extrapolated from the Harvard study to suggest that 180,000 people per year die in the United States as

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[12] Brennan, Troyen A., M.P.H., M.D., J.D., *et al*, "Incidence of Adverse Events and Negligence In Hospitalized Patients: Results of the Harvard Medical Practice Study I," 324 N. ENGL. J. MED. 370-376 (1991); Leape, Lucian L., M.D., *et al.,* "The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II," 324 N. ENGL. J. MED. 377-384 (1991); Localio, Russell, J.D., M.P.H., M.S., *et al.,* "Relation Between Malpractice Claims and Adverse Events Due To Negligence, 325 N. ENGL. J. MED. 245-251 (1991).

[13] Leape, *supra*, at 245-6.

[14] Brennan, *supra* note 12, at 370.

[15] *Id*.

[16] Leape, *supra* note 12, at 377.

[17] Localio, *supra* note 12, at 245.

a result of an iatrogenic (healthcare provider caused) injury.[18] Questions were raised as to whether the findings from the Harvard Medical Practice Study might be inappropriate because they were limited to one year and to New York. And while the findings were consistent with the California feasibility study, the Harvard Medical Practice Study had not been replicated in a large-scale study in the United States. Additionally, a population based study from Australia that used the Harvard Medical Practice Study methods and a study from a Chicago teaching hospital that used observational methods found considerably higher rates of preventable medical injury than the Harvard Medical Practice Study.[19] Accordingly, the Utah and Colorado study was designed to determine whether the Harvard study findings were similar to those of other states in different time periods.

The Utah and Colorado study used methods similar to the Harvard Medical Practice Study in order to estimate the incidence and types of adverse events and negligent adverse events in Utah and Colorado in 1992. The researchers selected a representative sample of hospitals from Utah and Colorado and randomly sampled 15,000 non-psychiatric 1992 discharges. Each record was reviewed by a nurse using eighteen criteria associated with adverse events. If one of the criteria was met, the record was then reviewed by a physician to determine whether an adverse event or a negligent adverse event occurred and to classify the type of adverse event. After completion of all reviews, two investigators independently reviewed each adverse event and negligent adverse event to insure that all events fulfilled the definition set forth in the study.[20]

The study concluded that the incidence and types of adverse events found in Utah and Colorado in 1992 were similar to those found by the Harvard Medical Practice Study from New York in 1984. Adverse events occurred in 2.9 percent of the hospitalizations in each state. In Utah, 32.6 percent of the adverse events were due to negligence. In Colorado, 27.4 percent were due to negligence. Death occurred in 8.8 percent of the negligent adverse events.[21]

V. INSTITUTE OF MEDICINE REPORT

The National Academy of Sciences is a private, non-profit society of distinguished scholars engaged in scientific and engineering research. Upon the authority of the charter granted to it by the U.S. Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific matters. The National Academy of Sciences established the Institute of Medicine in 1970 to examine policy matters pertaining to the health of the public and to advise the federal government.[22] The Institute of Medicine (IOM) initiated the Quality of Healthcare in America project in June of 1998. Its purpose was to develop a strategy to result in at least a threshold improvement in the quality of healthcare over the next ten years.[23] In 1999 the institute published its first report, entitled: *To Err is Human: Building a Safer Healthcare System*.[24] The IOM studied the literature on the frequency and cost of healthcare errors and the factors that contribute to their occurrence. Errors and adverse events were defined as follows:

> An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).
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> An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event." Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence

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[18] Leape, Lucian L., M.D., *et al*., "Preventing Medical Injury." 19 QUAL. REV. BULL. 144-149 (1993).

[19] Thomas, Eric, M.D., M.P.H., *et al*., "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado," 38 MEDICAL CARE 261-271 (2000).

[20] *Id*. at 262-263.

[21] *Id*. at 261.

[22] Kohn, Linda T., *et al*, *To Err is Human: Building a Safer Health System, supra* note 2, at iii.

[23] *Id*. at xi.

[24] *Id.*

> (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).[25]

The IOM looked at four questions:

1. How frequently did the errors occur?
2. What factors contribute to errors?
3. What are the costs of errors?
4. Are public perceptions of safety in healthcare consistent with the evidence?[26]

They concluded that between 44,000 and 98,000 Americans die in hospitals each year as a result of preventable medical errors.[27] Importantly, the IOM acknowledged that these extrapolations likely underestimate the occurrence of preventable adverse events. In looking at the cost of these errors, the IOM concluded that "the national cost of adverse events to be $37.6 billion and the cost of preventable adverse events to be $17 billion."[28] It further stated "it has been estimated that for every dollar spent on ambulatory medications, another dollar is spent on new health problems caused by the medication."[29] As to public perception, the IOM concluded:

> Although the risk of dying as a result of a medical error far surpasses the risk of dying in an airline accident, a good deal more public attention has been focused in improving safety in the airline industry than in the health care industry. The likelihood of dying per domestic jet flight is estimated to be one in eight million. Statistically, an average passenger would have to fly around the clock for more than 438 years before being involved in a fatal crash.
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> . . .
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> The American public is aware that healthcare is less safe than some other environments, but to date, it has made few demands on the healthcare industry to demonstrate improvement.[30]

The IOM found that licensing and accreditation processes of healthcare providers and organizations have focused only limited attention on the safety issue. Even these minimal efforts have met with resistance from healthcare organizations and providers. The researchers found that the decentralized and fragmented nature of the healthcare delivery system contributes to unsafe conditions. The IOM also found that the context in which healthcare is purchased in the United States further exacerbates the problem. Group purchasers have made few demands for improvement in safety. The IOM concluded that a comprehensive approach to improving patient safety is needed.[31] The Institute of Medicine made a series of recommendations to that end.[32]

The IOM report created a stir. President Clinton established the Quality Interagency Coordination Task Force. He directed the Task Force to evaluate the IOM's recommendation in *To Err is Human* and to respond with a strategy to identify prevalent threats to patient safety and to reduce medical errors.[33] In February, 2000 the Task Force presented its report: *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their*

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[25] *Id*. at 28.

[26] *Id*. at 29.

[27] *Id*. at 31.

[28] *Id*. at 41.

[29] *Id*.

[30] *Id*. at 42.

[31] *Id*. at 3.

[32] *Id*. at 69, 87, 111, 133, and 156.

[33] Quality Interagency Coordination Task Force, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*: Report to the President (Washington: QuIC Task Force, 2000).

Impact.[34] The Task Force reported that medical errors were **"[a] National Problem of Epidemic Proportion."**[35] The report concluded that research documented that the rate of healthcare errors is far higher than the rate of error in other industries.[36] It looked at the epidemiology of medical errors and adverse events and medical products' use or misuse.[37] The Task Force also looked at current programs in place to prevent medical errors and found that they were insufficient.[38] The Task Force concluded that there was a general lack of awareness about the problem:

> As stated earlier, the existence of medical errors has been known for some time. However, the fact that there has been very little success in reducing errors suggests that a general lack of awareness or alarm about errors is a factor in this failure.[39]

VI. HEALTHGRADES QUALITY STUDY

The Agency for Healthcare Research and Quality (AHRQ) became the lead agency for the federal government on quality in healthcare. In order to better track medical errors, the agency developed and released a computer program which included a set of Patient Safety Indicators ("PSI"). These were specifically designed for screening hospital administrative data for incidents of concern related to patient safety.[40] HealthGrades took the Agency's Patient Safety Indicators software and applied it to approximately 37 million Medicare discharges. In 2004, HealthGrades, Inc. released its study: *HealthGrades Quality Study: Patient Safety in American Hospitals*.[41] This was the first study to look at the potentially avoidable mortality and cost impact of patient safety incidents using the PSI's across all U.S. hospitals among the most concentrated at-risk patient population, Medicare patients.[42] The report was shocking. The authors concluded that their data clearly supported the Institute of Medicine's report and the findings from other studies which showed that medical errors and injuries from them are epidemic in the United States.[43] They found that even though there were "shocking and widely publicized" statistics on preventable deaths due to medical errors, there had not been improvements in patient safety since the publication of the Institute of Medicine's report five years earlier. Indeed, they found the previous studies had underestimated the number of deaths caused by preventable medical errors. HealthGrades also looked at some of the economic consequences of the medical errors.[44] The results are staggering. The 16-PSI's studied accounted for $8.54 billion in excess inpatient costs to the Medicare system over the three years studies.[45] They concluded:

> To extrapolate to the nation as a whole, we calculated that Medicare hospital discharges represented 45% of all short-term acute hospital discharges from 2000-2002 period. Using this finding and excluding obstetric patients, we calculated that an extra $19 billion was spent and over 575,000 preventable deaths occurred, as a direct result of the 2.5 million patient safety incidents that occurred in U.S. hospitals from 2000 through 2002.[46]

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[34] *Id*.

[35] *Id*. at 1.

[36] *Id*. at 34.

[37] *Id*. at 37.

[38] *Id*. at 41.

[39] *Id*. at 42.

[40] *Patient Safety Indicators*, Version 2.1, Revision 1. March 2004. (Agency for Healthcare Research and Quality. Rockville, M.D.).

[41] *HealthGrades Patient Safety In American Hospitals*, *supra* note 1.

[42] *Id*. at 7.

[43] *Id*.

[44] *Id*. at 1.

[45] *Id*. at 6.

[46] *Id*.

These costs are additional costs to the Medicare system as result of preventable errors. They do not account for the other economic and non-economic losses suffered by those hurt by the errors. And they are increasing.

In April 2006, HealthGrades published its *Third Annual Patient Safety in American Hospitals Study*.[47] It found:

> ▪Approximately 1.24 million total patient safety incidents occurred in almost 40 million hospitalizations in the Medicare population. These incidents were associated with $9.3 billion of excess cost during 2002 through 2004. For the second year in a row, patient safety incidents have increased--up from 1.14 and 1.18 million reported in HealthGrades' First and Second Annual Patient Safety in American Hospitals studies, respectively.
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> ▪Of the 304,702 deaths that occurred among patients who developed one or more patient safety incidents, 250,246 were potentially preventable.
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> ▪Medicare beneficiaries that developed one or more patient safety incidents had a one-in-four chance of dying during the hospitalization during 2002-2004 . This rate remains unchanged since our first study released July 2003.[48]

In April 2007, HealthGrades published its Fourth Annual Patient Safety in American Hospitals Study.[49]

VII. BARRIERS TO IMPROVEMENT

If the problem of patient safety is well known, at least within healthcare professional circles, why has it not improved? Last year, healthcare safety expert, Lucian Leape, M.D., addressed barriers to progress. He concluded:

> The combination of complexity, professional fragmentation, and a tradition of individualism, enhanced by a well-entrenched hierarchal authority structure and diffuse accountability, forms a daunting barrier to creating the habits and beliefs of common purpose, teamwork and individual accountability for successful interdependence that a safe culture requires.[50]
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> ...
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> Creating cultures of safety requires major changes in behavior, changes that professionals easily perceive as threats to their authority and autonomy.[51]
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> ...
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> In addition to these powerful cultural factors, lack of leadership at the hospital or health plan level impedes progress. Changing the culture, even changing a few practices and policies, requires that all personnel share a common vision and personally own safety. This cannot happen without commitment at the top level of the organization.[52]

This lack of leadership is clearly shown by the healthcare industry's lack of compliance with the Joint Commission on Accreditation of Healthcare Organization's Sentinel Event policy. The Joint Commission is the accrediting organization for hospitals in the United States. Its Sentinel Event policy provides that hospitals are supposed to report unexpected bad outcomes. The Joint Commission then conducts an in-depth analysis of the event to determine its "root cause." The concept is that in a non-accusatory way, the Joint Commission can help the hospitals it accredits focus on patient safety and prevent future mistakes. The root-cause analysis looks for system

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[47] H*ealthGrades Quality Study: Third Annual Patient Safety in American Hospitals Study, supra* note 1.
[48] *Id.* at 3.
[49] Healthgrades Quality Study: Fourth Annual Patient Safety in American Hospitals Study, supra note 1.
[50] *Id*. at 2.
[51] *Id*. at 6.

[52] Leape, Lucian L., M.D., "Five Years After To Err is Human: What Have We Learned, 293 JAMA 2384-2387 (2005).

failures in order to provide risk reduction strategies.[53] The Sentinel Event reporting, root-cause analyses and recommendations are shrouded in secrecy and not discoverable in litigation. If patient safety were indeed a concern of the healthcare industry's leadership, one would expect that hospital executives would be standing in line to avail themselves of theses services. However, the opposite is true. One only need look at the Sentinel Event reporting statistics to see how true.

For example, in the obstetrical arena there is debate about the number of children born with cerebral palsy as result of birth related injury. But, even taking the most conservative estimates, the gross number in the United States of these injuries is in the thousands.[54] Cases considered reviewable under the Joint Commission Sentinel Event Policy are "any prenatal death or major permanent loss of function unrelated to congenital condition in an infant having a birth weight greater than 2500 grams."[55] When such children are born, one would think their cases would be at the top of the list for hospitals to seek root cause analysis. The injury and damages to the child and family are dramatic. Future medical care costs are in the millions, if not tens of millions of dollars. These are the types of injuries responsible hospitals would want to prevent. Of the thousands of children born each year with cerebral palsy from 1996 until July 2004, a total of only seven cases were reported to the Joint Commission under the Sentinel Event Reporting Policy.[56] In July 2004 the Joint Commission published a Sentinel Event Alert. In looking at 40 cases of infant death and the seven cases involving permanent disability which actually were reported in the eight years, the Joint Commission found:

Root causes identified

In the 47 cases studied, communication issues topped the list of identified root causes (72 percent), with more than one-half of the organizations (55 percent) citing organization culture as a barrier to effective communication and teamwork, i.e., hierarchy and intimidation, failure to function as a team, and failure to follow the chain-of-communication. Other identified root causes include: staff competency (47 percent), orientation and training process (40 percent), inadequate fetal monitoring (34 percent), unavailable monitoring equipment and/or drugs (30 percent), credentialing/privileging/supervision issues for physicians and nurse midwives (30 percent), staffing issues (25 percent) physician unavailable or delayed (19 percent), and unavailability of prenatal information (11 percent).

Risk reduction in strategies

As required under the Sentinel Event Policy, based on their root cause analyses, organizations develop an action plan citing the steps they will take to reduce the risk of similar future adverse events. The risk reduction strategies identified by these organizations include:

- Revise orientation and training process (70 percent)
- Physician education and counseling (36 percent)
- Revise communications protocols (36 percent)
- Reinforce chain-of-communications policy (28 percent)
- Revise competency assessment (25 percent)
- Standardize equipment and drug availability (25 percent)
- Conduct team training (25 percent)
- Revise consultation and on-call policies and procedures (23 percent)
- Revise Medical Staff credentialing and privileging process (21 percent)
- Institute changes in the patient assessment policy (21 percent)
- Standardize the evaluation and monitoring process (21 percent)

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[53] *See generally*, Joint Commission on Accreditation of Healthcare Organizations, *2003 Comprehensive Accreditation Manual For Hospitals: The Official Handbook* at SE1-10.

[54] *See generally*, Volpe, Joseph M.D., *Neurology of the Newborn*, Saunders: Philadelphia, 2001 at 332.

[55] Joint Commission on the Accreditation of Healthcare Organizations, July 21, 2004: *Sentinel Event Issue* #30 at 1.

[56] *Id*.

- Revise the staffing plan and process (17 percent)
- Adopt American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologists (ACOG) guidelines for prenatal care (13 percent)
- Institute mock OB emergency training drills (11 percent)
- Revise the conflict resolution policy (8 percent)
- Revise transfer policies and procedures (4 percent)[57]

Had more of these cases been reported and strategies been adopted, thousands of babies could have been spared the horrific damages they now suffer. Since Sentinel Event reporting began, it is unlikely that a single hospital in Texas has reported a single child born neurologically impaired as a result of care in labor and delivery. It is thus similarly unlikely that a single Texas hospital has had the benefit of the Joint Commission's specific input for risk reduction strategies or recommendations in that area.

VIII. REPORTING

In 2003, Texas joined a growing number of states that required reporting of adverse events. Subchapter H of Chapter 241, Health and Safety Code, requires the Texas Department of State Health Services to develop a patient safety program for hospitals.[58] This is administered by the hospital licensing program and serves only as an information clearing house for hospitals concerning best practices and quality improvement strategies. Once per year on renewal of a hospital's license, the hospital must submit an annual report that lists only the number of specifically defined events. The hospital is supposed to conduct a root cause analysis of the event and develop a plan that identifies strategies to reduce the risk of a similar event occurring again. For each adverse event, the hospital has to provide a "best practices report" to the department. But the department may not require it to exceed one page in length.

There are a number of problems with the statute. First, the listing of reportable events is overly restrictive and will miss many preventable adverse events. For example, it includes "a prenatal death unrelated to a congenital condition in an infant with a birth weight greater that 2500 grams,"[59] but it specifically excludes the "or major permanent loss of function" language from the Joint Commission Sentinel Event policy.[60] Secondly, the hospital itself is the one that conducts the root cause analysis and develops the action plan. Neither the root cause analysis nor the action plan are submitted to the department. If the department does happen to review a root cause analysis or action plan during a survey, inspection or investigation, it "may not in any form, format or manner remove, copy, reproduce, redact, or dictate from any part of it."[61] Significantly, the department annually shall compile and make available to the public a summary of the events reported by the hospitals. Unfortunately, not much information is reported by the hospitals or the department. The latest Patient Safety Information Annual Occurrence Report is attached as Appendix I.

As of 2005, 22 states had enacted some sort of reporting requirement. Thus far there have been significant compliance issues. Moreover:

> [a]s currently implemented, most reporting systems are not able to identify error or monitor progress in the prevention of error. The full magnitude of the problem is still unknown and no one knows how many errors that are not being reported or whether reporting has any positive impact on patient safety.[62]

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[57] *Id*.

[58] V.T.C.A., HEALTH & SAFETY CODE § 241.201.

[59] *Id*. at § 241.202 (2).

[60] *Sentinel Event Issue* #30, *supra* note 50.

[61] V.T.C.A., HEALTH & SAFETY CODE § 241.203(e).

[62] Harrington, Maxine M., "Revisiting Medial Error: Five Years After the IOM Report, Have Reporting Systems Made a Measurable Difference?" 15 HEALTH MATRIX 329 at 381 (2005).

Comparison of the attached Appendix to the 2004 Health Grades Quality Study does not suggest complete reporting. Nonetheless, it is at least a small step in the right direction.[63]

IX. CAPS

Relevant final questions are: Will the recent enactment of caps in any way reduce the malpractice crisis or improve patient safety? Will they even reduce the perceived malpractice "insurance" crisis. The unfortunate answers to these questions is no for at least six reasons.

1. History tells us that caps on damages do not decrease medical malpractice insurance premiums. The medical malpractice "crisis" of the 1970's, the 1980's and the 2000's all have the same cause. There were sharp spikes in medical malpractice insurance premiums which were followed by demands from doctors and hospitals for liability reducing reform, in order to reduce their malpractice premiums. In California, MICRA capped non-economic damages at $250,000 in 1975. Malpractice insurance premiums continued to rise for thirteen years until the citizens of California adopted insurance reform.[64] This is well-known by the insurance companies, as is shown in a document submitted by GE Medical Protective Company, the largest physician medical malpractice insurer, to the Texas Department of Insurance to explain a proposed 19% premium hike six months after Texas enacted caps on damages. As stated by GE Medical Protective Company:

> **Limitations on non-economic damages**
>
> Non-economic damages are a small percentage of total losses paid. Capping non-economic damages will show a loss savings of 1.0%.[65]

2. Most patients who are injured by medical malpractice simply do not sue the healthcare providers that cause the injury.[66]

3. In Texas, there has not been an increase in medical malpractice lawsuit frequency or in claims paid over the last 15 years. Bernard Black, Charles Silver, David Hyman and William Sage did a comprehensive analysis of all closed claims maintained by the Texas Department of Insurance since 1988. They studied the data regarding claim frequency, pay-out frequency, payment amounts, defense costs and jury verdicts. They concluded that the actual data present a remarkable stability:

> Controlling for population growth, the number of paid claims (over 25,000 in real 1988 dollars) was roughly constant from 1991 through 2002. Controlling for quantity delivered (based on either real healthcare spending or number of physicians), the frequency of large paid claims declined over this period. The number of small paid claims declined sharply. Pay-out per claim on large claims was constant over 1988 through 2002, while jury awards were constant or even declined.[67]

They concluded that the rapid changes in insurance premiums in Texas that sparked the "crisis" here and in other states reflect insurance market dynamics, largely disconnected from claim outcomes.[68]

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[63] V.T.C.A., CIVIL PRACTICE & REMEDIES CODE § 74.301.

[64] *See* discussion *supra II. California Medical Insurance Feasibility Study.*

[65] The Medical Protective Company, "Texas Physicians and Surgeons Actuarial Tort Reform Memorandum", October 31, 2003.

[66] Leape, *supra* note 12 at 245. *see generally* Baker, *supra* note 6.

[67] Black, Bernard, *et al*., "Stability, Not Crisis: Medical Malpractice Claim Outcomes In Texas, 1988-2002," Columbia Law School, LAW AND ECONOMICS, Working Paper No. 270, University of Illinois, Law and Economics Research Paper No. LE05-002, University of Texas Law School, Law and Economics Working Paper No. 30 at 2, available at http://papers.ssrn.com/abstract.678601. see also, The Great Medial Malpractic Hoax, supra note 5.

[68] *Id*.

4. The spikes in medical malpractice insurance premiums are not as a result of the malpractice crisis. Instead, they are cyclical and driven by the insurance market.[69]

5. The spikes in medical malpractice insurance premiums did not decrease access to healthcare in the United States or in Texas. There is no evidence to suggest that even were the malpractice insurance premiums to decrease, that access healthcare would be impacted. In 2003 the United States General Accounting Office studied the impact of rising medical malpractice premiums on access to healthcare. The study was done with the support of (at least until the results became known) and with data supplied by the American Medical Association.[70] The report did not substantiate the claim that increasing medical malpractice premiums reduced access to healthcare. In its study of five states without major tort reforms, they concluded that "many of the reported physician actions and hospital-based service reductions were not substantiated or did not widely affect access to health care."[71] The study further concluded that "[a]though some reports have received extensive media coverage, in each of the five states we found that actual numbers of physician departures were sometimes inaccurate or involved relatively few physicians."[72] The report was also skeptical of the claim that the tort system encourages unnecessary defensive medicine. It noted that (1) some defensive medicine is good medicine, (2) managed care discourages bad defensive medicine, and (3) doctors practice defensive medicine because they make money from defensive medicine.[73]

Texas certainly did not lose doctors, according to the Texas Board of Medical Examiners, from 1997 through the present. The number of physicians in the state increased every year:[74]

1997	31,071
1998	31,459
1999	32,871
2000	33,122
2001	34,697
2002	35,618
2003	37,188
2004	39,631
2005	40,785
2006	42,022

Significantly, from 1997 through 2003, there was a 20% increase in the number of Texas physicians. That is not to say that there are not parts of Texas that lack adequate access to healthcare. But that access, or the lack thereof, is not a result of what physicians have to pay for malpractice insurance.

6. The cause and effect relationship is backwards. That is, there is no evidence that decreasing malpractice insurance premiums will increase patient safety. However, there is compelling evidence that increasing patient safety will reduce malpractice insurance premiums:

> Patient safety advocates often use the history of anesthesia to demonstrate that healthcare providers can greatly reduce the frequency of iatrogenic injuries by making delivery systems more impervious to human errors and mechanical problems. As it happens, this example also shows that tort liability can motivate providers to identify and correct short-comings in healthcare delivery systems. Anesthesia--the area in which the systems based approach to error reduction has been applied with the greatest success--actually

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[69] For an excellent discussion of this, *see* Baker *supra* note 7, at 45-67.

[70] United States General Accounting Office, *Report to Congressional Investigators: Medical Malpractice: Implications of Rising Premiums on Access to Health Care*, 203.GAO-03-836, Washington, D.C.

[71] *Id*. at 12.

[72] *Id*. at 17.

[73] *Id*. at 26-27; *see also* Baker, *supra* note 7, at 118-139.

[74] http://www.tmb.state.tx.us

> undercuts the conventional wisdom, as it was malpractice liability that motivated anesthesiologists to find and address the causes of mistakes.[75]

Surgical anesthesia at one time exposed patients to serious risks of injury and death. Today, anesthesia is exceptionally safe.

> Anesthesia's high level of reliability distinguishes it as the only medical practice area that approaches industrial standards of quality.[76]

Much of the credit for improving patient safety in anesthesiology goes to the American Society of Anesthesiologists (ASA). Anesthesiologists at one time felt that their insurance premiums were too high. In 1983, ASA launched a campaign that included a study of closed malpractice insurance claims. By studying these claims, the ASA discovered that human errors caused an extremely large portion of the anesthesia related injuries. They then developed a set of mandatory anesthesia monitoring standards and redesigned their procedures so fewer errors would occur-and also, so that when errors did occur, they would be less likely to injure patients. As a result of the ASA's efforts, insurance premiums for anesthesiologists have been drastically reduced.[77]

X. CONCLUSION

The overwhelming evidence developed over the last 40 years conclusively shows that there is a malpractice epidemic in the United States. It has not improved. Millions of patients have been killed in the epidemic. Many millions more have been injured.

There is very little relationship between the malpractice *crisis* and the malpractice *insurance* crisis. There is no evidence that capping damages will improve patient safety. Most patients who are injured due to malpractice do not sue. Capping the damages on those who do sue will not reduce the malpractice insurance premiums of those who visit injuries on their patients. And there is no rational basis to believe it will reduce malpractice. That is not to say that there are not ways to quickly and efficiently reduce malpractice. If the medical industrial complex was treated as any other major industry, this author believes the problem of patient safety would quickly improve. Only three steps are required:

First, we need mandatory root cause analysis across the board for all deaths and serious injuries. This is not a new concept. The NTSB investigates all airline fatalities, resulting in a much better safety record in that industry.

Second, the process needs complete transparency. To the extent any analysis of injury and death is ever done in hospitals today, it is shrouded in secrecy. The concept that credentialing privileges, peer review privileges and committee privileges improve patient safety makes no sense. The idea that legitimate and serious analysis will take place in secret by those with a financial interest in the outcome is hard to fathom. History shows it does not work. The argument that secrecy is needed, else no one will be willing to review the errors of their institution or colleagues is likewise without merit. Simply put, have someone else do it and publish the results. Again, this is not a new concept. Recently, the 2006 AHRQ National Health Quality Report assessed the state of hospital quality and patient

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[75] Hyman, David and Charles Silver, "The Poor State of Health Care Quality In The U.S.: Is Malpractice Liability Part of The Problem or Part of The Solution? 90 CORNELL L. REV. 893-993 (2005) at 917, *citing,* Leape, Lucian L., M.D., "Reporting of Adverse Events," 347 N.ENG. J. MED. 1633 (2002) and Gawande, Atul. *Complications: A Surgeon's Notes on An Imperfect Science,* New York: Picador, 2002.

[76] Gawande, *supra* at 919 *citing* Chassin, Mark R., "Is Health Care Ready For Six Sigma Quality?" 76 MILBANK Q (1998) at 569 and Islam, Salim D. and Andrew D. Auerbach, "The Impact of Intraoperative Monitoring on Patient Safety," AHRQ NO. 43, EVIDENCE REPORT/TECHNOLOGY ASSESSMENT, ed. Amy Markowitz, J.D.. University of California, San Francisco: San Francisco: 277-281.

[77] Gawande, *supra*, at 917-923, *see also*, Baker, Tom. *The Malpractice Myth*, *supra* note 7 at 93, 108-110.

safety in America.[*] It concluded that sustained forms and public reporting seems to make a difference in the area of patient safety.[**]

Third, hold the institutions and people responsible for the errors totally accountable for their mistakes and the harm caused. That is, without caps; without secrecy and without special procedural protection. The foxes now guarding the henhouses would clamor that this would trigger another insurance crisis. However, the measures in place today clearly do not work. And any artificial "insurance crisis" can and should be avoided by insurance reform, just like it did in California with Proposition 103.[78]

The citizens of the United States need appropriated and safe healthcare. These three simple steps would not make an industry that generates $100's of billions in revenue each year dry up and go away. It would, however, cause the healthcare industrial complex to put patient safety as a top priority at all levels. And it would bring healthcare in line with industry standards for safety.

[*] 2006 National Healthcare Quality Report. Rockville Md: Agency for Healthcare Research and Quality (2006).
[**] *Id*., *see also*, supra Note 50.
[78] *See Supra Note 9*

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	GENERAL AND SPECIAL HOSPITALS	GENERAL AND SPECIAL HOSPITALS	GENERAL AND SPECIAL HOSPITALS	GENERAL AND SPECIAL HOSPITALS	AMBULATORY SURGICAL CENTERS	PSYCHIATRIC HOSPITALS & CSU'S
TOTAL NUMBER OF FACILITIES	204	96	81	104	274	28
Occurrence Description	*Beds (under 50)*	*Beds (50-99)*	*Beds (100-199)*	*Beds (200 plus)*		
A medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient	1	4	3	17	1	0
A perinatal death unrelated to a congenital condition in an infant with a birth weight greater than 2,500 grams	2	1	5	11		
The suicide of a patient in a setting in which the patient received care 24 hours a day	0	0	0	1	0	2
The abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant	0	0	0	0		
The sexual assault of a patient during treatment or while the patient was on the premises of the hospital or facility	0	1	2	7	0	2
A hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities	1	0	1	1	0	0
A surgical procedure on the wrong patient or on the wrong body part of the patient	2	5	8	31	13	
A foreign object accidentally left in a patient during a procedure	3	2	13	53	2	
A patient death or serious disability associated with the use or function of a device designed for a patient that is used or functions other than as intended	0	0	0	9	1	0

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