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**HEALTH CARE LIABILITY REFORM AND QUALITY
ASSURANCE ACT OF 1995**

MAY 16 (legislative day, MAY 15), 1995.—Ordered to be printed

Mrs. KASSEBAUM, from the Committee on Labor and Human
Resources, submitted the following

REPORT

together with

ADDITIONAL AND MINORITY VIEWS

[To accompany S. 454]

The Committee on Labor and Human Resources, to which was referred the bill (S. 454) to reform the health care liability system and improve health care quality through the establishment of quality assurance programs, having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY

The Chairman's Amendment in the Nature of a Substitute for S. 454, the Health Care Liability Reform and Quality Assurance Act, takes an important step toward reforming the United States' costly and inefficient health care liability system. The legislation is

designed to: (1) improve the availability of health care services; (2) improve the fairness and cost-effectiveness of the current health care liability system; and (3) ensure that individuals with meritorious health care injury claims receive fair and adequate compensation. The legislation is based on the straightforward premise that those who are injured should be fairly compensated and those who are at fault should pay their fair share.

The legislation contains two titles. Title I is divided into two sections: Subtitle A contains reforms which apply in civil health care liability actions; and Subtitle B contains reforms regarding the liability of suppliers of raw materials and component parts used in medical devices. Title II of the legislation provides additional funding for State activities relating to the licensing, disciplining, and certification of health care professionals. It also establishes national guidelines on quality assurance, patient safety, and consumer information.

Title I, subtitle A—Liability reform

This subtitle contains the following medical liability reforms:

Statute of limitations. A health care liability action must be filed 2 years after the date a claimant discovers both the injury and its cause.

Full recovery of economic and noneconomic damages. The legislation allows injured patients to recover complete compensatory damages. It places no limitation on the amount claimants may recover for economic damages—such as past and future medical expenses, past and future earnings, loss of business or employment opportunities, and the cost of replacement services in the home—or non-economic damages such as pain and suffering, mental anguish, and loss of companionship.

Limits on punitive damage awards. Pursuant to an amendment offered in committee by Senator Dodd, the amount a claimant may recover for damages designed solely to punish health care professionals and other defendants will be determined by a judge in a separate proceeding. Unlike the original bill, punitive damages are no longer limited to \$250,000 or three times economic damages, whichever is greater.

Limits on attorneys' fees. To ensure that injured patients recover a greater share of their medical liability awards, attorneys' contingency fees are limited to 33⅓ percent of the first \$150,000 recovered and 25 percent of awards in excess of \$150,000.

Periodic payment of large damage awards. At the request of either the claimant or the defendant in a health care liability action, damage awards in excess of \$100,000 may be paid on a periodic basis consistent with the guidelines contained in the Uniform Periodic Payments of Judgments Act.

Collateral source reform. To help hold down health care costs, the legislation prevents claimants from recovering twice for the same injury by requiring that damages be reduced by the amount claimants receive from an insurance policy or other third party source.

State alternative dispute resolution. To promote the resolution of claims in a more convenient, timely, and affordable manner, the legislation encourages States to experiment with alternative dis-

pute resolution (ADR) mechanisms and requires the U.S. Attorney General to provide technical assistance to States.

Joint and several liability reform. To promote more equitable resolution of health care liability actions, defendants are responsible for noneconomic and punitive damages only in direct proportion to their own fault or responsibility.

Preemption of weaker State laws. The legislation preempts existing State laws which contain reforms that are weaker than those contained in the legislation. States subsequently may pass weaker malpractice laws only if they cite the authority of this legislation. Those weaker laws generally will govern only intrastate disputes. The legislation does not preempt current or future State laws which provide for greater restrictions on damage awards, shorter statutes of limitations, greater limitations on attorneys' fees, and more restrictive rules regarding periodic payment and several liability.

Title I, subtitle B, biomaterials access assurance

The reforms in this portion of the legislation are designed to avert an imminent shortage of raw materials used in lifesaving medical devices. The scarcity of these materials is a direct result of costly litigation.

This subtitle would not affect the ability of claimants to sue manufacturers or sellers of medical implants.

Instead, it would allow raw material suppliers to be dismissed from lawsuits against medical device manufacturers, without incurring extensive legal costs, where the raw material used in a medical device met contract specifications and the supplier cannot be classified as either a manufacturer or a seller of the medical device.

Title II—Protection of the health and safety of patients

Title II attempts to provide additional resources for State quality assurance programs and to strengthen the role of State provider licensing boards by requiring that at least 50 percent of all punitive damages awarded in health care liability actions be used for activities relating to the licensing, disciplining, and certification of health care professionals and for the reduction of malpractice-related costs in medically underserved areas.

In addition, the legislation requires the Agency for Health Care Policy and Research (AHCPR), in consultation with public and private sector entities, to establish guidelines on quality assurance, patient safety, and consumer information.

II. BACKGROUND AND THE NEED FOR THE LEGISLATION

A. Overview

The issue of medical malpractice, and its impact on the health care system as a whole, has been of concern to consumers, physicians, nurses, hospitals, insurers, and other participants in the health care system. The existing health care liability system serves neither patients nor providers well. It adds costs and delay, fails to ensure health care quality, and jeopardizes access to health care services. S. 454 recognizes these problems in its findings: “[T]he civil justice system of the United States is a costly and inefficient

mechanism for resolving claims of health care liability and compensating injured patients.” The findings state further that “the problems with the current system are having an adverse impact on the availability of, and access to, health care services and the cost of health care in this country.”

Although statutory and common law governing the resolution of health care liability disputes differs from State to State, there are common legal doctrines that increase the cost of and diminish access to health care. Many of these legal doctrines encourage the filing of lawsuits, discourage the settlement of meritorious claims and encourage the litigation of nonmeritorious claims. The negative impact of these doctrines has become clearer after decades of experience in numerous States.

The flawed tort system contributes to higher malpractice insurance rates, the cost of which is ultimately passed on to health care consumers. In some specialties and in certain areas of the country, premiums can exceed \$100,000 a year.

Not only does the health care liability system increase costs directly in the form of higher insurance premiums, but also indirectly, in the form of practices and procedures performed simply to avoid the threat of being sued. Although hard to quantify exactly, experts estimate that this “defensive medicine” adds anywhere from \$25 to \$45 billion a year to health care costs. A more reasonable system for resolving health care liability disputes, with the confidence it would instill over time, would begin to diminish the overtreatment encouraged in many States today.

According to recent studies, there is little correlation between the actual incidence of malpractice, the filing of legitimate claims and the ultimate award of damages. Many persons who have legitimate claims do not file suit, while many patients who file suit show no evidence of medical negligence. Further, there frequently is not an appropriate correlation between the economic loss suffered by an injured patient and the compensation received for such loss. This failure of the tort system leads to both over and underdeterrence and results in a legal system which fails in one of its most important functions—the encouragement of a safe and efficient health care system. In addition, the system is so inefficient and time consuming that deserving litigants often must wait years for their just due.

Quality health care involves not only performing the right tests and procedures, but also avoiding unnecessary health care. It is clear that the overdeterrence caused by a misfiring legal system leads to the “defensive medicine” discussed above. This overtreatment not only adds to the exploding cost of our health care system, but also takes a human toll as patients are put through additional tests and procedures that carry their own risks and burdens.

Throughout the 1980’s, numerous experts documented the impact of a flawed tort system on access to health care. Most acutely felt by women denied access to obstetric care, provider after provider cited malpractice concerns as a significant reason for abandoning part or all of his or her practice. Some States responded to this “access crisis” by passing reasonable health care liability reform. In many States, however, needed efforts were stymied. The impact of

this “access crisis” is still felt throughout rural areas of this country, with general practitioners and obstetricians sometimes moving across State lines to escape areas with high insurance rates and a large number of lawsuits.

Those States that have enacted reasonable tort reform, while permitting experimentation with alternative dispute resolution and enhancing nonlitigation methods of improving quality, have ameliorated some of the negative impact of the present system of resolving health care liability disputes on cost, quality and access.

B. Background on the health care liability system

1. The Present Health Care Liability System Is Not Working

Numerous reports, experts and task forces document the failings of the current system. For example, the 1995 Physician Payment Review Commission (PPRC) Annual Report to Congress states that “[t]he medical malpractice system does not adequately prevent medical injuries or compensate injured patients.” It also notes a widespread concern that the current functioning of the malpractice system “promotes the practice of defensive medicine and may impede efforts to improve the cost effectiveness of care.”

Paul Weiler, in his 1991 book, “Medical Malpractice on Trial,” stated that “[m]edical malpractice shares with product liability the economic dislocation of soaring claim rates, damage awards and insurance premiums.” Weiler also pointed out the damage that the current malpractice system wreaks on the provider-patient relationship in which two people who need to develop a relationship of trust begin to view each other as adversaries.

Former Secretary of Health and Human Services, Otis Bowen, M.D., convened a Department task force in 1986 to investigate the impact that growing medical liability and malpractice costs have on people’s access to health care. He summarized the impact of our malpractice system in an address to the Institute of Medicine as follows: “Two groups of patients have felt the greatest impact from these changes: those living in rural areas and those with low incomes living in the inner cities.”

Just last year, research analyst David Murray of the Hudson Institute and then Hudson Senior Fellow Representative David McIntosh concluded that “[l]egal liability has become a key factor driving up the costs and decreasing the quality of medical care in the United States.”

The current tort system in many States, coupled with the litigious nature of society, encourages a large number of nonmeritorious claims and excessive awards in many cases. The problem of excessive health care liability lawsuits is not abating. Across the country, the frequency of health care liability claims is increasing. According to estimates based on the American Medical Association’s (AMA) Physician Masterfile and liability claims data from the AMA’s Socioeconomic Monitoring System (SMS), the average rate of claims has increased every year since 1987. In just the 3 year period from 1991–93, the number of claims went from 33,424 medical professional liability claims in 1991, to 38,430 claims in 1992 and to 42,828 claims in 1993. Even in States like California, where strong health care liability insurance costs, the

number of malpractice cases has continued to increase. In 1993, there were 16.5 percent more cases reported than in 1992. That number has increased by 54 percent since 1989.

In addition, the amount and the unpredictability of awards continues to mount. For the approximately 3,000 claims reported annually to the Physician Insurers' Association of America (PIAA) Data Sharing Project, both the amount of total indemnity (verdicts and settlements) and the average indemnity more than doubled between 1985 and 1993. The average indemnity grew from approximately \$87,000 in 1985 to \$182,000 in 1993.

There has been a similar increase in the frequency of large jury verdicts. Jury Verdict Research reports that nearly one-third (32 percent) of medical malpractice verdicts in 1994 equaled or exceeded \$1 million, up from 14 percent in 1980. Also significant is the fact that the middle 50 percent of verdicts—called the “probability range” because it excludes the high and low outliers—now range widely from \$120,000 to \$1.3 million. Prior to 1988, the range was much narrower (e.g., \$150,000 to \$300,000 in 1984). What exists, then, is a high stakes litigation lottery, which is attracting increasing numbers of bounty hunters. Unfortunately, the current system rewards lawyers who file big ticket lawsuits with more interest in the sensationalism of the injury than the actual merit of the claim.

The present malpractice system disserves those injured by medical negligence, not only by creating perverse incentives to avoid the majority of bona fide cases, but in many other ways as well. The litigation system in many States often has the dual negative effect of both delaying and reducing the patient's recovery, since lawsuits can take years and a large percentage of the award goes to pay court costs and legal fees. It takes an average of approximately 5 to 6 years from injury to resolution. Meanwhile, the RAND Corp. estimates that only 43 cents of every dollar spent in medical liability or product liability litigation reaches the injured patients. Moreover, because a majority of legitimate claims are never brought forward, there are missed opportunities to resolve patient safety and quality issues that would improve care for all patients.

Thus, the PPRC Report and the Hudson Institute Briefing Paper—to which could be added a host of additional reports by the General Accounting Office (GAO), the Department of Health and Human Services Task Force on Medical Malpractice and Insurance, and others—collectively demonstrate that the current tort system drives up the cost of health care, is unable to resolve medical liability claims in a timely and cost-effective fashion, and makes only a haphazard contribution to deterring negligent behavior and improving the safety of health care.

2. The Costs of a Flawed Malpractice System

The health care liability system is costly and wasteful. In fact, the United States has the world's most expensive tort system. At 2.3 percent of gross domestic product (GDP), U.S. tort costs are substantially higher than those of any other country and 2½ times the average of all developed countries.

The Hudson Institute conducted a study examining the effect of liability on a large urban hospital in Indiana. Even in a State that

has taken steps to address the costs associated with medical liability, the study found that the direct and indirect costs of liability added a total of \$450 per patient admitted to the hospital, increasing medical costs at the hospital by 5.3 percent. As stated earlier, the study concludes that “legal liability has become a key factor driving up the costs and decreasing the quality of medical care in the United States.”

While nationwide trends are somewhat mixed on the physician side, it is clear that medical liability insurance premiums continue to outpace inflation by substantial margins, particularly in States that have not achieved effective liability reform. For example, malpractice premiums increased by 14 percent in New York in 1993.

Moreover, the AMA reports that the average physician medical malpractice premium was \$13,500 in 1992; the highest average figure recorded was \$33,500 for OB/GYN's. Other studies have shown annual premiums approaching or exceeding \$100,000 for certain specialties (OB/GYN's and neurosurgeons) in certain geographic areas (e.g., Manhattan and parts of Florida). The AMA analysis recorded an average annual increase in premiums of 3.7 percent over the 1985–92 period for all physicians. Malpractice premiums represented 3.5 percent of physician practice revenues and 7 percent of physician professional expenses in 1992. Between 1960 and 1988, total expenditures on medical liability insurance in the United States rose from about \$60 million to \$7 billion.

Malpractice insurance costs are linked to claims experience of insurers, with premiums varying markedly by specialty and geographic region. Overall, changes in malpractice premiums reflect the cyclical characteristics of the insurance industry as a whole. The mid-1970's crisis of availability was accompanied by a dramatic increase in premiums, which was followed by a leveling-off period. Another dramatic increase in premiums occurred in the mid-1980's; this was labeled the “crisis of affordability.” This was followed by another leveling-off period characterized by more favorable claims experience. While results are mixed, some recent reports show an increase in claims frequency. The high cost of health care liability that doctors, nurses, hospitals, product manufacturers, health insurers and others must pay in order to stay in business, is inevitably passed through into the prices of the products and services they provide. According to Lewin-VHI, the total cost of medical liability insurance, including self-insurance, is estimated at \$9.2 billion.

In addition to actual cost of liability insurance, there are even greater costs associated with “defensive medicine”—diagnostic tests and services motivated primarily by the fear of litigation and the perceive need to build a medical record that documents a health care professional's decision. Defensive medicine is more difficult to quantify precisely, but is attested to be every health care professional. A 1988 report by Medical Economics documented a range of actions taken in response to malpractice concerns. These included telling patients more about risks (87 percent of physicians surveyed), keeping more detailed patient records (85 percent), obtaining more consultations (70 percent), ordering more diagnostic tests (66 percent), taking more extensive initial histories (59 percent), scheduling more follow-up visits (54 percent), and delegating fewer

procedures to paramedics (28 percent). Lewin-VHI recently estimated that the combined cost of physician and hospital defensive medicine is as high as \$25 billion annually.

While the scope of liability exposure in managed care continues to evolve, it is already clear that these large delivery systems and health care organizations are targeted as “deep pockets.” A final cost factor that is potentially enormous, but has not yet been calculated, is the liability of health insurers and health networks for their utilization review activities that restrict payment for health care services. Recent verdicts and settlement reports suggest that payers who refuse to provide services may be exposed to multi-million dollar suits, even if the medical service demanded by patients has not been proven effective and clearly is excluded by the terms of the managed care plan. This phenomenon can be thought of as an institutional equivalent to defensive medicine. In 1993, for example, a California jury awarded \$89 million to the family of a woman who was denied an experimental treatment for advanced breast cancer. Most of the award consisted of punitive and non-economic damages. While this case was ultimately settled for a lower amount on appeal, it still serves as a compelling example that managed care organizations and health systems are being forced by the risk of excessive damage awards to provide treatment that is not necessarily needed or effective.

3. The Present Health Care Liability System Fails to Improve Quality

The current medical liability system fails to sort out meritorious claims from nonmeritorious claims and to fairly compensate those who are injured. The Harvard Medical Practice Study, based on a review of 31,429 medical records in 51 New York hospitals, concluded in 1991 that while only 280 patients suffered an adverse event due to negligence, only 1 in 16 received compensation from the tort liability system. Harvard Medical Practice Study, “Patients, Doctors and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York,” *New England Journal of Medicine*, July 25, 1991. On the other hand, at least half the claims that were filed were without merit—that is, 50 percent of the malpractice claims studies were not filed by a plaintiff who received negligent medical treatment. Similarly, of the over 101,000 closed claims and lawsuits reported to the Physician Insurers Association of America Data Sharing Project, only one-third contained any payments at all to the plaintiff.

These conclusions are reinforced by the GAO’s estimate that nearly 60 percent of all claims filed against physicians are dismissed without a verdict, settlement or payment, and by a recent study funded by the U.S. Agency for Health Care Policy and Research that found no relationship between prior malpractice claims experience and the technical quality of practice by Florida obstetricians. With so little correlation between the filing of lawsuits and negligent behavior, it is clear that the current medical liability system is not effective in deterring medical injury or negligence.

Opponents of S. 454 have contended throughout the debate on this legislation that “80,000 Americans die each year” as a result of medical negligence. This figure is drawn from an analysis of the

1991 Harvard Medical Practice Study by the Consumers Union, and not directly from the Harvard Study itself. The opponents of this legislation then go on to claim that "medical negligence is the third leading cause of preventable death in the United States after tobacco and alcohol-related deaths" and that it is responsible for killing more persons each year than firearms or automobile accidents.

This analysis is erroneous and misleading. First, the 1984 Harvard sample of 31,000 patient records identified 71 cases where a "negligent adverse event" was listed as a cause of death. It is difficult to see how one could justifiably extrapolate from 71 deaths in New York in 1984 to 80,000 deaths nationwide every year. See Appendix of this report containing: (1) June 14, 1994 letter from Ronald T. Kuehn, Partner, Ernst & Young Actuarial Services Group, to Martin Hatlie, Esq., Chair, Health Care Liability Alliance, concluding in part that: "* * * the Consumers Union claims that negligent doctors kill more Americans than guns or auto accidents cannot be sustained on their face, nor can they be accurately attributed to the Harvard Medical Practice Study"; and (2) June 24, 1994 letter from Paul C. Weiler and Troyen A. Brennan, Harvard Law School, to Hon. Pete Stark, stating: "We have always cautioned that this bare statistic can be more deceiving than revealing."

Second, the death rates of hospital patients are not comparable to other groups, such as those killed in automobile accidents. The authors of the Harvard study themselves take issue with these comparisons:

We caution, however, against too quick a comparison of such fatality figures. In our study a death was judged to be iatrogenic [meaning caused by medical care] if there was a clear causal link with medical management. But a substantial proportion of patients were gravely ill, and many would have died from their underlying illnesses in months, days, perhaps hours, even absent the mishap in treatment. * * * Unfortunately, we cannot say what proportion of deaths from medical adverse events involved a patient with relatively short life expectancies. We do know, however, that motor vehicle or workplace fatalities typically involve healthy individuals.

Paul C. Weiler et al., "A Measure of Malpractice," pp. 56-57 (Harvard University Press 1993).

Perhaps the best response to the claim that negligent doctors are responsible for 80,000 deaths each year comes from two of the Harvard Study's principal author themselves:

The Harvard Study has played an important role in teaching the medical and legal communities that real attention must be given to the harms as well as to the benefits that medical treatment can achieve for patients. That message will not be productive, though, if physicians (or nurses and other health care workers) are analogized to dangerous guns, drugs, or drivers. The key to less hazardous health care is careful epidemiological investigation of the circumstances in which medical mishaps occur, and de-

sign and investment in new techniques and technologies that can reduce the incidence of such injuries. * * * Litigation will not have that effect, though, if tort lawyers and their supporters indulge in a morality play about so-called "bad apple" physicians (who contribute to only a tiny proportion of the incidence of medical injury).

June 24, 1994 letter from Paul C. Weiler and Troyen A. Brennan, Harvard Law School, to Hon. Pete Stark at Appendix.

Observers of medical malpractice issues generally agree that it is important to develop alternative methods to improve the quality of services rendered to patients. A number of States and localities have taken steps designed to focus on quality concerns. These include strengthening State licensing and disciplining boards, increasing peer review and professional education activities, and improving quality assurance and risk management programs. Several other activities also are directed at improving the quality of services. The National Practitioner Data Bank is intended to serve as a flagging system to alert State Boards and hospitals to situations where further review of professional credentials may be warranted.

Those who argue that litigation is the best or only method of improving quality misapprehend the health care market today. There has been a revolution in the delivery of health care services over the past decade. Health care payers are demanding new approaches to delivering care and controlling costs. A decade ago, little or no emphasis was placed on systemic quality, outcomes research or coordinating systems of care. Today, hospitals and health care providers are clearly operating in a different environment where capitated payment are the norm, and solo fee-for-service medical practices increasingly are being displaced by large networks of physicians and other providers. Both public and private sector payers are demanding systemic quality measurements that can continually demonstrate better outcomes and healthier patients.

It is in this atmosphere that patient safety and risk management programs have been established and are flourishing. Risk management is a sound investment because it: (1) improves the quality of services provided to patients; (2) decreases unnecessary health care costs incurred as a result of substandard care or from preventable health risks that go unaddressed; and (3) promotes advances in medical treatment and technology designed to minimize patient exposure to risk.

The results of these activities are extremely encouraging. For example, anesthesiology has become much more safe in recent years because of the voluntary development over ten years ago of practice standards by the Harvard Medical School, for use in its affiliated hospitals. Since the adoption of these standards by the American Society of Anesthesiologists (ASA), insurance companies, managed care organizations, and even a number of State medical regulatory authorities (e.g., New York, New Jersey) have adopted substantially similar standards. Before the anesthesia standards were adopted by the Harvard Medical School in July 1985, there was one intraoperative accident for every 75,700 anesthetics administered and 1 death for every 151,400 anesthetics administered between January 1976 and June 1985. Afterward, between July 1985 and

June 1990, there were no deaths at all and only one intraoperative accident for all 392,000 anesthetics administered.

There are many other examples of risk management/quality improvement activities which are driving the trend toward reducing the potential for medical injuries that might result in a health care liability lawsuit. Private sector risk identification and prevention is, by far, preferable to time-consuming, counterproductive, expensive litigation.

4. Access to Health Care and Innovation Should be Promoted Not Thwarted

One of the most serious societal costs inflicted by the current liability system is reduced access to health care. Increasing premiums and the threat of liability have caused physicians and other health care providers to abandon practices or stop providing certain services in various areas of the country.

Access problems induced or exacerbated by liability have been most clearly documented among obstetrician-gynecologist (OB/GYN) physicians. More than one-half million residents of rural counties are without any physicians to provide obstetric services. An Institute of Medicine report found that the high cost of liability insurance and the threat of malpractice litigation has a particularly adverse effect on the delivery of obstetrical services to three categories of women: (1) those living in rural areas; (2) those with high risk pregnancies; and (3) those who are poor. Similarly, the National Rural Health Association reports that many States and local communities are experiencing a serious lack of obstetric services and that increasingly this can be attributed to the medical liability system.

According to a 1992 survey by the American College of Obstetricians and Gynecologists (ACOG), 12.3 percent of OB/GYN's nationally gave up obstetrics in 1992 as a result of liability concerns; almost one-quarter decreased the amount of high-risk obstetric care they provided. ACOG noted that increasing numbers of physicians are leaving obstetrics at an earlier age, and that family physicians are leaving obstetrics at an earlier age, and that family physicians and rural physicians also are discontinuing obstetric services.

5. Access to Life-Saving and Life-Enhancing Medical Devices is Directly Threatened by the Current Medical Liability System

Liability concerns increasingly are creating obstacles to the availability, affordability and innovation of medical drugs and devices, as well. Like malpractice law, products liability law is primarily State common (i.e., court-made) law. In all States, the manufacturer or seller of a defective product, or of a defective component part of a product, may be held strictly liable (liable even in the absence of negligence) for injuries caused by the defect. This principle of law, however desirable it may be generally, threatens to cause a public health catastrophe because of its effect on biomaterials suppliers—the suppliers of raw materials and component parts of medical implants.

Individuals who allege that an implant has caused injury often sue not only the manufacturer of the implant, but those who supply

raw materials and component parts to the manufacturer. The biomaterial suppliers are not responsible for designing, producing, or testing the implant, and therefore cannot be held liable unless the ingredients they supply are defective and cause injury. According to the Health Industry Manufacturers Association (HIMA), raw material suppliers have been found liable in only a fraction of these cases. One supplier has a 258 to 1 track record. But this does not prevent injured parties from joining them in lawsuits against implant manufacturers, and causing them to incur significant legal expenses. These expenses obviously make it less profitable for biomaterials suppliers to supply raw materials and component parts to implant manufacturers. Because sales to implant manufacturers constitute only a small portion of the overall market for these raw materials and component parts, some biomaterials suppliers have ceased supplying certain raw materials and component parts for use in implants.

On March 28, 1995, Senator Joseph Lieberman—the principal author of the biomaterials access assurance section of S. 454—testified before the committee that “the current legal system makes it too easy to bring lawsuits against raw materials suppliers and too expensive for those suppliers to defend themselves—even when they were not at fault and end up winning. Because of this, many suppliers have decided that the costs of defending these lawsuits are just too high to justify selling raw materials to the makers of implantable medical devices. In short, for those suppliers, it just isn’t worth it.”

The facts clearly demonstrate that the shortage of raw materials used in medical devices is a direct result of abuses of the liability system.

Recently, three major suppliers announced they would substantially limit or terminate their raw material sales to medical implant manufacturers because the risk of liability far outweighs the market return for these materials. On April 1, 1992, Dow Chemical pulled all of its medical grade resin and film from the implant market. On March 31, 1993, Dow Corning Corp. stopped supplying silicone for use in permanent medical implants in all reproductive, contraceptive, obstetric, and cosmetic applications. On January 31, 1994, DuPont ended a one year grace period and discontinued its supply of three materials used in permanent medical implants. The few remaining suppliers are threatening to do the same.

A recent market study by Aronoff Associates found that: (1) some medical device companies have less than an 18-month “transition” supply of raw materials stockpiled; (2) the combined size of the permanent medical implant markets for three types of raw materials studied is minuscule (\$600,000) compared with the other material markets, such as automotive and textile, for these three materials (\$10.5 billion); (3) the risk of liability far outweighs the market return for these materials, and is a major factor in the decision to supply or not supply the market; and (4) in many cases, no alternative material suppliers and no suitable replacement materials exist.

There is, however, much more at stake than simply protecting raw material suppliers from liability or making those raw materials available to the manufacturers of medical devices. There is an

imminent national public health catastrophe. As Senator Lieberman told the committee: “[w]hat’s at stake is the health of millions of Americans who depend on medical devices for their every day survival.”

Luke Lindenthal and his mother, Lynn, also testified before this committee on March 28, 1995. They told the members of the committee that, without the legislation, Luke’s life and the lives of nearly 8 million other Americans will be placed in significant jeopardy.

At earlier hearings on May 20, 1994, before the Subcommittee on Regulation and Government Information of the Senate Committee on Governmental Affairs, Senator Lieberman warned that “makers of many of the life-saving medical devices that we take for granted today may no longer be able to buy the raw materials and components that are necessary to produce their products. This is a public health time bomb, and it is ticking, and the lives of real people are going to be lost if it explodes.” He pleaded with this committee during his March 28 testimony not to let the nearly eight million people who owe their health and their lives to medical devices “become casualties of an outmoded legal liability system.”

C. Current State responses to malpractice concerns

Tort Reforms. Some States have instituted statutory reforms of tort litigation rules. These reforms generally have been designed to reduce the number of claims filed and the size of damage awards. However, these reforms have been uneven and, in many instances, nullified by constitutional challenges. Listed below are some of the more common reforms currently in place.

Limits on Damages. Compensatory damages reimburse the patient-plaintiff for the economic costs resulting from medical injury, including lost wages and medical bills. Noneconomic damages reimburse for associated pain and suffering. In case of egregious conduct, a jury may award punitive damages. A number of States have placed limits on noneconomic damages (e.g., \$250,000) and/or punitive damages. A few States have placed an overall cap on recoveries.

Periodic payments of awards. Periodic payments are made in lieu of a lump-sum award based on estimates of future costs.

Limitation on Joint and Several Liability. Traditionally, plaintiffs have been able to sue all those who may have had a role in causing an injury and to collect the full amount of damages from any defendant or combination of defendants. Plaintiffs may thus seek out a “deep pockets” defendant and collect a large amount from that defendant even though that defendant may have had only limited responsibility for the injury. Some States have limited each defendant’s liability to his or her proportion of responsibility for the injury.

Mandatory Offset of Payment from Collateral Sources. Traditionally, plaintiffs have been able to recover damages from the defendant even if most of the economic losses were reimbursed through other sources such as health insurance. Many States have adopted rules prohibiting this practice.

Limitation on Attorneys’ Fees. Attorneys’ fees are frequently believed to be too high, with observers noting that plaintiffs often re-

ceive less than the economic costs of their injuries. A number of States have attempted to limit attorneys' fees, typically through the use of a sliding scale.

Statutes of Limitation. Some States have shortened the statutes of limitation in order to reduce claims frequently, assist in actuarial predictability, and prevent unfairness of defending against very old lawsuits. (In many cases longer periods apply for injuries to minors.)

Pre-Trial Screening Panels. Some States have set up mandatory or voluntary panels to identify baseless claims. Panel findings may or may not be admissible at trial.

The experience of California is often cited in discussions of tort reforms. The State enacted the Medical Injury Compensation Reform Act (MICRA) in 1975; MICRA became fully operational in the mid-1980's after withstanding a constitutional challenge. Data from the State shows that malpractice premiums in California were higher than the national average in 1984 (before MICRA went into effect) and lower than the national average in 1994. Although it is difficult to quantify the direct effect of the MICRA reforms on the reduction of overall health spending in the State, these malpractice reforms—in combination with other health care restructuring—have contributed significantly to making the rate of growth of health care costs in California the lowest in the country.

III. LEGISLATIVE HISTORY AND COMMITTEE ACTION

S. 454, the Health Care Liability Reform and Quality Assurance Act of 1995, was introduced on February 16, 1995, by Senators McConnell, Lieberman, and Kassebaum. The bill was referred to the Committee on Labor and Human Resources. The committee held hearings on S. 454 on Tuesday, February 28.

The committee held an executive session on April 6, 1995. However, due to an objection, the committee was unable to consider any amendments or vote to report the legislation at that time. The committee held a subsequent executive session on Tuesday, April 25, 1995. During the April 25 executive session, the Committee on Labor and Human Resources held on Tuesday, April 25, 1995, an amendment in the nature of a substitute to S. 454 was brought up for consideration by Chairman Kassebaum. The Chairman's substitute was adopted by a roll call vote of 9 yeas to 7 nays.

Those voting to report the legislation favorably were Senators: Kassebaum, Jeffords, Coats, Gregg, Frist, DeWine, Ashcroft, Abraham, and Gorton. Those voting nay were Senators: Kennedy, Pell, Dodd, Simon, Harkin, Mikulski, and Wellstone.

During consideration of the measure, there were nine roll call votes taken on amendments. Three of the amendments passed. However, Senator Dodd's amendment modifying the punitive damage provisions of the legislation nullified one of the earlier successful amendments—an amendment offered by Senator Kennedy to exempt cases involving sexual abuse from the punitive damage cap. Six of the amendments failed.

1. Senator Kennedy offered an amendment in the nature of a substitute for the Kassebaum substitute. The Kennedy amendment would have: (1) capped attorneys' contingency fees at $33\frac{1}{3}$ of the first \$150,000 and 25 percent of amount over \$150,000; (2) mandated that States adopt alternative dispute resolution procedures; (3) included periodic payment reform; (4) included collateral source reform; and (5) authorized several State demonstration projects on liability reform. The amendment was defeated by a rollcall vote of 7 yeas to 9 nays.

YEAS	NAYS
Kennedy	Kassebaum
Pell	Jeffords
Dodd	Coats
Simon	Gregg
Harkin	Frist
Mikulski	DeWine
Wellstone	Ashcroft
	Abraham
	Gorton

2. Senator Kennedy offered an amendment that provided that the reforms contained in the legislation would not preempt State law. The amendment failed by a rollcall vote of 7 yeas to 9 nays.

YEAS	NAYS
Kennedy	Kassebaum
Pell	Jeffords
Dodd	Coats
Simon	Gregg
Harkin	Frist
Mikulski	DeWine
Wellstone	Ashcroft
	Abraham
	Gorton

3. Senator Wellstone offered an amendment requiring that information contained in the National Practitioner Data Bank be made available to the public. The amendment was defeated by a rollcall vote of 6 yeas to 10 nays.

YEAS	NAYS
Kennedy	Kassebaum
Pell	Jeffords
Simon	Coats
Harkin	Gregg
Mikulski	Frist
Wellstone	DeWine
	Ashcroft
	Abraham
	Gorton
	Dodd

4. Senator Kennedy offered an amendment to exclude from the cap on punitive damages actions involving “sexual abuse of a patient or comparably egregious conduct.” The amendment was defeated by a rollcall vote of 7 yeas to 9 nays.

YEAS	NAYS
Kennedy	Kassebaum
Pell	Jeffords
Dodd	Coats
Simon	Gregg
Harkin	Frist
Mikulski	DeWine
Wellstone	Ashcroft
	Abraham
	Gorton

5. Senator Coats offered a second degree amendment to Senator Kennedy’s amendment on sexual abuse, which would have excluded from the definition of “health care liability action” actions which constitute “sexual abuse” or the intentional withdrawal of medical care because of age, disability, mental ability, or physical condition. The amendment failed by a rollcall vote of 4 yeas to 12 nays.

YEAS	NAYS
Coats	Kassebaum
DeWine	Jeffords
Ashcroft	Gregg
Abraham	Frist
	Gorton
	Kennedy
	Pell
	Dodd
	Simon
	Harkin
	Mikulski
	Wellstone

6. Senator Kennedy offered a modified version of amendment No. 4, which provided that the limitation on punitive damage awards does not apply in cases of "sexual abuse" of a patient. The amendment passed by a rollcall vote of 15 yeas to 1 nay.

YEAS	NAYS
Kessebaum	Gregg
Jeffords	
Coats	
Fist	
DeWine	
Ashcroft	
Abraham	
Gorton	
Kennedy	
Pell	
Dodd	
Simon	
Harkin	
Mikulski	
Wellstone	

7. Senator Abraham offered an amendment to allow States to opt-out of the reforms contained in the legislation in certain circumstances. The amendment passed by a rollcall vote of 9 yeas to 7 nays.

YEAS	NAYS
Jeffords	Kassebaum
DeWine	Coats
Abraham	Gregg
Pell	Frist
Dodd	Ashcroft
Simon	Gorton
Harkin	Kennedy
Mikulski	
Wellstone	

8. Senator Dodd offered an amendment to strike the cap on punitive damages contained in the Kassebaum substitute. The amendment provided that a judge, not a jury, would determine the amount of punitive damages to be awarded in health care liability actions. The amendment also struck the provisions contained in amendment No. 6 on sexual abuse. The amendment passed by a rollcall vote of 9 yeas to 7 nays.

YEAS	NAYS
Jeffords	Kassebaum
DeWine	Coats
Kennedy	Gregg
Pell	Frist
Dodd	Ashcroft
Simon	Abraham
Harkin	Gorton
Mikulski	
Wellstone	

9. Finally, Senator Kennedy offered an amendment to strike the provisions in the Kassebaum substitute which required a party to pay reasonable court costs and attorneys' fees where the result at trial was 25 percent worse than the result at the alternative dispute resolution stage. The Kennedy amendment would have made these fee-shifting provisions a State option. The amendment was defeated by a rollcall vote of 7 yeas to 9 nays.

YEAS	NAYS
Kennedy	Kassebaum
Pell	Jeffords
Dodd	Coats
Simon	Gregg
Harkin	Frist
Mikulski	DeWine
Wellstone	Ashcroft
	Abraham
	Gorton

IV. COMMITTEE VIEWS

A. Legislative influences on S. 454

The committee believes that it is important to read this legislation in the factual and historical context in which it was developed. Two legislative efforts greatly influenced the development of this legislation: (1) the failure of the 103rd Congress to pass comprehensive health care reform legislation; and (2) the consideration by this Congress of S. 565, the "Product Liability Fairness Act of 1995."

As a result of last year's debate over comprehensive health care reform, many now believe that health reform legislation should be considered on a more incremental basis. Because nearly every major health care reform bill that was introduced or considered by various committees in both Houses of Congress last year contained provisions to reform the health care liability system—and because many of these reforms garnered bipartisan support—the authors of S. 454 believed that medical liability reform was a strong candidate for independent consideration in the 104th Congress.

As Senator Lieberman testified before the committee on March 28, 1995, “many of the ideas in [this legislation] were proposed or cosponsored by Democrats and Republicans in the last Congress as part of comprehensive health reform bills. A number of these ideas were embraced last year by a group of us participating in the Senate ‘Mainstream Coalition.’ But we had little chance to debate these issues in the last Congress. I am optimistic that we will have the opportunity in this Congress to pass a bipartisan medical malpractice reform bill.”

As reported, S. 454 does, in fact, incorporate many of the reforms that were embraced by members of both parties during last year’s health care reform debate.

In addition, two weeks before the substitute was reported by this committee, a product liability reform bill, S. 565, was reported favorably by the Committee on Commerce, Science, and Transportation and placed on the Senate calendar for immediate consideration. The committee believes that applying liability reforms only to medical products could lead to an increase—rather than a decrease—in costs associated with medical liability claims and, perhaps, a concomitant diminution of access to health care services. It is, for example, quite simple to transform a complaint against a drug manufacturer for the faulty manufacture of a drug to a complaint against a physician for the negligent prescription of the same drug. If lawsuits against health care providers, health care professionals, and health plans are allowed to proceed under rules that are more generous to claimants than those that apply to product manufacturers and distributors, the former will be at increased risk of exposure to liability actions.

The committee acknowledges that S. 565 influenced the development of this legislation in a more direct way. Some of the provisions in S. 454 were modified by this committee in an effort to make the legislation more compatible with S. 565. This legislation includes only three substantive reforms that are not contained in S. 565: (1) mandatory collateral source offsets; (2) periodic payment of future damages; and (3) limitations on attorneys’ contingency fees.

B. Overview of changes to S. 454 contained in the legislation adopted by the committee

The legislation ultimately adopted by the committee made several important modifications to S. 454, in addition to the amendments that were approved during the executive session. Many of these changes were made to address concerns raised by members who ultimately did not vote to report the legislation favorably. Nonetheless, the committee views these changes as a good faith attempt to improve the legislation. These changes include:

A definition of “economic losses” has been added to section 102 of the legislation.

The definition of “Health Care Liability Action” was modified.

The preemption provisions in section 103 of the legislation have been modified to delineate more specifically the scope of Federal preemption.

Section 105 has been modified to clarify that punitive damages may be awarded in cases where a claimant proves by clear and con-

vincing evidence that the defendant acted with “conscious, flagrant” disregard of a substantial and unjustifiable risk of unnecessary injury. The previous language required “conscious” disregard. The provision now corresponds more closely to S. 565, the products liability legislation.

Section 106 has been modified so that periodic payments are made in accordance with the guidelines contained in the Uniform Periodic Payment of Judgments Act (1990).

Section 107(c) of S. 454, which prevented a defendant in a health care liability action from being held vicariously liable for the direct actions or omission of others, has been deleted.

Section 110 of S. 454, which required plaintiffs to meet a higher standard of proof in certain health care liability actions involving services provided during labor or delivery of a baby, has been deleted.

The State-based alternative dispute resolution (ADR) mechanisms contained in section 111 of S. 454 have been modified in section 110 of the Chairman’s substitute so that: (1) States are encouraged, rather than required, to establish or maintain ADR mechanisms; and (2) the Attorney General is directed to provide assistance to States by developing guidelines with respect to arbitration, mediation, early neutral evaluation, early offer and recovery mechanisms, certificates of merit, and no-fault mechanisms, and to monitor and evaluate the effectiveness of State ADR mechanisms.

The requirement that a claimant prove his or her case “beyond a reasonable doubt” in cases litigated beyond the ADR stage has been deleted from the ADR provisions of the original bill and replaced with the following provision designed to encourage settlement. If a claimant seeks redress beyond ADR and receives at least 25 percent less damages in court, the claimant must pay reasonable legal costs incurred by the defendant. If a defendant seeks redress beyond ADR and is found liable for at least 25 percent more damages in court, the defendant must pay reasonable legal costs incurred by the claimant.

As originally drafted, section 112 of S. 454 required all claimants in health care liability actions to obtain a Certificate of Merit before filing a court action. This section has been deleted.

Section 201 has been renamed “Funding for State Health Care Quality Assurance and Access Activities,” and the reference to “health care quality assurance programs” has been deleted.

Sections 202 of S. 454, requiring States to set up risk management programs, has been deleted.

Section 203 of S. 454, required the public disclosure of certain information reported to the National Practitioner Data Bank, has been deleted.

A new section (section 202 of the Chairman’s substitute) has been added. This section requires the Agency for Health Care Policy and Research (AHCPR), in consultation with public and private sector entities, to establish guidelines on quality assurance, patient safety, and consumer information.

These changes are explained at greater length below.

It also should be noted that some members of the committee who voted to report the legislation favorably did favor stronger reforms than those contained in the legislation.

C. Detailed explanation of the legislation adopted by the committee

Title I—Health care liability reform—Subtitle A. Liability reform

1. Federal Interest and Federal Preemption

The findings and purposes section of the legislation contained in section 101 asserts the Federal Government's important interest in addressing the issue of health care liability reform. The committee believes that the Federal Government has a significant stake in reforming the health care liability system both because of the effect of the system on interstate commerce and because of the enormous amount spent by the Federal Government on health care.

While the views of individual members of the committee regarding the necessary scope of preemption may have differed somewhat, none of the members who voted to report the legislation favorably disagreed about the need for Federal action in the area of medical liability reform.

a. The Private Sector Deserves to Benefit From the Same Type of Protections That the Federal Government Has Afforded Itself in Health Care Liability Actions

The Federal Government already has taken significant steps to limit its own exposure for costs associated with health care liability. For example, damages resulting from health claims disputes and redress in claims dispute cases are limited for Federal employees receiving health coverage under the Federal Employees Health Benefit Act (FEHBA), and for Medicare beneficiaries. There are no punitive or extra-contractual damages allowed under FEHBA or Medicare. See *Hayes v. Prudential Ins. Co.*, 819 F.2d 921 (9th Cir. 1987); *Homewood Professional Care Ctr., Ltd. v. Heckler*, 764 F.2d 1242 (7th Cir. 1985).¹

Moreover, responding to an outcry from Federal Community Health Centers about skyrocketing malpractice insurance premiums, Congress in 1992 limited the exposure of centers and their providers to malpractice claims by placing them under the Federal Tort Claims Act and taking steps that go well beyond the reforms in this legislation.²

The committee believes that the private sector is entitled to the same type of protections that the Federal Government has extended to its own health providers.

¹ The Federal Government has strictly limited liability in other contexts, as well. For example, neither punitive nor extra-contractual damages are allowed against defendants under the Federal Employee Retirement Income Security Act (ERISA). See *Pilot Life Ins. Co. v. DeDeaux*, 481 U.S. 41 (1987).

² In addition to having judgments paid from a Federal fund, that act: (1) allows liability to be determined by a judge rather than a jury (28 U.S.C. 2402); (2) contains a 2-year statute of limitations that is more restrictive than the one contained in this legislation (28 U.S.C. 2401); (3) prohibits the awarding of punitive damages (28 U.S.C. 2674); (4) places a cap on lawyers' contingency fees of 25 percent of a litigated claim and 20 percent of a settlement (28 U.S.C. 2678); disallows prejudgment interest (28 U.S.C. 2674); and requires claimants to exhaust administrative remedies before proceeding to court (28 U.S.C. 2675).

b. As the Largest Single Payer of Health Care Services, the Federal Government Has a Compelling Interest in Health Care Liability Reform

While the Federal Government has limited its exposure to health care liability claims in certain instances, large gaps remain. In particular, liability for health care professionals and providers who treat Medicaid and Medicare patients remain subject to uneven and sometimes insufficient State medical liability reforms. The committee notes that approximately one-third of total health care spending in this country is paid by the Federal Government. According to the Congressional Budget Office, Federal spending for Medicare will reach \$177 billion in FY 95, while Medicaid grants to States will total \$96 billion. Therefore, the committee believes that there is a compelling Federal interest in reforming the Nation's outmoded medical liability system.

c. Federal Legislation is Necessary Because of the Increasingly Interstate Character of Health Care Delivery

The committee recognizes that health care markets are becoming increasingly regional, if not national. Telemedicine, by its very nature, is designed to overcome barriers to the delivery of medicine, including long distances, geographic limitations, and political borders. Some of the finest medical facilities in the United States—such as the Mayo Clinic in Minnesota, Stanford University in California, Barnes Hospital in Missouri, the Cleveland Clinic in Ohio, and the Dartmouth Medical Center in New Hampshire—treat patients from across the Nation, and around the world.

While the committee does not believe there is a need for absolute uniformity in all aspects of the health care system, it believes that some minimum level of medical liability reforms would greatly assist the continued development of a cost-effective private health care system. This is particularly true where, as under this legislation, insurers and other third party payers may be sued as defendants in health care liability actions.

As health care providers continue to consolidate and form integrated networks of care in response to market forces, economic pressure, and emerging treatment patterns, the number of individuals who receive health care services in one State while having them financed by entities in another will continue to increase. While the committee acknowledges that health care services are delivered locally, this does not necessarily mean that health care is delivered within State borders. To the contrary: more than 40 percent of Americans live in cities and counties that border on State lines; in 26 States, more than half of the population lives in cities and counties that border on State lines; and over 50 percent of the population in 26 States lives in border cities and counties. See Bernard's 1993 City and County Director; 1989 Rand McNalley Atlas. In these areas, it is even more likely that a patient will live or work in one State, receive health care services in another, and have his or her bills paid by a third-party payer in another State.

A recent analysis of health services purchased across State borders found, for example: (1) that Vermont and New Hampshire residents visit an out-of-State physician nearly one-quarter of the

time; (2) that Wyoming residents visit out-of-State doctors over one-third of the time; and (3) that nearly 40 percent of the patients admitted to Delaware hospitals travel from out of the State.

d. Federal Legislation is Necessary Because of State Constitutional Impediments

Some have argued that this legislation is an unnecessary intrusion into an area of the law that traditionally has been the domain of the States. The committee notes that many of the opponents of Federal medical liability reform are, at the same time, aggressively challenging State tort reform efforts by arguing that the reforms are unconstitutional under State constitutions. As a result, many States have been frustrated in their efforts to pass meaningful tort reform—making the need for this legislation compelling. For example: (1) statutes of limitations in health care liability actions have been held to violate State constitutions in Arizona; (2) limits on punitive damage awards in health care liability actions have been held unconstitutional in Alabama; and (3) periodic payment schedules for damage awards in health care liability actions have been held to violate State constitutions in Arizona, New Hampshire, and Ohio.

2. Purpose of the Legislation

The committee believes that the current medical liability system fails to fairly and adequately compensate injured patients and, at the same time, places enormous costs—both human and economic—on the Nation’s health care system. As a result of these costs, access to health care services is curtailed—most often for those individuals who are most in need of care. As outlined in section 101(b) of the legislation, the legislation is therefore designed to improve the fairness and cost-effectiveness of the current health care liability system.

3. Definitions

The committee believes that several of the definitions contained in section 102 of the legislation deserve further explanation.

To help ensure that injured claimants receive full and fair recovery for economic losses, the committee added a definition of “economic losses” to the legislation. This definition was not included in S. 454 as originally drafted. The types of losses listed as “economic” are not meant to be exclusive. Moreover, to make clear that triers of fact should not discriminate against women in the awarding of damages for economic losses, the legislation makes clear that the term “economic losses” is meant to include the cost of obtaining “replacement services in the home (including child care, transportation, food preparation, and household care).”

The legislation defines a “health care liability action” as a civil action against a health care provider, health care professional, health plan, or any other defendant joined in a malpractice lawsuit. Except where specifically noted, the committee intends for the reforms contained in the legislation to apply to every claim arising out of the provision of, payment for, or failure to provide or pay for

health care services or medical products, regardless of the theory of liability on which the action is based.

The committee believes that the failure to apply the reforms contained in the legislation to every type of claim against any defendant included in a civil health care liability action would lead to bizarre, inconsistent, and unfair results. If, for example, the reforms contained in this legislation did not apply to all possible defendants involved in a health care liability action, a jury may be free use less restrictive standards in determining whether to award punitive damages against the manufacturer of a medical device or find the manufacturer responsible for the total damage award in a case involving claims against both a health care professional for negligent implant of a medical device and against a manufacturer for negligent distribution of the medical device.

In short, failure to include a broad definition of health care liability action actually may lead to the unintended consequence of increasing litigation, increasing health costs, and continuing to allow an inequitable proportion of damage awards to be paid by defendants with deep pockets but little actual responsibility for the harm.

The committee intends for the definition of "Health Plan" to include insurers, Health Maintenance Organizations (HMO's), Preferred Provider Organizations (PPO's), and other similar entities. The reforms contained in the legislation apply to these entities in all health care liability actions, including those involving claims related to the payment for, or failure to pay for, health care services or medical products.

The term "Health Care Professional" is meant to include all physicians, nurses, and others who are licensed, registered, or certified in a State to provide health care services. It also applies to individuals who are otherwise certified to provide health care services, such as medical students and interns.

The committee intends that the term "Health Care Provider" be given the broadest possible interpretation. The committee intends for the term "Health Care Provider" to apply to hospitals, clinics, and any other organizations that may now or hereafter be engaged in the delivery or provision of health care items or services.

Depending on their organization structure and the types of health care activities in which they are engaged, HMO's, PPO's, and other similar entities may fall under this definition, as well as the definition of "Health Plan." The definition of "Health Care Provider" is also broad enough, for example, to include manufacturers and distributors of medical products who clearly are organizations "engag[e] in delivery" of health care items.

4. Applicability and Preemption

The preemption provisions contained in section 103 of the legislation are more detailed than those contained in S. 454 as originally drafted. The committee believes that this degree of precision is necessary for two reasons. First, it is necessary to give the States clear guidance as to the scope of the reforms contained in the legislation and to make explicit, where possible, the desire to protect State laws that impose greater restrictions on liability or damages. Second, it is designed to avoid costly and unnecessary litigation regarding the applicability of the legislation in particular lawsuits.

The Supreme Court has recently chastised Congress for not providing sufficient statutory guidance regarding the extent of Federal preemption provisions. See *New York Blue Cross Plans et al. v. Travelers Ins. Co. et al.*, Supreme Court Slip Opinion 93-1408, 93-1414 & 93-1415 (April 26, 1995).

Section 103(a) of the legislation specifies that, in general, the reforms contained in subtitle A of the legislation will apply to any health care liability action brought in any Federal or State court. The subtitle will not apply to any action for damages to the extent that the provisions of the National Vaccine Injury Compensation Program apply.

Section 103(b) of the legislation specifies that the provisions of subtitle A of title I shall preempt existing or subsequently enacted State laws only to the extent those laws are inconsistent with the provision of subtitle A and even there only to the extent that the State law is less restrictive. The committee does not intend to preempt State law to the extent such law: (1) places greater restrictions on the amount of or standards for awarding noneconomic or punitive damages; (2) places greater limitations on the awarding of attorneys fees for awards in excess of \$150,000; (3) permits a lower threshold for the periodic payment of future damages; (4) establishes a shorter period of time during which a health care liability action may be initiated or a more restrictive rule with respect to the time at which the period of limitations begins to run; or (5) implements collateral source rule reform that either permits the introduction of evidence of collateral source benefits or provides for the mandatory offset of such benefits from damage awards. Thus, the committee wishes to emphasize that this bill does not preempt State laws that impose greater restrictions on liability or damages, or the procedures or standards for determining liability or damages, than those provided in this legislation.

Section 103(b) of the legislation further specifies that the provisions of subtitle A shall not be construed to preempt any State law which permits State officials to commence health care liability actions as a representative of an individual, permits provider-based dispute resolution, places a limit on total damages awarded in a health care liability action; places a maximum limit on the time in which such an action may be initiated; or provides for defenses in addition to those contained in the act.

Section 103(c) allows States to pass laws which otherwise would violate the preemption provisions contained in section 103(a) and 103(b) of the legislation. Generally, State laws enacted pursuant to this section of the legislation may apply only to health care liability actions involving parties that are residents of the same State. Section 103(c) was added to the legislation by an amendment offered during the executive session on April 25 by Senator Abraham. The amendment passed by a roll call vote of 9 yeas to 7 nays.

The effect of the Abraham amendment, in combination with the other preemption provisions in the legislation is as follows: The legislation generally preempts existing State laws which contain reforms that are weaker than those contained in the legislation. It does not preempt stronger reforms, such as those described in sections 103(a) and 103(b). In addition, States subsequently may pass weaker malpractice laws to govern intrastate disputes, but must

cite the authority of this legislation. While several questions were raised about the practical impact of this new provision, it certainly is a more narrow modification to the legislation's preemption provisions than some of the other proposed modifications debated during the executive session on April 25 in that weaker State laws would continue to be preempted, unless a State took the affirmative action of passing a law to override this legislation.

Section 103(d) of the legislation contains several additional construction clauses that the committee believes are necessary to clearly delineate the scope of these reforms. This legislation would not affect State laws that provide for comprehensive caps on damages. Seven States have such caps: Indiana, Virginia, Colorado, Louisiana, Nebraska, New Mexico, and South Dakota. In some States, this limit is linked to a patient compensation fund. The committee does not intend for this legislation to prevent from those types of funds.

The committee wishes to emphasize that the legislation is not intended to preempt either State or Federal criminal causes of action. It also should be emphasized that the legislation is not intended to supersede the remedies, claims procedures, or other liability provisions contained in Medicare, the Federal Employee Health Benefit Act (FEHBA), the Employee Retirement Income Security Act (ERISA), or any other Federal law. Section 103(d)(6) states expressly that the medical liability reforms contained in the legislation do not supersede any provision of Federal law.

5. Arguments in Opposition to the Preemption Provisions Are Without Merit

During consideration of the legislation, it was argued that the so-called "one-sided" preemption provisions contained in this section of the legislation were both novel and, somehow, unfair. The committee believes these arguments lack merit.³

In support of the preemption provisions contained in this section of the legislation, the committee notes the long history of the Congress in setting minimum Federal standards and allowing the States significant flexibility beyond those standards. See Clean Air Act Amendments of 1990, P.L. 101-549; Safe Drinking Water Act, P.L. 93-523; Civil Rights Act of 1964, P.L. 88-352; Americans with Disabilities Act, P.L. 101-336. Moreover, nearly every health care reform bill introduced in the last Congress contained this type of Federal floor preemption clause for medical liability reform (See, e.g., President Clinton's "Health Security Act," H.R. 3600; Senator Dole and Senator Packwood's health care reform bill, S. 2374; Senator Chafee's "Health Equity Access Reform Today Act", S. 1770; Representative Cooper's "Managed Competition Act," H.R. 3222;

³The characterization that all of the preemption provisions in the legislation are "one-sided" is simply incorrect. Two examples are instructive. As explained more fully below, the preemption provisions allow State collateral source reform measures to differ widely from the provisions contained in section 108 of this legislation. States not only have the flexibility to adopt evidentiary collateral source rules and mandatory offset rules that permit introduction of collateral source benefits after trial, but may, in fact, adopt a whole range of collateral source rule reforms that are more favorable to claimants than those contained in this substitute. Further, the substitute makes clear that State laws limiting attorneys fees for awards of \$150,000 or less may be both more restrictive than the 33 $\frac{1}{3}$ percent set forth in section 109(a) of this legislation and less restrictive.

the House Republican Leadership Plan, H.R. 3080; the bipartisan "Mainstream Coalition" health bill; and the House bipartisan health reform bill).⁴

The committee believes that this legislation is loyal to that tradition and wholly consistent with principles of Federalism embodied in the Constitution of the United States.

The following are some additional examples of one-sided preemption.

Product Liability Legislation. Several members of this committee are original cosponsors of S. 565, the "Product Liability Fairness Act of 1995." S. 565 recently was reported favorably by the Committee on Commerce, Science, and Transportation. Among other similarities between this legislation and S. 565, the Product Liability Fairness Act contains nearly identical limitations on joint and several liability and a similar statute of limitations provision.

While S. 565 requires all product liability actions to be filed within 20 years from the time a product is delivered, it allows States to impose shorter statutes of repose. See section 9 of S. 565. In addition, S. 565 requires several liability for noneconomic damages, but permits States to pass tougher laws requiring several liability for economic damages. See section 10 of S. 565. Moreover, while S. 565 caps punitive damages at \$250,000 or three times the amount of economic damages, States may set lower limits or may prohibit the awarding of punitive damages altogether. See section 8(a) of S. 565.

General Aviation Revitalization. Another recent and relevant example of so-called "one-sided" preemption is legislation that was passed overwhelming by this body during the 103d Congress. S. 1458, the General Aviation Revitalization Act of 1994, provided in part that no civil action for damages arising out of an accident involving a general aviation aircraft could be brought against the manufacturer of the aircraft or the manufacturer of any component part of the aircraft, if the accident occurred more than 18 years after the date of the aircraft's delivery or the component part's installation. S. 1458 preempts State law only to the extent that such law permitted civil actions to be commenced after 18 years. See P.L. 103-298.

S. 1458 passed on March 16, 1994 by a vote of 91-8.

The Family Health Insurance Protection Act. Another recent example of so-called "one-sided preemption" is contained in S. 7, the "Family Health Insurance Protection Act," which was introduced on the first day of the 104th Congress by the Senator Daschle and several members of this committee who opposed the preemption provisions contained in the legislation. Sections 1011 and 1012 of S. 7 provide a clear example of "one-sided" preemption.

Section 1011 provides that State laws will not be preempted by the act only if they: (1) contain preexisting condition waiting periods that are "less than those" established in S. 7; (2) limit variations in premium rates "beyond the variations permitted" in S. 7; and (3) expand the size of the small group market to include groups "in excess of" the size set forth in the legislation.

⁴The committee notes that section 103(c) of the legislation (the subject of the Abraham amendment described above) provides the States greater flexibility than under any of these bills.

Section 1012 contains even more expansive one-sided preemption provisions. It states that: “Nothing in this Act shall be construed as prohibiting States from enacting [any] health care reform measures that exceed the measures established under this Act, including reforms that expand access to health care services (i.e., higher taxes), control health care costs (i.e., institute tighter premium caps or cost controls), and enhance quality of care.

As these examples make clear, those who oppose the preemption principles embodied in this legislation have repeatedly and enthusiastically embraced those principles in other legislative contexts. Therefore, the only logical conclusion that can be reached is that opposition to these preemption provisions is based largely on antipathy toward the substance of this legislation, and not on principles of Federalism.

6. Statute of Limitations

Section 104 of the legislation requires that all health care liability actions be filed within 2 years after a claimant has discovered, or should have discovered, both the injury and its cause. For example, a patient who experiences chest pains 1 year after having surgery but does not discover until 4 years later—in the exercise of reasonable care—that the injury was caused by a medical instrument left in his body during surgery, would not be required under this legislation to file a lawsuit against the operating physician or hospital until 2 years after he discovers the existence of the instrument.

Section 104 also provides that individuals who are considered disabled in the eyes of the law, such as minors, must file health care liability actions within 2 years after the date the disability ceases.

The committee recognizes that this statute of limitation standard is somewhat more liberal than standards that currently exist in many States where claimants are required to file civil lawsuits within 2 years from the date the claimant discovers his or her injury. The committee also notes, that unlike the medical liability reforms in existence in many States, the legislation contains no statute of repose requiring health care liability actions to be commenced within a certain period of time after an injury occurs.

Therefore, as noted previously, the committee believes that States should be free to establish a shorter period of time during which a health care liability action may be initiated or a more restrictive rule with respect to the time at which the period of limitations begins to run. States may also place a maximum limit on the time in which such an action may be initiated.

7. Reform of Punitive Damages

The committee believes that damages designed solely to punish defendants in health care liability actions should be limited to extraordinary circumstances. Therefore, under section 105 of the legislation, punitive damages may be awarded only where a claimant proves to the trier of fact by “clear and convincing evidence” that a defendant has violated the minimum Federal standards set forth in the legislation.

Under the legislation, States may require a higher level of culpability or willfulness before allowing punitive damages, have additional procedural requirements for seeking, considering, or awarding punitive damages, or they may prohibit punitive damages altogether as a general rule or in certain cases. The committee does not intend to preempt these more restrictive State laws.

Moreover, pursuant to an amendment adopted during the executive session on April 25 that was offered by Senator Dodd, a judge rather than a jury must determine the amount to be awarded for punitive damages in a subsequent proceeding.

The Dodd amendment, which was adopted by a roll call vote of 9 yeas to 7 nays, also struck a provision from the Chairman's substitute that limited punitive damage awards against health care professionals, health plans, health care providers and other defendants in a health care liability action to \$250,000 or three times economic damages, whichever is greater.

It is important to note here that the legislation does not prohibit injured patients from recovering complete compensatory damages. The legislation places no limitation on the amount claimants may recover for either economic damages (such as past and future medical expenses, past and future earnings, loss of business or employment opportunities, and the cost of replacement services in the home) or noneconomic damages (such as pain and suffering, mental anguish, and loss of companionship).

8. Periodic Payments

The committee believes that when large damage awards are required to be paid in a lump sum in medical liability cases, such awards can have a significant impact on the availability and affordability of liability insurance. Therefore, section 106 requires that where the amount of future damages awarded in a health care liability action exceeds \$100,000, either party may request that those damages be paid on a periodic basis.

The committee intends for the adjudicating body to look to the Uniform Periodic Payment of Judgments Act for guidance in structuring periodic payment awards. The committee believes it is important that judges have some guidance from a uniform, existing body of law in determining how to structure these awards. Moreover, because the nature of personal injuries and losses resulting from medical liability—as well as the ability of defendants to compensate injured patients—varies widely, the committee believes it is more prudent to reference an existing body of law than to try to craft legislative language to take into consideration every factor that must be considered in the awarding of future damage awards. Among other things, the Uniform Periodic Payment of Judgments Act contains provisions dealing with evidence and findings regarding changes in the purchasing power of the dollar, interest on periodic payments, the security of future payments, and requirements for qualified funding plans.

The committee believes that the adjudicating body should be given the discretion to waive the requirements of this section where such a waiver is in the interest of justice.

9. Scope of Liability

The common law rule of joint and several liability makes each and every defendant in a tort lawsuit liable for the entire amount of a claimant's damages. To promote more equitable resolution of health care liability actions, the committee strongly believes that defendants in health care liability actions should be held responsible for noneconomic and punitive damages only in direct proportion to their own fault or responsibility for an injury. This principle is embodied in section 107 of the legislation.

The committee believes that defendants in a lawsuit should not be liable for damages in excess of their degree of fault simply because they can afford it. The rule of joint and several liability too often turns lawsuits into searches for a marginally involved party whose pockets are deep enough to pay a sizeable award. Because the amount awarded for noneconomic and punitive damages, in particular, is so often based on subjective factors, the committee believes that this is one of the areas with the greatest potential for abuse in health care liability actions.

It is true, as defenders of the principle of joint and several liability argue, that the rule increases the probability that worthy claimants will be fully compensated. However, the committee believes that whatever desirability the rule of joint and several liability holds for claimants is far outweighed by the injustice that the rule does to defendants who are only minimally responsible for causing an injury.

The legislation takes a middle ground approach to reforming the rule of joint and several liability. The legislation only allows several, or "proportional," liability for noneconomic and punitive damages. The rule of joint and several liability, therefore, would still apply to awards of economic damages. Under the legislation, claimants still may recover all out of pocket expenses, including payments for past and future medical bills, rehabilitation expenses, lost wages, and the cost of replacement services in the home from any defendant, no matter what their degree of fault. The committee believes that this approach minimizes the gross unfairness to defendants resulting from the rule of joint and several liability while, at the same time, allowing a claimant's objectively verifiable monetary losses to be paid by a deep pocket defendant.

The committee notes that about half of the States have enacted some type of joint and several liability reform in order to apportion fault more fairly, and six States—Alaska, Arizona, Kansas, Utah, Vermont, and Wyoming—have totally abolished joint and several liability.

10. Mandatory Offsets For Damages Paid By A Collateral Source

To help hold down health care costs, the committee believes it is important to prevent claimants from recovering twice for the same injury. Therefore, sections 108 (a) and (b) of the legislation require that the total amount of damages awarded at trial be reduced by the amount of any other payment that has been, or will be, made to compensate the individual for the injury.

Section 108(c) of the legislation provides that the amount of the required deductions will be determined by the court in a pretrial

proceeding, and that no evidence shall be admitted at trial concerning the amount of any charge, payments, or damages for which a claimant has received payment from a collateral source or for which the obligation has been assured, or is likely to be assumed, by a third party.

Currently, successful claimants receive award for economic losses equal to their medical bills (plus lost wages, et cetera), even if those bills have been covered by the claimant's insurers. This results in unnecessary double recovery. Noneconomic losses are generally calculated as a multiple of economic losses, at a rate of two to four times economic losses. A system that bases the award on the claimant's medical bills creates a powerful incentive for overuse and even abuse of the health care system. Because those medical costs are often covered by insurance, claimants run no risk of out-of-pocket loss, even if the negligence case is unsuccessful. Therefore, in effect, the health insurance system is subsidizing frivolous cases, and driving up the cost of insurance for everyone.

A recent study by the Rand Corp. of auto accidents provides by analogy a stark demonstration of the existing incentives provided by the common law collateral source rule. According to the study, 33-43 percent of medical costs incurred after an automobile accident appear to be excessive. In 1992, excessive medical claims may have cost consumers \$13 to \$18 billion in auto insurance premiums.

The reasons are clear. As stated previously, the collateral source rule allows plaintiffs to claim as damages, expenses which have already been reimbursed by a third party. Thus, for every dollar spent on health services to treat an "injury" after an auto accident or an alleged incidence of malpractice, a claimant has a good chance of collecting back \$3 or \$4 in a successful lawsuit. If the lawsuit is lost, the claimant has spent little or none of his own resources. The powerful incentives for overtreatment cost every American through higher health insurance premiums, disability premiums and taxes.

The legislation addresses this incentive for excessive claims by insuring that plaintiffs cannot double recover for amounts paid by a third party. If a claimant cannot recover the costs of services paid for by someone else, then those amounts cannot be doubled or trebled to determine the amount of noneconomic damages. The Rand study indicates that not only is this system fairer, it also will save significant amounts in excessive health care costs.

The committee generally believes that reducing damage awards by the amount a claimant may receive from collateral source payments before trial is the most effective way to reduce health care liability costs and prevent double recovery. Under this system, the jury would still get all the necessary information about the scope of the injury, and the duration of any hospital stay or treatment. However, it would not get specific payment information about those amounts covered by insurance, an employer's wage continuation program, or other collateral payments. Injured claimants will receive full and fair compensation for their injuries. However, the incentive for overuse and abuse of the medical system will be reduced.

However, the committee wishes to make clear that States may maintain laws they already have in place, or may adopt collateral source reform laws in the future that differ from those specified in section 108 of the legislation. Section 103(b)(1)(E) makes clear that States may adopt collateral source rule reform that either permits the introduction of evidence of collateral source benefits to the trier of fact, or allows for the mandatory offset of collateral source benefits at some point other than during a pretrial proceeding.

Some opponents of the legislation argue against collateral source rule reform by claiming that employers, insurers and third party payers would be forced to subsidize the negligence of health care providers. The legislation should not be interpreted to require this subsidization. In fact, this legislation does not address the issues of “subrogation” or “contribution” at all. Those issues are left to the law of the individual States. Thus, if a health insurer or other “third party” insurer is now permitted under State law to recover from a negligent provider or the provider’s insurance company for the amount spent on injuries caused by that provider, this legislation should not be interpreted to preempt that State law. Of course, the opposite is also true. If State law disallow subrogation or contribution claims, those State laws would be controlling.

11. Treatment of Attorney’s Fees And Other Costs

To ensure that injured patients recover a greater share of their medical liability awards, section 109 of the legislation limits attorneys’ contingency fees to 33 $\frac{1}{3}$ percent of the first \$150,000 recovered and 25 percent of awards in excess of \$150,000. The provision applies to amounts recovered through either judgment or settlement. The legislation makes clear that the maximum amount that may be paid toward attorneys’s fees must be calculated based on the net amount a claimant recovers after taxes.

During the executive session on April 25, an amendment was offered by Senator Wellstone to limit defense attorneys’ fees to the amount recovered by a claimant’s attorney. Many members who supported the Chairman’s substitute were concerned that the amendment, as it was drafted, would create perverse incentives for defense attorneys. By linking defense attorneys’ fees to claimant’s contingency fees, the amendment—which eventually was withdrawn—would have allowed defense attorney’s to collect fees commensurate with the amount claimants received in damages; the more damages that were awarded to a claimant, the more a defense attorney would be allowed to collect from his or her client.

12. State-Based Alternative Dispute Resolution Mechanisms

To promote the resolution of claims in a more convenient, timely, and affordable manner, section 110 of the legislation encourages States to experiment with alternative dispute resolution (ADR) mechanisms and requires the U.S. Attorney General to provide technical assistance to States regarding various ADR mechanisms. The section further requires the Attorney General (in consultation with the Secretary and the Administrative Conference of the United States) to monitor and evaluate the effectiveness of State alternative dispute resolution mechanisms.

During the committee's deliberations, some members raised concerns about the ADR procedures in S. 454, as originally drafted. The original bill: (1) required States to adopt ADR procedures; (2) required parties to go through ADR before going to court; and (3) required the parties to meet a higher standard of proof ("beyond a reasonable doubt") in court if they rejected a reasonable settlement offer made during ADR.

In response, the substitute modified these provisions so that: (1) States may adopt ADR; (2) at the State's discretion, ADR may be binding or nonbinding; (3) parties need not meet a higher standard of proof if they reject a settlement offer; and (4) a modified fee-shifting rule applies equally to both plaintiffs and defendants in order to promote reasonable settlements.

An amendment offered by Senator Kennedy during the executive session on April 25 to make the fee-shifting provisions optional was defeated by a roll call vote of 7 yeas and 9 nays.

Subtitle B. Biomaterials access assurance

The reforms contained in title I, subtitle B of the legislation are designed to avert an imminent shortage of raw materials used in lifesaving medical devices. The scarcity of these materials is a direct result of costly litigation.

This legislation would not affect the ability of claimants to sue manufacturers or sellers of medical implants. Instead, it would allow raw material suppliers to be dismissed from lawsuits relating to the design or manufacture of medical implants, without incurring extensive legal costs. In order to be dismissed from a lawsuit, the legislation requires suppliers to prove that: (1) they cannot be classified as either a manufacturer or a seller of the medical device; and (2) the raw materials they supplied met contract specifications.

Title II—Protection of the health and safety of patients

A. Summary

As noted previously, title I of the legislation is designed to make the medical liability system more fair, equitable, and cost-effective. Title II of the legislation recognizes that quality assurance, patient safety, and consumer information are also powerful tools both for preventing malpractice actions and for measuring the performance of providers and health plans.

While the medical liability system provides some deterrence to negligent care, other mechanisms—such as quality assurance—can help further limit medical negligence. The Chairman's substitute contains major revisions to title II of S. 454, as originally introduced. The legislation has been strengthened by requiring that an independent advisory panel, within the Agency for Health Care Policy and Research, establish guidelines in the areas of quality assurance, patient safety, and consumer information.

B. Section 201

The committee was concerned that section 201 of S. 454, as originally drafted, could have been read to create an unfunded mandate on the States by requiring them to develop quality assurance programs without adequate funding. Therefore, the language in sec-

tion 201 of the legislation reported by the committee has been modified. The new language requires States to direct at least 50 percent of punitive damage awards in health care liability actions to State activities relating to the licensing, investigating, disciplining, and certification of health care professionals and to the reduction of malpractice-related costs for health care providers volunteering in medically underserved areas. The committee intends for this section of the legislation to help provide increased funding for current State activities.

C. Section 202

1. Advisory Panel

Both section 202 (Risk Management Programs) and 203 (National Practitioner Data Bank) were deleted from S. 454 by the Chairman's substitute, and replaced by a new section 202 which establishes an advisory panel within the Agency for Health Care Policy and Research. The purpose of the advisory panel is to bring together the many different public and private organizations that have been working to determine appropriate methods for measuring the quality, safety, and effectiveness of the health care delivery system.

It became evident during the committee's deliberations that many consumers do not have ready access to information regarding: (1) the licensing and disciplining of providers; (2) judicial proceedings against providers; and (3) health care quality, outcomes, and patient satisfaction. To help empower consumers to make more informed choices about the safety and effectiveness of health care services, the committee believes it is important to: (1) determine what information is currently available; (2) assess the reliability and validity of such information; and (3) evaluate methods for making valid and reliable information available to health care consumers.

The committee intends for the panel to establish consensus guidelines in the areas of quality assurance, patient safety, and consumer information. The committee hopes that the panel's efforts will bring together purchasers, consumers, providers, and health plans to begin developing guidelines on mutually useful comparative data.

The committee intends for the advisory panel to consist of at least 15 members but no more than 21. The members of the panel should be chosen from public and private organizations which have exhibited expertise in the areas of risk assessment, risk management, quality assurance, patient safety, and performance measures for providers and health plans. The public entities would include both Federal entities (such as the Health Care Financing Administration (HCA), the Centers for Disease Control (CDC), PROPAC, and the Physician Payment Review Commission) and State associations (such as the Federation of State Medical Boards and the National Association of Insurance Commissioners). Private sector organizations would include professional associations such as the American Dental Association, specialty provider organizations that have established practice guidelines, the American Medical Association, the Health Insurance Association of America (HIAA), and

managed care health plan associations. Other private sector members should include consumer groups, private foundations, the National Committee for Quality Assurance, the Joint Commission on Accreditation of Health Care Organizations, and employer purchaser representatives, including those involved in the development of the Health Plan Employer Data Information Set (HEDIS).

2. National Practitioner Data Bank

In 1986, Congress enacted the Health Care Quality Improvement Act, which authorized the Secretary of Health and Human Services (HHS) to establish the National Practitioner Data Bank (NPDB or Data Bank). The NPDB is designed to provide hospitals and group practices with information to make decisions about hiring, credentialing, and disciplining practitioners, thus allowing hospitals and medical groups to take responsibility for the quality of physicians in their facilities.

The NPDB, which is now operated by a contractor to the Health Resources and Services Administration (HRSA) of the Public Health Service (PHS), collects information that falls into two main categories: (1) disciplinary actions taken against a physician's license (submitted by State medical boards), clinical privileges (submitted by hospitals) and sanctions by society memberships (submitted by peers); and (2) malpractice lawsuits (actions taken by patients or consumers). The NPDB contains information on malpractice payments resulting from both judgements and settlements.

Hospitals and other health care entities, licensing boards, and professional societies must report to the Data Bank all adverse actions they take that affect a practitioner's clinical privileges for more than 30 days. Malpractice insurers are required to report the following information on all lawsuits resulting in payment: date, amount paid, judgement or settlement, description of the acts and omissions, and injuries or illnesses upon which the case was based. Physicians are permitted to write a brief appendage (limited to 60 characters) to any report of which they are the subject. Hospitals, group medical practices, professional societies, State licensing boards, and practitioners are the only entities that have access to the NPDB. They are required by law to query the Data Bank for each practitioner seeking clinical privileges or licensure.

The Health Care Quality Improvement Act expressly provides that all information reported to the Data Bank must be kept confidential. Moreover, many States strictly protect the confidentiality of information submitted to the NPDB. The committee therefore was concerned that making information submitted to the NPDB public would override State confidentiality laws.

Although the Office of Inspector General (OIG) has completed some cursory reports on the NPDB, the NPDB has not been thoroughly evaluated to determine if the information it collects is valid and reliable. The four reports written by the OIG focused on two areas of concern: (1) reporting data as required and (2) the utilization of that data. These OIG reports reveal that there has been a steady increase in the use of the NPDB since it was first opened in September 1990. Hospitals reported that the information from the NPDB resulted in a decision to deny practice privileges to a physician in 1 percent of all cases. Approximately 1,000 physicians

have been reported each year since the NPDB opened, but 75 percent of all hospitals have never reported to the Data Bank as required by law. In addition, a substantial number of State licensing board actions are not reported to the NPDB as indicated by the fact that only 3,154 of 8,000 practitioners who had disciplinary actions taken by State licensing boards were reported to the NPDB between 1990 and 1993. This variance can be partially attributed to the difference in reporting requirements between the States and the NPDB.

As originally drafted, S. 454 would have allowed consumers access to the NPDB for the limited purposes of reviewing disciplinary actions. The committee weighed very carefully the benefits of opening the NPDB to the public. However, it ultimately decided that it was more desirable at this time to have a panel of experts develop reliable guidelines on quality assurance, risk assessment, and patient safety, and to further evaluate the quality and reliability of information available in the Data Bank.

In arriving at this decision, the committee relied in part on the history of the Data Bank and the views of those who were involved in its development.

For example, a letter submitted by the National Council of Community Hospitals (NCCH), which was instrumental in developing the NPDB legislation in 1986, stated:

The Data Bank legislation was supported in 1986 by a broad spectrum of interests on the understanding that information submitted to the Data Bank would be used for professional review activity and would not be publicly available. Efforts made to delete the confidentiality provision were rejected by the sponsors of the legislation. It would be unfair now to change the understanding on which the bill was enacted, and tilt the law's carefully constructed balance.

Another letter submitted by the American Dental Association stated:

Information in the Data Bank was intended for "knowledgeable" individuals and not for public release. The House Commerce Committee recognized this when it created the Data Bank stating the law "* * * does not necessarily require extensive descriptions of the acts or omissions nor of the injuries or illnesses upon which the action or claim was based. It does, however, require sufficient specificity to enable a knowledgeable reviewer to determine clearly the circumstances of the action or claim."

In addition, the committee took into consideration the fact that much of the disciplinary information in the Data Bank is accessible to the public directly through State medical boards, and the fact that all 50 State dental boards make their actions available to the public through newsletters, professional journals, and newspapers.

Of greater significance to the committee was strong evidence that the information in the Data Bank is neither valid nor reliable. The committee believes it would be irresponsible for Congress to knowingly provide access to consumers that is inaccurate and unreliable.

This, coupled with the fact that the information was intended for “knowledgeable reviewers” and was expressly agreed to be kept confidential, convinced the committee to take a more prudent approach to releasing information contained in the Data Bank.

It has come to the attention of the committee that HRSA has contracted with Walcoff and Associates to do a 2-year in-depth assessment of the accuracy and effectiveness of information collected in the Data Bank. This evaluation is expected to be completed within the next few months. The legislation requires the advisory panel to review all evaluations completed on the Data Bank by the Government Accounting Office, the OIG at HHS, and Walcoff and Associates, and report to this committee within 6 months as to whether the Data Bank is fulfilling its Congressional mandate. In addition, the legislation requires that, within 1 year, the advisory panel must submit to this committee an independent evaluation on the value of permitting consumers to have access to the information in the Data Bank.

An amendment offered by Senator Wellstone, but rejected by the committee by a vote of 10–6, would have gone beyond the original language in S. 454 and made available to the public within 6 months all of the information contained in the Data Bank, including information regarding malpractice actions. Although the amendment required the Secretary of HHS to evaluate the Data Bank within 3 months, it did not request any information regarding the amount of time it would take to make the information in the Data Bank user-friendly or the costs associated with such an endeavor.

The committee is committed to making valid and reliable data on providers and health plans available to the consumer. During consideration of S. 454, many members of the committee expressed their strong desire to hold hearings on the information contained in the advisory panel’s reports soon after it is available and, if necessary, to hold oversight hearings on the panel’s activities.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 28, 1995.

Hon. NANCY L. KASSEBAUM,
*Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.*

DEAR MADAM CHAIRMAN: The Congressional Budget Office (CBO) has reviewed S. 454, the “Health Care Liability Reform and Quality Assurance Act of 1995”, as ordered reported by the Committee on Labor and Human Resources on April 25. CBO estimates that the bill would not significantly affect direct spending.

S. 454 would implement a number of measures intended to expand the availability of health care services that may have been curtailed by fear of suits for malpractice, improve the cost-effectiveness of the current system of malpractice litigation, and reduce uncertainty in the amount of compensation provided to injured individuals. The bill would limit the number of situations in which punitive damages may be awarded, make defendants’ liable for puni-

tive and noneconomic damages only in proportion to their share of fault or responsibility, reduce damage awards to individuals by the amount of any payments received from third-party sources, and limit contingency fees paid to attorneys. The bill would also place limits on the liability of biomaterials suppliers whose products are used for implants.

For several reasons, CBO assumes that any reduction in health expenditures as a result of the proposed reforms would be negligible. First, although official measures are not available, malpractice premiums appear to account for a very small share of total health spending. In 1990, estimates of total malpractice premiums paid by health care providers ranged from about \$5 billion to about \$10 billion, compared with national health expenditures of about \$700 billion that year. Malpractice liability insurance is a similarly small component of the composite price indices used by Medicare to update reimbursements to health care providers.

Second, efforts to streamline and standardize malpractice awards could result in more compensation being paid for certain types or cases of malpractice and less compensation being paid for others. In changing the awards to claimants, these efforts could also affect the number of malpractice actions brought. As a result, premiums for malpractice insurance could increase or decrease, and there is no evidence available to judge which outcome is more likely.

Third, the bill allows states to choose which, if any, provisions would apply to lawsuits involving their residents. S. 454 could affect malpractice damage awards only in states that do not already have similar provisions in state law, and states with less restrictive liability laws might choose to maintain current practices.

Finally, any reduction in malpractice awards that might occur would not necessarily reduce malpractice insurance premiums, nor would it necessarily be reflected in the amounts paid by either private or public health care payors. Although any reduction in awards would reduce malpractice insurers' costs, it would take time before competitive pressures generated lower malpractice insurance premiums. Similarly, even if a reduction in malpractice insurance premiums occurred, health spending would be affected only if competitive pressures forced providers to reduce their prices.

S. 454 would also require the Attorney General and the Secretary of Health and Human Services to develop guidelines for alternative dispute resolution mechanisms and to monitor and evaluate the effectiveness of State alternative dispute resolution mechanisms. The bill also would require the Agency for Health Care Policy and Research to establish an advisory panel, conduct a survey collecting extensive data with respect to quality assurance, risk assessment, patient safety, and patient satisfaction, establish health care guidelines based on the information gathered in the survey, and prepare several reports. CBO estimates that the cost of these provisions would be no more than \$5 million in each year, assuming that the necessary funds were appropriated.

CBO estimates that enactment of S. 454 would have no significant effect on the budgets of state and local governments.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lisa Layman.

Sincerely,

JUNE E. O'NEILL, *Director*.

VI. REGULATORY IMPACT STATEMENT

The committee has determined that there will be only a negligible increase in the regulatory burden of paperwork as the result of this legislation.

VII. SECTION-BY-SECTION ANALYSIS

Section 1. Short Title

The act may be cited as the "Health Care Liability Reform and Quality Assurance Act of 1995."

TITLE I—HEALTH CARE LIABILITY REFORM

Subtitle A. Liability reform

Section 101. Findings and purpose

Section 101(a) of the legislation states that Congress finds that the civil justice system of the United States is a costly and inefficient mechanism for resolving health care liability claims and compensating injured patients. Further, problems associated with the current system are having an adverse impact on availability of, access to, and cost of care. The Congress finds that the health care and insurance industries affect interstate commerce and that the current health care liability litigation systems affect interstate commerce by contributing to the high cost of health care and health care liability insurance premiums. The Congress also finds that current health care liability litigation systems have a significant impact on Federal spending because of the large numbers of persons receiving health benefits under Federal programs, the large number who benefit from the exclusion from Federal taxes of amounts spent to provide benefits, and the large numbers of providers who receive Federal payments for services.

Section 101(b) of the legislation specifies that it is the purpose of the act to implement reasonable, comprehensive, and effective health care liability reform designed to: (1) Ensure persons with meritorious claims receive fair and adequate compensation; (2) improve the availability of health care services in cases where liability actions have been shown to be a factor in decreased service availability; and (3) improve the fairness and cost-effectiveness of the system by reducing uncertainty and unpredictability in the amount of compensation provided to injured persons.

Section 102. Definitions

Section 102 of the legislation includes definitions. "Claimant" is defined as a person who commences a health care liability action and any person on whose behalf such an action is brought (including a decedent).

"Clear and convincing evidence" is defined as that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be

established; the measure or degree of proof is more than that required under preponderance of the evidence but less than that required for proof beyond a reasonable doubt.

“Collateral source rule” is defined as a rule, established by statute or common law, that prevents the introduction of evidence regarding collateral source benefits or that prohibits the deduction of collateral source benefits from an award of damages in a health care liability action.

“Economic Losses” are defined as objectively verifiable monetary losses incurred as a result of the provision of (or failure to provide or pay for) health care services or the use of a medical product. Included are past and future medical expenses, loss of past and future earnings, cost of obtaining replacement services in the home (including child care, transportation, food preparation and household care), cost of making reasonable accommodations to a personal residence, loss of employment, and loss of business or employment opportunities. Economic losses are neither noneconomic losses nor punitive damages.

“Health care liability action” is defined as a civil action against a health care provider, health care professional, health care plan, or other defendant in which the claimant alleges injury related to the provision of, payment for, or the failure to provide or pay for health care services or medical products, regardless of the theory of liability on which the action is based. Included is a right to legal or equitable contribution, indemnity, subrogation, third-party claims, cross claims, or counter claims.

“Health plan” is defined as any person or entity which is obligated to provide or pay for health benefits under any insurance arrangement. Included is any person or entity acting under contract or arrangement to provide, arrange for, or administer any health benefit.

“Health care professional” is defined as any individual who provides health care services in a State and who is required by Federal or State laws or regulations to be licensed, registered, or certified to provide such services. Also included is an individual who is certified to provide health care services pursuant to a program of education, training and examination by an accredited institution, professional board, or professional organization.

“Health care provider” is defined as an organization or institution that is engaged in the delivery of health care items or services in a State and that is required by Federal or State laws or regulations to be licensed, registered or certified to deliver such items or services.

“Health care services” are defined as any services provided by any health care professional, health care provider, or health plan that relate to the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of human beings. Included are services provided by an individual under the supervision of a health care professional.

“Injury” is defined as any illness, disease, or other harm that is the subject of a health care liability action.

“Medical product” is defined as a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act or a medical device (as defined in section 201(h) of such act. Included is any

component or raw material used therein. Excluded are health care services as defined above.

“Noneconomic losses” are defined as losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of consortium, loss of society or companionship (other than the loss of domestic services), and other nonpecuniary losses incurred by an individual with respect to which a health care liability action is brought. Noneconomic losses are neither economic losses nor punitive damages.

“Punitive damages” are defined as damages awarded for the purpose of punishment or deterrence, and not for compensatory purposes, against a health care professional, health care provider, or other defendant in a health care liability action. Punitive damages are neither economic nor noneconomic damages.

“Secretary” is defined as the Secretary of the Department of Health and Human Services.

“State” is defined as the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

Section 103. Applicability

Section 103(a) of the legislation specifies that (except as provided in section 103(c), below) this subtitle A will apply to any health care liability action brought in any Federal or State court. The subtitle will not apply to any action for damages to the extent that the provisions of the National Vaccine Injury Compensation Program apply.

Section 103(b) of the legislation specifies that the provisions of subtitle A of title I shall preempt State law only to the extent State law is inconsistent with the provisions of subtitle A. Such subtitle will not preempt State law to the extent such law: (1) places greater restrictions on the amount of or standards for awarding noneconomic or punitive damages; (2) places greater limitations on the awarding of attorneys fees for awards in excess of \$150,000; (3) permits a lower threshold for the periodic payment of future damages; (4) establishes a shorter period of time during which a health care liability action may be initiated or a more restrictive rule with respect to the time at which the period of limitations begins to run; or (5) implements collateral source rule reform that either permits the introduction of evidence of collateral source benefits or provides for the mandatory offset of such benefits from damage awards.

Section 103(b) of the legislation further specifies that the provisions of subtitle A shall not be construed to preempt any State law which permits State officials to commence health care liability actions as a representative of an individual, permits provider-based dispute resolution, places a limit on total damages awarded in a health care liability action; places a maximum limit on the time in which such an action may be initiated; or provides for defenses in addition to those contained in the act.

Section 103(c) of the legislation provides that the provisions of this subtitle shall not apply to a health care liability action involving parties that are residents of the same State if the action is brought in State court and the State has enacted a law: (1) specifically citing the authority of this subsection; and (2) proclaiming that the State has determined that such provision shall not apply

to such actions. With respect to a health care liability action involving parties that are residents of more than one State, State choice-of-law rules will govern if each State has enacted a law pursuant to this subsection. For purposes of this section, a corporation is deemed a resident of the State in which it is incorporated and in which its principal place of business is located.

Section 103(d) of the legislation specifies that nothing in subtitle A is to be construed to: (1) waive or affect any defense of sovereign immunity asserted by any State under provision of law; (2) waive or affect any such defense asserted by the U.S.; (3) affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976; (4) preempt State choice-of-law rules with respect to any actions brought by a foreign nation or one of its citizens; (5) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss an action of a foreign nation or of one of its citizens on the ground of inconvenient forum; or (6) supersede any provision of Federal law.

Section 103(d) of the legislation specifies that nothing in subtitle A of title I shall be construed to establish any jurisdiction in the U.S. district courts over health care liability action on the basis of Federal question grounds specified in section 1331 or 1337 of title 28 of the U.S. Code.

Section 104. Statute of limitations

Section 104 of the legislation specifies that a health care liability action may not be initiated unless a complaint is filed within the 2-year period beginning on the date the claimant discovered, or should have discovered, the injury and its cause. An action relating to a claimant under legal disability may be filed within 2 years after the date on which the disability ceases. If the commencement of an action is stayed or enjoined, the running of the statute of limitations is to be suspended for the period of such stay or injunction.

Section 105. Reform of punitive damages

Section 105(a) of the legislation specifies that an award of punitive damages may only be made, if otherwise permitted by law, if it is proven by clear and convincing evidence that the defendant: (1) intended to injure the claimant for a reason unrelated to the provision of health care services; (2) understood the claimant was substantially certain to suffer unnecessary injury and deliberately failed to avoid such injury; or (3) acted with a conscious flagrant disregard of a substantial and unjustifiable risk of unnecessary injury which the defendant failed to avoid in a manner which constitutes a gross deviation from the normal standard of conduct.

Section 105(b) of the legislation provides that no punitive damages may be awarded against a defendant if no judgment for compensatory damages (including nominal damages under \$500) is rendered.

Section 105(c) of the legislation provides that the trier of fact shall determine whether punitive damages shall be allowed and, if a trier of fact determines that such damages are allowed, there will be a separate proceeding conducted by the court to determine the amount of punitive damages to be awarded.

Section 105(c) of the legislation further requires that in determining the amount of punitive damages, the court shall consider: (1) severity of harm caused by the defendant; (2) duration of the conduct or any concealment of the conduct; (3) the profitability of the conduct; (4) the number of products sold or medical procedures rendered for compensation of the kind causing harm to the defendant; and (5) the total deterrent effect of other damages and punishment imposed upon the defendant as a result of the misconduct. The court must clearly state its reasons for setting the amount of punitive damage awards under these standards.

Section 105(d) of the legislation specifies that nothing in this act is to be construed as implying a right to seek punitive damages where such right does not exist under Federal or State law.

Section 106. Periodic payments

Sections 106 of the legislation provides that the adjudicating body, at the request of either party, will order that future payments in excess of \$100,000 be paid on a periodic basis. The adjudicating body is to establish the payment basis in accordance with the Uniform Periodic Payments of Judgments Act, as promulgated by the National Conference of Commissioners on Uniform State Laws in July 1990. The adjudicating body may waive the requirements for periodic payments if it determines the waiver is in the interests of justice.

Section 107. Scope of liability

Section 107(a) of the legislation specifies that the liability of each defendant in a health care liability action for both punitive and noneconomic damages is several only; it may not be joint. A defendant is liable only for the amount of punitive or noneconomic damages allocated to the defendant in direct proportion to his or her percentage of fault or responsibility for the injury suffered by the claimant.

Section 107(b) of the legislation requires the trier of fact to determine, with respect to punitive or noneconomic damages, the extent of each party's fault or responsibility for the injury and assign a percentage of responsibility to each party.

Section 108. Mandatory offsets for damages paid by a collateral source

Section 108(a) of the legislation specifies that the total amount of damages received by an individual in a health care liability action shall be reduced by any other payment that has been, or will be, made to compensate the individual for the injury.

Section 108(b) of the legislation provides that the amount of the reduction equals the total amount of payments that have been or will be made to pay the costs of or compensate the individual for the injury minus any amount paid by the individual (or by the individual's spouse, parent, or legal guardian) to secure the payments.

Section 108(c) of the legislation provides that the amount of the required deductions will be determined by the court in a pretrial proceeding. No evidence is to be admitted at trial concerning the amount of any charge, payments, or damages for which a claimant has received payment from a collateral source or for which the obli-

gation has been assured by a third party. Further no evidence may be admitted at trial as to the amount of any charge, payments, or damage that the claimant is, or with reasonable certainty, will be eligible to receive payments from a collateral source whose obligation will with reasonable certainty be assumed by a third party.

Section 108(c) of the legislation further provides that the jury, if any, will be advised that the claimant's medical expenses and lost income have been or will be paid by a collateral source or third party except for those damages which the court permits to be introduced into evidence. Further, the jury is to be advised that the claimant will receive no award for damages that have been or will be paid by a collateral source or third party.

Section 109. Treatment of attorneys' fees and other costs

Section 109(a) of the legislation places a limit on attorneys' contingency fees. An attorney representing a claimant on such basis may not charge, demand, receive, or collect in excess of specified amounts. The limits are 33 $\frac{1}{3}$ percent of the first \$150,000 (or portion thereof) recovered by judgment or settlement (based on after tax recovery) and 25 percent of any recovery over \$150,000 (based on after tax recovery). If a judgment or settlement includes periodic or future payments of damages, the computation of the limitation on attorneys' fees is to be based on the cost of the annuity or trust established to make the payments. If an annuity or trust is not established, the payment is to be based on the present value of the payments.

Section 109(b) of the legislation defines "contingency fee" as any fee for professional legal services which is, in whole or in part, contingent upon the recovery of any amount of damages, whether through judgment or settlement.

Section 110. State-based alternative dispute resolution mechanisms

Section 110(a) of the legislation states that each State is encouraged to establish or maintain alternative dispute resolution mechanisms that promote the resolution of health care liability claims in a manner that is affordable for the parties involved, provides for timely resolution of claims, and provides the parties involved with convenient access to the dispute resolution process.

Section 110(b) of the legislation requires the Attorney General (in consultation with the Secretary and the Administrative Conference of the U.S.) to develop guidelines for alternative dispute resolution mechanisms that may be used by the States to resolve health care liability claims. The guidelines are to include procedures with respect to arbitration, mediation, early neutral evaluation, early offer and recovery mechanism, certificate of merit, and no fault. Section 110(b) of the legislation further defines each of these terms.

"Arbitration" is defined as a nonjury adversarial dispute resolution process which may (subject to early neutral evaluation) result in a final decision as to facts, law, liability, or damages. The parties may elect binding arbitration.

"Mediation" is defined as a settlement process coordinated by a neutral third party without the ultimate rendering of a formal opinion as to factual or legal findings.

“Early neutral evaluation” is a process in which the parties make a presentation to a neutral attorney or to other neutral evaluator for an assessment of the merits, to encourage settlement. The evaluator’s opinion is to be kept confidential if the parties do not settle and proceed to trial.

“Early offer and recovery mechanism” is used when a health care provider, health care organization, or any other alleged responsible defendant may offer to compensate a claimant for his or her reasonable economic damages, including future economic damages, less amount available from collateral sources.

“Certificate of merit” is a requirement that a claimant in a health care liability action submit to the court prior to trial a written report by a qualified specialist. The report is to include the specialist’s determination that, after a review of the available medical record and other relevant material, there is a reasonable and meritorious cause for filing of the action against the defendant.

“No fault” refers to a statute under which certain health liability actions are barred and claimants are compensated for injuries through their health plans or other appropriate mechanisms.

Section 110(c) of the legislation specifies that the extent to which any party may seek further redress in a Federal or State court (subsequent to the decision of the alternative dispute resolution mechanism) is dependent upon the methods of alternative dispute resolution adopted by the State. Under certain circumstances, the party initiating the court action pays the reasonable costs (including legal fees) incurred in the court action by the other party or parties to such action. This occurs if the claimant initiates the court action and such claimant receives a level of damages under the decision of the court that is at least 25 percent less than under the State alternative dispute resolution method. This also occurs if the party initiating the court action is the health care professional, provider, health plan or other defendant and such defendant is found liable for damages at least 25 percent more under the decision of the court than under the State alternative dispute resolution method.

Section 110(d) of the legislation provides that the Attorney General may provide technical assistance to the States in establishing or maintaining alternative dispute resolution mechanisms in this section. The section further requires the Attorney General (in consultation with the Secretary and the Administrative Conference of the United States) to monitor and evaluate the effectiveness of such State alternative dispute resolution mechanisms.

Subtitle B. Biomaterials access assurance

Section 121. Short title

Section 121 provides that subtitle B may be cited as the “Biomaterials Access Assurance Act of 1995.”

Section 122. Findings

Section 122 sets forth fifteen congressional findings to explain the need for this legislation. They say essentially that suppliers of raw materials and component parts that are used both for medical devices and in a variety of nonmedical products have ceased to sup-

ply certain raw materials and component parts for use in medical devices because the costs associated with litigation far exceed the total potential sales revenue from sales to the medical device industry. Therefore, in order to safeguard the availability of a wide variety of medical devices, immediate action is needed to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices, and to provide expeditious procedures to dispose of unwarranted suits against suppliers so as to minimize litigation costs.

Section 123. Definitions

Section 123 contains eleven definitions of terms used in subtitle B. A “Biomaterials supplier” is defined as “an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.” A biomaterials supplier “includes any person who—(i) has submitted master files to the Secretary of Health and Human Services for purposes of premarket approval of a medical device; or (ii) licenses a biomaterials supplier to produce component parts of raw materials.

“Claimant” is defined as any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant; the term is not limited to the individual who received the implant, but includes any person who claims to have suffered as a result of the implant. The term does not include, however, a provider of professional services where the sale or use of an implant is incidental of the transaction and where the essence of the transaction is the furnishing of judgment, skill, or services; and it does not include a manufacturer, seller, or biomaterials supplier.

“Component part” is defined as a manufactured piece of an implant, even if it has significant nonimplant applications and, alone, has no implant value or purpose, but, when combined with other component parts and materials, constitutes an implant.

“Harm” is defined as any injury or damages suffered by an individual, including any illness, disease, or death resulting from that injury or damages, and any loss to that individual or any other individual resulting from that injury or damage. The term does not include, however, any commercial loss or loss of or damage to an implant.

“Implant” (which is an essential term in the above definition of “biomaterials supplier”) is defined as a medical device intended by its manufacturer “(i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or (ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days.” The term “implant” also includes “suture materials used in implant procedures.”

“Manufacturer” is defined as any person who is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360(a)(1)) of the implant; and who is required to register with the Secretary of Health and Human Services pursuant to section 510 and to include the implant on a list of devices filed with the Secretary pursuant to section 510(j).

“Medical device” is defined as a “device,” as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(h).

“Qualified specialist” is defined as a person “qualified by knowledge, skill, experience, training, or education in the specialty area that is the subject of the action.”

“Raw material” is defined as a substance or product that has a generic use and may be used in an application other than an implant.

“Secretary” refers to the Secretary of Health and Human Services.

“Seller” is defined as a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce. It does not include, however, a seller or lessor of real property; a provider of professional services where the sale or use of an implant is incidental of the transaction and where the essence of the transaction is the furnishing of judgment, skill, or services; or a person who acts in only a financial capacity with respect to the sale of the implant.

Section 124. General requirements; applicability; preemption

Section 124(a) provides that in any civil action covered by subtitle B, a biomaterials supplier may raise any defense set forth in section 125, and the Federal or State court in which the action is pending shall, in connection with a motion for dismissal or a judgment based on such a defense, use the procedures set forth in section 126.

Section 124(b) provides that subtitle B shall apply to any civil action in Federal or State court against a manufacturer, seller, or biomaterials supplier for harm allegedly caused by the implant, except that a suit brought by a purchaser of a medical device for use in providing professional services for loss or damage to an implant or for commercial loss shall be governed by applicable commercial or contract law.

Section 124(c) provides that subtitle B supersedes State law only to the extent that subtitle B establishes a rule of law applicable to the recovery of damages for harm caused by an implant. Any other issue shall be governed by applicable Federal or State law.

Section 124(d) provides that subtitle B shall not be construed to affect any defense available to a defendant under any other Federal or State law, and shall not be construed to create a new Federal cause of action or new Federal court jurisdiction.

Section 125. Liability of biomaterials suppliers

Section 125(a) provides that a biomaterials supplier shall not be liable for harm caused by an implant except as provided in subsections (b), (c), and (d) of section 125, which cover, respectively, biomaterial suppliers who manufacture implants, who sell them but do not manufacture them, and who merely deliver raw materials or component parts.

Section 125(b) provides that a biomaterials supplier that is a manufacturer of the implant may be held liable in accordance with applicable law only if it has registered with the Secretary of Health

and Human Services pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), and included the implant on a list of devices filed with the Secretary pursuant to section 510(j). It could also be held liable if the Secretary issues a declaration that the supplier was required to do either of these two things and failed to. The Secretary may issue such a declaration after providing notice to the affected persons and an opportunity for an informal hearing. The Secretary must issue a final decision within 180 days after receiving a petition seeking a declaration, and any applicable statute of limitations shall not run while a petition is pending.

Section 125(c) provides that a biomaterials supplier that is the seller but not the manufacturer of the implant may be held liable if it held title to the implant after the manufacture of the implant and the entrance of the implant in the stream of commerce, and if it subsequently resold the implant.

Section 125(d)(1) provides that a biomaterials supplier that is not a manufacturer or seller of the implant may be held liable for harm caused by the implant only if the claimant proves by a preponderance of the evidence that the raw materials or component parts delivered by the supplier either did not constitute the product described in the contract between the supplier and the person who contracted for delivery of the product, or “failed to meet any specifications” specified by the legislation. These include specifications that the biomaterials supplier received and did not expressly repudiate, published, provided to the manufacturer, submitted to the Secretary for purposes of premarket approval of medical devices, or included in the submissions for premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j), and such specifications received clearance from the Secretary.

Section 125(d)(2) provides that a biomaterials supplier that is not a manufacturer or seller of the implant may be held liable for harm caused by the implant only if the claimant proves by a preponderance of the evidence that “such conduct was an actual and proximate cause of the harm to the claimant.”

Section 126. Procedures for dismissal of civil actions against biomaterials suppliers

Section 126(a) provides that a defendant biomaterials supplier may move to dismiss an action subject to this subtitle on the grounds that it is not a manufacturer, not a seller, that the claimant failed to establish that it furnished raw materials or component parts in violation of contractual requirements or specifications set forth in section 125(d)(1), or that the claimant failed to comply with the procedural requirements of section 126(b).

Section 126(b) provides that, in any suit against a biomaterials supplier that is subject to this subtitle, the claimant must name the manufacturer of the implant as a party to the action unless the manufacturer is subject to service of process solely in a jurisdiction where the biomaterials supplier is not subject to service of process, or an action against the manufacturer is barred by applicable law. Subsection (b) also would require a claimant to submit an affidavit that he had consulted with a qualified specialist. The affidavit

must include a written determination by the qualified specialist that the raw materials or component parts used in the manufacture of the implant violated contractual requirements or specifications set forth in section 125(d)(1), and that the raw material or component part was a cause of the harm alleged by the claimant. The affidavit must also state that, on the basis of the consultation with the qualified specialist, the claimant or his attorney “has concluded that there is a reasonable and meritorious cause for the filing of the action against the biomaterials supplier.”

Section 126(c)(1) provides that, if the defendant moves to dismiss the action, it may submit an affidavit demonstrating that it has not included the implant on any list file with the Secretary pursuant to section 510(j). In response, the claimant may submit an affidavit demonstrating that the Secretary has issued a declaration under section 125(b) or that the defendant is a seller who is liable under section 125(c).

Section 126(c)(2)(A) provides that, if the defendant moves to dismiss under paragraph (1) or (3) of section 126(a) (there is no paragraph (3); paragraph (2)(A) may be intended), then no discovery shall be permitted except discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted in accordance with this section.

Section 126(c)(2)(B) provides that, if the defendant moves to dismiss under subsection (a)(2) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery limited to issues that are directly relevant to the pending motion to dismiss or the jurisdiction of the court.

Section 126(c)(3)(A) provides that, unless the claimant submits a valid affidavit that demonstrates that the defendant is a manufacturer or seller, the court shall not consider it to be one. Section (c)(3)(B) provides, in such case, the court shall grant the defendant’s motion to dismiss on the ground that it is not a manufacturer or seller.

Section 126(c)(4)(A) provides that the court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted pursuant to this section. Section 126(c)(4)(B) provides that, if the court determines that the pleadings and affidavits “raise genuine issues as concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).”

Section 126(d)(1) provides that a biomaterials supplier shall be entitled to summary judgment if the court finds there is no genuine issue as concerning any material fact for each applicable element set forth in section 125(d). A court shall consider a genuine issue of material fact to exist only if the evidence the claimant submits would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

Section 126(d)(2) provides that if the court permits discovery prior to ruling on a motion for summary judgment, such discovery shall be limited solely to establishing whether a genuine issue of

material fact exists. Section 126(d)(3) provides that a biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 125(d) or the failure to establish the applicable elements of section 125(d) solely to the extent permitted by applicable Federal or State rules for discovery against nonparties.

Section 126(e) provides that, if a claimant has filed a petition for a declaration pursuant to section 125(b) with respect to a defendant, the court shall stay all proceedings until the Secretary issues a final decision on the petition.

Section 126(g) provides that the manufacturer of an implant shall be permitted to file and conduct a proceeding on any motion for summary judgment or dismissal filed by a biomaterials supplier if the manufacturer and any other defendant enter into a contract under which the manufacturer agrees to bear the cost of the proceeding or to conduct the proceeding.

Section 126(h) provides that the court shall require the claimant to compensate the biomaterials supplier (or a manufacturer appearing in lieu of the biomaterials supplier pursuant to subsection (f) for attorney fees and costs if the claimant named or joined the biomaterials supplier and the court found the claim against the biomaterials supplier to be without merit and frivolous.

Subtitle C. Applicability

Section 131. Applicability

Section 131 of the legislation specifies that title I applies to all civil actions covered under the title that are commenced on or after the date of enactment. This includes any such action with respect to which harm asserted in the action or the conduct that caused the injury occurred before the date of enactment.

TITLE II—PROTECTION OF THE HEALTH AND SAFETY OF PATIENTS

Section 201. Additional resources for State health care quality assurance and access activities

Section 201 of the legislation specifies that each State must require that not less than 50 percent of all punitive damage awards resulting from all health care liability actions in the State be used for certain specified activities. Such activities are those relating to: (1) licensing, disciplining, and certification of health care professionals in the State; and (2) the reduction of malpractice-related costs for health care providers volunteering to provide health care services in medically underserved areas. This requirement applies in States where punitive damages are otherwise permitted by applicable State law.

Section 202. Quality assurance, patient safety and consumer information

Section 202(a) of the legislation requires the Administrator of the Agency for Health Care Policy and Research to establish an advisory panel within 90 days of enactment. The panel is to coordinate and evaluate methods and procedures to enhance the quality, safety, and effectiveness of health care services provided to patients.

The Administrator is to ensure that members of the panel include representatives of public and private sector entities having expertise in quality assurance, risk assessment, risk management, patient safety, and patient satisfaction. The Administrator, acting through the advisory panel, is required to conduct a survey of public and private entities involved in quality assurance, risk assessment, patient safety, and patient satisfaction. The survey is to include the gathering of data with respect to: (1) performance measures of quality for health care providers and health plans; (2) developments in survey methodology, sampling, and audit methods; (3) methods of medical practice and patterns, and patient outcomes; and (4) methods of disseminating information concerning successful health care quality improvement programs, risk management and patient safety programs, practice guidelines, and patient satisfaction.

Section 202(b) of the legislation requires the Administrator (in accordance with chapter V of title V of the U.S. Code, relating to administrative procedure) to establish health care quality assurance patient safety and consumer information guidelines within 2 years. The guidelines are to be modified periodically when determined appropriate by the Administrator. The guidelines are advisory and not binding.

Section 202(c) of the legislation requires the Administrator, within 6 months of enactment, to submit an initial report to the Senate Committee on Labor and Human Resources and the House Committee on Commerce. The report is to contain: (1) data concerning the availability of information relating to risk management, quality assessment, patient safety, and patient satisfaction; (2) an estimation of the degree of consensus concerning the accuracy and content of such data; (3) a summary of the best practices used in the public and private sectors for disseminating information to consumers; and (4) an evaluation of the reliability and validity of information in the National Practitioner Data Bank.

Section 202(c) of the legislation further requires the Administrator, within 1 year of enactment, to prepare and submit to the same congressional committees an interim report based on the results of the advisory panel survey. The report is to include: (1) consensus of indicators of patient safety and risk; (2) assessment of consumer perspective on health care quality that includes an examination of: information most often requested; types of technical quality information that consumers find compelling; amount of information they consider sufficient and amount they consider overwhelming; the manner in which such information should be presented; and recommendations for increasing consumer awareness; (3) proposed methods, building on existing data gathering and dissemination systems, for ensuring such data is available and accessible to consumers, employers, hospitals, and patients; (4) existence of legal, regulatory, and practical obstacles to making such data available and accessible to consumers; (5) privacy or proprietary issues involved; (6) assessment of the appropriateness of collecting such data at the Federal or State level; (7) evaluation of the value of permitting consumers to have access to the National Practitioner Data Bank; and (7) the reliability and validity of data collected by State Medical boards.

Section 202(c) of the legislation further requires submission by the Administrator of annual reports (beginning within one year of submission of the interim report) to the same congressional committees. The annual report is to give an account of the advisory panel's progress in creating a consensus with respect to its findings and in developing and modifying the required guidelines. The advisory panel is to terminate on the date that is 3 years after the date of enactment.

TITLE III—SEVERABILITY

Section 301. Severability

Section 301 of the legislation specifies that if any provision of this act, any amendment of the act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, it shall not affect the remainder of this act, the amendments made by the act, or the application of such provisions to any person or circumstance.

MINORITY VIEWS OF SENATORS KENNEDY, PELL, SIMON,
HARKIN, MIKULSKI, AND WELLSTONE

We respectfully dissent from the decision of the committee to report favorably to the full Senate S. 454, the Health Care Liability Reform and Quality Assurance Act of 1995.

At the outset, we wish to emphasize that we are not opposed to medical malpractice reform per se. Last year we each supported a comprehensive health care reform bill that contained significant efforts to improve the malpractice liability system. This year, during the committee's markup of S. 454, we each voted for a substitute amendment that would have implemented such reforms.

But we cannot support S. 454 in its current form. It will not reduce health care costs or increase access to health care. It is ill-considered legislation that will do little to prevent malpractice and that will reduce the ability of the tort system to deter negligent medical care. In addition, it would deny adequate compensation to severely injured patients and violate basic principles of federalism and fairness.

I. IMPROVEMENTS TO THE MEDICAL MALPRACTICE SYSTEM SHOULD BE ACCOMPLISHED AS PART OF A COMPREHENSIVE HEALTH CARE REFORM BILL

We regret that the committee has chosen to address the subject of medical malpractice in isolation rather than as part of a broader health care reform measure. The committee's action reflects misplaced priorities and limits the scope of the reforms that can appropriately be considered.

The health care crisis in this country is profound. Last year, the number of Americans without health insurance increased by more than a million people, 800,000 of whom were children. Employee Benefits Research Institute, "Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 1994 Current Population Survey," February 1995. Costs are spiraling out of control. Our health care system needs urgent repair, and malpractice reform is, at most, one small piece of the puzzle.

Proponents of malpractice reform speak of a crisis. But the real health care crisis is that so many of our fellow citizens lack access to affordable care. By the year 2000, only about half of working Americans and their families will be protected by health insurance through an employer. As recently as 1987, two-thirds had this protection. In just 5 years, 50 million Americans will have no coverage. And if current efforts to cut Medicaid and Medicare are successful, the number could be much higher. William S. Custer, Custer Economic Research, testimony before the Senate Committee on Labor and Human Resources, March 14, 1995.

Eighty-five percent of those who have no insurance are members of working families. Employee Benefits Research Institute, supra,

February 1995. They face a health care crisis every day. But even those who currently have coverage cannot be complacent, because if they lose their job, or change jobs, or get seriously ill, their health insurance is in jeopardy.

Senior citizens still have no drug coverage and inadequate home care coverage. Last year the average senior had to spend one-quarter of his or her income to purchase health care, and that doesn't even count people who were in nursing homes and hospitals.

Health care costs are out of control. Americans spent \$1 trillion on health care last year—and that number will double in 10 years. Congressional Budget Office, testimony before Senate Budget Committee, February 1, 1995. Health care costs are devastating to both the Federal budget and to the family budget.

This is the health care crisis we should be talking about, and these are the people who need protection. Last year this committee favorably reported S. 2296, a health care reform bill that would have begun to address this crisis.

Clearly the committee's priorities this year are misplaced. But the choice to proceed in this fashion is more than ironic—it has substantive consequences. Malpractice reforms that might appropriately be considered in the context of national health care reform cannot be accomplished in a free-standing bill.

For example, S. 454 as introduced contained an important proposal requiring States to establish a health care quality assurance program. Sections 201 and 202 of the original bill introduced by Senators McConnell, Lieberman, and Kassebaum would have required each State to strengthen licensing boards and undertake related steps to improve the quality of health care provided in each State. At its February 28 hearing on this bill, the committee heard testimony from Laura Wittkin of the Center for Patients' Rights that stricter disciplining and licensing of physicians is necessary to prevent malpractice before it occurs.

But, the Chairman's substitute did not include this provision, apparently due to concerns that the proposal might constitute an unfunded Federal mandate on the States. Such a requirement could fairly be imposed in a more comprehensive health care reform bill that creates a Federal-State partnership to improve the health care system. In a broader health bill, States might be asked to assume this responsibility for improving health care quality in exchange for being relieved of other financial obligations. But in a free-standing bill, the imposition of this responsibility on the States is more troublesome.

Similarly, a comprehensive reform bill that guarantees consumers access to affordable health care might reasonably limit to some extent the legal remedies available to consumers in the event of malpractice. The Congress might conclude that such trade-offs are warranted. But the current bill merely deprives consumers of legal rights without offering them improved access in return.

In sum, there are malpractice reforms that are unacceptable to us in isolation, but which we might entertain as part of a bill that addressed the broader health care crisis. We urge the committee to abandon its narrow focus on the malpractice liability system in favor of a more comprehensive approach to the health care crisis facing the American public.

II. THE CURRENT TRENDS IN MEDICAL MALPRACTICE LIABILITY DO NOT JUSTIFY THE REFORMS PROPOSED IN S. 454

We disagree with the description of current malpractice liability trends presented by the committee earlier in this report. As we understand the relevant research, it does not lend support for the radical surgery on the tort system proposed in this bill.

As many as 80,000 Americans die each year in hospitals, and an additional 1.3 million are injured, as a result of medical negligence. Harvard Medical Practice Study, "Patients, Doctors and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York," *New England Journal of Medicine*, July 25, 1991; *Washington Post*, February 18, 1992. By this measure, medical malpractice is the third leading cause of preventable death in the United States after tobacco and alcohol-related deaths. As many as a quarter of all patient deaths could have been prevented but for negligent medical care. *Annals of Internal Medicine*, October 1, 1988.

S. 454 further shields negligent doctors and their insurance companies from liability in a malpractice compensation system that already offers considerable protection to doctors and insurance companies.

Fewer than 2 percent of malpractice victims ever file suit, and the rate of medical malpractice claims has declined steadily since 1985. Harvard Medical Practice Study, *supra*; 57 *Consumer Reports* 443, July 1992. Patients won fewer than one-third of malpractice verdicts in a 1994 study, and the size of their awards has dropped significantly in the last year alone. *New York Times*, "Study Finds Sharp Drop Last Year in Awards for Medical Malpractice", January 27, 1995.

According to a landmark 1993 study by the Office of Technology Assessment, "[s]ince 1988, premiums and claim frequency have declined." OTA also found that direct insurance losses declined by 2.7 percent annually from 1985 to 1991. Office of Technology Assessment, "Impact of Legal Reforms on Medical Malpractice Costs" October 1, 1993 (hereinafter "1993 OTA Report").

Contrary to the perceptions of some physicians, "unjustified payments [in malpractice litigation] are uncommon * * * physicians usually win cases in which physician care was deemed to meet community standards." Taragin, et. al., "The Influence of Standard Care and Severity of Injury on the Resolution of Medical Malpractice Claims", 117 *Annals of Internal Medicine* 780, 1992.

Earlier in this report, the committee cites the much-trumpeted "crisis" facing obstetricians seeking malpractice insurance. But whatever insurance difficulties these physicians faced a decade ago, those problems have abated. According to statistics published by the American Medical Association, annual professional liability claims per 100 physicians dropped for obstetricians by 22.7 percent between 1985 and 1990. A.M.A. Center for Health Policy Research, "Socioeconomic Characteristics of Medical Practice 1992."

"Professional liability premiums for some obstetrician-gynecologists have fallen dramatically in recent years because of greater physician participation in risk management, quality assurance and documentation of care * * * Over the last 4 years, premiums

charged by physician-owned insurance companies have fallen more for [Ob-Gyn's] than for any other specialists * * *” American Medical News, “Quality Assurance Prenatal Systems Reduce Risk for OB’s”, February 22, 1993.

The legal system pays only one malpractice claim for every fifteen torts inflicted in hospitals. “[R]ather than a surplus, there is a litigation deficit because so many injured people wind up undercompensated.” Business Week, “A Malpractice Conundrum: Actually, Too Few Claims Are Filed”, March 27, 1995.

Part of the reason claims are not filed is that the legal system is inaccessible to so many citizens, a problem that would be exacerbated by the proposals in this bill. But it is also attributable to the malpractice reforms already adopted in many States under pressure from the powerful medical and insurance lobbies.

Despite the claims of their backers, such reforms have not lowered health care costs. California, for example, enacted sweeping malpractice reforms in 1975, including a \$250,000 cap on non-economic damages. But a study released recently by a nonprofit insurance watchdog organization in California found that health care costs in that State rose 343 percent between 1975 and 1993, nearly twice as fast as the rate of inflation. Proposition 103 Enforcement Project, “MICRA: The Impact on Health Care Costs of California’s Experiment With Restrictions on Medical Malpractice Lawsuit,” April 25, 1995.

According to this new study, the cost of medical care grew faster in California than the national average since 1975, and the rate of growth in California is accelerating compared to that of the rest of the country.

Similarly, in Indiana, malpractice reforms have not caused health care costs to decrease relative to neighboring States. Consumers derive no benefit from malpractice reform, but if they fall victim to medical negligence they are likely to end up undercompensated for their injuries. Coalition for Consumer Rights, “The Myth of Medical Malpractice Savings: The Nothing for Nothing Trade Off in Indiana’s Health Care System,” February 1992; Indianapolis Star, “Malpractice Laws Stacked Against Victims,” June 26, 1990.

The General Accounting Office surveyed six States that had limited recoveries in malpractice cases and found that insurance companies in those States were enjoying profits that averaged 122 percent above the national average. GAO, “Medical Malpractice: Six State Case Studies Show Claims and Insurance Costs Still Rise Despite Reforms,” December 1986. According to a respected trade publication, the “price of medical malpractice and professional liability coverage for health care organizations remains stable and capacity is plentiful.” Business Insurance, “Malpractice Coverage in Stable Condition,” March 28, 1994.

Malpractice reform will not address the fundamental problems facing our health care system. It hasn’t in California or Indiana, and it won’t elsewhere. Even if the bill resulted in a decrease in medical malpractice premiums, that would barely cause a dent in overall health care costs since malpractice premiums amount to less than one percent of the Nation’s health care budget. 1993 OTA

Report, *supra* at 1; Congressional Budget Office, "Economic Implications of Rising Health Care Costs" 4, October 1992.

Nor will legal reforms make a dent in the prevalence of malpractice itself—instead, we need more effective means to discipline the few bad apples in the medical profession who cause upwards of 45 percent of all unnecessary injuries. In California, an auto mechanic is more likely to get in trouble for a faulty tune-up than is a doctor for a botched operation. Testimony of Blaine Nye, "Academic Task Force for the Review of the Insurance and Tort Systems" 169, June 11, 1987; Court and Rosenfeld, "Patients Need Protection", USA Today, April 14, 1995.

Finally, malpractice reforms will have little effect on "defensive medicine," an elusive phenomenon invoked repeatedly by proponents of S. 454. "Overall, a small percentage of diagnostic procedures—certainly less than 8 percent—is likely to be caused primarily by conscious concern about malpractice liability * * * To the extent that reforms do reduce defensive medicine, they do so without differentiating between defensive practices that are medically appropriate and those that are wasteful or very costly in relation to their benefits." Office of Technology Assessment, "Defensive Medicine and Medical Malpractice" 1-2, July 1994.

III. THE REFORMS IN S. 454 ARE ILL-CONSIDERED

A. The one-way preemption of State Law violates basic principles of federalism

S. 454 preempts a wide array of State malpractice laws. Members of the new majority in Congress continually remind us that Washington doesn't have all the answers and that State legislatures are wise because they govern closer to the people. The Congress is currently considering proposals to transform multibillion dollar entitlement programs into block grants because the States are reputed to be better situated to administer those efforts. But when it comes to malpractice, apparently, the States can't even be trusted to write the laws that will govern litigants in State court.

The preemption language in S. 454 is also objectionable because it is imbalanced. It strikes down laws that benefit consumers, while preserving State laws that benefit insurance companies. If preemption of State tort laws were appropriate, and many of us think it is not, it should at least be accomplished in a fair and even-handed manner. The one-way preemption in this amendment ensures the absence of the national standard that the proponents say they want.

One-way preemption may affect particular States in an unforeseen and undesirable way. For example, the Michigan Medical Society has urged the committee not to preempt that State's law on joint and several liability. Letter to Senator Kennedy from Dr. Jack L. Barry, April 20, 1995. Doctors might have been expected generally to favor repeal of joint liability, but at least in Michigan, physicians fear such a move would increase insurance premiums.

During the committee's consideration of this bill, Senator Kennedy unsuccessfully offered an amendment to strike the preemption provisions in the Chairman's substitute. That amendment reflected the conclusion that the Labor Committee arrived at last

year after 2 days of debate on malpractice reforms during the health care mark-up that Federal malpractice reforms should only apply in those situations where no State law is applicable. If the Federal Government is to involve itself in this area of the law, we believe it should do so cautiously and with respect for State prerogatives.

The Abraham amendment approved by the committee permitting States to “opt-out” of the reforms in this bill would have begun to address the federalism concerns in the bill. But see VI, *infra*.

B. It is unwise to limit the doctrine of joint and several liability in the manner proposed by proponents of this bill

S. 454 severely limits the longstanding legal doctrine of joint and several liability, leaving patients vulnerable to inadequate compensation. For at least a hundred years, it has been recognized as unacceptable to force an innocent patient to bear the cost of other people’s negligence if one of more of the wrongdoers are available to ensure compensation. We should approach such an enduring rule with great caution.

The provision in S. 454 limiting joint liability is particularly pernicious because it applies to noneconomic damages only. Individuals who suffer economic damages—often young professionals—would be allowed to invoke the doctrine of joint and several liability to ensure full compensation, even if one or more of the wrongdoers is bankrupt or otherwise unavailable to provide compensation. But elderly or disabled plaintiffs who typically do not suffer substantial economic harm but who may have substantial non-economic damages will be denied the benefit of joint liability.

In this way, S. 454 disadvantages those without substantial earning power and threatens their ability to obtain compensation for the injuries they suffer as a result of medical negligence.

C. The fee-shifting provision in S. 454 is unjustified

Under section 110 of S. 454 as reported, States are “encouraged” to adopt Alternative Dispute Resolution systems, and technical assistance from the Federal Government is authorized. But ultimately, States can chose to adopt any form of ADR that they want, even an ADR system that is completely unfair to patients.

That of course is true now. But section 110(c) of the pending bill provides a new twist. Under that section, a party who rejects the result of the ADR process and proceeds to trial risks being required to pay the other sides’ costs and attorney fees if the verdict at trial is 25 percent less than the result of the ADR process. This is a modified version of the so-called “loser pays” English Rule.

We have serious concerns about the way in which the English Rule chills access to the courts. Rather than a gentle incentive, the English Rule can serve as an insurmountable form of intimidation if a party lacks substantial resources and fears having to pay the fees of a law firm whose partners may be billing at \$400 an hour. Even the English are considering abandoning the English Rule because of its discriminatory impact on less well-off litigants.

But whatever the merits of such fee-shifting proposals, it is clearly unfair to impose a Federal fee-shifting requirement based on the result of a standard-less ADR process. It is impossible to predict

what process might be adopted in any given state or whether it will be a fair process. Without Federal standards, the ADR process should not be granted unique weight in Federal law.

Imagine a State that adopted an ADR process run solely by doctors, or insurance companies. A patient might receive an inadequate result from such a process, but proceeding beyond that process by filing a lawsuit would leave the patient vulnerable to staggering level fees.

This would be true even if the patient actually proved malpractice and prevailed at trial, but did somewhat worse than expected. That is an unacceptable burden to place upon any litigant, and imposition of a Federal rule of civil procedure of this nature is plainly wrong.

Unfortunately, the committee rejected an amendment offered by Senator Kennedy which would give States discretion to adopt such a system, rather than imposing a Federal fee-shifting requirement on litigants in all fifty States.

D. Medical consumers should be afforded access to information about the fitness of their doctors

As introduced, S. 454 contained a worthwhile provision that would have genuinely prevented malpractice. The bill directed the Secretary of Health and Human Services to promulgate regulations for public dissemination of information in the National Practitioners' Data Bank. Patients need and deserve access to current information about the fitness of their doctors.

But the Chairman's substitute, and the bill reported favorably by the committee, delete this provision. As a result, S. 454 now contains a serious omission: it denies patients necessary information about their doctors, even when those doctors may have repeatedly committed malpractice or may have been repeatedly disciplined.

During the committee's mark-up of S. 454, Senator Wellstone offered an amendment that addressed this flaw by improving the reliability of information in the HHS Practitioner Data Bank and authorizing responsible dissemination of the vital information it contains. Unfortunately, the amendment was defeated.

IV. THE COMMITTEE CORRECTLY REJECTED A CAP ON PUNITIVE DAMAGES AND SHOULD NOT RECONSIDER THAT DECISION

During the mark-up of S. 454, the Labor Committee adopted a Dodd amendment effectively striking the cap on punitive damages included in the bill as introduced. That modification substantially improved the bill.

S. 454 sets an exceedingly high standard for the award of punitive damages. Basically a doctor would have to act with the intention of causing harm or with conscious, flagrant disregard for such a harm. This is as high a standard as virtually any punitive damage standard in law today. Under this or any other standard, punitive damages would only rarely be awarded in malpractice cases because most malpractice results from mere negligence.

But the few cases that would surmount this hurdle involve outrageous conduct by a defendant. For example, punitive damages are currently awarded now in cases of sexual abuse on the operating table. Other cases in which punitive damages might be award-

ed include those where a doctor operates on a patient under the influence of alcohol or drugs, where a doctor practices medicine after multiple suspensions of his license, or where a hospital intentionally destroys evidence of malpractice after the fact in order to avoid liability. It is incomprehensible that we would let defendants off the hook by capping damages in cases that would shock the conscience of any reasonable observer.

Caps on punitive damages would disproportionately affect women, who are awarded 68 percent of the punitive damage awards in malpractice cases. Keonig and Rustad, "His and Her Tort Reform: Gender Injustice in Disguise," delivered at the Annual Meeting of the Law and Society Association at 87, June 18, 1994.

In recent months, several doctors have been prosecuted criminally in outrageous cases of malpractice. That is a controversial option, but if punitive damages are not available in an amount that will sufficiently punish the wrongdoer, criminal prosecution may be the only sanction available in the worst cases.

Passage of the Dodd amendment during the mark-up was therefore a welcome development. Some of us were concerned that the amendment took away from the jury the authority to set the amount of the punitive damages, but supported the amendment because of the overriding need to eliminate the cap itself. Others of us believe authority to determine the amount of punitive damages properly rests with the judge.

But in any event, there is still considerable sentiment in the Senate to cap damages, even in malpractice cases (see VI, *infra*). We urge that the Senate follow the approach of the Labor Committee in rejecting such caps.

V. THE COMMITTEE SHOULD HAVE RESTATED ITS SUPPORT FOR THE MALPRACTICE REFORMS CONTAINED IN LAST YEAR'S HEALTH CARE REFORM BILL

Our rejection of S. 454 does not mean we should not take some action to reform the medical malpractice system. There are a series of modest steps Congress can take to assist the States and improve the efficiency of the malpractice system in a way that will benefit both doctors and patients.

Last year, the Labor and Human Resources Committee favorably reported a health care reform bill which contained such sensible reforms. We required alternative dispute resolution to provide for streamlined consideration of malpractice claims. We capped attorney fees to make sure that patients get fair compensation for their injuries. And most importantly, we provided seed money to let the States experiment with innovative models such as enterprise liability, no-fault funds and practice guidelines.

Some of last year's reforms are included in S. 454. But in other ways that we have described, the bill goes far beyond the boundaries of last year's bipartisan approach. During the committee's consideration of S. 454, we supported a substitute amendment that contained the reasonable reforms proposed by the Labor Committee last year. Regrettably, a majority of the committee no longer supported that approach this year.

VI. CONSIDERATION OF MALPRACTICE LEGISLATION BY THE FULL SENATE SHOULD REFLECT THE WORK OF THE COMMITTEE OF JURISDICTION

Shortly after the committee voted to report S. 454 to the full Senate, but before this report was filed, Senator McConnell offered an omnibus malpractice reform proposal as an amendment to a product liability bill then under consideration on the floor of the Senate.

The McConnell amendment resembled the bill reported by the Labor Committee, but it deleted two amendments that had been adopted by the committee with bipartisan support during its markup of the bill. The Senator from Kentucky had every right under the Senate rules to proceed in this manner, but his action represented a circumvention of the committee process. That process is designed to ensure that major proposals before the Senate reflect the collective judgment of the committee with expertise about the subject matter at hand.

First, the McConnell amendment deleted a provision authored by Senator Dodd striking the cap on punitive damages but reserving for the judge the right to determine the amount of the award. (See IV, *supra*) Second, the McConnell amendment deleted a provision authored by Senator Abraham allowing states to "opt out" of the provisions in S. 454 by passing a law declining Federal preemption in whole or in part.

These two amendments improved the bill and we urge that they be included in any future malpractice proposal considered by the full Senate.

VII. CONCLUSION

In pursuing ill-considered malpractice reform, this committee violates the ancient dictate: First, do no harm. Some of the proposals in S. 454 will cause harm to thousands of our fellow citizens by reducing the ability of the tort system to deter negligent medical care and denying adequate compensation to severely injured patients.

EDWARD M. KENNEDY.
CLAIRBORNE PELL.
PAUL SIMON.
TOM HARKIN.
BARBARA A. MIKULSKI.
PAUL WELLSTONE.

ADDITIONAL VIEWS OF SENATOR CHRISTOPHER J. DODD

In recent years, this committee has struggled with the critically important issue of medical malpractice reform. Chairman Kassebaum, Senator McConnell, and my colleague from Connecticut, Senator Lieberman, deserve commendation for their efforts in crafting S. 454, the Health Care Liability Reform and Quality Assurance Act of 1995. Although I have significant concerns about that bill and the substitute measure Chairman Kassebaum offered for the committee's consideration, these proposals help further the debate. Hopefully, the members of this committee will continue to work together on reform proposals and find a comprehensive solution that can be enacted into law.

Although there is some disagreement within the committee concerning how best to reform the medical malpractice system, there is clear agreement that the present system is not working as well as it should.

This committee has heard testimony that the current system is not adequately compensating injured patients or preventing medical injuries. On the other hand, there is ample evidence that many unwarranted lawsuits are being filed. For example, a 1987 General Accounting Office study found that about 60 percent of all claims filed against physicians are dismissed without a verdict, settlement or payment to the plaintiff.

Given these and similar problems, which are chronicled more extensively in the committee report, we ought to improve the medical malpractice system so that it better serves patients, doctors, and health care institutions. We need to have a system that quickly and fairly compensates people who are injured while receiving medical care. We also need to prevent incentives for doctors and hospitals to practice defensive medicine—to conduct tests and procedures that simply run up costs.

However, we need to be very cautious in our approach to reform. A person's relationship with his or her doctor is very complex. There is an element of trust that is not present in most commercial transactions. We must not adopt reforms that would destroy that trust.

This committee made substantial progress toward medical malpractice reform during the last Congress. Working with the Clinton administration's health care proposal, Senator Kennedy offered a comprehensive approach to medical malpractice reform. I concur with the statements in the minority views concerning the advantages of dealing with medical malpractice in the context of broader health care reform.

Although Senator Kennedy's health care bill, including the medical malpractice provisions, were eventually killed by Republican opposition, a bipartisan agreement on medical malpractice reform is still possible. There is some common ground, for example, between

Senator Kennedy's proposal and the legislation offered by Senator Kassebaum. Both bills would limit the contingency fees attorneys could receive to 33.33 percent of the first \$150,000 and 25 percent of amounts above \$150,000. Similarly, both measures would allow for the offset of collateral source payments and for the periodic payment of future damages. This suggests that further efforts may yield other areas where agreement could be reached.

The Kassebaum bill also contains an important section on biomaterials authored by Senator Lieberman. That provision is designed to ensure that manufacturers of life-saving and life-enhancing medical devices will have access to raw materials. It has now passed the Senate as part of the Product Liability Fairness Act of 1995, and I commend Senator Lieberman for his efforts on this issue.

Prior to the markup, I had concerns about several aspects of Senator Kassebaum's bill—primarily the cap on punitive damages, the preemption provisions, and the requirement that a party pay the other side's costs in certain circumstances. Although Senator Kassebaum and her staff were cooperative in discussions concerning these provisions, we were unable to reach an agreement prior to the markup.

In order to address concerns about the cap on punitive damages, I offered an amendment that was passed by the committee.

Originally, the Kassebaum bill contained a provision capping punitive damages at three times economic damages or \$250,000, whichever is greater. While that provision addressed concerns about juries awarding excessive amounts in punitive damages, it would severely restrict a jury's ability to punish particularly egregious conduct.

In order to better balance those competing concerns, my amendment does not cap punitive damages. Instead, it would institute a procedure in which the jury determines whether punitive damages should be awarded, but the judge sets the amount of the punitive damages. To guide his or her determination of the appropriate amount, the judge would have to consider a list of factors relating to the nature of the misconduct. This list of factors is derived from factors in the Kassebaum bill and a Kansas statute that follows a similar procedure.

In addition to the Kansas statute, this procedure is also used in existing Federal law. For example, the Petroleum Marketing Practices Act, 15 U.S.C. Section 2805(d)(2) (1988), requires that the judge determine the amount of punitive damages. Furthermore, this approach has received widespread support over the years. During the Carter administration, the Commerce Department recommended that judges set the amount of punitive damages and incorporated that procedure into a uniform product liability code. Similarly, Vice President Quayle's Council on Competitiveness endorsed this approach. Finally, a number of commentators, including former Attorney General Griffin Bell, have urged that judges determine the amount of punitive damages. (See, e.g., Griffin B. Bell & Perry E. Pearce, "Punitive Damages and the Tort System," 22 *U. Rich. L. Rev.* 1, 17 (1987); James G. Ghiardi, "Punitive Damages Awards—An Expanded Judicial Role," 72 *Marq. L. Rev.* 33 (1988);

James G. Ellis, "Punitive Damages, Due Process and the Jury," 40 *Ala. L. Rev.* 975, 1003–07 (1989).)

In my view, a procedure in which the judge determines the amount of punitive damages offers several advantages. First, by placing the responsibility for the amount of damages in the hands of the judge, it will provide for less arbitrary, more reasoned awards. Now, there is no question that the jury plays a critical role in our legal system. But it has been widely recognized that there are problems with juries assessing punitive damages. For example, Justice Rehnquist has written that "punitive damages are frequently based upon the caprice and prejudice of the jurors." *Smith v. Wade*, 461 U.S. 30, 59 (1983). Even former Justice Marshall, arguably one of the more liberal justices to have served on the court, once observed: "Because juries are accorded broad discretion both as to the imposition and amount of punitive damages, * * * the impact of these windfall recoveries is unpredictable and potentially substantial." *International Brotherhood of Electrical Workers v. Foust*, 442 U.S. 42, 50 (1979).

My amendment addresses the problem by giving the judge, who will have more experience considering cases, the responsibility for determining the amount. Having an experienced and well-trained judge determine the appropriate amount should also cut down on the biases and prejudices that can affect some juries. Of course, judges are not always perfect. But the fact that they will have more experience considering cases should result in more uniform, less arbitrary, awards.

In considering this issue, it is important to keep in mind the function of punitive damages. They are a quasi-criminal sanction intended to punish. They are damages above and beyond the damages awarded to compensate victims for their injuries. With that underlying purpose, it is appropriate that the judge determine the amount. Throughout our criminal system, at both the Federal and State level, the determination of the appropriate sentence in a criminal case is frequently left up to the judge.

Because the amendment does not cap punitive damages, this approach will not limit the deterrent effect of punitive damages. Judges will have the flexibility to assess high awards when a defendant acts in a particularly egregious way.

Finally, the flexibility in this approach will also help solve the problems that can arise when punitive damages are assessed as some sort of multiple of other damages—whether it is three times economic damages, two times compensatory damages, or some other formula. Regardless of the formula, that approach leads to wealthier individuals receiving higher punitive damage awards. That result makes no sense. Punitive damages are designed to punish misconduct, and there is no reason why the amount of the punishment should depend on the economic status of the victim.

Although my amendment improves the punitive damages provision in the bill, I continue to have concerns about the preemption and "loser pays" provisions.

Generally, the bill preempts State law, but there are exceptions for State laws that are more favorable to defendants, including greater restrictions on non-economic or punitive damages and,

shorter periods for injured people to bring lawsuits. In my view, the preemption provisions should be fairer to plaintiffs.

Consider the way in which the preemption provisions would affect State statutes of limitations. The Kassebaum bill would set a Federal standard—an injured person would have 2 years from the date on which they discovered the injury and its cause to file a lawsuit. This 2-year period is a reasonable middle ground; some States have a longer statute of limitations, other States have shorter periods. But the bill goes further and says that shorter State statutes of limitations are not preempted.

This approach suggests that States that are limiting the amount of time in which injured people can sue are headed in the right direction. I have not seen any data to support that approach. In my view, we need to more carefully consider the effect that this preemption provision would have on injured people.

I have no problem with the Federal Government preempting State law—there are many areas, including product liability law, where we need to set Federal standards. But if we're going to preempt State law, we should adopt an approach that does not carve out particular provisions that might be favorable to either plaintiffs or defendants.

During the markup, I voted for an amendment offered by Senator Abraham that would allow States to opt-out of the reforms in the bill. While this amendment may mitigate the effect of the preemption provisions, we should explore other preemption options prior to further consideration of this bill.

I am also opposed to the modified “loser pays” provision in the measure, which affects parties proceeding through alternative dispute resolution (ADR). Under the bill, parties are not required to go through ADR. However, if the parties go through ADR, and then a party wants to go to court, that party must do 25 percent better in court or else pay the other party's attorneys fees.

This provision would discourage people from going through ADR. Instead of risking a situation where they might have to pay fees, they would go directly to court. In my view, we need to encourage people to use ADR—which can be cheaper and quicker than a full-blown court case.

In the securities litigation reform bill I have drafted with Senator Domenici, S. 240, we try to encourage use of ADR. In that bill, the prevailing party could be awarded attorneys fees, if the other party unreasonably refused to proceed to ADR or refused to accept an ADR result, and asserted a claim or defense that was not substantially justified. In contrast to the Kassebaum bill, the incentive is to proceed to ADR. If a party proceeds to ADR, there's no risk of having to pay the other side's fees.

I voted in favor of Senator Kennedy's amendment to strike the modified loser pays provision in the bill. That amendment was defeated, but I will continue to work with my colleagues to improve this provision.

Given my remaining concerns, I voted against favorably reporting the Kassebaum bill. However, I commend Senators Kassebaum, McConnell, and Lieberman for their hard work on the underlying legislation, and I look forward to working with them and my col-

leagues on this committee as we try to find a balanced approach to medical malpractice reform.

CHRIS DODD.

A P P E N D I X

ERNST & YOUNG,
ACTUARIAL SERVICES GROUP,
Philadelphia, PA, June 14, 1994.

Re review of Consumers Union press release.

MARTIN HATLIE, Esq.
*Chair, Health Care Liability Alliance,
Washington, DC.*

DEAR MARTY: We have reviewed the statement by Kristen Rand, Counsel for Consumers Union (CU), which claims that negligent doctors kill more Americans each year than are killed by firearms or in automobile accidents (CU Press Statement May 16, 1994). Based on a review of this statement and the sources it cites, we conclude that this claim is not justified. It is based upon extrapolation from an extremely small sample of data which is of itself subject to much variation, and it uses the sample selectively for a purpose clearly unintended by the original researchers.

THE HARVARD MEDICAL PRACTICE STUDY

CU's press statement relies heavily on facts attributed to the Harvard Medical Practice Study, a 1991 study which reviewed a sample of 31,429 patient records drawn from 51 New York hospitals, all in calendar year 1984. The study methodology relied on physician review panels, which attempted to determine based on examination of selected patient histories, whether an "adverse event" (AE), i.e., definable injuries caused at least in part by medical management, had occurred in each of the cases reviewed.

Based on a series of screening criteria used to indicate a possible AE, 22,378 records were eliminated. Then two physicians independently examined the remaining 7,743 records and through a judgmental process identified 1,278 AE's. This physician review process also made determinations as to which AE's were caused by negligent care. Disagreements were resolved by a third physician reviewer. Of the 1,278 AE's identified, 1,133 could be used to calculate the overall rate of adverse events, and of these, 280 were selected where negligent behavior appeared to be a factor in causing the AE. Using the study estimate that 25.4% of the negligent events resulted in death, that would mean that in approximately 71 of the hospitalizations where negligent AE was determined, the patient died. It is this sample of approximately 71 deaths in New York in 1984 that forms the sole basis of CU's claim that "negligent doctors kill 80,000 patients each year".

HARVARD STUDIED SYSTEMS PROBLEMS, NOT INDIVIDUALS

A first, obvious, error in CU's statement is the assertion that the negligent adverse events charted in the Harvard study were all attributable to negligent doctors. The Harvard researchers attempted to track adverse events in 51 New York hospitals, in which patients were treated by a variety of health care personnel and incurred a variety of adverse events, including falls from hospital beds. The Harvard Study plainly does not support the finding that physician malpractice caused every death of a patient who suffered a negligent AE. Although this is a somewhat technical distinction, CU's rhetorical "spin" on the Harvard study is notable. The Harvard researchers focused on patient safety hazards and potential solutions in health care delivery systems, not individual "bad" actors.

UNJUSTIFIED EXTRAPOLATIONS ACROSS TIME AND GEOGRAPHY

A second, and more significant, error lies in CU's extrapolation from the 71 negligent AE's identified by Harvard as a factor in patient death to the claim that 80,000 die each year. The Harvard study addressed a single year—1984—and has produced no data relevant to hospital care in the last ten years. Extrapolating from this sample to all 1984 New York hospitalizations, the Harvard researchers estimated that a negligent AE was a factor in 6,895 deaths.

While this statewide estimate may be supportable from the Harvard sample, it is completely unsound to assume that every other state in the nation would have similar death rates, and that further, these rates would have continued to have been exhibited year after year from 1984 to the present. This expansion is especially questionable in light of the advances which have occurred in medical technology, managed care and peer review, among other factors, since 1984. Even within New York, the authors of the Harvard Study found substantial variation among the 51 hospitals studied in both the rate of AE's and the percentage of AE's due to negligence. Brennan, Troyen A. et al., *Hospital Characteristics Associated With Adverse Events and Substandard Care*, JAMA, v. 265, no. 24, 3265 (1991). Given this variation, CU's claim of 80,000 deaths due to doctor negligence each year is statistically insupportable. Similar claims to the effect that the Harvard Study shows that "Every 7 minutes a Person Dies Because of Medical Malpractice" are equally without foundation. (See New York Times Ad [California Edition] June 1, 1994, p. A-18.)

COMPARISON WITH GUNSHOT AND MOTOR VEHICLE VICTIMS OVER REACH

CU alleges that every year: "Negligent doctors kill more than twice the number of people killed by firearms. Negligent doctors kill twice the number of people killed by auto accidents. Negligent doctors kill nearly 4 times the number of people who die from household product-related accidents."

Even if one assumes that CU's unsubstantiated extrapolation nationwide from 1984 New York data were valid, the comparison between deaths of hospitalized patients and deaths due to automobile

accidents or gunshot wounds is unjustified, due to what must be assumed to be significant differences in the health status and social characteristics of the different populations. The fact that those who enter a hospital are, almost by definition, unhealthy, automatically introduces bias in comparison with automobile passengers or those killed by firearms, who are presumably healthy until the accident occurs.

In fact, the Harvard study did not even attempt to measure the health status of those patients for whom an AE was a factor in death, and the authors acknowledge that this is a significant limitation in their ability to conclude that malpractice caused the deaths they studied. Here is what they say about the kinds of comparisons that CU attempts to draw:

We caution, however, against too quick a comparison of such fatality figures. In our study a death was judged to be iatrogenic if there was a clear causal link with medical management. But a substantial proportion of patients were gravely ill, and many would have died from their underlying illnesses in months, days, perhaps hours, even absent the mishap in treatment * * *. Unfortunately, we cannot say what proportion of deaths from medical adverse events involved patients with relatively short life expectancies. We do know, however, that motor vehicle or workplace fatalities typically involve health individuals. Weiler, Paul C. et al., *A Measure of Malpractice*, pp. 56–57 (Harvard University Press 1993)

A related bias factor also acknowledged by the Harvard Study authors arises from the complexity of health care delivery systems. The authors correctly observe that in highly technical systems, even minor errors may have disastrous consequences. Leape, Lucian L. et al., *The Nature of Adverse Events in Hospitalized Patients*, *New England Journal of Medicine*, v. 324, no. 6, 380–381 (1991). It is impossible to reduce this number to zero. Some patients will suffer adverse events and some will die, regardless of the training or competency of the practitioner or the quality of the care rendered in the health care delivery system. Thus a comparison of hospital deaths to deaths from other causes will be biased unless the former is adjusted to recognize the factor of complexity.

PEER REVIEW PROCESS PROBLEMS MAKE RESULTS QUESTIONABLE

A fourth weakness with CU's assertions arises from the potential for bias introduced in asserting causation when the outcome is death, and this outcome is known to the researchers. In the Harvard Study process, a number of criteria were applied in determining which hospital records were to be reviewed by physician panels. One of these was the death of a patient in the course of receiving medical care. By informing the physician reviewers in advance that a death had occurred, a growing body of post-Harvard Study research indicates that a predisposition that something "wrong" must have happened is created. Caplan, Robert A., et al.; *Effect of Outcome on Physician Judgments of Appropriateness of Care*, *JAMA*, v. 265, no. 15, 1957–1960 (1991). The Caplan study reported an inverse relationship between the severity of outcome and judgments

of appropriateness of care in sets of identical cases where only the outcomes were changed.

An additional difficulty with the use of peer review panels is that in many cases the reviewers disagree as to the quality of care provided, and therefore on the issue of negligence, based solely on review of the hospital records. Goldman, Ronald L., *The Reliability of Peer Assessments of Quality of Care*, JAMA, v. 267, no. 7, 958–960 (1992); see also Rubin, Haya R., et al., *Watching the Doctor-Watchers: How Well Do Peer Review Organization Methods Detect Hospital Care Quality Problems?*, JAMA, v. 267, no. 17, 2349–2354 (1992), Hayward, Rodney A., et al., *Evaluating the Care of General Medicine Inpatients: How Good Is Implicit Review?*, Annals of Internal Medicine, v. 118, no. 7, 550–556 (1993), Wilson, David S., et al., *Identification of Preventable Trauma Deaths: Confounded Inquiries?*, The Journal of Trauma, v. 32, no. 1, pp. 45–51 (1992). In the Rubin study, it was found that two out of three cases that passed initial screening for appropriate care by one panel were later found to exhibit below standard care by another panel. In addition, the screening appeared to be only slightly better at correctly identifying below standard care. This result also was obtained in the Goldman study. The other studies—all published in reputable peer reviewed journals—have observed similar problems in the use of physician panels to identify preventable deaths.

This body of research is forcing the medical community to question and rethink peer review methodologies, like the one used in the Harvard Study. These concerns are particularly applicable to the findings in the Harvard Study, because “Physician confidence in their judgments of causation of AE’s spanned a broad range * * *” (Harvard Medical Practice Study, Executive Summary, p. 3 (1991)). In order to confirm an instance of an AE, two physicians were required to agree on each case, with a third reviewer making the final decision if the primary reviewers disagreed. This occurred in 1,808 cases. This number is larger than the total number of adverse events finally agreed upon. In addition, of a sample of 318 cases selected from two hospitals for duplicate review, in 21 cases the two groups disagreed on the existence of negligence, while agreement from both groups occurred in only 4 cases. This process of physician review allows for the possibility of bias such as has been found in later studies, particularly when the outcome is death.

CONCLUSION

For all of these reasons, the Consumers Union claims that negligent doctors kill more Americans than guns or auto accidents cannot be sustained on their face, nor can they be accurately attributed to the Harvard Medical Practice Study. Although it goes beyond the scope of this paper, it is notable that:

Nothing in the Harvard Study supports a conclusion that the malpractice system is adequately protecting consumers, deterring medical malpractice or identifying incompetent practitioners. The Harvard researchers found a crude deterrent effect at best, that in their judgment does little to improve the quality or safety of health care. The authors state:

Our data reflect a tenuous relation between proscribed activity and penalty and thus are consistent with the view that malpractice claims provide only a crude means of identifying and remedying specific problems in the provision of health care. Localio, A. Russell, et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence*, *New England Journal of Medicine*, v. 325, no. 4, 249 (1991).

Nothing in the Harvard Study suggests that the current malpractice system is cost-effectively resolving claims or fairly compensating patients who are injured by medical malpractice. The following quotations are representative of the authors' findings:

First, one must acknowledge that the tort system does not view the compensation of accident victims as its primary objective. *Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York: A Report by the Harvard Medical Practice Study To the State of New York*, pg 8-3, (President and Fellows of Harvard College, 1990) (hereinafter *Patients, Doctors, and Lawyers*).

Why so few injured patients file claims has not been widely researched. Many may receive adequate health or disability benefits and may not wish to spoil longstanding physician-patient relationships. Others may regard their injuries as minor, consider the small chance of success not worth the cost, or find attorneys repugnant. Trial lawyers usually accept only the relatively few cases that have a high probability of resulting in a judgment of negligence with an award large enough to defray the high costs of litigation. Localio, A. Russell, et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence*, *New England Journal of Medicine*, v. 325, no. 4, 249 (1991).

Simply estimating the population frequency of injuries caused by negligence and the frequency of malpractice litigation by the entire population cannot help resolve a fundamental question concerning malpractice litigation: whether it compensates those patients who are actually harmed by negligent care. *Patients, Doctors, and Lawyers*, pg 7-4.

Nothing in the Harvard Study suggests that placing reasonable limitation on non-economic damages in malpractice claims is contrary to public policy. Several of the Harvard researchers have advocated "no-fault" proposals that incorporate significant limits on non-economic damages, or would eliminate this aspect of compensation altogether in the interest of cost containment. For example, see Brennan, Troyen A., *Improving the Quality of Medical Care: A Critical Evaluation of the Major Proposals*, *Yale Law & Policy Review*, v. 10, pg 432 (1992).

Consumers Union's assertion that malpractice claims costs have been dropping steadily over the past five years is wrong. We have analyzed this issue in a separate report.

Please let us know if you require any additional analysis on this subject.

Sincerely,

RONALD T. KUEHN, FCAS, MAAA, CPCU, ARM, FCA, *Partner*.

HARVARD LAW SCHOOL,
Cambridge, MA, June 24, 1994.

Re Harvard medical practices study.

Hon. PETE STARK,
House of Representatives,
Washington DC.

DEAR MR. CHAIRMAN: The two of us were among the principals involved in the Harvard Medical Practice Study in New York. Our attention has been drawn to a number of comments made in the current debate about health care reform that appear to misconstrue the findings and implications of our Study. We are writing to you because of our high regard for your long-standing commitment to improving the nation's health care system.

A common theme in opposition to malpractice reform is the assertion that 90,000 deaths a year can be attributed to medical injuries involving negligence on the part of some health care provider (not just physicians). This number is an extrapolation from the findings of our study in New York. However, in our numerous scholarly writings on this topic, we have always cautioned that this bare statistic can be more deceiving than revealing. A substantial proportion of such fatalities were suffered by patients already gravely ill, and who likely would have died not long afterwards even if no mishap had taken place in their treatment. While much smaller in magnitude, the Harvard Study did find that a considerable number of patients suffered serious permanent disabilities, nearly half of which involved provider negligence. Again, we have always underlined that the vast bulk of such negligence consisted of monetary inadvertent mistakes—the kind of human error we are all prone to, but that here takes place in an inherently risky treatment setting. As we explain to our students at Harvard, when a teacher makes a mistake in the classroom, he can come in the next day and correct it; that luxury is not available to a physician engaged in a delicate operation on a patient's brain or spine.

The Harvard Study has played an important role in teaching the medical and legal communities that real attention must be given to the harms as well as to the benefits that medical treatment can achieve for patients. That message will not be productive, though, if physicians (or nurses and other health care workers) are analogized to dangerous guns, drugs, or drivers. The key to less hazardous health care is careful epidemiological investigation of the circumstances in which medical mishaps occur, and design and investment in new techniques and technologies that can reduce the incidence of such injuries. Malpractice litigation can stimulate such productive efforts within the health care community, epitomized by the Harvard Anesthesia Injury Study of the mid-1980s. Litigation will not have that effect, though, if tort lawyers and their supporters indulge in a morality play about so-called "bad apple" physi-

cians (who contribute to only a tiny proportion of the incidence of medical injury).

The Harvard Study documented not just the failings of medical treatment, but also those of malpractice litigation. Most valid medical malpractice claims are not filed (particularly by the poor and the uninsured); most malpractice claims that are filed are the wrong ones; though the litigation process does do a good job of shifting out valid from invalid claims, it does so only by expending more money on lawyers than it does on patients; and the money that does end up with victims is distributed more erratically than equitably (in terms of patient losses). Again, though, we have been careful to attribute these failings of litigation to the difficult obstacles faced by tort law in trying to come to grips with the complexities of medical treatment, rather than to the political stereotype of “greedy” personal injury lawyers.

Just as with health care, a major improvements can and should be made in the tort system, not for the benefit of physicians (or lawyers) but for patients who need a better deal from both of these professional groups. The most important legal area needing reform is the law of tort damages. Last there be any misunderstanding of our views on that score, we are strongly opposed to the favored Republican proposal of a California-style \$250,000 cap on pain and suffering damages. (We have still not heard anyone explain why, if a fixed 1975 dollar cap on physicians’ earnings is obviously inequitable, it would be fair to impose precisely this kind of cap on awards to severely-injured patients.) Together with a dozen of the nation’s tort scholars who made up the American Law Institute’s Tort Reform Study of the late-1980s, we developed a set of proposals for reforming the law of tort damages that we are all convinced would be far more effective and equitable for injury victims than the status quo. If you are interested, we would be delighted to share with you some of our ideas—in particular, pain and suffering *guidelines*, instead of a cap.

Irrespective, though, of one’s policy views and recommendations, we are committed to a truly informed debate about the malpractice system. That is why we have taken the time to write you this letter, which we would greatly appreciate your sharing with your colleagues.

Sincerely yours,

PAUL C. WEILER,
Henry J. Friendly, Professor
of Law, Harvard Law
School.

TROYEN A. BRENNAN,
Professor of Law and Public
Health, Harvard School of
Public Health, Associate
Professor of Medicine,
Harvard Medical School.