CURRENT ISSUES RELATED TO MEDICAL LIABILITY REFORM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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CURRENT ISSUES RELATED TO MEDICAL LIABILITY REFORM

THURSDAY, FEBRUARY 10, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:05 p.m., in room 2123 of the Rayburn House Office Building, Hon. Nathan Deal (chairman) presiding.

Members present: Representatives Deal, Hall, Upton, Norwood, Shimkus, Shadegg, Pickering, Pitts, Bono, Ferguson, Myrick, Burgess, Barton (ex officio), Brown, Rush, DeGette, Capps, Allen, Baldwin, and Dingell (ex officio).

Staff present: Chuck Clapton, chief health counsel; Cheryl Jaeger, professional staff; Eugenia Edwards, legislative clerk; David Nelson, minority counsel; Jonathan Cordone, minority counsel; and Jessica McNiece, research assistant.

Mr. DEAL. The chairman will recognize himself for 5 minutes for an opening statement.

Since this is my first hearing and the first time that I have presided over this subcommittee, first of all, let me welcome all of the members of the subcommittee on both sides of the aisle. I think we do have a very good working group and they will improve their tardiness, I am sure, as the year goes along. I am sure we will have many other members that will join us here in just a few minutes.

We like to try to start as close to the time as possible, but especially today, since we did have a rather long panel to testify to our subcommittee.

I would like, first of all, to thank also those of you who are going to testify, because we know that you have taken time out of your busy schedules and traveled many miles to be here with us. And this is the first time this subcommittee has actually taken up the subject of medical liability in this session, but it is not the first time the subcommittee has visited the issue, obviously.

We are addressing, in this Congress, the issues that were addressed in previous Congress. And since it was not finalized, even though the House did act on the issue, it still remains unresolved.

There is no denying, I think, that there is a medical liability crisis in this country. And I don't think any of us deem it necessary to go to great deal in reporting the statistics involved. We have seen about the astronomical increases in the rates of medical malpractice insurance and the billions of dollars that are probably

being placed in the litigation costs as well as in, perhaps, unnecessary intensive practices. So it is a serious problem.

I come from a largely rural District in Georgia, and I view this problem primarily as one of the access to healthcare. When the only ob-gyn within a 200-mile radius of your home refuses to see you because you are a high-risk patient, then there is a problem. When you have to be flown to a neighboring State just to receive a common medicine procedure that you normally would have been able to receive in your hometown, then there is a problem. And when people are literally dying because of lack of access to a local trauma center, I think there is a problem.

What would any medical student, for example, be interested in starting his or her medical practice in rural Mississippi where the statistics indicate that the average physician's salary is only $72,000? But the annual premium for medical malpractice is $70,000. That doesn't sound like a very good career move to me.

Clearly something, I think, has to be done. That is why we have invited such a wide range of people and witnesses today to testify on this subject. I have spent 23 years of my career as a trial lawyer, and I realize if I say that, some of those in the position may need to get in step, but I also served as a judge and as the chairman of our Senate Judiciary Committee in the State of Georgia before coming to Congress, and during that period of time, I participated in and was active in the introduction of legislative changes to the tort system. Since I left there, of course, the problem has gotten significantly worse. And I might just add, at this very minute, the Georgia House of Representatives is debating a medical liability reform bill, and hopefully before the end of the day, we will have some resolution on it.

But I recognize that this problem is not one of a single source, and there is no magic bullet or any Band-Aid that is going to simply fix everything that we might think is wrong. But I do think that if we begin the process, as we do today, by listening to those in the community, those that are affected by it, and working with our colleagues on both sides of the aisle, hopefully we can come up with some solution that will begin to heal the process.

As Members of Congress, we have plenty of venues in which we express our opinions in, but we rarely, I think, have an opportunity to hear from such a wide variety of witnesses as we will have today.

I would remind the subcommittee that we are not here to debate the merits of any particular piece of legislation, either past or present. We are here to learn, hopefully, from the distinguished panel of witnesses that will address us here in just a few minutes.

I would hope that as this hearing today proceeds and as this subcommittee does its work during the year, that on both sides of the aisle, we would agree to have two things: open minds and hearts that are not hardened.

I have the great pleasure of having a fellow classmate of mine in my freshman class, and my former neighbor, both in Longworth and now in the Rayburn building, as the ranking chairman of this subcommittee, and it is indeed my pleasure to recognize him, Mr. Sherrod Brown from Ohio at this time for his opening statement.

[The prepared statement of Hon. Nathan Deal follows:]

PREPARED STATEMENT OF HON. NATHAN DEAL, CHAIRMAN, SUBCOMMITTEE ON HEALTH

Let me just start off by thanking our witnesses for appearing before the subcommittee today. This subcommittee values your expertise and we are grateful for your cooperation and attendance. I know several of our witnesses have literally traveled thousands of miles and put their busy lives on hold in order to be with us today, and I think we should be respectful of their time and devote as much of this hearing as possible to listening to what they have to say.

This is not the first time this subcommittee has taken up the subject of medical liability reform and the fact we are having to address this issue again in the 109th Congress is evidence to the fact that we as a legislative body have not yet been able to do the job our constituents sent us here to do and find a satisfactory solution to this ongoing crisis.

There is no denying the fact there is a medical liability crisis in this country, and I do not need to repeat the staggering statistics about the astronomical rates of increase in the cost of medical liability insurance over the past few years or talk about the billions of dollars wasted each year due to frivolous lawsuits and doctors forced to practice defensive medicine in order for us all to recognize that we have a serious problem on our hands that must be addressed as soon as possible.

Coming from a largely rural district in North Georgia, I view this problem primarily as one of access to heath care. When the only OB/GYN within a two-hundred-mile radius of your home refuses to see you because you are high-risk patient, there is a problem with the current medical liability system. When you have to be flown to a neighboring state just to receive a common medical procedure that was once available in your own hometown, there is a problem with the current medical liability system. And when people are dying because their local trauma center closed down, there is a problem with the current medical liability system.

Why would any medical student be interested in starting his or her practice in rural Mississippi where the average annual physician salary is only $72,000, if he or she expects to pay as much as $70,000 per year in malpractice premiums? That doesn't seem like a smart career move to me.

Clearly, something has to be done, and that is why we have invited such a wide range of witnesses to appear before us today.

I have spent over 23 years of my career as a trial lawyer, which are two words that often make physicians scowl a little bit. I have also served as a judge and was the Chairman of the Judiciary Committee in the Georgia State Senate for eight years where I was active in introducing legislation to help curb the growing problems in our state's tort system. From this experience, I recognize this problem does not have a single source and there is not a magic bullet or a Band-Aid solution that will make it go away. That is why I am looking forward to having a cooperative and productive hearing this afternoon and to working with my colleagues on both sides of the aisle to come up with effective legislative solutions to this crisis in our healthcare delivery system.

As Members of Congress, we have plenty of other venues available to us to express our own opinions, but rarely will we have an opportunity like this to get such wide coverage of this complex and important issue. Let me remind this subcommittee that we are not here to debate the merits of any past or pending legislation; we are here to learn from our distinguished panel of witnesses in order for us to work toward a solution to this growing crisis.

And I'll now yield to the ranking member of this subcommittee, my freshman class colleague and my former neighbor in both the Longworth and Rayburn Buildings, Mr. Brown of Ohio, for his opening statement.

Mr. BROWN. Thank you, Mr. Chairman. And I enthusiastically welcome you, applaud the decision of Chairman Barton and of your committee for putting you in this position and I look forward very much to continuing the relationship we have had for 12 years in working together on all of these issues.

Here is what I hope Congress will do when it comes to medical malpractice. First, we should sit down and figure out what the medical malpractice system should and should not be. Should it be about deterrence, about compensation, about punishment, all, or none of the above? Should we look dispassionately at how—then we should look dispassionately at how the current medical malpractice system measures up. Then we should decide without prejudice

whether we should fix the current system or scrap it. Then we should look, again with prejudice, at various fixes or alternatives.

But I don't think we will do any of that, because special interest groups have a chock-hold on the process here in this Congress. And by special interest groups, I mean the insurers, the doctors, the lawyers, the drug companies, the medical device companies, the HMOs, and even consumer groups that have a vested interest in the outcome of our debate. But I also mean the political parties, of which all of us are members, which have close and long-standing relationships with those special interests.

I hope I am wrong. Maybe we can set all of that political baggage aside and focus on the terrifying realities of medical malpractice, the reality that 100,000 Americans die every year from medical errors, the reality that good doctors are leaving the medical profession because of rising malpractice premiums, the reality that defensive medicine makes America's health care system less personal and more expensive, the reality that malpractice insurance premiums increases sometimes have more to do with insurance company profits than they do with malpractice awards.

I hope we can work together to erect a system that provides justice to the victims of malpractice, a system that won't punish doctors for honest mistakes, a system that gets to the root of the problem by helping to reduce both the frequency and the severity of medical errors.

But to do it, we have to ask difficult questions. We have to ask the trial lawyers why doctors are sometimes corralled into scattershot lawsuits. Why don't they crack—we have to ask them why don't they crackdown on the unsavory characters who peddle personal injury lawsuits on television and charge exorbitant fees. We have to ask the doctors tough questions, too. Just 5 percent of physicians were involved in 54 percent of medical malpractice payouts during the 1990's. We have to ask the doctors why it is that some of their colleagues with track records like that are—with that kind of incompetence, remain board certified. We have to ask the health care providers why they shouldn't be required to report medical errors, since the resulting data would, in fact, greatly enhance our efforts to keep such errors from recurring. We would have to ask insurers why they should not be held accountable for the business decisions they have made that put doctors' economic securities—security and patients' health security at risk. We would have to ask consumer groups why they so adamantly defend a system that fails all too many people. And we would politely tell the drug industry, the medical device industry, and the HMOs that we are not going to let them cash in on this gravy train, cash in on the medical malpractice issue, or dodge responsibility when they, the drug industry, the insurance industry, and the medical device industry, actually do harm. If we didn't know before how low they would go, we sure do now.

Based on recent legislation and legislative approaches in the process on this issue, I am not confident we will take that approach. I expect, instead, we will hear from the same predictable—we will hear the same old predictable inflexible story from all sides. I expect we will consider the same old partisan bill, a bill that punishes the wrong people and provides the wrong response to the

wrong problem. But if I am wrong, Mr. Chair, I stand ready to talk with you and others about a new way to address this problem, a way that puts partisanship aside and commits to asking the difficult questions and making the difficult choices.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Sherrod Brown follows:]

PREPARED STATEMENT OF HON. SHERROD BROWN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Thank you, Mr. Chairman, and thanks to our witnesses for joining us this morning.

Here's what I hope Congress will do when it comes to medical malpractice.

First we should sit down and figure out what the medical malpractice system should and should not do. Should it be about deterrence? Compensation? Punishment? All or none of the above?

Then we should look dispassionately at how the current medical malpractice system measures up.

Then decide, without prejudice, whether we should fix the current system or scrap it.

Then we should look again, without prejudice, at various fixes or alternate systems.

But I don't think we'll do any of this, because special interest groups have a choke-hold on the process here in Congress.

And by special interest groups, I mean the insurers, doctors, lawyers, drug companies, medical device companies, HMOs, and consumer groups that have a vested interest in the outcome of our debate.

But I also mean the political parties of which we are all members—which have close and long-standing relationships with those special interests.

Maybe I'm wrong. Maybe we can set all of that political baggage aside and focus on the terrifying realities of medical malpractice:

The reality that 100,000 Americans die every year from medical errorsThe reality that good doctors are leaving the medical profession because of rising malpractice premiums

The reality that defensive medicine makes America's health care system less personal and more expensive

And the reality that malpractice insurance premium increases sometimes have more to do with insurance company profits than with malpractice awards.

Maybe can work together to erect a system that provides justice to the victims of medical malpractice. A system that won't punish doctors for honest mistakes. A system that gets to the root of the problem, by helping to reduce the frequency and severity of medical errors.

But to do it, we'd have to ask some hard questions and make some tough choices.

We'd have to ask the trial lawyers why doctors are sometimes corralled into scattershot lawsuits.

And why they don't crack down on the unsavory characters who peddle personal injury lawsuits on television and charge exorbitant fees.

We'd have to ask the doctors some tough questions too.

Just 5% of doctors were involved in 54% of medical malpractice payouts during the 1990s. We'd have to ask the doctors why it is that some of their colleagues with track records of incompetence remain board-certified.

We'd have to ask all of the health care providers why they should not be required to report medical errors, since the resulting data would greatly enhance efforts to keep such errors from occurring.

We'd have to ask insurers why they should not be held accountable for the business decisions that put doctors' economic security and patients' health security at risk.

We'd have to ask consumers groups why they are so adamantly defending a system that fails so many people.

And we'd politely tell the drug industry, the medical device industry, and the HMO industry that we're not going to let them cash in on the medical malpractice issue or dodge responsibility when they do harm. If we didn't know before how low they would go, we sure do now.

Based on recent legislation and legislative process on this issue, I am not confident we will take that approach.

I expect instead that we will hear the same old, predictable, inflexible story from all sides. And I expect we will consider the same old partisan bill—a bill that punishes the wrong people and provides the wrong response to the wrong problem.

But if I am wrong, Mr. Chairman, I stand ready to talk with you about a new way to address this problem. A way that puts partisanship aside and commits to asking the tough questions and making the tough choices.

Mr. DEAL. Thank you, Mr. Brown.

I am going to call on the chairman of the full committee at this time, Mr. Barton, for his opening statement.

Chairman BARTON. Thank you, Chairman Deal.

And I want to say welcome to chairing the Health Subcommittee. This is the first subcommittee hearing that you are chairing. It won't be the last. And you start off with a difficult issue, so I appreciate your leadership on this.

I want to thank our witnesses for being here today. This is an important issue. It is an issue that the Congress has attempted to resolve on several occasions the last several years, and in each case, bills have passed the House but have not passed the Senate.

I think it is beyond question that the current medical liability system is broken. We have statistics that show that we had the most expensive tort system in the world, and it cost $180 billion last year, which is about 2 percent of our GNP. My home State of Texas had medical malpractice claims that were skyrocketing. Doctors are leaving practice. Insurers are leaving the State. Several years ago, we passed something called "Proposition 12," which capped some of these claims, changed the system for filing claims. Last year, medical malpractice premiums fell about 16 percent, I think, in our State.

So I am looking forward to this hearing and listening to this first panel and the other panels. I would hope that this would be an issue that we can work with our friends on the minority side on a bipartisan basis. In the past, that has not been the case, but maybe in this Congress, it will be the case. We do need to move legislation and not just move it through the committee and through the floor, but we need to go to conference with the Senate and put a common sense bill on the President's desk for his signature.

So I look forward to the hearing and look forward to the markup and then moving the bills that are going to result from this hearing.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Chairman Deal, for holding this hearing today. It marks the first hearing on health care issues for our Committee in the 109th Congress. It is entirely appropriate that the first hearing focuses on medical liability, which is one of the most pressing problems currently affecting patient access to health care services.

The current medical liability system is broken. It denies patients access to critical health services. It wastes billions of healthcare dollars annually, by forcing doctors to practice defensive medicine. It also unnecessarily burdens injured patients, by forcing them into a liability lottery that denies them access to fair, predictable and timely compensation.

My home state of Texas provides an excellent example of the harm that can be done by an out-of-control medical liability system. In the years before Texas adopted medical liability reforms, doctors and other health providers faced a severe crisis. The price of medical liability insurance had increased so dramatically—a 147 percent increase for some—that doctors could no longer bear the costs of obtaining cov-

erage, forcing them to abandon specialty practices, retire early, or move to another state. When this happens, the real victim is the patient in need of care who simply can't find a qualified doctor to provide it. Insurers began leaving the state, which forced over 6,500 doctors to seek alternative coverage. More than half of all Texas physicians surveyed were considering early retirement and nearly a third said they were considering reducing types of services they provide.

In 2003, Texas passed Proposition 12, a voter initiative that allowed the state to adopt several meaningful medical liability reforms. Passage of these reforms produced real changes in Texas. Since 2003, premiums charged by the largest medical liability insurer in Texas have dropped 16.4 percent. Patients are also now receiving better access to care, because of the increases in the number of licensed physicians in specialties like neurosurgery. Enactment of Proposition 12 is reversing the culture that dragged Texas into a crisis in the first place. We shouldn't have to reach such crisis in every state before we act.

Today we have the opportunity to learn more about the options available to us to improve the medical liability system. I encourage my colleagues to listen to the facts, explore the issues carefully, and commit to taking action. It's time for this Congress to enact common-sense reforms that protect injured patients while restoring sanity to our judicial process for all Americans. I look forward to this challenge.

I thank the witnesses for their testimony.

Mr. DEAL. Thank you, Mr. Chairman.

I recognize the ranking member of the full committee, Mr. Dingell, for an opening statement.

Mr. DINGELL. Mr. Chairman, thank you for the courtesy.

Congratulations on your first hearing.

Mr. Chairman, the rising cost of malpractice insurance is a real problem for doctors and patients alike. This is a serious concern and it deserves serious and deliberate consideration. Unfortunately, the White House and my colleagues on the Republican side, are again responding with proposals that would overhaul the judicial system well beyond the issues that are required to be addressed to deal with the problem of medical malpractice.

While inefficiencies in our courts are a contributing factor, they are by no means the only cause or even the largest single cause of the current crisis. Physicians and other medical providers deserve immediate assistance, not hollow promises that are, in fact, designed to shield large corporations from their responsibilities to both doctors and patients. Past and current Republican proposals would provide virtual immunity baths for HMOs, for insurance companies, and for drug and device manufacturers. I find it curious that not one of these companies has come forward to explain why it needs special protections, yet my colleagues on the majority side seek to grant them status under the law that is unprecedented. Why is this immunity bath necessary, and why must it encumber medical malpractice legislation, which has an opportunity to do a great deal of good and to be properly focused on a serious problem?

Moreover, it is not enough to say that the regulators alone will protect the public. The committee has a long and proud history of overseeing the Food and Drug Administration. For decades, we have uncovered grave threats to the safety of food, drugs, devices, and blood where FDA could not, or would not, pay sufficient attention. Recent bipartisan investigations into antidepressants and a class of painkillers, known as COX-2 inhibitors, have again revealed that the FDA by itself cannot be relied upon to assure that our prescription medications are properly labeled as to the real risks and benefits.

The leadership on the other side of the aisle is once again asking physicians and patients to cross their fingers and hope that some

of the benefits bestowed upon insurance companies, HMOs, and drug and device companies will trickle down to them. Lots of luck.

At the same time, women, seniors, and low-income families are being asked to pay the very real human cost of medical negligence and misbehavior they are powerless to change. This is wrong.

Thank you, Mr. Chairman.

Mr. UPTON [presiding]. Thank you, my friend from the State of Michigan.

I am the acting chairman for a moment while Chairman Deal is visiting with some folks, but I want you to know that I was next on the list anyway, so I will make my—it is not just because I am the——

I commend my chairman, both chairmen, Chairman Barton and Chairman Deal, for holding today's hearing to address and assess the need to enact a Federal medical liability reform to—as it pertains to the growing malpractice insurance crisis impacting physicians, hospitals, and other health care providers in many States and address some of the factors fueling the double-digit increases in health care premiums with which both large and small employers and individuals and families across the Nation are grappling with.

My State of Michigan has already put into place a number of important reforms similar to the Federal reforms that we are contemplating today. As a result, Michigan is not experiencing this serious medical liability insurance crisis that is gripping many other States, but we are not immune from such experiences as sharp increases in premiums and insurers withdrawing from our market.

Several years ago, an emergency physician group in my District, serving one of the largest hospitals in my District, almost lost its medical liability insurance. Had help not come at the very last minute, an entire community could have lost access to emergency care. Similarly, recently a large physician practice serving the poor and uninsured in Southwest Michigan could not afford to renew its malpractice insurance policy because of a sharp increase in their premium. They were eventually able to find more affordable insurance, but only by increasing their exposure.

While I have been, thus far, very supportive of Federal medical liability reform, I hope that, as this process moves along, we will be mindful of one potential problem that a Federal preemption of certain State laws could pose for physicians. Specifically, many Michigan physicians are concerned that a Federal law which preempts our State's joint and several liability provision and replaces it with a fair share liability provision will force many of them to purchase significantly more coverage than they do now under our own State law. With that said, Michigan physicians, like physicians across the country, are concerned about the rising costs of health care in this country. And whether it be for employers who struggle to continue to provide coverage for their workforce and retirees, or the double-digit annual increases in the growth of Medicare and Medicaid programs, we know that defense medicine, and all that it entails in extra costs and procedures, is one of those factors fueling the double-digit increases and that medical liability reform across the Nation is one part of the solution to reigning in health care costs for all of us and moving us toward the goal of ensuring

that every American has ready access to high-quality, affordable health care.

I look forward to working with the members of this committee in a bipartisan basis to get this legislation through the House, working with the Senate, and on to the President's desk. And I would yield my—the balance of my time and recognize the good gentleman from Chicago, my friend and member of the powerful Subcommittee on Telecommunications, Mr. Rush, for an opening statement.

Mr. RUSH. Thank you, Mr. Chairman, for that fine introduction, and I want to thank you for recognizing me. And I want to thank the subcommittee chairman for holding this hearing.

I want to welcome our panelists, also, that are before us today.

Mr. Chairman, this is a tough issue for me, and I am very aware of and sensitive to the problem of rising malpractice insurance premiums that doctors are facing. In my Home State of Illinois, we are almost at a crisis level. I talk to doctors in my State all of the time, and many of them are thinking about moving across the border to Wisconsin where premiums are considerably cheaper. Many have already done so. And Joe, I am always concerned over the lack of quality health care in poor, undeserved communities, and I am very worried that rising malpractice insurance costs will only exacerbate this problem.

But the question is how do we reform the system and provide premium relief to doctors? Do we reform civil procedures? Do we reform the insurance markets? Do we cap damage awards?

Mr. Chairman, public policy is almost always about cost-shifting. The problem with capping non-economic damage awards, often referred to as "pain and suffering," is that it merely shifts costs from doctors onto the patients or the victims. This is a simple fact that the proponents of damage caps ignore or are unwilling to acknowledge. Such advocates are too quick to argue that doctors would immediately benefit from lower insurance premiums. But they refuse to, on the other hand, acknowledge that the people who will suffer most from such caps are lower-income adults who suffer from egregious, inexcusable, and devastating medical errors, such as the death of a spouse. These lower-income victims do not, relatively speaking, benefit from unlimited economic damage awards, because their financial horizons are not as rosy as higher-income victims. Thus, in the proposal to cap non-economic damage awards is a discrimination against lower-income victims.

Proponents of such strict damage caps should at least be honest and acknowledge that they are advocating for this type of cost-shifting from doctors to lower-income victims. I think this type of honesty and candor will serve to elevate this debate. I, for one, am open-minded on this issue, and I am willing to look at all solutions that will serve my constituents and Illinois doctors as well. But let us be honest about the costs and benefits of all of these myriad of proposals.

With that, Mr. Chairman, I—again, I want to thank you, and I yield back the balance of my time.

Mr. UPTON. The gentleman's time has expired.

The gentleman from Georgia for an opening statement, Mr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman. I am going to defer my time for questioning, but I would like to take a minute and welcome my constituent from Watkinsville, Georgia, Sherrie Campbell. I know what her problem has been very well, because it is in my District, and I am very excited about her coming up here and telling this committee what happens when you don't have Congress act on tort reform.

Welcome, Sherrie.

Mr. UPTON. The gentleman defers.

Mr. Burgess for an opening statement.

Mr. BURGESS. Well, thank you, Mr. Chairman.

And I, too, want to thank you for holding this hearing on an issue that is important to me and to patients throughout the country.

Before I came to Congress, I was a simple country doctor with 25 years of experience, and I have seen up close and personal how the liability crisis has impacted others in my profession and the patients that we serve. And I would agree with the ranking member from Ohio. In a perfect world, we would have a perfect bill, but this is Congress. And the best we can hope for is a common sense bill, and perhaps a bill that takes good ideas that have worked in those great laboratories across the land, called States, to take these good ideas from State legislation that would work on a national basis. Texas—my home State of Texas, has new legislation. In the past 18 months, this legislation has provided real relief. And in fact, premiums in my State, medical liability premiums have decreased or remained flat or, if they have increased, they have increased at one-half to one-third the rate of neighboring States, most importantly in a State that had gone from 17 insurers down to 2. We now have new insurers coming back into the marketplace, which is just absolutely critical.

A perineotologist in from my District, a young man who had studied in obstetrics and gynecology and gone on to do specialty work in high-risk pregnancies, they have made him a target for liability suits, had to stop his practice after 2 or 3 years, because he simply could not afford the $125,000 premium that he was faced with. This is a young man that had trained in our State institutions. So we, the taxpayers of Texas, had, essentially, paid for his education, and now he was going off to work in private business, because he could not afford to continue to practice his medicine. Our community lost a young man in the prime of his career in a sorely needed specialty because of the medical liability situation.

On a recent trip to Alaska, I went through the town of Gnome. And you can imagine Gnome, Alaska, a Congressional delegation coming through causes a lot of excitement. And the doctors from the hospital were there to meet us for lunch as part of a big chamber group. Well, they heard that I was a doctor. One of them came up to me and said, "Boy, I sure hope you do something about liability reform, because we can't afford an anesthesiologist at our hospital because of the premiums." And I said, "Well, what type of medicine do you practice?" He said, "Just like you, I am an ob-gyn." And I said, "Bubba," that is a Texas expression, "Bubba, what do you mean you practice ob without an anesthesiologist? What do you do if you have to do a C-section?" He said, "Then we call a plane,

and we transfer the patient to Anchorage." And Anchorage is about a 1½ hour flight from Gnome, Alaska. And they do, on occasion, have bad weather in that State. I fail to see how we are advancing the cause of patients' safety by allowing this situation to continue.

And I will yield back.

Mr. UPTON. The gentleman's time has expired.

The gentlelady from Wisconsin, Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman.

I wanted to start out by taking a moment to describe the medical liability insurance situation in my Home State of Wisconsin.

In short, we don't have a crisis in Wisconsin. Medical liability insurance is both available and affordable for Wisconsin's physicians. When Wisconsin addressed this issue in 1975, we started from the premise that you don't deal with rising malpractice insurance costs by blaming the victims. You start by addressing the insurance issues. And Wisconsin did this in three ways.

First, we required that all doctors have malpractice insurance.

Second, we created an insurer of last resort, the Wisconsin Health Care Liability Insurance Plan, commonly known as WICLIP in Wisconsin, to provide affordable malpractice insurance to those who couldn't find any in the private market. WICLIP has been very successful, keeping the rate of increase at or near inflation in recent years.

Finally, we created the Wisconsin Patients Compensation Fund. The Patients Compensation Fund covers all economic damages exceeding $1 million per occurrence or $3 million per year. The Patient Compensation Fund rates, paid by all health care providers in the State, have fallen during recent years. By pooling risk and making sure all doctors have coverage, Wisconsin has successfully addressed this issue. And these actions controlled malpractice costs long before Wisconsin capped non-economic damage.

This brings me to my final point. This should be a State issue. Each State has the authority and capacity to address any problems they have. A one-size-fits-all approach can be overly broad and encroach upon traditional State authority. Soaring malpractice insurance rates need to be addressed with two principles in mind. First, do no harm to the victims in medical errors. And second, start by addressing the problems of inadequate or expensive insurance.

In light of these two principles, narrow Federal caps on non-economic damages are not the way to address the problems with malpractice insurance. We need to put victims first in this debate and find constructive and effective ways to reduce medical errors.

Thank you, Mr. Chair. I yield back.

[The prepared statement of Hon. Tammy Baldwin follows:]

PREPARED STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Thank you Mr. Chairman. And thank you to the witnesses who have come to testify before us today.

I want to start out by talking just a little bit about the medical liability insurance situation in my home state of Wisconsin. In short, we don't have any sort of crisis in Wisconsin. Medical liability insurance is both available and affordable for Wisconsin's physicians.

When Wisconsin addressed this issue in 1975, we started from the premise that you don't deal with rising malpractice insurance costs by blaming the victims. You start by addressing the insurance issues.

And we did this in three ways. First, we required that all doctors have malpractice insurance.

Second, we created an insurer of last resort—the Wisconsin Health Care Liability Insurance Plan—to provide affordable malpractice insurance to those who couldn't find any in the private market. WICLIP has been very successful, keeping rate increases at or near inflation in recent years.

Finally, we created the Wisconsin Patients Compensation Fund. The Patients Compensation Fund covers all economic damages exceeding $1 million per occurrence or $3 million per year. The PCF rates—paid by all health care providers in the state—have fallen during recent years.

By pooling risk and making sure all doctors have coverage, Wisconsin has successfully addressed this issue. And these actions controlled malpractice costs long before Wisconsin capped non-economic damages.

That brings me to my final point. This should be a state issue. Each state has the authority and capacity to address any problems they have. One-size-fits-all approaches are overly broad and encroach on traditional state authority.

Soaring malpractice insurance rates need to be addressed with two principles in mind. First, do no harm to the victims of medical errors. Second, start by addressing the problems of inadequate or expensive insurance. In light of these two principles, narrow federal caps on non-economic damages are not the way to address the problems with malpractice insurance.

Caps in Wisconsin have not resulted in lower heath care costs. Health care costs are rising for many other reasons. We need to put victims first in this debate and find constructive and effective ways to reduce medical errors.

Mr. DEAL. The Chair recognizes Ms. Bono.

Ms. BONO. Thank you, Mr. Chairman. I will waive other than to thank you for this very important hearing and look forward to hearing from all of our witnesses.

And with that, I yield back.

Mr. DEAL. Ms. DeGette, you are next. Would you like to go ahead and try to get your statement in——

Ms. DEGETTE. Yes, sir.

Mr. DEAL. [continuing] before we go vote?

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Chairman, I welcome your leadership of this committee and also your opening remarks about bipartisan solutions. I truly hope that this hearing marks a fresh start for the 109th Congress on this issue, because, frankly, we had a disgraceful record on this issue in the 108th Congress.

Sitting on this subcommittee when we marked up the medical malpractice bill in the 108th Congress, I was dismayed, to say the least, about the complete lack of willingness on the part of the majority to negotiate with anybody. It got to the point, for example, when there was a problem with the definition of the statute of repose in the bill, when I approached the sponsor of the legislation and asked him to work with me on making the definition of that narrow technical term, the common standard definition, he said, "I can't make one change to this bill without going back and talking to the groups who wrote the bill." And he went back and talked to the groups who wrote the bill, and they said no, and they wouldn't even change that one thing.

We can have medical malpractice reform, if we want to. We could come up with a negotiated agreement, but it really is going to take bipartisan cooperation and discussion. Issues like should we really put caps on non-economic damages but, at the same time, not spend one instant in the bill talking about insurance companies and insurance practices for malpractice insurance. Doctors in many parts of the country are getting hammered with increasing mal-

practice insurance costs, but the bill in the 108th Congress did nothing, not even a study, to look at the malpractice insurance industry.

Now if we really wanted to fix this crisis, I would suggest any legislation would involve an examination of malpractice insurance writing policies and how we can fix that. That is what worked in California.

To give you an example, in Colorado, my home State, where we have had insurance reform for many years, insurance—or I am sorry, malpractice reform and caps on non-economic damages, insurance companies took in over $119 million in premiums in 2001, but yet they paid out only $36 million in claims. So I think everything needs to be on the table. And the first thing that needs to be on the table, Mr. Chairman, is the question of is Congress really the uber State legislature. Is the issue of the inaction of State legislatures, in some states, an issue that we should take to Congress and take rights away from victims of medical malpractice in order to try to help a problem that, frankly, is not going to be helped unless we look at every aspect of the issue?

With that, Mr. Chairman, I ask unanimous consent to put my full statement in the record and yield back.

Mr. DEAL. Without objection.

We are going to try one more quickly.

Mr. Ferguson, are you prepared to make an opening statement?

Mr. FERGUSON. Thank you, Mr. Chairman.

Mr. DEAL. I will recognize you for 3 minutes.

Mr. FERGUSON. Thank you.

Good afternoon. Thank you, Mr. Chairman. Congratulations on your chairmanship, and I look forward to working with you and all of the members of the subcommittee. And thank you, too, for bringing this important issue before the subcommittee. This affects our Nation's doctors. It affects so many people, but it ultimately affects every single one of us and our families. I became familiar with this issue when we had our—a child a couple of years ago, and my wife's doctor said, "Well, I am trying to find someone who can cover for me if I am not going to be there, because my partner," this—my—our physician's medical practice partner had just left New Jersey because she couldn't afford the insurance premiums any longer. My wife's physician, her insurance premiums had gone up 40 percent that very year, and this is a bright, talented physician who was considering giving up the practice of obstetrics altogether, because she couldn't afford her insurance premiums any longer. This is clearly a crisis. We had physicians and hospitals and medical specialists, they are severely limiting their practices because of the cost of insurance and overburdening this fear of litigation. Some health care providers are even leaving the State, as I mentioned, and others are just leaving the practice of medicine.

In November 2002, a study by the Medical Society of New Jersey, in my Home State, discovered that 45 percent of medical practices reported that they had adjusted their operations because of problems with the costs of medical liability insurance. These are making changes in the practices, which had a severely negative impact on patient care. They were declining to purchase new equipment. They were laying off staff. They were refusing to accept new pa-

tients. According to the American College of Obstetricians and Gynecologists in New Jersey, 65 percent of the hospitals report that physicians are leaving because of insurance—higher increased insurance premiums.

This longer—this problem can't be—go unaddressed any longer. It is imperative that this committee and the Congress act in a way that it can ensure that all Americans have access to quality health care. We have to preserve the sacred relationships between patients and doctors. We have to encourage bright, young, talented professionals. We have to encourage them to go into the field of medicine. So many young people today are not even considering going into the field of medicine today because of the fear of litigation and the fear that they won't even be able to make ends meet as a trained health care professional.

The message is clear. Physicians and other health care providers want to continue helping patients in need. And patients don't want to lose these trusted relationships that they enjoy with their doctors. Without Federal legislation—I would love it if every State handled this problem in a way that was best for them, but in my Home State of New Jersey, they passed a bill. Frankly, it was a substanceless bill. It was—put a little Band-Aid on a gaping wound. It did not solve the problem.

There is a need for Federal legislation. This problem is not going to go away. We need to address it, and I look forward to addressing it this Congress.

Thank you, Mr. Chairman.

Mr. DEAL. Thank you.

I am going to recognize Mr. Brown very quickly.

Mr. BROWN. Yes, thank you, Mr. Chairman.

Before we break, I would like to recognize Tammy Baldwin for her first hearing on—it is her first year on the full committee, her first day on this subcommittee and recognize Congressman Allen, who is a second-termer on the full committee and his first time on this subcommittee, and Lois Capps, who has been on this subcommittee for a long time.

Ms. BALDWIN. I want to make a statement, if I could——

Mr. DEAL. Well, we don't have time. We are going to have to go vote. I would like to also recognize our two new members who are here, Ms. Bono from California, and Dr. Burgess from Texas.

With that, we are getting close on this vote. We are going to stand in recess. And the best estimate I can give you is probably going to be 45 minutes, it looks like, at least, before we get back. We will stand in recess.

[Brief recess.]

Mr. DEAL. The subcommittee will come to order.

We are in a time bind for some of our witnesses, and so we are going to try to get this opening statement process completed as quickly as possible.

Ms. Capps, you would be next.

Ms. CAPPS. Thank you, Mr. Chairman.

I do think it is important for the Congress and this committee to address barriers to access to health care. One emerging barrier seems to be the rise in medical malpractice insurance rates taking place in various parts of the country. We should do something

about this, but we should be sure we are actually solving the problem and not making a bigger mess. There is serious debate about why premiums are rising and what should be done to stem their growth.

The truth is that the experts are uncertain what exactly is driving premiums. The evidence is mixed. The majority has put forth proposals in the last two Congresses to limit consumers' ability to hold accountable negligent doctors, profit-driven HMOs, insurance companies, and prescription drug companies. They claim that excessive or frivolous lawsuits are the cause of rising premiums. The problem is that these lawsuits are, by definition, not frivolous. Where the large damages are awarded, a jury has found that the patient has been severely harmed. We should not leap to the conclusion that capping the damages an injured person receives because of malpractice is the way to solve the problem. The majority proposal will penalize innocent victims of medical negligence.

Furthermore, this proposal goes far beyond patients and doctors. The majority's bill would protect drug companies, HMOs from lawsuits filed by injured people. In 3 years of considering this issue, the majority has not presented a shred of evidence that drug companies that make billions of dollars in profits need these protections. If the majority's proposal were to become law, the ability of injured patients to hold negligent drug companies would be dramatically limited, and we have all seen the recent stories about Vioxx. They highlight the fact that drug companies may harm patients. They expose how dangerous the majority's bill could be.

I believe the majority should be given a chance to defend their proposal, so I hope, Mr. Chairman, you will hold additional hearings on the legislation itself, and I hope we will hold a markup on any legislation to be considered on the floor. The Energy and Commerce Committee has a rich legislative history. We should not allow ourselves to simply become a select committee without a legislative role.

I yield back.

Mr. DEAL. I thank the gentlelady.

I believe we have now finished opening statements.

Mr. BROWN. Mr. Chairman, I think Congressman Allen is—do you want to make a statement? Okay. Yes, he was—I know he was on his way, and none of those people look like Tom Allen. I was talking about the other three.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Thank you, Chairman Deal, for organizing this hearing, the first of our Subcommittee in the 109th Congress. I'm pleased to be here today to address what I feel is the most crucial health care issue in my district today: the medical liability crisis.

We have all heard the stats on the lack of physicians in our areas, and my home county is probably the hardest hit due to the legal climate that we face.

As the representatives from the American Tort Reform Association can testify today, their group has named Madison County its "Number One Judicial Hellhole" in the country for 2004.

Some may suggest moving to another county to avoid this situation. Unfortunately for my constituents, our neighboring county of St. Clair has been named "Number Two" on the list!

Hospitals in those two counties have lost more than 160 doctors because of the medical liability crisis. These physicians just cannot afford to pay their premiums, which have skyrocketed in recent years.

President Bush outlined his plan for addressing this issue when he visited my district on January 5th. He is committed to Medical Liability Reform this year—and I believe that the House and Senate should be, too.

In rural areas like my district, we already have "access-to-care" problems strictly by nature. But when we hear the staggering news of physician resignations, it affects all aspects of life-not just health care.

Without immediate action, the possibility for economic growth in Southern Illinois will be seriously threatened. To stay competitive in a global marketplace and keep jobs in America, we must ensure that our nation's health care delivery system is fully intact.

I again would like to thank Chairman Deal for holding this hearing, and I look forward to the testimony from our witnesses.

PREPARED STATEMENT OF HON. PAUL E. GILLMOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. Chairman, I congratulate you on your new position and thank you for kicking-off the 109th Congress by delving into our nation's medical liability system and the need to reform it. Furthermore, I am honored to be sitting as a member of this subcommittee for the first time in my career.

I'd also like to commend the well-balanced panel of witnesses. I am confident we will hear from all sides of this issue today. Of note, like many other states, the current medical liability system continues to be of great concern to Ohio physicians and patients alike. In particular, I look forward to learning more about the relationship between health care costs and malpractice litigation, and whether patients are being compensated fairly. I am also anxious to hear about the level of impact that tort reform and medical liability measures, passed previously by the House, could have on our current crisis.

Over the last two Congresses our body has aggressively pursued reform that is both fair and efficient. Once more, I am glad that we continue to bang away at this issue and remain optimistic that our panel will be instrumental in improving a patient's care and access to specialty services, as well as our nation's healthcare delivery system as a whole.

Again, I thank the Chairman, and yield back the remainder of my time.

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Mr. Chairman, for holding this hearing on the medical malpractice situation in many of our states. This is an important issue that has been discussed exhaustively in this committee in the past several Congresses. However, in years past, the committee has been able to address this issue with respect to specific legislation. Then, I expressed concerns that the committee was rushing to pass legislation which I thought would do little to solve the problem of escalating malpractice premiums. But now, we can't even effectively discuss our options in addressing this issue because we have no piece of legislation to examine. On top of that, once a legislative vehicle is eventually identified, we have no assurance that the committee will address it through regular order. Yet again, the committee's response to this issue is occurring too soon and too fast.

In addition to procedural concerns, I remain concerned that we're overstepping our jurisdictional boundaries with our action on this issue. For more than 200 years, the states have had jurisdiction over this issue, and it should continue to be that way. At least 38 states have addressed this issue by capping either punitive damages, non-economic damages, or both. Having served in the Texas State Legislature, I know first-hand that state legislatures are best positioned to determine whether and how to address the medical malpractice situation in their individual states. The situation is different in each state, and a Washington-knows-best approach ignores the hard work and tough decisions that individual states have made.

The legislation we've considered in years past has had significant flaws, and I hope that the majority's delay in producing a legislative vehicle indicates their intent to remedy some of the problems associated with their previous bills. Two particular provisions come to mind. First, previous bills have included a firm $250,000 cap on non-economic damages without providing for inflation adjustment in future years. While that figure mirrors California's MICRA law, it is important to recog-

nize that California's cap has not been adjusted for inflation in approximately thirty years. Further, California's law was crafted during a time when a $250,000 cap would have sufficed for all but the most egregious jury awards—which, I might add, the judge has the discretion to overturn. That is certainly not the case in the 21st Century, and who are we to put a price on pain and suffering? A cap on non-economic damages would create a one-size-fits-all figure for each and every case of medical malpractice. Members of Congress do not hear the details of each medical malpractice case. Members of juries do, which is why they are best equipped to determine the appropriate non-economic damages based on the facts of each case.

The medical liability reform bills previously passed by the House also contained a dangerous provision that would provide drug companies and device manufacturers with an affirmative defense against punitive damages as long as their products had FDA approval. This provision presupposes that FDA approval is an air-tight process whose integrity need not—and legally cannot—be questioned. Considering the FDA's recent track record with regard to Vioxx and other pharmaceuticals that have been removed from the pharmacy shelves, it is clear that the integrity of the FDA approval process has been compromised. Until some serious reforms are implemented at the FDA, the FDA stamp of approval should not provide any company with an affirmative defense against punitive damages. Such a provision would only provide drug and device manufacturers with even less of an incentive to report known adverse events before their products go to market and ensure that their products are as safe as possible.

Given these serious outstanding issues, Mr. Chairman, I think it is unwise to proceed with this discussion until we have a specific proposal to discuss. Above all, I would hope that the committee would recognize the grave issues surrounding this debate—both substantively and jurisdictionally—and afford us the regular order that should accompany any reform as serious as medical liability reform.

Thank you, and I look forward to the witness testimony.

PREPARED STATEMENT OF HON. THOMAS H. ALLEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MAINE

Thank you, Mr. Chairman.

President Bush says there is a medical liability crisis and his medical malpractice proposals will stop frivolous lawsuits against doctors. The President has not told the public that his proposals will probably contain unrelated liability protection to the drug and medical device industries, HMOs and other health insurance companies.

No medical malpractice reform should protect pharmaceutical and medical device companies from punitive damages. They are fully capable of defending themselves. The Food and Drug Administration approves drugs or medical devices for safety and efficacy, but numerous examples exist of companies not disclosing all their data. The Republican plan to introduce the bill after this hearing, by-pass Subcommittee and Full Committee mark-ups and move the bill to the House floor should be reconsidered.

This Committee knows better than to trust the FDA to provide the prescribing community and the American people with timely, appropriate information about the risks and benefits of specific drug therapies.

We know better than to rely on the competency and independence of the FDA on matters related to drug safety, particularly post-market safety, because our Subcommittee on Oversight and Investigations has conducted investigations for decades that have exposed glaring weaknesses in the regulatory framework and performance of the FDA relating to the safety of prescription drugs (including blood which is classified as a drug) and medical devices.

In the past Congress alone, we examined the systemic and personnel weakness in that Agency that have led doctors and their patients to rely on the claims of the makers of Accutane and the antidepressants Zoloft, Paxil, Effexor, Serizone, Remeron, and Celexa when the FDA knew of dangers that were not addressed in the labeling of those drugs.

From public accounts, we can expect that the O&I investigation into the marketed Cox2 drugs, Vioxx, Celebrex and Bextra, will ultimately reach the same conclusion.

This is not the hearing to go into the specifics of these case studies; Accutane and the SSRI case studies are in our record. Nor is it the time and place to hash out the various causes, insufficiencies in the law, questionable policy choices or failures at the FDA, including incompetence and possible malfeasance.

But, given this Committee's experience, we must not allow a medical malpractice bill to limit the tort liability of companies with great financial resources simply because they received FDA approval for a harmful product.

Republicans and Democrats alike have recognized the FDA's recent incompetence when it comes to protecting the public and ensuring drug safety. At our first Oversight hearing on September 9th, 2004 Chairman Barton stated, "The conduct by the FDA has only reinforced my past sentiments that the Food and Drug Administration really stands for Foot Dragging and Alibis, and that is not acceptable." Also at that hearing, Rep. Walden noted, "The regulatory agency charged with protecting the public health is preventing a company from disseminating important safety information to parents, the public, and physicians."

On September 23rd Chairman Barton said, "Time after time in reviewing the documents and reviewing the transcripts and the testimony, it really does appear to me that the FDA has gone out of its way to short circuit findings."

Senate Republicans concur that the FDA has proven unable to do its job effectively. At a Senate Finance hearing on November 18th of last year, Senator Grassley stated, "What's come to light about Vioxx since September 30th makes people wonder if the FDA has lost its way when it comes to making sure drugs are safe." He continued on to say, "One of my concerns is that the FDA has a relationship with drug companies that is too cozy," and that, "The FDA has also stood watch over failures when it comes to drug safety."

My Republican colleagues are clearly aware of the FDA's recent failures and yet it seems only a matter of time before they will introduce tort reform legislation that contains, once again, the FDA defense. But we all know that the FDA is unable—on a continuing basis—to protect the public from dangerous drugs. To rely upon the FDA for assurance that approved medicines are sold with the most recent and relevant information regarding their safety and efficacy profiles is simply folly. Stripping patients of their right to legal recourse is not the answer. The FDA defense for tort claims against companies making drugs or medical devices has no place in any bill, certainly not one dealing with malpractice claims against physicians.

Mr. DEAL. We do have some witnesses that have got some airplanes to catch, I know, and you know, we always have the right. I would ask the ranking member if they do want to make an opening statement, if they will stick around until after this second panel, we would be glad to have a closing statement, if they would like to do that, or they can submit it for the record, obviously.

Let us begin with our first panel. And thank you for being patient. And thanks to the others, also.

First of all, Dr. James R. Bean, a neurosurgeon from Kentucky, would be the first person to testify. I understand you have been in surgery yesterday. We do appreciate your taking time to come to be with us today.

We also have Dylan Malone, Sherrie Campbell, Monty Huggins, and Mary Rasar. And you each have 5 minutes.

And Dr. Bean, we will start with you.

STATEMENTS OF JAMES R. BEAN, PHYSICIAN ADVISORY COUNCIL, ALLIANCE OF SPECIALTY MEDICINE; MONTY HUGGINS; SHERRIE CAMPBELL; DYLAN MALONE; AND MARY RASAR

Mr. BEAN. Mr. Chairman, I appreciate the opportunity to come and speak. My name is Jim Bean, and I am a neurosurgeon. I have been in practice for 20 years in Lexington, Kentucky, so I have had some chance to view what has been going on. I do speak for the Alliance of Specialty Medicine, 13 special societies also.

Before I make my statement, though, I just want to recount a story that happened to me when I was in practice in about 1982. When I was in surgery, we had a call from the emergency room. A girl of 3 years old, had come to the emergency room, had fallen down stairs. Her mother was a realtor. She had been in a house and fell down the stairs and 15 minutes later vomited. Fifteen minutes later, the child is in the emergency room drowsy. We did a

quick CAT scan and saw that there was a growing blood clot, called an epidural hematoma. So he called up there. Knowing that this child had only a limited time, I said, "Vinnie, I will finish my surgery. Put her in the other room." I left there in 10 minutes, did the surgery, took out the blood clot. By that time, she was in a coma with a dilated pupil, meaning the end was near, and she recovered. And the point was, it was fast. It was a child, and it was fast. And I got a letter and a picture from her mother about 15 years later, back in the mid-1990's. She graduated from high school.

The point of the story, though, is this is unlikely to happen in today's environment, because what we have is neurosurgeons no longer treating pediatric patients. 75 percent, because of liability, won't see them. And if a child were in that hospital, they would be transferred another hour or 2 away, and that is too late. So we have disasters that not only are waiting to happen, but they are happening. I hear about them. I hear about them in Illinois. I hear about them in Oregon and other places where the liability crisis is occurring. And it is not just neurosurgery. We have obstetricians. 15 percent of them are baby doctors, and they don't deliver babies. You have heard about it, but I want to emphasize. Even high-risk treatment, 25 percent of obstetricians won't take a reduced, high-risk treatment. Why? Because they can't afford the liability.

We think the cause is simple. We know that there is debate about it, but we see the rising jury awards, and we see our premiums going up. And what it appears to us, from the data, is that the amount of money going out has to be an amount matched by the amount of money going in. That is how you pay those things. We have seen our premiums rise, across the country, among neurosurgeons, 84 percent, on an average, good States and bad, over the last 4 years, since the year 2000. Some States have had enormous rises, 300 percent. One of the worst States in the country is Illinois where right now the median, the average neuro premium is $200,000. Now I don't know how they continue the payment, but that is why they are leaving. They can't stand to stay and pay it.

This is a problem across the country. It is not just a few States. There are only seven States that we can identify that are truly stable, and I don't think that it is an accident that these are States that have had liability reform for virtually 30 years, like California, New Mexico, and Louisiana, and Indiana, and Wisconsin. You know, what is a paradox is Illinois is between Wisconsin and Indiana. They pay $200,000 on an average in Illinois. You can go across the State line to Indiana, and you can pay $40,000, or you can go up to Wisconsin and pay $30,000. They are the same doctors that do the same work. Why do they have to pay so much more? Because we have a bad system, and it needs to be fixed. And it is a national problem, and we think it needs a national solution. Everybody in every State, every citizen deserves the same chance of access to health care. We are losing it. We are losing it right now, and it is getting worse year by year, so delay is not going to help. Delay and debate aren't solving the problem.

We think there is a solution. There are many proposals that we are anxious to entertain, and though we do know there are solutions and the MICRA reforms that are in California's bill from 1975 are proven to hold rates down. The rates across the country

have increased at three times the amount that the rates have in California. You know the provisions of the bill. I won't go through them, but I do think that it is important to consider this a national dilemma that needs a national solution. What I think we need to bring is fairness and balance and uniformity to the medical liability system across the country. Full economic damages, a limit on non-economic awards, which now are 60 percent of the award, and protect every person. We want to protect those that are medically injured, but we also want to protect every person who needs specialty and emergency care and that they can get it near home when they need it and where they need it.

Thank you very much.

[The prepared statement of James R. Bean, follows:]

PREPARED STATEMENT OF JAMES R. BEAN ON BEHALF OF THE ALLIANCE OF SPECIALTY MEDICINE

Chairman Deal, Ranking Member Brown, and Members of the Subcommittee, my name is James R. Bean, MD. I am a practicing neurosurgeon from Lexington, Kentucky, a member of the Alliance of Specialty Medicine's Physician Advisory Council and the current Treasurer of the American Association of Neurological Surgeons. On behalf of the Alliance, a coalition of 13 medical societies representing 200,000 specialty physicians in the United States, I appreciate the opportunity to testify before you today regarding the effect that our current medical litigation system is having on patient access to healthcare.

Nearly two years ago, this subcommittee held a similar hearing to assess the need for federal medical liability reform legislation. At that time, subcommittee members were informed of a growing healthcare crisis that was seriously affecting patient access to care in at least twelve states. As you know, the House of Representatives responded by passing the HEALTH act, not once, but twice. The Alliance endorsed this legislation then, and we continue to support its passage. Unfortunately, the Senate was unable pass this bill and Congress adjourned without solving the problem. I am sorry to inform you today, that not only has the crisis not subsided, indeed, it has worsened. According to the American Medical Association, there are now twenty states in "full-blown" crisis and twenty-four states and the District of Columbia are showing warning signs of a potential crisis Only six states—California, Colorado, Indiana, Louisiana, New Mexico, and Wisconsin—are considered safe, and the common denominator is that they have all implemented effective medical liability reform. I therefore have the regrettable task of bringing you up-to-date on the status of this ongoing crisis.

And it is a crisis. The media now report on a daily basis that as medical liability insurance becomes unaffordable or unavailable, more and more doctors, especially specialists, are no longer performing high-risk procedures, or they are being forced to move their practices to states with stable medical liability systems, or they are simply retiring from medical practice—leaving gaping holes in the healthcare safety net.

Much of the "face" of this crisis has centered around the great difficulties that pregnant women are having in finding obstetricians to deliver their babies, but the simple truth is that this is a problem that potentially affects all of our citizens: the mother whose little boy has fallen off of the jungle gym and needs an orthopaedic surgeon to fix his broken arm; the teenager who has been in a serious car accident and needs a neurosurgeon to treat his severe head injury; the woman who needs a pathologist to evaluate her Pap smear to screen for cervical cancer; the elderly man who has a poor heart and needs a cardiologist or cardiothoracic surgeon to unblock a clogged artery or replace a failing valve; the woman who has a family history of breast cancer and needs a radiologist to perform a mammography to make sure she is cancer free; the business man who needs a gastroenterologist to treat his ulcer; the man who needs a urologist to screen for prostate cancer; and for millions, a nearby emergency department that is open to avoid unnecessary delays in getting treatment when time is of the essence.

THE MEDICAL LIABILITY CRISIS: PATIENT ACCESS TO MEDICAL CARE IS IN JEOPARDY

As the subcommittee considers the current state of this national healthcare problem, I'd like to draw your attention to a growing body of evidence that does in fact demonstrate just how serious this crisis has become.

Doctors are No Longer Performing Complex and High-Risk Medical Procedures

America's women are at particular risk of losing access to vital healthcare services. The August 2003 General Accounting Office report entitled, "Medical Malpractice: Implications of Rising Premiums on Access to Health Care," confirmed that rising medical liability insurance premiums have contributed to reduced access to obstetrical services, particularly in rural locations. According to a 2004 professional liability survey conducted by the American College of Obstetricians and Gynecologists, ob-gyns have made a number of practice changes as a result of the medical liability crisis:

- One in seven has stopped practicing obstetrics because of the risk of liability claims;
- Because of the risk of liability claims or suit, 22 percent decreased the amount of high-risk obstetric care; 14.8 percent stopped offering or performing VBACs; 9.2 percent decreased the number of deliveries; 12.3 percent decreased gynecologic surgical procedures performed; and 5.6 percent no longer perform major gynecologic surgery;
- Because of liability insurance costs and availability, 25.2 percent decreased the amount of high-risk obstetric care; 12.2 percent decreased the number of deliveries; 14.8 percent decreased gynecologic surgical procedures performed; and 5.4 percent no longer perform major gynecologic surgery

Patients in need of care from surgical specialties like orthopaedics and neurosurgery are likewise affected by the crisis, as these physicians are also restricting their practices. According to the American Association of Orthopaedic Surgeons, rising liability premiums have caused 55 percent of orthopaedic surgeons to avoid at least some procedures due to liability concerns; 39 percent now avoid performing spine surgery; and 6 percent have eliminated all surgery.

The American Association of Neurological Surgeons and the Congress of Neurological Surgeons report similarly alarming findings. Based on a 2004 national survey of U.S. neurosurgeons, the AANS and CNS found that over one-half of survey respondents have limited services because of rising medical liability insurance premiums and/or increased risk of suit. Of those limiting services, 70 percent refer complex cases to other neurosurgeons; 71 percent no longer perform aneurysm surgery; 23 percent no longer treat brain tumors, 75 percent no longer operate on children; and 34 percent no longer perform complex spine procedures. These patients are typically sent to academic medical centers or large tertiary care hospitals for treatment, often requiring patients to travel great distances to receive neurosurgical care.

Even specialists who are not usually considered "high-risk" cite medical liability pressures as the reason why they are restricting services. For example, according to the American Urological Association, over 41 percent began referring complex cases in the past two years and one in four no longer perform such procedures as cystectomy (which is complete bladder removal, usually for cancer patients).

The elderly may also be particularly affected, as decreases in reimbursements for complex medical procedures have declined to the point where Medicare no longer even covers the cost of medical liability insurance. Specialists with a high volume of Medicare patients, such as cardiologists and cardio-thoracic surgeons, and their patients who need high-tech, lifesaving heart therapy, will likewise feel the effects of the crisis.

Patient Access to Emergency and Trauma Care is at Risk

While the medical liability crisis affects patients who need many types of medical care, access to timely and efficient emergency and trauma care services is in particular jeopardy. When patients rush to the ER, they assume the hospital will be open and doctors will be there to treat them. However, because of the medical liability crisis, this is no longer always the case. The liability crisis is now severely straining our nation's already stressed emergency medical system, as patients who have no access to doctors inevitably end up on the emergency department's doorsteps, further exacerbating the hospital emergency department overcrowding problem.

In addition, to secure affordable medical liability insurance or to minimize their risk of lawsuits, many physicians, including neurosurgeons, orthopaedic surgeons, cardiothoracic surgeons, obstetricians and cardiologists are no longer serving "on-call" to hospital emergency departments. For example, according to a 2004 hospital emergency department survey conducted by The Schumacher Group, three of four emergency departments diverted ambulances in the last 12 months in part because no specialists were available. Of these, one third diverted patients six or more times a month and an additional 28 percent diverted patients three to five times a month.

More than one-fourth of hospitals reported losses in specialty coverage related to a fear of lawsuits.

The above referenced August 2003 GAO report confirmed that rising medical liability premiums have contributed to reduced access to emergency surgery services, particularly in rural locations, because certain high risk specialists like neurosurgeons and orthopaedic surgeons are no longer serving on-call to hospital emergency departments. Over one-third of surveyed neurosurgeons have reported that they have altered their emergency and/or trauma call coverage because of liability concerns. Neurosurgeons across the country are now limiting the types of emergency cases that they treat, they are limiting the hours that they serve on-call, or they have stopped providing emergency call altogether. Twenty-one percent of orthopaedic surgeons have likewise eliminated emergency department call.

Doctors are Moving to States with a More Favorable Medical Liability Climate

Every state that is experiencing a medical liability crisis reports that doctors are leaving in droves in search of another location in which to practice where the medical litigation climate is more favorable. The list of states experiencing the exodus of doctors continues to grow, and as with other elements of this crisis, specialists are most likely to "hit the road" in search of a safe haven state. Pennsylvania has been especially hard hit, and some counties no longer have any practicing orthopaedic surgeons and 12 maternity wards closed in Philadelphia alone. Moreover, 80 percent of Pennsylvania medical students are leaving the state, instead of staying to practice in this highly litigious area of the country. Neurosurgery's survey data show that nearly 19 percent of practicing neurosurgeons either plan to, or are considering, moving their practice to another state where the medical liability costs are relatively stable. Prior to the recent enactment of medical liability reform, Mississippi had lost 35 percent of its neurosurgeons in a two year period. Last year, 21 out of 79 neurosurgeons surveyed in Missouri stated that they were considering leaving the state, and today, there are no longer any neurosurgeons in Southern Illinois.

Doctors, Trauma Centers and Other Medical Providers are Closing their Doors

An even more troubling aspect of the current crisis is the fact that many physicians are simply finding it impossible to stay in practice at all, and once gone, they are not easily replaced. In extreme cases, emergency departments and trauma centers have been forced to shut down completely because the physicians have been unable to secure medical liability insurance at any price. The GAO confirmed that the medical liability crisis caused trauma centers to close in Florida, Mississippi, Nevada, Pennsylvania and West Virginia. The same has been true in other states, including Arizona, Maryland, Ohio and Texas. These closures are coming during a time when the number of visits to the nation's emergency departments climbed over 20 percent from 89.8 million in 1992 to 107.5 million in 2001.

Within the past several years, nearly 700 mammography facilities have closed nationwide. The continued and steady closing of mammography facilities throughout the country has led to increased waiting times for women seeking both screening mammograms and diagnostic mammograms. The longer waiting times are now on the brink of affecting clinical outcomes for those women who must wait for a possible diagnosis of breast cancer.

Individual physicians are also retiring. In the case of neurosurgery, in 2001 alone, 327 board certified neurosurgeons retired, representing an alarming 10 percent of the neurosurgical workforce in the United States. In addition, another 33 percent of neurosurgeons report that they are planning to retire early. Five percent of orthopaedic surgeons have retired earlier than they otherwise would have.

Current and future shortages of high-risk specialty physicians will increase the magnitude of the problem. According to the American Hospital Association's March 2003 Liability Insurance Survey, over one-half of hospitals across the country reported difficulty in recruiting physicians because of the medical liability crisis. A recent study of third and fourth-year medical students found that nearly one-half said the current crisis was a significant factor in their specialty choice, with many future doctors no longer choosing high-risk specialties such as ob-gyn. In the 2004 National Resident Matching Program, the number of ob-gyn training slots filled by U.S. medical school seniors declined for the third year in a row to 65.1 percent—a decrease of 20 percent over the past decade. The number of U.S. medical students entering neurosurgery and emergency medicine residencies declined to 86 percent and 77.5 percent, respectively. Finally, applications to medical schools have dropped 22 percent since 1997. With an increasingly aging population, the country can ill-afford

to lose good doctors prematurely and to have a healthcare litigation system that deters our best and brightest from choosing medicine as a career.

CAUSE OF THE CRISIS: THE CURRENT MEDICAL LITIGATION SYSTEM IS BROKEN

The root cause of this problem is quite simple: the unrestrained escalation of jury awards and settlements, in even a small number of medical liability cases, is driving up doctors' liability insurance premiums and is forcing some insurance companies out of business altogether. This problem is making it difficult, and sometimes impossible, for doctors to obtain affordable liability insurance so they can remain in practice. There is a wide body of evidence to substantiate these conclusions.

Medical Liability Awards are On the Rise

Medical liability awards have been growing steadily, and according to closed claims data from the Physicians Insurance Association of America (PIAA), the median jury award nearly doubled from 1997 to 2003, increasing from $157,000 to $300,000. The average award increased from $347,134 in 1997 to $430,727 in 2002. Data collected by Jury Verdict Research (JVR), which reports statistics for a smaller number of cases that reach the trial stage, reflects these same trends. According to JVR, the median medical liability jury award had doubled from $500,000 in 1995 to over $1 million in 2002 and the average jury award has soared to an astonishing $6.2 million, up from $1.8 million in 1996. Finally, the number of mega-verdicts is also on the rise. In 1997, only two medical liability verdicts topped $20 million. In 2001 and 2002, however, seven of the top 20 awards were related to medical liability, including a $95.2 million birth injury judgment in New York. The combined total of these seven awards was nearly $3 billion.

Overall medical liability tort costs are rapidly increasing, and far outpace the growth in medical costs generally. For example, according to the Insurance Information Institute, from 1975 through 2000, medical liability costs have grown a whopping 1,642 percent as compared to a 449 percent increase for general medical costs.

Increased Awards and Settlements Mean Insurers are Paying Out More than they are Collecting, Necessitating Steep Premium Increases

A June 2003 General Accounting Office (GAO) report, entitled "Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates," confirms what we already know: increased losses on claims are the *primary* contributor to higher medical liability insurance premium rates.

Indeed, according to the Insurance Information Institute, which analyzed data from A.M. Best (an independent insurance rating agency that analyzes insurance companies' overall financial strength and creditworthiness), the cumulative underwriting loss for the medical liability insurance sector from 1990 to 2001 was nearly $10 billion. This dramatic rise in medical liability awards and settlements has meant that professional liability insurers have been paying out more than they have been collecting in premiums. In 2002, medical liability insurance companies were paying out $1.65 in claims for every medical liability premium dollar collected. In 2003, according to the National Underwriter Data Services, insurers were paying approximately $1.38 for every premium dollar collected. While the ratio of payouts to premium dollars collected has become more aligned, insurance companies are still finding it necessary to raise physicians' premiums to keep pace with anticipated claims. Obviously, this situation is not sustainable, and this trend is therefore forcing insurance companies, which must set their rates based on anticipated future losses, to steeply increase doctors' medical liability premiums to ensure adequate reserves to pay future judgments.

As a result, over the past several years, physicians across the country have faced double, and sometimes triple, digit rate increases. Alliance members, including high-risk specialists like neurosurgeons, orthopaedic surgeons, obstetricians, cardiothoracic surgeons and emergency physicians, have been disproportionately affected by these premium increases. For example:

- According to one national survey of neurosurgeons, between 2000 and 2004 the national average premium increase was 84 percent, from $44,367 to $81,749. The median rate for neurosurgeons in Illinois is now $200,000 and in some states, neurosurgeons' premiums have reached nearly $400,000 per year.
- Rates for ob-gyns continue to be among the highest. According to the Medical Liability Monitor's 2004 rate survey, in 2004, obstetricians paid $277,241 in Florida, up from $249,169 in 2003. Illinois ob-gyns received a 66.9 percent increase in 2004, paying $230,428 as compared with $138,031 in 2003. And in Pennsylvania, premiums for ob-gyns increased 34.4 percent in 2004 to $172,178 from $128,114 in 2003.

- Utah orthopaedic surgeons saw medical liability rate increases of 60 percent from 2002 to 2003 and in Texas they have risen by more than 50 percent. In Pennsylvania, a survey conducted in June 2002 revealed rate increases as high as 59 percent. In other areas of the country, orthopaedic surgeons are finding that their premiums have risen by over 100 percent, even if they have never had a claim filed against them.
- Over the past several years, over 95 percent of emergency medicine physicians have experienced medical liability premium increases, with approximately 69 percent facing increases between 60 to 500 percent. This is attributed to the fact that emergency medicine physicians are almost always named in any litigation that arises from a patient encounter that begins in the emergency department. Since most hospital admissions now come through the emergency department, these doctors are experiencing steep premium rises even though the lawsuits against them may have no merit and result in either dismissal or a defendant's verdict.
- Even those specialists who are not in high-risk categories are affected by this upward trend in premium costs. For example, 80 percent of recently surveyed dermatologists reported that their premiums increased over the past years and those dermatologists who were insured by a state plan were paying nearly double what their colleagues were paying in the private market.

Medical Liability Insurance is Unavailable

Not only are medical liability insurance premiums rising at astronomical rates, but many doctors have found it increasingly difficult to obtain medical liability insurance at any price. Citing the increases in liability losses, several companies, including, St. Paul, MIXX, PHICO, Frontier Insurance Group and others, have either recently stopped selling medical liability insurance or have gone out of business, leaving thousands of doctors scrambling to find replacement coverage. Of the companies that have remained in the market, many are no longer renewing insurance coverage for existing policyholders and/or they are not issuing new insurance policies to new customers. This is particularly true in states that have no effective medical liability reform laws in place.

The June 2003 GAO report confirmed that the declining profitability of the medical liability insurance market has caused many insurers to either stop selling medical liability policies altogether or reduce the number of policies they sell, putting even greater pressure on the remaining insurance companies to raise their premiums to cover expected losses. Alliance members have witnessed the impact of this problem first hand. For example:

- In 2002, nearly 40 percent of orthopaedic surgeons in Pennsylvania were not able to renew their medical liability coverage with the same carrier and 31 percent did not find new coverage.
- In 2002, 15 percent of dermatologists experienced difficulties securing their liability insurance. In some cases, dermatologists in solo practice who have never even been sued were forced to turn to the state for coverage because the remaining insurers in their area made a blanket decision to no longer insure solo practice physicians, regardless of specialty.
- A recent study found that in recent years, approximately 33 percent of surveyed neurosurgeons have switched insurance companies, and of these, 41 percent did so because their insurance company failed or withdrew from the market. In addition, neurosurgeons in Florida have been unable to obtain medical liability insurance at any cost, forcing them to "go bare" or self-insure. Across the nation, even those neurosurgeons who only have one claim against them (regardless of the outcome of the case) are finding it difficult to find insurance coverage.
- Three of four insurance carriers with the largest market share in Missouri recently stopped writing policies in that state. This means that physicians can often obtain a quote from only one company. For example, one group of 12 cardiologists could get only one quote with an 80 percent increase for 2003.

SCOPE OF THE CRISIS: A NATIONAL PROBLEM THAT REQUIRES A FEDERAL SOLUTION

Those who oppose federal legislation to fix this crisis cite various reasons in support of their contention that this is not a national problem that merits a federal solution. In particular, they note that the regulation of insurance and healthcare is generally left to the states and therefore this is a matter that the states should attend to. The Alliance respectfully disagrees with these objections. Today, healthcare delivery has no borders and it should be equal from state to state. We currently have a patchwork of liability reforms, and because of this uneven system, access to healthcare varies according to the liability climate of each state. Every patient,

every citizen, in every state deserves equal protection under the law, both in compensation for negligent injury, and in timely access to healthcare, particularly emergency and specialty care. The undisputed truth is that one way or another, this problem now touches nearly every American and a federal solution is therefore a national imperative.

Nearly All States are Facing a Medical Liability Crisis

According to the American Medical Association, there are now twenty states in "full-blown" crisis: Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Texas, Washington, Nevada, West Virginia, and Wyoming. Twenty-four states and the District of Columbia are showing warning signs of a potential crisis. For high-risk specialists like neurosurgeons, the situation is even more widespread than the AMA reports, as the American Association of Neurological Surgeons and Congress of Neurological Surgeons have identified at least 22 states that are currently facing a medical liability crisis, with another 16 facing a potential crisis.

Every American Pays the Costs of the Current Medical Litigation System

According to the U.S. Department of Health and Human Services (HHS), in its 2003 report entitled, "Addressing the New Health Care Crisis: Reforming the Medical Litigation System to Improve the Quality of Health Care," the current medical litigation system imposes enormous direct (e.g., premiums, legal fees, expenses and payouts) and indirect costs (e.g., defensive medicine) on the health care system. In 2004, for example, 55 percent of surveyed neurosurgeons reported that they are practicing defensive medicine and have altered their treatment protocols because of liability concerns, including ordering more diagnostic or other tests. These costs are passed on to all Americans in the form of increased health insurance premiums, higher out-of-pocket medical expenses and higher taxes. The report estimates that enacting federal medical liability legislation could save between $70-120 billion in health care costs each year. These savings would in turn lower the cost of health insurance and make health care more affordable and available to many more Americans.

Federal Medical Liability Reform Will Save the Federal Government Money

Each year, the Federal Government pays for the increased costs associated with the current medical litigation system through various health care programs, including Medicare, Medicaid, Community Health Centers and other health care programs for veterans and members of the armed forces. Citing the findings of the Department of Health and Human Services and the Congressional Budget Office's (CBO) cost estimate of HR 5, the HEALTH Act, the Congressional Joint Economic Committee concludes that federal medical liability reform legislation that includes a cap on non-economic damages would generate significant fiscal savings for the Federal Government. The combined annual budget savings attributed to decreased direct and indirect costs would total approximately $12.1 billion to $19.5 billion. Over a ten-year period (2004-2013), if medical liability reform legislation passed, a total of between $67 billion and $106 billion in savings would accrue to the federal government.

States Face Significant Barriers to Implementing Medical Liability Reforms

Many states face barriers—some legal and some political—to enacting effective medical liability reform laws. Some states, including Florida and Ohio, have enacted medical liability reform laws, only to have their state Supreme Courts strike them down as unconstitutional. Other states, like Arizona, Kentucky, and Pennsylvania have explicit constitutional prohibitions on damage limits. Still others, like Montana, have not had their laws tested and reviewed by their highest court. In addition, new laws passed by Mississippi and West Virginia may also face court challenge, and it will be years before it is determined whether these laws pass state constitutional muster. As a consequence, despite the increasing medical liability crisis in many of these states, they are essentially powerless to act to effectively solve the problem.

SOLUTION TO THE CRISIS: MEDICAL LIABILITY REFORM LEGISLATION PATTERNED AFTER CALIFORNIA'S MICRA

The cornerstone of any legislation should include the principles that injured patients deserve their day in court and that they are entitled to receive full, just and fair compensation. Congress should therefore adopt medical liability reforms that have a proven track record and will help strike the necessary balance between com-

pensating injured patients and ensuring access to healthcare for all Americans. Fortunately, Congress does not need to start from scratch and identify and implement a solution that is untested. Faced with a similar crisis in the early 1970's, the state of California, with bipartisan support, enacted the Medical Injury Compensation Reform Act or MICRA. The Alliance believes that any federal reform must contain the key elements of MICRA, which include:

- Providing full compensation for all economic damages, including medical bills, lost wages, future earnings, custodial care and rehabilitation;
- Placing a fair and reasonable limit of $250,000 (without exceptions or an inflationary adjuster) on non-economic damages, such as pain and suffering;
- Resolving claims quickly by establishing a reasonable statute of limitations for filing a lawsuit;
- Ensuring appropriate payments are there when patient need them by allowing for periodic payments of damages rather than lump sum awards;
- Maximizing the amount of the award that goes to injured patients by placing reasonable limits on attorneys' fees;
- Focusing liability on those at fault, not on "deep pockets," by eliminating joint and several liability; and
- Preventing double recovery of damages through collateral source reform

Congress may want to consider additional reforms (which were not included in last-year's House-passed version of the HEALTH Act) that would:

- Ensure that juries are advised by actual experts by establishing expert witness standards; and
- Unclog the courts and reduce the societal costs of lawsuits by limiting frivolous lawsuits

In addition, Congress should ensure that federal medical liability reform does not preempt effective state reforms.

As the subcommittee moves forward with its deliberations on this legislation, the Alliance urges you to keep in mind the following points about the effectiveness of MICRA:

MICRA Fully Compensates Injured Patients Quickly

First and foremost, under MICRA, patients receive full compensation for legitimate injuries resulting from medical negligence. Detractors of federal reform legislation are attempting to obfuscate the facts by scaring the public and policymakers into believing that injured patients will only receive a maximum of $250,000 to compensate them for their injuries. This is simply not the case. Patients receive full compensation for all of their quantifiable needs, with up to an *additional* $250,000 for non-economic damages, such as pain and suffering. To demonstrate this fact, the Californians Allied for Patient Protection recently compiled a sample of total awards (including both economic and non-economic damages) provided to injured patients. For example, in December 2002, a 5 year-old Alameda County boy with cerebral palsy and quadriplegia because of delayed treatment of jaundice after birth was awarded $84,250,000; a 3 year-old Contra Costa County girl with cerebral palsy as a result of birth injury was awarded $59,317,500 in October 2002; a 30 year-old homemaker from Los Angeles with brain damage because of lack of oxygen during recovery from surgery, was awarded $12,558,852 in July 2002; and in November 2000, a 25 year-old San Bernardino County woman with quadriplegia because of failure to diagnose a spinal injury was awarded $27,573,922.

Medical liability claims are also paid most quickly in California versus all other states. According to the National Practitioner Data Bank's 2003 Annual Report, in 2003, the mean delay between an incident that led to a payment and the payment itself was 4.59 years. In California, it was 2.98 years. The slowest state to close claims was Massachusetts, which was 6.19 years.

MICRA Significantly Minimizes Premium Increases

Opponents of reform cite statistics that over the past several years, premiums for doctors in California have also been rising; thus somehow proving that MICRA does not have any impact in holding down the costs of medical liability insurance. While it is true that premiums are on the rise in nearly all states, including California, the rate of increase of premiums for California doctors is significantly lower than in other states, and over time, MICRA has, in fact, stabilized medical liability insurance premiums as compared to the rate of increase in the rest of the country. According to data from the National Association of Insurance Commissioners, from 1976 to 2002, liability premiums for California physicians rose only 245 percent as compared with 750 percent of physicians in the rest of the United States. Data from a survey of neurosurgeons validates these trends, and both actual premiums and the

rate of increase for neurosurgeons in California, as compared to neurosurgeons who practice in states where there are no reforms in place, are significantly lower.

Federal Government and Other Experts Agree that MICRA Works

U.S. Government experts and others agree that MICRA does in fact hold down the costs of medical liability insurance, and over the years there have been a number of studies that have identified MICRA's $250,000 cap on non-economic damages as a critical element in stabilizing premium costs. For example, dating back to September 1993, the former U.S. Office of Technology Assessment (OTA), in a report entitled, "Impact of Legal Reforms on Medical Malpractice Costs," concluded that caps on damages were consistently found to be an effective mechanism for lowering medical liability insurance premiums. Most recently, the U.S. Department of Health and Human Services, Congressional Budget Office and Joint Economic Committee issued reports evaluating the HEALTH Act, came to the same conclusion, and the GAO, in its August 2003 report, found that "premium growth was lower in states with non-economic damage caps than in states with limited reforms." In addition to these government experts, others have studied the effectiveness of MICRA. A 2004 study by the RAND Corporation, entitled "Capping Non-Economic Awards in Medical Malpractice Trials" concluded that MICRA's contingency fee reform and limit on noneconomic damages has decreased insurer payouts and redistributed more money from personal injury attorneys to injured patients. Finally, according to Kenneth Thorpe, in a study published in the January 2004 edition of Health Affairs, insurance premiums are 17 percent lower in states with caps on noneconomic damages and they are one-quarter lower in states with both caps on noneconomic damages and discretionary collateral offsets.

States with Damage Caps Have More Doctors Available to Treat Patients

Opponents of medical liability reform cite various statistics to claim that tort reforms, especially caps on damages, have had no affect on stemming the tide of this crisis. In addition, in its August 2003 Report, the GAO asserts that its analysis of medical licensure data proves that not only are physicians not moving or retiring as a result of increased medical liability premiums, but in the crisis states it reviewed there actually was an increase in the number of licensed physicians. The Alliance takes issue with these claims for several reasons:

- Medical licensure data is in no way indicative of the number of physicians who are actually practicing medicine in a particular state. Rather, it merely means that a certain number of physicians hold a license to practice medicine. Physicians tend to hold multiple state licenses and typically retain their licenses when they relocate or retire from active practice. Thus, taken alone, medical licensure data provides no useful information to prove or disprove the affects of the medical liability crisis on physician supply.
- According to a July 2003 study conducted by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality, entitled "The Impact of State Laws Limiting Malpractice Awards on the Geographic Distribution of Physicians," states that have enacted laws capping damage payments in medical liability cases have more physicians per capita than those who have no cap or very high damage caps. The study found that in 1970, before any states had a law capping damage payments, in all states there were virtually identical levels of physicians per 100,000 citizens. Thirty years later in 2000, however, states that had adopted a cap averaged 135 physicians per 100,000 citizens, while states without caps averaged 120.
- The May 2003 Joint Economic Committee study concluded that "the number of doctors at the state level is sensitive to the malpractice insurance costs: higher premiums reduce the number of practicing physicians."

The clear and simple truth is that MICRA and other similar laws work. For nearly three decades, this law has ensured that legitimately injured patients get unfettered access to the courts and receive full compensation for their injuries, while at the same time providing stability to the medical liability insurance market to ensure that doctors can remain available to care for their patients.

Americans Overwhelmingly Support a MICRA-Style Solution

Americans are becoming acutely aware of the impact this crisis is having on the nation's healthcare system and the care they receive. Studies show that they overwhelmingly favor passage of federal legislation to reform the current medical liability system and create a system that balances the rights of patients to obtain appropriate compensation for injuries caused by medical negligence with the rights of all citizens to have access to medical care. A March 2004 poll conducted by Wirthlin Worldwide for the Health Coalition on Liability and Access found that:

- 82 percent of the Americans surveyed believe that doctors are being forced to leave their practices because excessive litigation has put the cost of medical liability insurance out of reach.
- By a huge margin, 72 percent of those surveyed said that health care expenses for all people are being driven up by the rising cost of medical liability lawsuits.
- The high number of medical liability lawsuits is unjustified, according to 55 percent of the survey respondents. Only 16 percent say that the number of lawsuits against health care providers is lower than justified.
- Three-quarters of Americans want Congress to pass reforms to fix the medical liability crisis. 72 percent favor a law that guarantees full payment for lost wages and medical expenses but limits non-economic damages; 73 percent want to limit the amount of money personal injury trial lawyers can get from the excessive litigation settlements their clients receive.

A January 2005 poll conducted by Public Opinion Strategies for the American College of Emergency Physicians reached similar conclusions, confirming that three out of four (75 percent) of Americans recognize the current system interferes with physicians' ability to provide quality care; 85 percent of Americans believe the current legal system—with no consequences for pursuing frivolous lawsuits and publicity about large monetary awards—is responsible for rising medical insurance costs; and 73 percent favor liability reform that includes placing limits on non-economic (pain an suffering) damages.

WITHOUT REFORM THE STATE OF AMERICA'S HEALTH NOW AND IN THE FUTURE IS AT RISK

Clearly the health of our nation's citizens is at considerable risk. Because of the medical liability crisis, more and more people are finding it difficult to get the specialized medical attention they need, when they need it. This is causing a national health care emergency. Thus:

- When patients can't find a specialist close to home, they must sometimes travel great distances, often going out of state, to get their medical care.
- When fewer specialists are available, hospital emergency departments and trauma centers must shut their doors, and patients with emergency medical conditions lose critical life-saving time searching for an available emergency room.
- When specialists stop performing high-risk medical services, patients are often referred to academic medical centers, and these medical facilities are already overburdened and are ill equipped to handle the increase in patient volume.
- When specialists retire at an early age, the looming shortage of doctors is accelerated, which, if left unchecked will place additional burdens on the health care system as the population ages and requires more medical care from an increasingly shrinking pool of practicing doctors. Once gone, these doctors are hard to replace, and those states currently facing a medical liability crisis are having a difficult time recruiting new physicians to their communities adding to the shortage of doctors in many parts of the country.
- When the practice of medicine becomes so uninviting, fewer and fewer of our nation's best and brightest will want to become doctors, thus jeopardizing our country's status as one of the finest healthcare systems in the world.

We have reached a very important juncture in the evolution of the U.S. healthcare system. At a time when lifesaving scientific advances are being made in nearly every area of healthcare, patients across the country are facing a situation in which access to health care is in imperiled. Thus, as the Congress deliberates the many facets of this issue, the Alliance urges you to continue to keep in mind that this issue is not about doctors, lawyers and insurance companies. Rather, it is about patients and their ability to continue to receive timely and consistent access to quality medical care. By reforming the medical litigation system, the crisis will ultimately be abated. Patients are calling for reform. Doctors are calling for reform. President Bush is calling for reform. The Alliance is hopeful that the Congress's continued efforts to highlight and debate this crisis will lead to the passage of MICRA-style medical liability reform legislation so all Americans are able to find a doctor when they most need one. Ultimately, when the question "Will your doctor be there?" is asked, the answer must be an unqualified yes.

Thank you for considering our comments and recommendations. The Alliance of Specialty Medicine, whose mission is to improve access to quality medical care for all Americans through the unified voice of specialty physicians promoting sound federal policy, stands ready to assist you on this and other important health care policy issues facing our Nation.

THE MANY FACES OF THE MEDICAL LIABILITY CRISIS

Arizona

Ob-gyn: Deborah Wilson made the tough decision to stop delivering babies in June 2003. "It was a really tough decision. I just knew I couldn't do it anymore once I realized the risks. You've just got a target on your back." Dr. Wilson delivered approximately 50 babies a month for over 17 years. One of the many patients forced to find a new obstetrician was Patty Jasinski, who was seven months pregnant with her second set of twins at the time. Dr. Wilson was Jasinski's obstetrician for nearly two decades, helping her through five miscarriages, an ectopic pregnancy and the birth of her first set of twins. (*East Valley Tribune,* April 2004)

Neurosurgeon: Timothy Putty, MD writes: "A 60ish year old man presented to St. Joseph's Emergency Dept. with a cerebral hemorrhage. The ED physician tried to find a neurosurgeon to care for this patient. None of the neurosurgeons that go to that particular hospital was available or on call. The ED physician tried to transfer to another hospital in Tucson, but none had neurosurgical coverage that evening, and the University Hospital was full (on diversion). This patient was subsequently flown out of the city, to San Diego, and I believe ultimately died" (American Association of Neurological Surgeons/Congress of Neurological Surgeons 2004)

Florida

Neurosurgeon; Mildred McRoy suffered a hemorrhagic stroke in February and was rushed to JFK Medical Center in Atlantis, Florida for treatment. However, JFK stopped providing around-the-clock neurosurgical coverage in July because of the medical liability crisis. In fact, there wasn't a single neurosurgeon on call in all of Palm Beach County. Ms. McRoy was transported 40-miles away to North Broward Medical Center more than eight hours later. She was operated on by neurosurgeon Gary Gieseke, but died after being in a coma for several days. Almost all of the neurosurgeons at the hospital are "bare" and are not willing to take on the risk of emergency procedures without insurance. The hospital has begun paying for on-call services in an effort to provide the necessary 24/7 coverage. (*Palm Beach Post,* March 6 and 18, 2004)

Orthopaedic surgeon; Diana Carr, MD writes: "In my community only two orthopaedists (including myself) of the five will see children. My practice is limited to pediatric upper extremity. The other pediatric orthopaedic surgeon is on call in rotation with the three others who do no pediatrics. The 75-percent of the time he is not on call, children have to go to Tampa, Orlando or St. Petersburg where pediatric orthopaedists are available. This is a two-hour ride each way for the initial appointment and all follow-ups." (American Association of Orthopaedic Surgeons)

Ob-gyn; Manatee Obstetrics & Gynecology physicians will end obstetrical services at the practice September 2004 due to rising medical liability costs, leaving hundreds of expectant mothers to find a new baby doctor this fall. State Rep. Bill Galvano, R-Bradenton, is an immediate victim of this escalating crisis. His pregnant wife, Julie, was scheduled to deliver their third child at Manatee in October. (Bradenton Herald, April 15, 2004

Georgia

Ob-gyn; In 2003 there were three obstetricians in Eastman, Georgia. Today there is one. One moved out-of-state and the other 42-year old doctor quit obstetrics. (Medical Association of Georgia, 2004); Dr. Patricia Ritchie Haynes recently quit her 23-year ob-gyn practice at Piedmont Hospital after learning her malpractice premium was going to rise by 50 percent in one year. (Atlanta Journal-Constitution, Feb. 8, 2004); The Athens Women's clinic, which has offered obstetrics services for 35 years, announced May 21 that the state's medical liability crisis was forcing it to no longer deliver babies. It will continue to offer gynecological services. (*Athens Banner-Herald,* May 21, 2004)

Emergency Physicians; "At my hospital in Atlanta, GA, the surgeons (including orthopedists) decided that due to . . . skyrocketing premiums, they would work less call, leaving us for several months with every third day with surgeons and orthopaedics on call. My hospital is the designated site for Hartsfield Airport, the busiest airport in the nation. Multiple patients have had to be transferred and a colleague had a stabbing that had a significant delay in care due to lack of coverage." (American College of Emergency Physicians, 2005)

Neurosurgeon; Last year there were four neurosurgeons in Albany, Georgia and the local hospital had neurosurgical trauma coverage 24 hours a day, seven days a week. Today there are two and the hospital only has a neurosurgeon on-call 50 percent of the time. If area residents suffer a head or spinal injury, stroke or other

neurosurgical emergency on the "wrong day" they must be air-lifted to Macon or Columbus, if a neurosurgeon is available there. (Medical Association of Georgia, 2004)

Illinois

Neurosurgeon; In February 2004, 85-year-old retired machinist Fred Andricks tripped and hit his head. Because of the medical liability crisis there are no neurosurgeons left in Belleville. After a delay, Mr. Andricks was transferred to a St. Louis, MO medical center where he received treatment. Unfortunately he died the next day from swelling of the brain. After learning of her father's fate, Lisa Kasten said "All the talk was that this was going to happen and that someone would not get care when they needed it. I just never realize it would be my dad." (American Association of Neurological Surgeons/Congress of Neurological Surgeons 2004)

Emergency Physician; In August 2004, a cable snapped when Richard Rhodes was unloading his stock car into a garage, injuring his hand. He was rushed to the Alton Memorial Hospital emergency room with his thumb and little finger missing. There were no doctors at the hospital available to reattach his fingers. The emergency room physician called more than six hospitals in an effort to transfer Mr. Rhodes, but no other hospitals or accepting transfers for this type of injury. After several hours, Mr. Rhodes was airlifted to a hospital in Springfield and his fingers were reattached. Unfortunately because of the delay, the reattachment did not take and his thumb had to be amputated two weeks later. Mr. Rhodes blames the loss of his thumb on the medical liability crisis in Illinois. Mr. Rhodes said, "The doctor did everything he could to find someone to help. I kept saying that I had insurance. But what's a sense of having insurance if you can't find anyone to work on you?" (*The Telegraph,* August 2004)

Urologist; Roger Rives MD and David Didomenico are the only two urologists and Sarah Bush Lincoln Health Center in Mattoon. In an effort to reduce their professional liability risks, they have stopped performing more risky, highly invasive procedures, including prostate and bladder surgery. They have tried to recruit a third urologist for more than 18 months, but have been unsuccessful. (*The Journal Gazette and Times-Courier,* August 2004)

Orthopaedic Surgeon; "A five-year-old child was struck by an auto in Naperville and sustained a fracture of the femur and a small skull fracture with minimal underlying brain contusion. Such injuries would typical be treated by urgent casting by an orthopaedic surgeon and then a neurosurgeon would follow along to make sure the patient's brain injury remained stable. In this case, the neurosurgeon on call will not see any patient under 18. A pediatric orthopaedic surgeon was in attendance, waiting to treat the femur fracture, but without a neurosurgeon to follow the patient, transfer to Loyola had to be arranged. At Loyola, no pediatric orthopaedic surgeon was available, so the adult orthopaedic trauma surgeon had the child's leg placed in traction, inserting a pin just above the knee in order to hang the weights which pulled on the leg. The plan was to keep the child in traction for a few weeks, and then place the child in the cast. The family, after 2 days at Loyola, desired transfer of care back to their home town. The child was taken out of traction, placed in an ambulance, and transferred back to Edward Hospital in Naperville. He was eventually casted and sent home. The liability crisis has created a situation where this patient had to endure two useless ambulance rides with a broken femur, several extra days of hospitalization, and insertion and removal of a traction pin. This waste of resources and interference with medical care is repeated endlessly across the nation." (American Association of Orthopaedic Surgeons)

Ob-gyn; Kim Dahlem, a mother of one, wants to have another baby next year, but she has a problem: She must find a doctor who will deliver it. The obstetrician-gynecologist who delivered her daughter in February 2003 recently decided, after 30 years in practice, to stop delivering babies because he could not afford the high cost of medical malpractice insurance. Dahlem, 32, does not live in Joliet or southern Illinois, areas reported to have lost many obstetricians because of the skyrocketing cost of professional liability insurance. She lives in northwest suburban Cary, and her gynecologist, Dr. Donald DeDonato, practices in Arlington Heights. "It's heartbreak," Dahlem said of losing the physician who helped her through a difficult first pregnancy. "He was a blessing . . . I was comfortable with him. It's hard having that ripped from you." (*Chicago Tribune,* September 22, 2004)

Kentucky

Ob-Gyn; Cynthiana doctor Greg Cooper was forced to give up delivering babies after 23 years of practice because of rising medical liability costs. Beth Lisak, Dr. Cooper's secretary, was forced to find a new ob-gyn when she was seven months pregnant because the doctor could no longer deliver her baby. (The Courier-Journal, October 17, 2004)

Mississippi

Emergency physician; According to an emergency physician from Jefferson City, their practice had never had a physician leave until the last 2 years when they lost four. Two went to states with lower malpractice insurance rates, one went to work at an urgent care center because it has lower malpractice rates and one left clinical medicine altogether. (American College of Emergency Physicians, 2005)

Neurosurgeon; Mississippi surgeon John Lucas, III, MD, related that his son was in a car accident and needed immediate neurosurgical intervention, but the area's neurosurgeons had already either quit doing head trauma cases or had moved away. His son had a correctible problem if immediate attention by a neurosurgeon could be given. Dr. Lucas did everything he could to expedite the transfer and find a neurosurgeon. Unfortunately, the transfer came too late and his son John Lucas, IV died. (American Medical Association, 2004)

Missouri

Orthopaedic Surgeon; Poplar Bluff internist Donald Piland said, "Last year a patient of mine fell on the ice during the winter and suffered a compound fracture of the lower leg. Subsequently, she lost her leg due to a lack of orthopaedic coverage in our community. We had recently lost three orthopaedic surgeons in a span of one year, partly because they couldn't afford malpractice insurance premiums in the state of Missouri." (Daily American Republic, March 17, 2004)

Neurosurgeon; Robert Grubb in St. Louis, Missouri wrote "I recently received a patient in a transfer from a small town in northeast Arkansas with a severe cervical spinal injury following a motor vehicle accident. The primary care physician said he called 17 different hospitals closer than St. Louis over a 24-hour period and could not find anyone to take the patient because no one had an available neurosurgeon. The patient was finally transferred to Barnes Jewish Hospital in St. Louis after more than 24-hours, way beyond the optimal time for treating such a devastating injury." (American Association of Neurological Surgeons/Congress of Neurological Surgeons, 2004)

New Jersey

Neurosurgeon; Mark McLaughlin writes, "I recently saw a patient from about 50 miles away who had been progressively going quadriplegic because no neurosurgeon would take on her highly risky upper cervical compression for liability reasons. By the time I saw her she was permanently disabled and did not make a good recovery." (American Association of Neurological Surgeons/Congress of Neurological Surgeons, 2004)

Thoracic Surgeon; Dr. John A. Heim, a cardiovascular thoracic surgeon from Cherry Hill, was forced to close his practice and move when his medical liability coverage increased from $190,000 this year and from $80,000 the year before. "I spent four years in medical school, eight years training after that, 10 years in the community doing expert surgery, and it really doesn't mean anything because if I don't get affordable medical malpractice insurance I [can't practice]," he said. (*Asbury Park Press,* March 20, 2003)

North Carolina

Ob-gyn; Dr. Mary-Emma Beres stopped delivering babies after her premiums increased from $17,500 to $60,000, leaving only one doctor in all of Allegheny County who can perform Caesarean sections. (*Raleigh News & Observer,* March 30, 2003)

Neurosurgeon; Mark Lyerly, states that "In the past 10 months, numerous patients with intracranial hemorrhage or head injuries have been transferred out of our hospital ER because there is only neurosurgical ER coverage 14 days a month. Unfortunately, better outcomes would have been seen if patients were treated locally instead receiving delayed treatments hours later. The ER had 24/7 neurosurgical coverage, but we had to cut back because our professional liability premiums have almost doubled in the past three years even after cutting our coverage from $3/$5 million to $1/$3 million." (American Association of Neurological Surgeons/Congress of Neurological Surgeons, 2004)

Ohio

Ob-gyn; Over the course of her pregnancy, Sharon Minson of northeast Ohio had four different ob-gyns because rising professional liability insurance rates kept forcing her doctors to stop delivering babies. "When you're pregnant, it should be a happy time," she said. "I just wanted continuity of care. You can't switch around like that." In the past two years, 46 of 72 ob-gyns have left Summit County in the past two years and more than 190 doctors have left Summit, Medina and Portage counties in that time frame. (*Akron Beacon-Journal,* October 21, 2004)

Gastroenterologist; In July Cleveland gastroenterologist Gary Gottlieb of Mayfield Heights announced he was leaving Ohio after receiving a professional liability premium bill for $85,000, more than five times the amount he paid in 2002. Dr. Gottlieb will move to Arizona. In Arizona Dr. Gottlieb will pay between $5,000 and $12,000 for insurance. Dr. Gottlieb's partners have been unable to replace them. All of the gastroenterology fellows at The Cleveland Clinic have decided to leave Ohio to pursuit their careers elsewhere because of the high malpractice rates in Northeast Ohio (*Cleveland Jewish News,* July 2004)

Neurosurgeon; Thomas Hawk of Columbus has stopped providing trauma and emergency call in an effort to reduce his liability premiums. He also writes, "I see lots of patients each week from West Virginia who cannot find neurosurgical care and are coming all the way to Columbus, Ohio to get care." (American Association of Neurological Surgeons/Congress of Neurological Surgeons)

Pennsylvania

Orthopaedic surgeon; Shawn Hennigan, MD, recently moved from Pennsylvania to Wisconsin solely because of the medical liability crisis in Pennsylvania. (American Association of Orthopaedic Surgeons, 2004); David Yanoff, who has offices in Lehighton, Palmerton and Tamaqua, Pennsylvania, is closing up his practice and moving to Idaho because of skyrocketing professional liability premiums. Yanoff founded Mahoning Valley Orthopedics 16 years ago. (*The Morning Call,* February 21, 2004)

Neurosurgery; In 2004, a 17-year old boy suffering a head injury in a car accident in Chester County, Pennsylvania died after no neurosurgeon could be found to treat his injury. The boy was originally taken to Brandywine Hospital, which lost all of its neurosurgeons because of the medical liability crisis. Hours later, he was transferred to Crozier-Chester Medical Center in Delaware County, but his brain had already begun to swell and nothing could be done. (*The Morning Call,* November 28, 2004)

Neurosurgeon; Recently, in Pottstown a 20 year old fell down a flight of stairs. He sustained significant head trauma. Several years ago he would have been taken to Pottstown Memorial Hospital where two full time neurosurgeons were on staff. At this time, though, since no local neurosurgeons were available, he had to go to Lehigh Valley Hospital. Because of inclement weather it was not possible to fly him by helicopter. He was, therefore, placed in an ambulance and arrived at Lehigh approximately an hour later. Within ten to fifteen minutes of arriving at Lehigh Valley he was in the OR but died there of a massive bleed. I do not know if it would have made a difference if this patient had been treated sooner but I surely know he had no chance with the situation as it now exists. (pamedicalcrisis.com, *Volume II, Issue No 5*)

Tennessee

Neurosurgeon Rick Boop of Memphis writes, "I have seen three **children** die recently of shunt malfunctions in **ERs** without a neurosurgeon who can perform procedures on children. All neurosurgeons can provide a simple shunt revision, but many are being forced to drop their pediatric privileges in order to obtain or reduce their liability premiums. All three of these children died while awaiting helicopter transport to a children's hospital." (American Association of Neurological Surgeons/ Congress of Neurological Surgeons, 2004)

Texas

Ob-gyn; Ken First, MD, and orthopaedic surgeon writes, "My wife was an ob/gyn for 15 years. She had one legal case that was dropped in her entire career. She delivered a great many babies. Several years ago, my wife gave up obstetrics because the malpractice premiums were so high. She then practiced just gynecology surgery and primary care. The insurance rates were still high, and she was forced to retire leaving a ton of women without their doctor. She gave up her medical career to sell Mary Kay cosmetics. She works fewer hours and is already making a solid income without the liability." (American Association of Orthopaedic Surgeons, 2004)

Emergency physician; An emergency physician who was chairman of the hospital's Emergency Department for over 10 years, quit medicine less than a year ago because of the exorbitant liability premium rates in Texas. Another left the ER because of the medical liability situation, noting that "I feel like I've—wasted a residency and a lot of my life." (American College of Emergency Physicians, 2005)

Ob-gyn; Two Dallas doctors, with over 40 years combined experience, quit obstetrics in 2004 due to high medical liability insurance premiums, leaving only 9 obgyns in the area. (Fellow communication to the American College of Obstetricians and Gynecologists, 2004).

Neurosurgeon; Houston neurosurgeon Bruce Ehni writes "We are the recipient of much more serious and risky cases that would have otherwise been cared for locally. Here at our hospital in Houston we are receiving hemorrhages, traumas and other dire emergencies from as far away as El Paso and Brownsville—sometimes up to 600 miles or more! Some of these cases include: a patient with head trauma and a blown pupil flown in from Harlington (400 miles away); an aneuryrmal hemorrhage with intracranial hemorrhage flown in from Laredo (300 miles away); and a brain tumor causing abrupt paralysis flown in from San Antonio (200 miles away). All of these communities have neurosurgeons. The "bad" cases end up in Houston despite the presence of neurosurgeons locally because everyone is trying to avoid being sued. It is bad for patients and bad for us. We are being dumped on endlessly." (American Association of Neurological Surgeons/Congress of Neurological Surgeons, 2004)

Washington

Emergency physician; Dr. Paul Casey, Chief, Emergency Medicine, Chief of Staff, Providence Campus, President-elect, Washington Chapter, American College of Emergency Physicians wrote in a letter to Senator Patty Murray, "After significant soul searching, I have decided to leave the state I love, my friends and colleagues and the patients I enjoy caring for . . . providing quality care for our patients is becoming unbearingly difficult, if not impossible in some instances. Emergency physicians can no longer afford to bear the financial brunt of a failing health care system." (Excerpts from a letter to Senator Patty Murray, 2004, Washington State Medical Association)

Neurosurgeon; Patient Wendy Piscopo, a lifelong Democrat, testified before the Washington State House of Representatives Judiciary Committee on February 26, 2004. She said the following: "I once again require surgery in the same area of my back, but the wonderful neurosurgeon I had found after a long search decided suddenly to retire, just days before I was to schedule my surgery. Due to the skyrocketing cost of malpractice insurance, he decided to retire rather than to cave in to the system. It is hard for a Medicare patient to find a doctor she trusts, who will not rush her surgery because he has to treat as many patients as he can in a day to pay his insurance premiums . . . I lost so much when I lost Dr. Souri. I lost a lot of my energy. It took me a year to find Dr. Souri—a long time to sit in pain. I lost faith in the party I voted for—I thought the Democrats were here to fight for the voiceless. And now I must start again looking for a surgeon I trust, one who will see me as a person and not just another welfare case to rush out of the office. I implore you to pass a limit on the non-economic damages in medical malpractice lawsuits."

Ob-gyn; Dr. Gregary Blackner, Olympia family practitioner, stopped delivering babies January 1, 2003 facing a 40 percent increase in insurance rates. "I had patients sitting in my office, sobbing over it. I had delivered their first three or four kids, and now I can't deliver their new one. They couldn't understand." (*The Olympian,* 5/13/03)

Wyoming

Ob-gyn; Dr. Bert Wagner will no longer deliver babies due to the increasing liability crisis in Wyoming. Dr. Willard Woods had to give up the obstetrical portion of his practice because he could no longer get liability coverage . . . the remaining doctors are on call every other night. Some pregnant women are faced with driving 70 miles to get obstetrical care. He had delivered more than 1,000 babies, including the entire starting rosters of 2 local high school basketball teams. (Wyoming Medical Society)

Mr. DEAL. Thank you very much, Doctor.

Mr. Huggins.

STATEMENT OF MONTY HUGGINS

Mr. HUGGINS. Mr. Chairman and members of the subcommittee, I also want to thank you for inviting us here today. This is—I will try to get through this. I have only shared this a few times. It is very personal with me.

My name is Monty Huggins, and I am from Knoxville, Tennessee. I was born and raised in the Florida Panhandle. Myself, my wife, and our families have been active Republicans my whole life,

and have believed in the platform that we have stood for for so many years, and that is up until now.

I am here today, because I am concerned that Congress is trying to take away my rights and the rights of people like me, because my wife, Janice, suffered a heart attack and passed away in my arms on September 25 this past fall. She had been taking Vioxx for a little over a month prior to the death, and she was in perfect health with—39 years old. She was in great shape, no history of heart problems in her family, and she didn't smoke, drink, and wasn't overweight in the slightest. And I want to show a picture here, a picture of her. And she was prescribed Vioxx by her doctors that she had—because she had early onset of arthritis and had been taking the drug for about a month, right up until her death.

Janet was involved with her work. She worked for our government. She was a project scheduler on large projects, like the Cleveland Brown Stadium and currently working on a project, a $350 million project with the Department of Energy. She enjoyed her work a lot, took a lot of pride in it, and was great with her coworkers.

Personally, on a personal basis, Janet loved hiking, cooking, and doing other family activities and a graduate of the Indiana University. Anything she could do to spend more time with me or her son was definitely her top priority. Janet also had, and both of us had, a close relationship with God and was involved in various ministries and projects for the inner city. We originally met through a church ministry and just celebrated our 1-year anniversary in Gatlinburg, Tennessee the week before she died.

My wife was an amazing human being. She was a wonderful mother to her 9-year-old son, and we miss her very much. Her death, as you can imagine, has impacted our lives, especially for me after waiting 39 years to find the love of my life and to be taken away senselessly. Elijah, her son, will grow up without the love and tenderness of his mom and the advice of her. And he will not get to enjoy the pleasures and benefits of having her be there for his graduation, marriage, and grandkids. The morning I was getting ready for her funeral is the morning that they actually pulled Vioxx off the market. I was putting my jacket on when my sister came into the room and said that she had just heard on the news. At that point, we really had not put the two and two together, but we were fishing for answers. And of course, the autopsy later on revealed that she did die of a blood clot in her left artery.

This medicine that our doctor gave her basically was given to her to make her feel better, and the medicine was supposed to ease the pain. And if they had pulled this drug off the market just 6 to 8 weeks earlier I really believe, with all of my heart, my wife would still be here.

The proposed medical malpractice bill supported by the President will protect, I believe, the makers and the drug companies. Why do we want to protect companies that have knowingly killed, you know, people, and especially at a time that we know that our own government, the FDA, is doing a lousy job of protecting us from these drugs?

When I heard about the guy from the FDA talking to the Senate, it really made me angry. The way I understand it, he is one of the

top safety officials who approve drugs for the government. He is one of the top safety guys telling the Senate that he and everyone else at the FDA can't do one thing to protect the American people from medicines that can kill you.

Our own government is to—is here to protect us, and now that we want to give companies like Merck a free ride and protect them from accountability. And that is so important to me is holding them accountable for what is going on. People need to know about this. Because my wife is not the only one who has died from Vioxx, I could have potentially killed thousands—it could have potentially killed thousands of others, too.

If I may have a few more minutes.

Mr. DEAL. I am sorry that time is up. Could you summarize very quickly for us?

Mr. HUGGINS. Yes, sir.

The pharmaceutical companies—they should be held accountable, especially for my wife's death and others to come. This proposed bill would prohibit anyone from punishing drug companies for their bad conduct. There has to be a deterrent. And as far as I am concerned, Merck took my wife away from me.

And that is all I have got to say.

[The prepared statement of Monty Huggins follows:]

PREPARED STATEMENT OF MONTY HUGGINS

Mr. Chairman and Members of the Subcommittee: Thank you for inviting me to testify before you today. My name is Monty Huggins and I'm from Knoxville, Tennessee. I was born and raised in the Florida Panhandle. I'm a life-long, active Republican, having believed in the platform we have stood for, for many years, that is, until now. I'm here today because I'm concerned that Congress is trying to take away the rights of people like me. You see my wife Janet suffered a sudden heart attack and passed away on September 25, 2004. She had been taking Vioxx for about one month prior to her death and she was only 39 years old.

She was in great shape and had no history of heart problems. She didn't smoke and she wasn't overweight in the slightest. She was proscribed Vioxx by her doctors because she had an early onset of rheumatoid arthritis and had been taking the drug for one month, right up until her death.

Janet was very involved in her work. She was project scheduler on large contracting projects like the Cleveland Brown Stadium and a $350 million project with the Department of Energy. She enjoyed her job very much and took pride in the projects that she worked on.

Personally, Janet loved hiking, cooking and doing other family activities. Anything she could do to spend more time with me and our son was always her top priority. Janet also had a very close relationship with God and was involved in a variety of church activities and projects for the needy. We originally met through a church ministry and had just celebrated our one-year anniversary in Gatlinburg the weekend before she died.

My wife was an amazing human being and a wonderful mother to her 9-year-old son. We both miss her very much. Her death has impacted our lives in so many ways. Elijah, her son, will grow up without the love, tenderness, and advice of his mom. He will not get to enjoy the pleasures and benefits of having her there for his graduations, marriage and grandkids. The morning I was getting ready for her funeral is the morning they pulled Vioxx from the market. This was medicine that our doctor gave her to make her feel better. Medicine that was supposed to heal her. If they had pulled this deadly drug from the market even six to eight weeks earlier, my wife would still be alive today.

The proposed medical malpractice bill supported by the President will protect the makers of drugs like Vioxx. Why do we want to protect companies that may have knowingly killed people? Especially at a time when we know that our own government is doing a lousy job of protecting us from dangerous drugs.

When I heard about that guy from the Food and Drug Administration talking to the Senate it made me extremely angry. The way I understand it he's one of the top safety officials who approves drugs for the government. Here's one of the top

safety guys telling the Senate that he and everyone else at the FDA can't do one thing to protect the American people from medicines that can kill you.

Our own government can't protect us and now they want to give companies like Merck a free ride and protect them from accountability? People need to know about this. Because my wife is not the only one who has died from Vioxx—it could have potentially killed thousands of others too.

I am not here before you just for me. I am here representing the tens of thousands that have been affected by this drug and more importantly to help make sure that we don't have another Vioxx. A defective drug does not discriminate. This affects everyone in this room. We all take prescription drugs for various ailments and over the last several years we have seen the failure of the FDA to protect us. There must be deterrents to make sure that pharmaceutical companies do not knowingly put defective drugs on the market all in the name of profits.

This just isn't right. We depend on our government to protect us from things like this. And now that they can't do anything to get dangerous medicines off the market, it's just plain wrong to give the big drug companies this kind of legal protection.

These pharmaceutical companies should be held accountable if their drug caused my wife's death and the deaths of others and not be allowed to escape responsibility. This proposed bill would prohibit anyone from punishing drug companies for bad conduct.

As far as I'm concerned Merck took my wife away from me. They should be punished—not let off the hook.

Thank you for allowing me to be here today.

Mr. DEAL. We thank you, Mr. Huggins, and we certainly extend our sympathy to you for your loss.

Ms. Campbell, you are recognized for 5 minutes.

STATEMENT OF SHERRIE CAMPBELL

Ms. CAMPBELL. Thank you, Chairman Deal, Ranking Member Brown, members of the committee, for the opportunity to share my story.

I almost didn't make it here today, because, while I was arriving at the Atlanta airport yesterday, my father was in Crawford Long Hospital having emergency open-heart surgery. When I asked my tearful mother if I should stay, she literally said, "No, go up there and take care of the doctors so they can take care of us."

My name is Sherrie Campbell, and I live in Watkinsville, near Athens, Georgia. I am honored to be here today to speak with you about an issue that directly affected me and my family, the loss of my ob-gyn. Women and gynecologists have a special relationship. She is the person in whom a woman trusts so many of her health care needs, and in some cases, even her chances for survival. It is often a unique and long-term relationship, one that can last through many stages of a woman's life, including the most joyous occasions.

On January 15, 2004, I was sitting in an examination room waiting on my gynecologist, who has been my doctor for the last 10 years. I wanted to schedule a tubal ligation, because I had turned 40 a couple of weeks earlier. I was in for a shock when my gynecologist, Dr. Cindy Mercer, breezed in and said, "Good news; your pregnancy test is positive." I was advised to have extra tests to ensure everything was normal, because of my advanced maternal age. And I was pleased to have a wonderful team taking care of me, including Dr. Mercer, as well as the ob nurses and techs.

I trusted these women with my health and my baby's life. I had read about the difficulty obs were having in paying for liability insurance, in some cases paying six-figure insurance premiums. And I remember talking to Dr. Mercer about it later on. She said she

did not know how long they would be able to continue delivering babies. Well, that worried me, so I called back the next week just to verify that they would, indeed, be able to deliver my baby due in September. I was stunned when I—when they told me no. I could not believe that Dr. Mercer and her partners would not be able to help me through my pregnancy.

In the middle of my pregnancy, I was going to have to switch to a doctor I didn't know. The race was on. It takes at least a month to get in with an ob-gyn in Athens, because there are so few doctors. And I had to find a new doctor before all of those other pregnant women, 160 of them, found out the same news. I was lucky enough to find another obstetrician to deliver my baby, but I had influential friends who offered to help me get an appointment.

Do we need to network to get a doctor's appointment now? When I returned to Dr. Mercer's office to pick up my records, I learned that the wonderful staff, Lee Ann and Katie and Amy, who had helped me through my first pregnancy, would be losing their jobs. I realized that these women's lives were going to be more rocked than mine.

My new doctor recommended that I schedule a cesarean section for my delivery. I don't know if I needed one or if the doctor just wanted to be sure he wouldn't get sued. I don't begrudge him that. It certainly doesn't help me, and the rest of the women in Athens, if he gets sued and is forced to leave, too. Right now, one out of every two deliveries in Athens are C-sections. The national average is 26 percent, according to a Wall Street Journal article I read recently. In fact, no patient in Athens can have a V-back now.

Finally, a week before my scheduled surgery, during Hurricane Francis, I had my beautiful, healthy baby girl, Claire Amelia. When Dr. Mercer and her group were forced to drop obstetrics, the women in Athens lost one-third of the obstetricians in town. The remaining obstetricians are working very hard and still can not meet the needs of our community. I don't even know if any of them will take high-risk patients these days. I know, too, that the doctors must test beyond the norm just to be safe.

But what does that do to our health care costs, my health care costs? If there are no doctors, who will deliver our babies? Who will deliver my children's babies 20 years from now. We have the finest health care system in the world, but we need your help to give doctors the freedom to take care of us. Women in my community are wondering where they are going to go for health care.

Members of the committee, I ask for your help. I appreciate your attention and your hard work to solve this complex problem.

Thank you.

[The prepared statement of Sherrie Campbell follows:]

PREPARED STATEMENT OF SHERRIE CAMPBELL

Thank you Chairman Deal, Ranking Member Brown and Members of the Committee for the opportunity to share my story.

My name is Sherrie Campbell, and I live in Watkinsville, Georgia, outside of Athens, Georgia. I am honored to be here today to speak with you about an issue that has directly affected me and my family, the loss of my ob-gyn. Women and ob-gyns have special relationships. He or she is the person in whom a woman entrusts so many of her healthcare needs, and, in some cases, even her chances for survival. It is a unique and often long-term relationship, one that can last through many stages of a woman's life, including the most joyous occasions.

On January 15, 2004, I was sitting in an examination room waiting on my ob-gyn, who has been my doctor for the last ten years. I was actually searching for a good time to schedule a tubal ligation because I had turned forty a couple of weeks earlier. However, I was in for a shock, as my ob-gyn, Dr. Cindy Mercer, breezed in, saying, "Good news, your pregnancy test is positive." Those seven words, especially the last one, gave me the biggest surprise of my life.

After the initial shock, my husband and I settled in to the fact that we were going to have our second child. As a result of my advanced maternal age, I was advised to begin the process of having extra tests conducted to ensure everything was proceeding normally. During my first ultrasound, Dr. Mercer joined Amy, the ultrasound tech, and me, to be sure everything looked okay. I was glad to see Lee Ann and Angela, the OB nurses in the office again after they had taken such good care of me during my first pregnancy. I trusted these women with my health and my baby's life. I initially resisted taking the blood test to check for Downs Syndrome, knowing that we wanted whatever baby we were given, but the spina bifida test is done at the same time, and I wanted to give the baby a chance if there were any problems. Given my age, I was also sent to the prenatal specialist in Athens. The blood test showed I had a 1 in 35 chance of having a handicapped child, and the worry was never far from the surface.

In the meantime, my husband's and my own stress level was high. He had just changed jobs and we were in the midst of changing insurers, and I had a sluggish first trimester. Despite this, I was so looking forward to my next monthly OB visit because it was with Dr. Mercer. I had read about the difficulty obstetric doctors were having trying to find insurance, and in some cases paying six-figure insurance premiums, and I remember talking to her about it. I asked her if they were feeling the same kind of pressure. Dr. Mercer said that she did not know how long they would be able to keep delivering babies as recently, one of the seven doctors that delivers babies at the Athens Women's Clinic, where Dr. Mercer works, had been sued. As a result of that one suit, the Clinic had already been forced to stop its indigent care services because their insurance premiums had risen so drastically they could no longer afford to provide free care.

I was very worried about Dr. Mercer and the other doctors, and so I called back early the next week to verify that she would be able to deliver my baby, due in September. Sadly, I was told no. I was just stunned. I was halfway through a pregnancy with my choice of doctors whom I trusted, revered even, and suddenly I was lost. I could not believe that Dr. Mercer, with whom I had entrusted my healthcare with for 10 years, would not be able to help me through my pregnancy. As I mentioned, being advanced in age for this delivery made it even more important to me that I have access to a physician that knew and understood my fears and concerns. Without Dr. Mercer I was unsure who would help me if the pregnancy turned difficult.

Now, the race was on. It takes at least one month to get in with a new OB/GYN in the Athens area because there are so few doctors, and I knew I didn't have a prayer of getting in to see another doctor quickly. And, I had to find a new doctor before all those other pregnant women found out the same news. A friend of mine had told me about her good experience with the Women's Center of Athens, and I immediately called for an appointment. Apparently, I was one of the first to call because they took me. My friend who had recommended the Women's Center is a woman of influence at the University of Georgia. She told me she'd make a phone call to get me in if they wouldn't see me. I spoke with another friend, the wife of an influential health care provider in Athens, who also told me that she'd make a phone call to get me in to see someone else.

Is this good medicine? Does it now take networking to get in to see a doctor? And what about the women who don't have the same friends I do? What about the women who are new to the area? Unfortunately, I wasn't thinking about them at the time. I did what it took to find the best care for my family. And that is what we all want.

When I returned to Athens Women's Clinic to pick up my records to take to the Women's Center of Athens, I spoke to Katie, the receptionist, who was about to lose her job. And Amy, the ultrasound tech, who sat with me during the first tests, told me that she was scared and worried about her family's finances because she too was about to be laid off. The Clinic's OB nurse Lee Ann was laid off too, and she is now working in a hospital. I began to realize that no matter how much I felt I'd been abandoned, these women's lives were rocked even harder than mine.

I wanted to help my friends but I also had to worry about my pregnancy. When I finally met with my new doctor—it was recommended that I schedule a Caesarian-section for my delivery. I couldn't decide if I needed one, or if the doctor needed to be sure he wouldn't get sued. I don't begrudge him that. It certainly doesn't help me and the rest of the women in Athens if he gets sued and is forced to leave

too.Thankfully, I was fortunate to find Dr. Halbach, a wonderful ob-gyn who could help me deliver.

Just after midnight on September 7, a week before my scheduled surgery, and during the hurricane, I left the bed to lie on our sofa and time what I thought were Braxton-Hicks contractions. I found I was mistaken when my water broke around 2:30. I was relieved beyond measure that Dr. Halbach was on call that night, and delivered our beautiful, healthy, baby girl, Claire Amelia.

As I spent my three days in the hospital recovering from surgery, I asked the nurses and doctors plenty of questions. I was surprised at how many C-sections were being performed; I later found out that one out of every two deliveries in Athens are C-sections. The national average is 26%, according to a *Wall Street Journal* article I read recently.

My story doesn't end here. I had my follow-up appointment with Dr. Halbach and wished everyone there farewell because I wanted to continue to see the gynecologist of my choice. A week later, I developed a breast infection, which is an unpleasant experience for a nursing mother. Who was I supposed to call? I chose the obstetrician at the Women's Center of Athens, the group that had helped me deliver Claire Amelia in my time of need and they were gracious as always. About a month ago, however, Claire stopped nursing abruptly and I experienced the familiar pain of another infection. The hormones that go along with nursing are strong and I tearfully called the obstetrician's office again. I was told the nurse would be on the phone for a while and they didn't have any appointments open. And then the receptionist asked, "Are you still our patient?" For some reason, perhaps hormones, I was devastated by that question. No one wanted to take care of me. I made an appointment for the next day, knowing that would be too late as my milk supply was dropping rapidly. Eventually, I was able to get an appointment with a gynecologist back at the Athens Women's Clinic, my original doctor's office. Although they could not deliver my baby, at least I still had the opportunity to see them for my other health needs. Some women aren't so lucky. Many ob-gyns have actually retired, or left one state for another. I am thankful Dr. Mercer has decided not to leave Athens.

When Dr. Mercer and her group were forced to drop obstetrics, women in Athens lost one-third of the ob-gyns in town. The remaining obstetricians in Athens are working extremely hard and very long hours to take care of us. There aren't that many ob-gyns left. I don't know how many will even take high-risk patients these days. I'm glad that my advanced maternal age did not prevent me from getting the care I needed. I know too that doctors are testing us beyond the norm, just to be safe. Is that good medicine? Is every doctor doing it? How does that affect our health insurance costs?

These doctors aren't faceless, deep-pocketed, cosmic healers. In Athens, we have a community. Our oncologists cry with us, our obstetricians cuddle our babies, our pediatricians' children go to Mother's Morning Out with our children, they go to dinner with us, they are our clients, they worship with us, they are our friends. I know that sometimes things can go wrong during delivery, and sometimes mistakes are made. But we must weigh the effects of the current system on all women. If there are no doctors, who will deliver our babies? What will happen when Claire and my son, Thomas are ready to start their families? If they choose to stay in the Athens area, who will deliver their babies twenty years from now? Will we depend solely on emergency room doctors? We have a country where a woman can choose to have a baby underwater if she wants. Why can't I choose the doctor I want? Who is so intent on making it impossible for them to practice?

We have the finest health care in the world, and our doctors cannot practice out of fear. Members of the Committee, I came here to ask your help. We need some help to give our doctors freedom to take care of us. Women in my community wonder where they are going to go for health care.

I don't know the answers, but I'm here begging for your help because you have the resources to see the big picture. I appreciate your attention and your hard work to solve this difficult problem.

Mr. DEAL. Thank you, Ms. Campbell.

Mr. Malone, you are recognized for 5 minutes.

STATEMENT OF DYLAN MALONE

Mr. MALONE. Mr. Chairman, members of the subcommittee, thank you for having me here to speak on behalf of my son, Ian, who died before he ever said a word. He was the victim of medical

negligence during a botched delivery. He died last May. He didn't live to see his fifth birthday.

He is not alone. Medical malpractice is the leading cause of death in America. According to the National Academy of Sciences Institute of Medicine study, about 98,000—the figure was mentioned earlier, about 98,000 Americans die every year due to preventable medical errors. That is more people than die from highway accidents, breast cancer, drunk driving, and AIDS. It is a serious problem. I agree with Dr. Bean, and I agree with Ms. Campbell: the health care system is in trouble. But it is more than a fiscal crisis. There is a patient safety crisis here, too.

Ian was a lot more than a statistic to my wife and I. He was our son. And you never saw a more excited expectant father than I was that summer of 1999 when they gave my wife a drug called Cytotec to induce labor. We didn't know that the manufacturer of Cytotec had forbidden doctors to use it to induce labor. The physician knew, but we didn't.

In fact, Cytotec causes such violent contractions and such unnatural contractions, it is used as an abortion pill in some South American countries and in Third World countries. Every bottle of this drug has a pregnant woman on it with a "no" sign drawn through her. So to hide that from us, the obstetrician dispensed the pills in a simple brown envelope.

The Cytotec caused such unnaturally powerful contractions that literally smothered Ian in the womb. His heartbeat began to falter. It stopped completely about 20 minutes before he was born, he was stillborn. He was more of a gray color than blue, and they had to resuscitate him. Worse yet, then they falsified the chart to show a good heartbeat throughout the entire delivery and to say that he was breathing and that he had a heartbeat at delivery. They didn't make any mention of Cytotec, so the intensive care unit staff had no idea what a severe injury they had just had transferred to their facility. And that altered his course of treatment and made his outcome much, much worse.

His severe brain damage left him unable to swallow. He couldn't hold his head up. He could never speak. He had to be fed through a tube in his intestines 20 out of every 24 hours of the day. He was on dozens of medications. He had dozens of seizures a day. Eventually, because he couldn't swallow or manage his airway, aspiration pneumonia caught up with him, and he got a terrible fever and died.

The insurance company, by the way, didn't want to pay for this care during this time. They coldly suggested that if were to surrender our custodial rights and put him up for adoption, the State could provide for the nursing care he needed, which gets to the core of the reason why I am here. You know, if you cap the amount of money available to an injured person after a medical error, you are not doing anything about the number of stories like this one. You are only shifting the burden to the taxpayer. And I say, if you want to lower the cost of medical malpractice, you need to lower the incidents of malpractice.

I didn't know it then, but I now know that the obstetrician that was responsible for my son's death had lost eight malpractice suits before I had ever laid eyes on the man. Even though the State

agreed with this, by the way, we filed a complaint against his license, and they felt that he was guilty of gross negligence and misconduct and that he had falsified his chart. And so they took action. They gave him a $1,000 fine. He still practices today. And other children have died under his care in the meantime.

It is a handful of repeat offending physicians. I am sure Dr. Bean is an excellent physician. Most doctors are. They are highly skilled, caring people. But it is a handful of irresponsible physicians that are doing the lion's share of the damage, and that is the way—you know, there are 100 ways you could tackle this problem. And I beg you not to fixate on the one solution that punishes the victim and makes the burden harder on my family.

You know, he was an infant. He didn't have a job. His economic loss was zero. So you are capping the funds available to help him.

I also suggest that you reform the insurance industry so that they will stop price gouging hardworking physicians, like Dr. Bean. No—if they are going to hold massive price hikes, they should hold hearings to explain why they need them, like they do in California. You can also reduce transactional costs in the courts by putting reasonable limits on the number of expert witnesses. There are all kinds of patient safety measures you could take that could fill stacks of volumes. There are so many good ideas on the table.

So I urge you to think of the problem this way. I see my time is about up. If 100,000 Americans die every year from preventable medical errors, why don't you cap that number instead of eroding my son's right to seek compensation so that we can take good care of him and he could have a good quality of life during the 4½ years he did live?

[The prepared statement of Dylan Malone follows:]

PREPARED STATEMENT OF DYLAN MALONE

Mr. Chairman and Members of the Subcommittee: Good afternoon and thank you for this opportunity to speak on behalf my son Ian, who died last May, never having spoken a word. The victim of medical negligence during a botched delivery, he did not live to see his fifth birthday.

Ian is not alone. Medical errors are one of the leading causes of death and injury in our nation. As many as 98,000 Americans die every year as a result of preventable medical errors according to a National Academies of Sciences Institute of Medicine study.

More people die from medical negligence and mistakes each year than from highway accidents, drunk driving, breast cancer and AIDS.

According to a 1997 University of Chicago study the number of injuries caused by medical accidents in inpatient hospital settings could be as high as three million and cost as much as $200 billion.

But Ian was more than a statistic to my wife and I, he was our son. You never saw a more excited father-to-be than I was in the summer of 1999 when Christine was prescribed the drug Cytotec to induce labor, we didn't know that the drug's manufacturer warned against the possibility of serious brain damage if used by pregnant women, but our doctor did.

In fact, the drug is used in third world countries to induce abortions because it causes violent contractions. Every bottle of Cytotec shows a pregnant woman with a no sign drawn through her. To hide this from us the doctor gave us the pills in a simple brown envelope.

The Cytotec caused such unnaturally powerful contractions that Ian was literally smothered in the womb; they lost his heartbeat about 20 minutes before he was delivered. A stillborn, his little body color was more grey than blue, and he had to be resuscitated.

Because Ian's health care providers falsified his chart to show a steady heartbeat throughout labor, made no mention of Cytotec, and listed him as breathing with a

heartbeat at delivery, the intensive care unit had no idea of the severity of his injuries. This cover-up attempt probably made Ian's outcome even worse.

The resulting severe brain damage left Ian unable to swallow, so the secretions had to be suctioned from his mouth by machine. He was fed by way of a tube into his abdomen, and suffered from seizures and aspiration pneumonias. The insurance companies didn't want to pay for his care—they coldly suggested we put him up for adoption.

Eventually we set out to tell Ian's story to a jury. There was a settlement and we were able to provide the hundreds of thousands of dollars of care Ian needed every year.

I am committed to honoring his memory by fighting to improve the system for those who will come after him. I strongly believe that there are many things we can do to prevent many instances of negligence and medical errors.

I want people to know that medical negligence is a serious problem in this nation, and that instead of fixing it, President Bush wants to pass a law that would target all victims of medical negligence no matter how severe the injury or how horrible the care.

This is a very important point. The backers of this radical proposal to change medical malpractice in our country would hurt ALL victims—not just those who have so-called frivolous cases. It really offends me when I hear that word. I want the President to fix the health care mess and to stop blaming victims like my son Ian. My son's life was not frivolous.

Let's start with medical negligence and medical errors. The President wants to cap medical malpractice awards at $250,000—I say if we're going to have a cap—let us cap the number of people who suffer from medical negligence every year. It's a national scandal that as many as 100,000 people die from medical errors annually.

We didn't know it then, but the doctor who killed Ian had lost eight suits before we ever saw him, and he is still practicing medicine today. In fact, other children have been terribly injured or have died under his care since Ian's birth, largely because the medical board refuses to act on his license, for Ian's injury he paid only a $1,000 fine. Of course, most doctors are highly skilled and care deeply about helping their patients. However, a small minority of doctors are causing the majority of the damage, and we have to deal with this life and death issue.

We also need to make sure that insurance companies don't gouge doctors for their medical malpractice insurance premiums. Doctors should only have to pay rates that are based on what the insurance companies have actually paid out in claims.

The bottom line is that I think it should be up to juries to decide whether a lawsuit shouldn't be in court. I trust juries, not the insurance companies and HMOs. We all should. It's one of our most valued rights as Americans.

People need to know that this debate is really about protecting our constitutional right to a trial by jury. And when they do, I don't think the American people will stand for this assault on one of our most fundamental freedoms.

Nearly 100,000 Americans die every year from preventable medical errors, that's the number we need to cap.

Thank you for allowing me to be here today.

Mr. DEAL. Thank you, Mr. Malone. We certainly all are sorry for the loss of your son.

Ms. Rasar, you are recognized for 5 minutes.

STATEMENT OF MARY RASAR

Ms. RASAR. Thank you.

Chairman Deal, Ranking Member Brown, distinguished members of the House Energy and Commerce Subcommittee on Health, it is an honor for me to be here. Though given the experience of my family—given the experience that my family and I had, if I could take it back, I would rather not be here.

July 4, 2002, my dad was returning a rental car. His name is James. Friends called him "Fisty." He was struck by a young man driving a big truck, and he was sideswiped. They wanted to take him to—they needed to take him to a level one trauma center in Las Vegas, which they had a level one trauma center in Las Vegas until the day before my dad's accident. It was closed because the orthopedic surgeons who worked at the center lost their medical li-

ability insurance coverage. A very large insurance company that insured over 40,000 physicians across the United States, had stopped writing medical liability policies only for 1 month before.

Rather than sending my dad to the hospital that he needed to get help, they had to—the paramedics had to take him to the nearest hospital to try to stabilize him so they could transport him hours away to Salt Lake City's level one trauma center. They couldn't stabilize him. He died. My dad died alone. My sister and I didn't have an opportunity to say goodbye to him. He was my only living parent. My mom had died just a few years earlier to cancer. And I hear all of these victims, and they are all sad. I mean, we all have to experience loss, but my dad didn't get treated just because he couldn't—the doctors couldn't get insurance. And they couldn't get insurance, because the insurance company wouldn't cover the doctors anymore.

That doesn't seem right. He wasn't rich. He was a hardworking man. He worked his whole life. He was in the military. He served in the Air Force. He worked at the Golden Nugget. He had insurance. It is not like he didn't have insurance, but he just couldn't get treated. So he just died. They just let him die. They did everything they could. One of the things that bothers me most is the things that my dad has missed. He had a full life. We had—we experienced trauma in our family growing up, too. But some of the things he has missed, he has missed his oldest son's graduation from high school. He has missed his oldest grandson's graduation from the Air Force basic training. He missed his grandson, Jeremy, my nephew's marriage. He missed the birth of his first great-granddaughter. I miss him a lot, you know.

Mr. Chairman, the increase in medical malpractice insurance premiums caused by frivolous lawsuits and out-of-control jury awards has a consequence in the lives of real people. No one is denying the victims of malpractice their day in court, or even looking to deny them unlimited economic damages for mistakes made by doctors, but because of frivolous lawsuits and out-of-control jury awards, my father, my children's grandfather, did not stand a chance. He was taken from us, and our family will be forever affected because of this crisis.

In the months that have passed, I have taken the opportunity to learn about this growing crisis. Doctors are being forced from their practices due to rising and outrageous medical liability insurance. I have learned that the problem is not unique to Nevada. It is growing, and it is finding victims like our family all across America. It is real for the expectant mothers in Maryland, West Virginia, Mississippi, and Pennsylvania who can't find an ob-gyn. It is real for parents of children in Florida who can't find a pediatric neurosurgeon. And it is very real for the elderly in Arizona who depend on their orthopedic surgeons and who are told that their trusted doctors are moving to States where practicing medicine is affordable and less risky.

The fact is, Mr. Chairman, my father did not have to die. After speaking with numerous specialists, I am convinced that he would be living today had the trauma center been open. So in our family, as we consider this terrible tragedy of losing someone we love so dearly, it is clearly understood that he did not die because of a car

accident but because of the crisis within our Nation's health care delivery system.

And as true as this is, there is an equal truth, Mr. Chairman: you and your colleagues can fix this problem. You can do something about it. To make sensible reforms denies no one of his or her rights, but sensible reforms will save lives. Please, Mr. Chairman, pass necessary medical liability reform. It really matters in life and death.

Thank you.

[The prepared statement of Mary Rasar follows:]

PREPARED STATEMENT OF MARY RASAR

Chairman Deal, Ranking Member Brown, distinguished members of the House Energy and Commerce Subcommittee on Health:

It's an honor for me to be here, though given the experience my family and I have had to endure I would certainly give up this honor—particularly if giving it up could bring back my father . . . my children's grandfather . . . Jim Lawson, a man known to his friends as Fisty.

However, if by sharing my Dad's story, I can save even one family from the tragedy we have had to needlessly endure, then I am not only honored to be here, Mr. Chairman, but I am grateful for this opportunity.

On July 4, 2002, my father was returning a rental car to McCarran International Airport in Las Vegas, Nevada, when he was his hit by a young man driving a large truck. His injuries, though serious, were not immediately life-threatening, but he had to be stabilized with the kind of equipment that is only found in a Level One trauma center.

Fortunately, a Level One center with the exact equipment that was needed to save his life was only five minutes away. Unfortunately, it was closed. Only days before, the orthopedic surgeons who worked at that center had lost their medical liability insurance coverage. A very large insurance company, that had covered over 40,000 physicians across the United States, had stopped writing medical liability policies only the month before.

Rather than sending my father to the hospital with the best possible trauma care, the paramedics did the best they could and rushed him to a community hospital, where they attempted to stabilize him for air transport to the next closest Level One center hours away in Salt Lake City, Utah. Unfortunately, the transfer was too late, and without the proper equipment, my father died in the process.

Mr. Chairman, the continued increase in medical malpractice insurance premiums, caused by frivolous lawsuits and out-of-control jury awards has a consequence in the lives of real people. No one is denying the victims of malpractice their day in court—or even looking to deny them unlimited economic damages for mistakes made by doctors. But because of frivolous lawsuits and out-of-control jury awards my father—my children's grandfather—did not stand a chance. He was taken from us. And our family will be forever affected because of this crisis.

In the months that have passed, I have taken the opportunity to learn more about this growing crisis—doctors are being forced from their practices due to rising and outrageous medical liability insurance. I have learned that the problem is not unique to Nevada. It is growing and is finding victims like our family, all across America. It is real for the expectant mothers in Maryland, West Virginia, Mississippi, and Pennsylvania who can't find an ob/gyn. It is real for parents of children in Florida who can't find pediatric neurosurgeons. And, it is very real for the elderly in Arizona who depend on their orthopedic surgeons and are told that those trusted doctors are moving to states where practicing medicine is affordable and less risky.

The fact is, Mr. Chairman, my father did not have to die. After speaking with numerous specialists I am convinced that he would be living today had the trauma center been open. So in our family, as we consider the terrible tragedy of losing someone we loved so dearly, it is clearly understood that he died not because of a car accident, but because of the crisis within our nation's health care delivery system.

And as true as this is, there is an equal truth, Mr. Chairman: you and your colleagues can fix this problem. You can do something about it. To make sensible reforms denies no one of his or her rights. But sensible reforms will save lives. Please, Mr. Chairman, please pass necessary medical liability reform. It really is a matter of life and death. Thank you.

Mr. DEAL. Thank you, Ms. Rasar. We likewise extend our sympathy to you and your family for the loss of your father.

I am going to recognize myself now for the questioning period of 5 minutes. I would remind all of us that we have a second panel of many members, and some of them have airplanes to catch this afternoon, too, so I will not use my entire 5 minutes. I would encourage everybody to be as brief as possible in their questioning.

Dr. Bean, let me start with you.

We are in a quandary, obviously, as to what the relationship is between capping non-economic losses and access to health care. Ms. Rosenbaum, I believe who is going to testify in our second panel, in her written testimony, indicates that she doesn't think there is necessarily that relationship between those caps and access that, in fact, those caps might encourage bad medical practices. Would you comment on that, please?

Mr. BEAN. I would like to answer the last question first. I can think of no doctor that practices bad medicine simply because there is or isn't a cap. That doesn't happen. And as far as it being a deterrent to bad practice, I don't think that happens either. It is not a quality issue. Neurosurgeons are sued about once every 2 years. If being sued is a sign of quality or not, then we are all incompetent. We shouldn't be practicing. It is not a sign of quality. It just happens because of the high risk.

As far as the non-economic damage, we believe there are economic consequences. People need to be treated. They have to have replacement of their income. They have to have living accommodations, and it may be for years. All of that should be provided. It is the non-economic damage that is unquantifiable that can go through the roof. That 60 percent or more, as I said, of what the award is constituted of in these big cases, that is what we see as driving the jury awards higher and higher. And like I said before, it is a simple equation. What is paid out has to be paid in. And it is the high-risk people like ob and what I do that this burden falls on.

It is a matter of balance. Yes, I want to compensate everybody who is medically injured. And yes, I know medical injuries would happen—will happen, and I know I want to prevent them. They will always happen, to some degree. But if we don't strike a balance and decide that so much can be paid an no more, then we can never stop this crisis from building and driving necessary doctors out of practice. Congress has had to decide before what is the value of suffering. It is hard to place a price on suffering, but you have had to do it. You had a victims fund. You had to come up with a price on the ultimate suffering. It was $250,000. At some point, our resources run out, and we destroy the system that everybody depends on, and that is why we think that a cap on non-economic damages is the balance that keeps the system operational.

Mr. DEAL. Thank you, Doctor.

I am going to forego the rest of my time.

Mr. Brown, you are recognized.

Mr. BROWN. Thank you, Mr. Chairman.

All of us on this panel, Republicans and Democrats, want to solve this problem for doctors and for patients. We—but Dr. Bean, my question is for you. We—first of all, we know several things. We

know the drug industry gave tens of millions of dollars to re-elect the President. We know that HMOs gave millions of dollars to Republican leadership. We know this legislation, which is billed as a malpractice—medical physician malpractice reform includes provisions to protect the drug industry to—from lawsuits, to absolve the drug industry, HMOs, and the medical device industry from punitive damages. We know that the President and Republican legislative leaders are campaigning all over the country talking only about the physicians and access to care but rarely mentioning the protections for the drug industry, the insurance industry, and medical device industry.

And we also know this bill won't pass when it looks like this, in large part because it does absolve the drug industry, the insurance industry, the medical device industry from responsibility for their actions. We also know this bill could pass if we took those industries out and focused on malpractice reform and focused on really helping this accessibility for patients to medical care.

So my question is, would you recommend to this panel, Dr. Bean, that we remove the provisions protecting the drug industry, HMOs, and medical device industry so we could focus on your profession and access to care for everyone in this country?

Mr. BEAN. Mr. Brown, that is a difficult question, because I can't write the legislation or make the accommodations that have to be made between the Republicans and the Democrats. I am focused on physician liability. I know there are other—some other issues, particularly in—that relate to physicians, say, in using drugs. And when we take new devices and use them with the best evidence that they are safe, and when we give drugs, we use them with the best evidence that they are safe, we do want to be protected until we find new evidence that it isn't. Now——

Mr. BROWN. But if I——

Mr. DEAL. [continuing] as far as the bill goes in that regard, I think it should be part of the legislation. I can not tell——

Ms. DEGETTE. Will the gentleman yield?

Mr. BROWN. Well, go ahead. Yes, I will yield to my—I am sorry to interrupt. We only have 5 minutes, and I——

Ms. DEGETTE. Dr. Bean, the question is, though, and I hope Mr. Brown was going to ask this, I understand why you folks would want to be immunized, but why should Congress also immunize the pharmaceutical companies and the manufacturers of the medical devices? That is not what you are talking about.

Mr. BEAN. No, I am truly talking about the dilemma of losing physicians. And that was my focus in the——

Mr. BROWN. Okay. I think that that tells us—you know, I say to you again that—and I have had this conversation with dozens of doctors in my District and all over this—the Nation's capitol and all over Ohio that this proposal won't—that frankly, for purposes of fund raising, for purposes of political gain, the physicians are being used by my friends on the other side of the aisle in order to protect the drug industry, the insurance industry, and the medical device industry to raise money both—and political support both from you and your organizations and millions of dollars from the drug industry, and we are never going to solve this problem.

We are going to see a panel like this 2 years from now with the human tragedies that Ms. Rasar and Mr. Malone and Mr. Huggins have had, human tragedies that none of us can understand unless it has happened to us. We are going to have those again in 2 years, because this Congress is dysfunctional because of its addiction to drug industry, insurance industry, and medical device industry money. And until the doctors understand that you—that we care about what happens to you but we don't want to protect Merck when they don't come forward and tell the truth about Vioxx, or we don't want to protect these other drug industries—other drug companies and other insurance HMOs and other medical device industries when this—that is what will happen if we continue down this road.

I would—I have 40 seconds left. Mr. Huggins, you wanted to say a couple more things before your 5—when your 5 minutes were up. Would you like to take a minute, my last minute or——

Mr. HUGGINS. Yes, the one thing——

Mr. BROWN. If that would help you. Okay.

Mr. HUGGINS. Okay. Sorry. One thing I wanted to mention is I—Dr. Bean here, I feel for him. And I feel for Ms. Campbell here. My personal—my best friend and workout partner is one of the top pulmonologists in the State of Tennessee, and he was there at my side at the hospital. He got there when my wife came in. And we have talked on this issue. I know how high his premiums are. I know what he has to pay. We have talked about it a lot. And my heart goes out to him, because he has to pay a lot.

Now he feels as I do, that it needs to start with the insurance industry and regulation of bad doctors practicing medicine, because it is only a handful. And if we start it there, the one thing that really troubles me, being a lifelong Republican, is the fact that the platform that I have believed in for so many years is—has to do with limiting government in our lives and giving rights to the State. And what you guys are proposing is the absolute 180 degrees. It is getting government—telling myself, as an individual, what I can recover from loss and what my loss is and tell me what it is.

Mr. DEAL. Mr. Huggins, I am going to have to cut you off.

Mr. HUGGINS. Thank you.

Mr. DEAL. You have been about a minute past Mr. Brown's time, and I sensed a hardening of his heart, and I just didn't want it to go any further.

Mr. HUGGINS. Yes, sir.

Mr. DEAL. I am going to recognize Dr. Burgess next.

Mr. BURGESS. Thank you, Mr. Chairman.

I will just have to say I find some of the remarks coming from the other side unfortunate. I thought this was a panel convened to access information from this—from the witnesses and not to hold forth on political agendas.

Dr. Bean, I agree with you, and I agree with you wholeheartedly that the question does become about what will the system—what can the system bear and how do you compensate people for their loss. And to that end, I would like to ask Mr. Malone, and again, just everyone else up here on the panel, I feel for you, for your loss

of your son Ian, can you tell us, sir, did you pursue litigation against your physician?

Mr. MALONE. Yes, we did. We—the suit is still pending against the obstetrician. Although Ian was born in the summer of 1999, we did settle with the new birth center that he was delivered at for the amount they had insurance for, which is a $2 million settlement. Of course Ian's medical bills were several hundred thousand dollars a year, and he lived for 4½ years, so after you pay court costs and expert witnesses and you do that math, you can see that that money was needed, which is why we are still pursuing the obstetrician.

I should also mention that when I was last in Washington, DC, my son was still alive, and I was lobbying for patient safety changes. And during the interim, Ian has died. And since the last time I have pled with the Congress for new patient safety changes to go after repeat offending doctors, that obstetrician mutilated a child in a very bizarre forceps delivery and killed him, killed a little boy last Christmas.

So I—this is not—I apologize for the melodrama, but this is not tax code. People are dying, and I urge you to act.

Mr. BURGESS. A couple of other questions, then, along that line just for my clarification. Do you mind me asking what State you come from?

Mr. MALONE. Washington State.

Mr. BURGESS. Okay. And your son was born at a birthing center?

Mr. MALONE. Right, a new one, a new facility built just about one mile from the major facility where—that we traditionally use. With my wife's—Ian was not our first child. With my wife's prior delivery, she had refused anesthetic, so—to try it natural. She was in the hospital setting, but she—so she thought she would take it to the next step. If she wasn't going to avail herself for the anesthesiologist, why not be in the nice, clean, beautiful birth center that is right next to the hospital.

Mr. BURGESS. Just for my own satisfaction, do they do cesarean sections at the birthing center?

Mr. MALONE. No, they—that is why they are so close. They transfer, if they need a C-section, to the hospital. They have an arrangement set up for that. We asked a lot of questions along those lines before we chose them.

Mr. BURGESS. You know, Cytotec—of course, I was a practicing obstetrician before I came to Congress, and off label use of Cytotec is not that uncommon. I will just tell the other members of the panel that.

Mr. MALONE. Right.

Mr. BURGESS. I would say what is uncommon would be to use a potent medication like that in a birthing center. That is clearly a—in Texas, at least, a departure for the standard of care. Back in the 1980's, when there was some trouble with credentialling, this Congress, and I obviously wasn't here then, passed laws that required physicians to register, and I have registered with the National Practitioner Data bank. And unfortunately, that information is not generally available to the general public. In Texas where we passed some significant liability reforms, which included caps, and I eluded to some of the benefits from that, and I hope we get to hear

from my good friend, Mr. Montemayor, here in a little bit, about the—what has happened down in Texas, and I hope you will stay around for that. But one of the other things that we did was all of the information collected on a physician from the Texas State Board of Medical Examiners is now instantly available on the Internet. Every month, it goes up. And I know this because I was a little bit late in paying my licensure fee because I am up here in Congress and I don't have a secretary to do it for me anymore, and sure enough, my name was up there as delinquent for non-payment of fees, and they didn't give me much of a grace period. But it just underscores the point that this information does need to be available to consumers. And as a doctor, I have no problem with that. I think what we have done in Texas, perhaps, could be a model for other areas. Of course, bearing in mind what Dr. Bean has said, we are all sued. You can be the best doctor in the world, and you are still going to accumulate lawsuits. In fact, if you are a good doctor, people are going to seek you out when they have more than just the average amount of difficulty, and as a consequence, bad results can follow, and as a consequence, lawsuits can follow.

I would just also, with my last 5 seconds, I do hope this panel will refrain from the use of the word "frivolous" when it talks about lawsuits. I support the President in this endeavor, but I don't like the use of that language. As we have seen here today, there is always a human tragedy at the base of every story, and that is a word we should avoid.

Mr. DEAL. I thank the gentleman.

Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman.

And I would like to add my thanks to all of the witnesses, particularly those of you who have lost family members. It can't be easy coming here. And you all give us a good dimension.

Dr. Bean, I wanted to talk with you, because I want you, and your members, to understand, also, the members on both sides of the aisle understand there is an issue with malpractice, with doctors having increasing malpractice insurance rates. We want to get to the bottom of that and try to deal with it. But I did want to ask you a few questions.

You are here representing the Alliance of Specialty Medicine, is that correct, Doctor?

Mr. BEAN. That is correct.

Ms. DEGETTE. And I believe you said in your opening and then, again, in response to the chairman's question that the obvious problem here is the payouts are quite a bit more than the insurance premiums, which is why premiums have to go up. Is that correct?

Mr. BEAN. That is the understanding.

Ms. DEGETTE. Yes.

Mr. BEAN. The information we have is $1.65 going out in 2002 for $1 coming in.

Ms. DEGETTE. Uh-huh. Well, if staff could put up this chart, please. It should be up on the screen. There we go.

[Chart.]

This is according to an independent agency, which shows that actual payouts by malpractice insurance companies are $55.43 per every $100 of premiums written. Do you see that?

Mr. BEAN. That is right.

Ms. DEGETTE. And so what this incurred is the $80.48, that is what the malpractice insurance companies said that they would have to pay out, but in fact, they only paid out $55.43. Is that—do you see that there, too?

Mr. BEAN. I see that.

Ms. DEGETTE. And Doctor, this is the kind of chart that people like me look at and we say, "Well, maybe part of the problem is the way malpractice insurance companies are writing their insurance policies." Would you have any disagreement with that?

Mr. BEAN. Not on the face of it, no.

Ms. DEGETTE. Okay. If you could move the microphone a little closer.

Mr. BEAN. Certainly.

Ms. DEGETTE. Thanks.

Mr. BEAN. No, not on the face of it, but I—if there is more comment, but what I can say is this. Surely it is an arcane, actuarial system in figuring out the rates in insurance, and I certainly don't understand. I have to look at simple figures like you do. But what I do understand is this. Insurers have dropped out of virtually every State. If it was such a lucrative business, they would stay and make money, but they are leaving. We have trouble finding——

Ms. DEGETTE. Well, let me ask you this, Doctor, because as a representative of your group, I assume you wouldn't have any objection, as part of legislation, to doing some kind of a study about how malpractice insurance companies write their insurance policies, would you?

Mr. BEAN. Certainly not.

Ms. DEGETTE. Absolutely——

Mr. BEAN. I would have no——

Ms. DEGETTE. [continuing] because your real problem, I think as you testified more than once, is that doctors are having to leave the practice of medicine, emergency trauma centers are having to close down because they—doctors just can't afford to pay these premiums, isn't that right?

Mr. BEAN. That is true.

Ms. DEGETTE. Would you be surprised to know that when we considered this legislation in the Energy and Commerce Committee last year, the sponsor of the bill told me that the groups said that they would not allow such a study to be conducted as part of the legislation?

Mr. BEAN. I am—can't say I would be surprised. I wasn't aware of that.

Ms. DEGETTE. But your group wouldn't object to that?

Mr. BEAN. No, as a matter of fact, we would like to look at other additional elements as well, like expert witness standards.

Ms. DEGETTE. Absolutely. And——

Mr. BEAN. There is more to this.

Ms. DEGETTE. Right.

Mr. BEAN. When you talk about the MICRA elements, most of those are to stop the hemorrhage or loss at the end of the line. We would like to stop it at the beginning. There is more to it.

Ms. DEGETTE. Now when you refer to "MICRA," Doctor, what you are talking about is the tort reform legislation that was passed in California, correct?

Mr. BEAN. Correct.

Ms. DEGETTE. But the bill that was passed by the House last year is different in a number of respects from MICRA, isn't that correct?

Mr. BEAN. There are other elements. That is correct.

Ms. DEGETTE. And the other thing we learned in our hearings last year, in the 108th Congress, was, in fact, after Congress passed this tort reform bill, it had caps on non-economic damages and everything else. Malpractice premiums still didn't go down for the doctors in California until after a voter initiative capping malpractice insurance premiums was passed. Isn't that correct?

Mr. BEAN. I don't think that is—I have heard that, and I have—and what happened is MICRA was passed in 1975.

Ms. DEGETTE. These have to pass through court challenge, which takes a while before the insurance premiums actually come down. That initiative, Prop 103, was passed in 1988. By 1985, I think the effect of the cap in California was visible. Around the country, between 1985 and 1987, there was a big spike. That was the second crisis after 1975 to 1986.

Ms. DEGETTE. Well, in fact——

Mr. BEAN. I don't think that——

Mr. DEAL. I am going to have to call time.

Mr. SHIMKUS. Mr. Chair, a parliamentary inquiry.

Mr. DEAL. Who is——

Mr. SHIMKUS. Mr. Chairman.

Mr. DEAL. Yes.

Mr. SHIMKUS. Is it not proper that if we are using a graph and a chart from some consumer that we know who they are and that we have a copy of that?

Ms. DEGETTE. You bet you. Mr. Chairman——

Mr. SHIMKUS. Would you provide that to us?

Ms. DEGETTE. [continuing] this is from the Best State Line Report. It is an independent group. I would be happy——

Mr. SHIMKUS. I would like——

Ms. DEGETTE. Mr. Chairman, would—excuse me, Mr. Shimkus, I would be—I would ask unanimous consent to place it in the record of the hearing.

Mr. SHIMKUS. And if we would have copies of it——

Mr. DEAL. Without objection——

Mr. SHIMKUS. [continuing] for the presentation, that would be appreciative.

Mr. DEAL. Would you distribute it to members, also?

Ms. DEGETTE. Yes. Counsel has it, Mr. Chairman.

Mr. DEAL. All right. Let me ask the members, if they would, if at all possible, let us try to keep the questioning to an absolute minimum. We have several witnesses on the next panel that are going to have to leave, and we are not going to be able to hear from them at all if we don't get to them rather quickly.

Let us see. Who is next? Dr. Norwood is next.

Mr. NORWOOD. Mr. Chairman, I will pass on questioning to get to the next panel, if you please.

Mr. DEAL. Thank you.

Ms. Capps.

Ms. CAPPS. Dr. Bean, I wanted to follow up on an answer that you gave to Chairman Deal's question. You pay—you pointed out that Congress set an amount for 9/11 victims.

Mr. BEAN. Yes, ma'am.

Ms. CAPPS. And some payments were as high as $6.3 million. The average payment was for a death in that tragic event was about $2 million, I believe. And I wondered if you would be willing, speaking for your organization, to consider raising the caps to that level for victims of medical malpractice. A yes or no answer.

Mr. BEAN. Yes, the answer is no, and the reason is that we have evidence across the States that the effect on premiums is in direct relation to the cap on non-economic damages. Anything that high would have virtually have no effect——

Ms. CAPPS. Who—so do you——

Mr. BEAN. [continuing] in——

Ms. CAPPS. Excuse me. But do you believe, then, that what Congress did was wrong?

Mr. BEAN. No, I don't believe what Congress did in that situation was wrong. In terms—and the illustration was that there is a need, at times, to decide on the value of suffering. And in this case, we are trying to strike a balance between what money is in the medical system and what can be paid out for injuries.

Ms. CAPPS. Okay. I want to ask you one more question, but with a yes or no, because I have—I want to be able to elicit more information from a couple of our witnesses.

Tell me if your organization would support efforts to aggressively regulate insurance providers along side of implementing caps to make sure doctors absolutely reap the savings the caps theoretically create.

Mr. BEAN. I have no expertise. The answer is yes if—just as in State regulation, if there is a regulation to be done that would improve the consistency of premiums, certainly.

Ms. CAPPS. Thank you.

Both Mr. Huggins and Mr. Malone, your stories are compelling, and thank you, Ms. Campbell, for being a witness here today as well.

Mr. Huggins, it is clear that Vioxx, and to generalize on that drug company, is a great concern to you. And the fact that we are now exempting them or—in this legislation, I wonder if you would comment for a minute or so on that a bit more.

Mr. HUGGINS. Well, primarily—excuse me. Primarily, I don't—personally, I don't understand why pharmaceutical companies have been included into this bill.

Ms. CAPPS. It concerns some of us, too.

Mr. HUGGINS. I am looking at Merck and many other companies that are all traded on the market. And what you are proposing is the fact that I do not have a right to sue a pharmaceutical company for what I feel I should be compensated for, for whatever rea-

son, from a fault of a drug company when they are traded on the market every day.

Ms. CAPPS. Um-hum.

Mr. HUGGINS. And to me, that—it—to me, it raised the line of my constitutionality, my constitutional right to be able to say what I feel my loss is when I am—you know, I am holding accountable a drug company. And you know, it is traded on the market every day. I don't—I personally don't understand what this has to do with this bill.

Ms. CAPPS. I certainly appreciate your statement.

Mr. Malone, I am a nurse, and you are concerned about patient safety and really focusing on that just makes my heart glad. And I wonder if you, in the short time that I have remaining, would say another word about how you feel, you have been through the mill on this, ways that we, in Congress, could focus in that—in ways that we should in this topic.

Mr. MALONE. Well, indeed, some of it is a State issue, and some of it can be done here at the Federal level. Obviously, cooperation between States, you hear horror stories about physicians who go from State to State. Dr. Anderson, our physician, even went from country to country to avoid detection as a—such as scoundrel went across the Canadian border several times. But some things that can be done are changing the makeup of medical review boards, more transparency in settlements. Secrecy agreements are very hard on patient safety. You know, there are a variety of things, and I am out of time.

Ms. CAPPS. I would——

Mr. DEAL. Thank you.

Ms. CAPPS. I hope we can continue to use your expertise. Thank you.

Mr. DEAL. Ms. Bono.

Ms. BONO. Mr. Chairman, I think I am going to yield at this point and wait for the second panel.

Mr. DEAL. Thank you.

Ms. Myrick.

Ms. MYRICK. No, Mr. Chairman. I will yield at this time, also.

Mr. DEAL. I believe that covers everybody then.

Thank you all for doing so. Thanks to all of you on the panel for being here. We appreciate your testimony and you being present for this hearing. If we can now go to the second panel, ladies and gentlemen, if you will take your seats.

Thank you, ladies and gentlemen. We are pleased to have such a distinguished panel, and we will try to move as quickly as possible, because I do understand the travel plans are here.

And first is Mr. Montemayor, is that correct, who is the insurance commissioner from the Texas Department of Insurance. And I believe I will just introduce each of you as we go along.

Mr. Montemayor.

STATEMENTS OF JOSE MONTEMAYOR, CPA INSURANCE COMMISSIONER, TEXAS DEPARTMENT OF INSURANCE; J. ROBERT HUNTER, DIRECTOR OF INSURANCE, CONSUMER FEDERATION OF AMERICA; JAMES HURLEY, AMERICAN ACADEMY OF ACTUARIES; SARA ROSENBAUM, HIRSH PROFESSOR AND CHAIR, DEPARTMENT OF HEALTH POLICY, THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER, SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES; SHERMAN "TIGER" JOYCE, AMERICAN TORT REFORM ASSOCIATION; GURKIRPAL SINGH, ADJUNCT PROFESSOR OF MEDICINE, DEPARTMENT OF GASTROENTEROLOGY, STANFORD BUSINESS SQUARE; JOSEPH P. GLENMULLEN, PSYCHIATRIST, HARVARD LAW SCHOOL, MENTAL HEALTH LAW SCHOOL HEALTH SERVICES; RICHARD F. KINGHAM, COVINGTON & BURLING; SIDNEY M. WOLFE, DIRECTOR, HEALTH RESEARCH GROUP, PUBLIC CITIZEN; AND VICTOR E. SCHWARTZ, SHOOK, HARDY & BACON, L.L.P.

Mr. MONTEMAYOR. Thank you, Mr. Chairman. It is a pleasure to be here. And members, it is a real honor to be here and give you our perspective on this particular line of insurance from a regulatory standpoint and also from how we see the market in some of the issues that are underpinning the medical malpractice issues.

As many of you may not know, the insurance commissioners are on a State by State basis. In Texas, the insurance commissioner is elected by the Governor and with the advice and consent of the Senate and basically is in charge of regulating the insurance markets within the State.

Part of the regulatory duties are, obviously, then to license insurance companies, monitor their solvency levels, approve their rates or monitor their rates, in the Texas cases monitor their rates, and also approve the insurance contracts themselves, the forms.

There is also the National Association of Insurance Commissioners. And the role of the National Association is an organization of insurance regulators from all 50 States, the District of Columbia, and the U.S. territories, and it dates back to the 1800's. It provides a forum for the development of uniform policy on insurance matters where appropriate. And obviously, they are very, very focused on solvency and financial aspects of this.

In terms of my own activities at the NAIC, I Chair the National Property and Casualty Insurance Committee and the Subcommittee for Market Conditions Working Group, which was established in 2003 to look at, particularly, distressed lines within property and casualty. The very first one that came up for study, and the one with most urgency, was this one, medical malpractice. And we heard a lot of testimony on the causes and solutions for what came to be known as the medical liability insurance crisis.

We assigned some researchers and eventually produced a pretty good-sized report, which I will forward to your committee clerk so you can have use of it. But we basically looked at a number of the States, all 50 States' premiums and what was happening in the—within the market. The overarching conclusion was that underwriting losses, as Dr. Bean, I think, on the previous panel pointed out, it is what comes in and what goes out, were the major single contributing factor influencing the rate increases being experienced

by physicians and other health providers over the past several years.

The report provided data, research sources, and a list of the market interventions available for consideration to State regulators as well as to policymakers, such as the U.S. Congress or the State legislators.

The Texas experience, basically, manifested itself in its fullness on this last set of crises, probably around 1999 to 2000. Nursing home licensed insurers participating totally in our market dropped from eight to just one. Licensed insurers for physicians medical malpractice, I used to have about 17 in the market. We dropped to four. Many of them actually went completely insolvent, broke, and had to be put into receivership, because losses greatly exceeded their premiums. In fact, there were about 6,500 doctors displaced where they lost their insurance coverage completely either because the insurance company went out of business or stopped writing the line because their own regulator basically said, "No more. That is all there is you can handle."

Over 11 medical malpractice insurance with more than 6,500 physicians withdrew effectively from the market. There were several rate increases from 1999 to 2002. Those increases range from 23 percent to about 117 percent. The Joint Underwriting Insurance Association, which is one of the tools effectively used in some of the markets, grew to something like 3,000 physicians, and we physically got involved in trying to place many of these dislocated physicians. The largest medical malpractice writer, the Texas Medical Liability Trust, not an insurance company, but a creature of the legislature, that acts effectively as an insurance company, increased its rates over 140 percent over that 4-year period and had to, in addition to that, assess an extra $5,000 per physician just to maintain an ability to continue to write. And we had had a cap effectively on non-economic damages since, let us see, 1977, and it was due to inflation. Because of a series of interventions in court, it basically was applicable only in cases of wrongful death, and that had climbed to about $1.7 million.

The way that Texas legislature responded, they adopted a law to effectively place limits on non-economic damage, made provisions for periodic payments for future damages as they became accrued. It is stipulated that pre-judgment interest was not awardable on future damages. And in terms of the class actions, it required that Texas courts keep plaintiff attorney fees in proportion to the actual work done. They took the unusual step to also put in front of the voters a constitutional amendment to immediately get at the benefits to be had from these tort reforms. And so the law went into effect, basically, with those reforms on the 1st of September. The voters were voting to ratify a constitutional amendment specifically empowering the State legislature to adopt those limitations 10 or 12 days later, and they became effective.

Our experience since——

[The prepared statement of Jose Montemayor follows:]

Overview of the Texas Medical Malpractice Market

Presented to the

Energy and Commerce Subcommittee on Health

Jose Montemayor, CPA
Commissioner, Texas Department of Insurance
February 10, 2005
Washington, D.C

Part I - ORAL TESTIMONY

I. Commissioner of Insurance – Jose Montemayor, CPA

As the first state insurance commissioner to testify before this committee, I offer some background information on my role as commissioner.

A. Texas Commissioner of Insurance - Background

1) Appointed by the Governor with the advice and consent of the Texas Senate
2) Department's chief executive and administrative officer
3) Approximately 940 agency employees
4) Approximately $50 million budget
5) Establish agency operating procedures and enforce Texas insurance laws
   - Includes disciplinary and legal actions against violators
6) Often called to comment on pending or proposed legislation relating to insurance

II. Texas Department of Insurance – Duties

A. Regulatory Duties

1) Licensing insurance companies and agents
2) Maintaining insurer solvency
3) Regulating rates
4) Regulating policy forms (contracts)
5) Protecting and educating insurance consumers

6) Performing many other duties, from oversight of the Texas Joint Underwriting Association, Texas' insurer of last resort for healthcare providers, to reviewing insurance related appeals.

B. Other Information

1) 2003 Fiscal Year Report published in October 2004 listed about $80 billion in annual written premium
   - The department licenses or registers about 2,500 insurers of all types as well as agents, escrow officers, risk managers, adjusters, and other insurance personnel in tens of thousands.
2) Department strives to maintain a financially safe, efficient, and fair insurance marketplace for Texas citizens

III. National Association of Insurance Commissioners (NAIC)

A. The Role of the NAIC

1) Organization of insurance regulators of the 50 states, District of Columbia and U.S. territories, created in 1871
2) Provides a forum for the development of uniform policy on Insurance matters where appropriate
3) First major step was to develop uniform financial reporting by insurance companies
4) Helps regulators fulfill the obligation to protect the interests of their state's insurance consumers

B. My NAIC Activities

1) Chair of the NAIC Property and Casualty Insurance
2) Chair of the subcommittee, Market Conditions Working Group
   - Working Group details (2003 to 2004)
     a. Monitor availability and affordability of property and casualty insurance and, for the most distressed lines, provide reports with market-monitoring information, solutions, and regulatory responses.
        i. The "most distressed line" was medical liability insurance
     b. Heard testimony on causes and solutions for what came to be known as the medical liability insurance crisis.

c. Assigned researchers to assemble and edit a final report. The result was the Medical Malpractice Insurance Report: A Study Of Market Conditions And Potential Solutions To The Recent Crisis of September 12, 2004.

   i. Report stated that "research indicates that underwriting losses were the major factor influencing the rate increases experience by physicians and other health are providers over the past several years."

   ii. Report provided data, research sources, and a list of the market interventions available to state regulators.

IV. The Texas Experience - Prior to Tort Reform

A. Crisis

1) Nursing home licensed insurers dropped from 8 to 1
2) Licensed insurers for physicians medical malpractice dropped from 17 to 4
3) Over eleven medical malpractice insurers with more than 6,500 physicians withdrew from the market or became insolvent
4) Severe rate increases from 1999 to 2002
   - Seven large medical malpractice insurer increases ranged from 22.5% to 117.2%
5) Texas JUA insured 3,000 physicians during the crisis who were unable to find standard coverage
   - As recently as 2000, the JUA insured 100 physicians
6) The largest medical malpractice insurer, Texas Medical Liability Trust (a self-insurance trust for the Texas Medical Association), increased rates 147% over four years and assessed members (insureds) $5,000 each to maintain surplus
7) The 1977 cap on pain and suffering originally climbed to over $1.7 million due to inflation and became limited to only wrongful death cases due to Texas Supreme Court decisions on constitutionality

V. **Texas Responds with Tort Reform**

A. **Texas Legislature Enacted Tort Reform**

1) Effective September, 2003

- Voters approved a constitutional amendment supporting the reforms the same month

2) The reforms included

- Caps on non-economic damages (aka pain and suffering)
- Periodic payment provisions for future damages as accrued
- Prejudgment interest not awardable on future damages
- Class Actions - require Texas courts keep plaintiff attorney fees in proportion to actual work done

B. **Regulatory reforms**

1) No significant changes. Texas continued vigorous enforcement of statutory restrictions on excessive medical liability rates.

VI. **The Texas Experience - Post Tort Reform**

A. **New Entrants in the Medical Liability Market**

1) A cumulative total of 19 New Medical Malpractice carriers have either entered the market or soon will. Three existing insurers announced they will expand or have expanded physician writings in Texas:

B. **Licensed Neurosurgeons**

1) A critical specialty, increased 8% after tort reform (according to the Texas State Board of Medical Examiners)

- Some towns report an improvement in 24/7 trauma center coverage

C. **Physician Rates**

1) Rate decreases

- The largest writer, Texas Medical Liability Trust, $189,000,000 written premium, decreased rates by 16.4%
- CNA, a small writer, decreased rates 11.5%

2) Other Rate Changes
   - The Doctors Company, $15,000,000 written premium, reduced scheduled 20% increase to 0.7%
   - Medical Assurance, $5,000,000 written premium through a purchasing group, announced an increase of 34.4% before tort reform, but effective after. They subsequently lowered these rates between 5% to 8%.
   - Other insurers eliminated increases
3) TDI disapproved requested increases for two large insurer's after the reforms became effective
   - One insurer is currently contesting the disapproval

D. Hospital Rates

1) The largest writer, Health Care Indemnity, $129,500,000 written premium, reduced rates 13% 1/1/04

E. Overall Experience

1) Data from medical liability insurers indicates new claims spiked the summer before tort reform became effective, but fell to significantly below pre-reform levels in early 2004.
2) Anecdotal evidence suggests that this lower level of claims activity persisted throughout 2004

Part II - WRITTEN TESTIMONY

I. Introduction

Professional liability is insurance not one in a hundred of our fellow citizens purchases directly. Yet, it affects us all. Whether you visit a lawyer, talk to your tax accountant, get a flu shot or a hair cut, a portion of your fee pays for professional liability.

On one hand, this raises the cost of the services received. On the other, it protects the public against professional misadventure and allows the professional to pursue a career without fear of financial catastrophe.

As we Texans learned over many years, professional liability insurance is vital for the functioning of our health care system and our economy.

II. Brief History Of Texas Medical Malpractice Market

A. Background

- In the 1940s, Texas had a system of regulated, price controlled insurance including medical malpractice. The princely sum of $15 bought a physician $15,000 limits to cover then rare suits. This system lasted until 1955 when premiums doubled creating the first malpractice liability crisis.
- 1955 - The Legislature removed insurance for Texas physicians, hospitals, and other professions (attorneys, architects, etc.) from regulation. Rates stabilized through competition at $200 per year for physicians.

B. 1970's Crisis And Initiatives Implemented To Alleviate It

- In 1974, physician medical malpractice losses doubled. Rates increased as much as 400% over 1972 levels. Carriers writing medical malpractice for physicians declined from about fifty to two or three. Medical professionals asked for legislative help.
- In 1975 and 1977, the Legislature placed insurance rates for hospitals, physicians, and other healthcare providers back under rate regulation. The Texas JUA was created in 1975 to provide last resort medical malpractice coverage to medical professionals not able to obtain it in the standard market. Over 4,000 physicians received JUA coverage before the crisis moderated. A self-insurance trust (Texas Medical Liability Trust) was authorized for statewide medical association members.
- Tort reforms were enacted through the Medical Liability and Insurance Improvement Act of 1977:
  - A cap on pain and suffering damages of $500,000 increasing with inflation.
  - Statute of limitations shortened to two years for adults and age 14 for minors.
  - Plaintiff attorneys must give ninety days notice of intent to file suit.
  - Expert witness requirements were tightened.
  - Informed consent and disclosures were standardized.
  - Carriers insuring hospitals must provide loss control information.
  - Crisis moderated in late 1970's, however the number of med-mal insurers never reached pre-crisis levels.

C. 1980's Crisis And Initiatives Implemented To Alleviate It

- Rates soared to an average of $8,000 per physician. Over 2,000 physicians temporarily sought insurance at the JUA until the medical malpractice markets slowly recovered.
- Legislative initiatives included:
  - Market Assistance Plan (MAP) established for medical malpractice and other liability.
  - Carriers insuring physicians must provide insureds loss control information.

- Additional medical providers were brought into rate regulation.
- Established a short-lived plan to subsidize medical malpractice costs through insurers. This was the Omnibus Healthcare Rescue Act or HB18 of 1989. It provided premium discounts by paying part of the indemnity of certain claims in exchange for a physician insured providing free care to some patients and taking risk management/loss control courses. The plan was active from about 1991 to 1995.

- Rates stabilized for a period of time

  Some legislative tort reform was delayed until 1995
  - Changed the minimum requirement for joint and several liability responsibility for an entire award from 10% to 50%.

    Tightened venue requirements to prevent venue shopping of medical malpractice claims.

    Strengthened the requirements for expert witnesses and required larger court bonds for a time extension to produce an expert witness.

D. 2000 - 2003 Medical Malpractice Market Before Latest Reforms

- Nursing home licensed insurers dropped from 8 to 1.
- Licensed insurers for physicians medical malpractice dropped from 17 to 4.
- Over eleven medical malpractice insurers with more than 6,500 physicians withdrew from the market or became insolvent.
- There were severe rate increases from 1999 to 2002. Seven large medical malpractice insurers increased rates ranging from 22.5% to 117.2%
- Texas JUA insured 3,000 physicians unable to find standard coverage.
- The largest medical malpractice insurer, a self-insurance trust (Texas Medical Liability Trust) for the Texas Medical Association, increased rates 147% over four years and assessed members $5,000 each to maintain surplus.

- The 1977 cap climbed to over $1.7 million due to inflation and became limited to only wrongful death cases due to Texas Supreme Court decisions.

III. History of Texas regulatory framework for medical malpractice markets

A. 1948 to 1955, liability rates (including medical malpractice) were set, standard and uniform, for all insurers in accord with national statistics.

B. 1955 to 1975, professional liability (including medical malpractice) rates were deregulated.

C. 1975 to 1993, most professional liability rates regulated via prior approval system in accord with an adequate, reasonable, not excessive standard.

D. 1993 to present, medical malpractice liability rates are regulated via a file and use system. Approval may be withdrawn if rates are found to be excessive after filing.

IV. Latest Texas Reforms

A. Tort Reform (2003) and its Components

- Caps On Non-Economic Damages. Award cannot exceed $250,000 for physicians or $250,000 for each healthcare institution. Aggregate cap may not exceed $750,000 regardless of number of defendants.
- Periodic Payments. Provides provisions for payment of future damages as accrued. Limitations on plaintiff attorney fees.
- Prejudgment Interest. No prejudgment interest is awardable on future damages.

- Vendor's Endorsements. Insurers may not exclude physicians or other healthcare providers in product liability (i.e. drug) cases.
- Informed consent. Suits based on failure to disclose risks can be based only on risks influencing patient decisions. Created the Texas Disclosure Panel to identify such risks.
- Class Actions. Requires that a court use lodestar method of calculating attorney fees. (The lodestar method requires fees to be in proportion to the amount of actual work done on a case.) Stays proceedings pending appellate ruling on class certification.
- Emergency Care. Reduces liability for most emergency care, now including emergencies in a clinic or hospital not done by emergency specialists.
- Admissibility of Evidence. Excludes nursing home inspection reports not related to the basis of a claim.

B. Regulatory Reforms

- No significant change.

C. Other Texas Department of Insurance / Legislative Initiatives

- Updated the Texas JUA to recognize current market standards:
  - Added claims-made policies to be compatible with contemporary physician policy forms.
  - Created moderate cost, prior acts coverage for run-off (tail) of physicians caught by insurer insolvency. It can also be purchased if less expensive than the tail offered by a withdrawing company.
  - Made not-for-profit nursing homes, assisted living facilities, ambulatory surgicenters, and perfusionists eligible for JUA coverage.
- Adopted Best Practices for Risk Management and Loss Control that may be used by nursing homes.

- Initiated a rate disapproval hearing on medical malpractice business moved to a risk purchasing group (RPG) to prevent RPGs from becoming rate regulation refuges (Still pending as off February 4, 2005).

V. Reforms' Effect on Texas Medical Malpractice Market

A. How Medical Malpractice Companies Have Responded (i.e. rates)

1) Physician Rates Since September 2003

- Rate decreases
  - The largest writer, Texas Medical Liability Trust, with $189,000,000 in written premium (2003) reduced their rates by 16.4% since September 01, 2003 (-12% on January 01, 2004 and another 5% on January 01, 2005).
  - A small writer, Continental Casualty Company, with $800,000 in written premium (2003) reduced their rates by 11.5% on February 01, 2004.
- Proposed Rate Increases Eliminated / No Changes in Rates
  - Most companies fall into this category.
  - The Doctors Company had an indicated rate change prior to the consideration of HB 4 of about +20% but filed in October 2003 for no change. May 01, 2004 they implemented an increase of +0.7%. Doctors Company writes $15,000,000 in physician premium (2003).
- Rate Increases Disapproved
  - The Texas Medical Liability Insurance Underwriting Association (JUA) filed for a 35.8% increase which was disapproved November 2003. The JUA has $58,000,000 in physician premium (2003).
  - The Medical Protective Company (Med Pro) filed for a 19% increase, which was disapproved April 20, 2004. Med Pro has $134,000,000 in physician premium (2003). Med Pro moved its physicians to its purchasing group July 01, 2004 and implemented a 10% increase. TDI staff brought an enforcement

action against this carrier. From July 12 through July 14, 2004 a hearing was held before the State Office of Administrative Hearings (SOAH) on both the 10% increase and the disapproved 19% increase.

The SOAH administrative law judge (ALJ) issued his initial Proposal For Decision (PFD) on November 23rd. The ALJ ruled that:

> Based on information received from the parties on November 16, 2004, the resulting rate indications would be -5.7 percent for claims made coverage and +3.6 percent for occurrence coverage if all the ALJ's rate recommendations were utilized. The combined rate would be -3.8 percent [i.e., lower], giving 80.0 percent weight to claims made and 20.0 percent weight to occurrence.

In doing so, the ALJ accepted TDI's actuarial analysis of the rates charged by The Medical Protective Company and MPSA Purchasing Group, Inc. However, in order to find that the rates were "excessive" the ALJ also had to find that a reasonable degree of competition does not exist in the medical professional liability insurance marketplace. The ALJ found instead that a reasonable degree of competition does exist in Texas and has proposed a decision in favor of The Medical Protective Company based on the competition part of the rate statute.

The matter has been presented to the Commissioner of Insurance for a final determination.

- Other Rate Changes
  - Prior to September APIE filed for an increase of 16.6% above their 1994 rates. This applied to non-purchasing groups physicians only. They wrote $0 outside their purchasing groups in 2003 and $54,000,000 within their purchasing groups (2003).
  - The Medical Assurance Company, which writes solely through their purchasing group last increased rates 34.4% effective November 15, 2003. They now report new and lower rates effective January 1, 2005, averaging between a 5 and 8 percent decrease. Medical Assurance writes $5,000,000 in physician premium (2003).

2) Hospital Rates Since September 2003
   - The largest writer, Health Care Indemnity, with $129,500,000 in written hospital premium (2003) reduced its rates by 15% in January 01, 2004.

B. Availability of Medical Malpractice Insurance

C. New Entries Into the Market
- In late 1999, 17 companies reported writing physicians medical professional liability insurance. That number decreased to 4 by early 2002.
- Presently, a cumulative total of 15 New Medical Malpractice carriers have now either entered the market or soon will.
  - 11 risk retention groups have been registered since September 2003
  - 2 new admitted companies
  - 1 admitted company filed for a new PL program for Dentists

- 1 company has filed for a name reservation and has indicated to TDI it will soon file as an admitted carrier in Texas.

- The following companies have announced they will expand or have expanded physician writings in Texas:
  - The Doctors Company – admitted
  - Everest National Insurance Company - admitted
  - The Medical Assurance Company – admitted
  - Catlin Insurance Company Ltd. – surplus lines

D. Other HB 4 Issues

- Insurers dealt with an influx of medical liability claims that began in June 2003 and ended September / October 2003.
- New claims spiked in June, with elevated levels in July, August and a larger spike in September.
- The anomaly must be taken into consideration, though not over-adjusted for or treated as a long-term trend.
- Data from two large med mal carriers through spring 2004 indicates that reported claim activity after the spike is at levels well below normal. Anecdotal indications are this moderated claim level has continued through 2004.

Recent Entries/Applicants – Physicians and Other Medical Professional Liability Insurance (cumulative since 2003)

A. Risk Retention Groups (RRGs)

1) Registration Completed Since May 03 (As of October 2004)

- Allied Professionals Insurance Company, RRG
  Registered on 2/23/04 – Active – Writing Acupuncturists, Chiropractors, Massage Therapists
- Applied Medico – Legal Solutions, RRG
  Registered on 10/7/03 – Active – Writing emergency medical physicians
- CARE RRG
  Registered on 2/23/04 – Active – Open to all physician specialties
- Centurion Medical Liability Protective RRG, Inc,
  Registered on 7/27/04 - Active - Writing physicians
- Eldercare Mutual Insurance Company RRG
  Registered on 2/13/04 – Active – Writing long-term care facilities
- Emergency Medicine RRG, Inc,
  Registered on 6/9/04 – Active – Writing emergency medical physicians
- Emergency Physician Ins Co, RRG,
  Registered on 10/7/03 – Active – Writing emergency medical physicians
- Green Hills Insurance Company, RRG
  Registered on 05/03/2004 - Active - Has no Texas physician insureds yet

- Health Network Providers Mutual Insurance Company, RRG
  Registered on 12/31/03 – Active – Writing Memorial Herman Health Network Providers only

- Lake Street Risk Retention Group, Inc.
  Registered on 12/31/03 – Active – Writing hospitals and physicians

- Physicians Specialty Ltd., RRG
  Registered on 1/26/04 – No Texas physicians yet. Temporarily focusing attention on ER group in CA.

2) Filed for Risk Retention Group – Registration Pending

- Oceanus Insurance Company, A Risk Retention Group
  Filed for registration on 1/27/05 – Plans to write various physician specialties

B. Surplus Lines

1) Registration Completed

- Catlin Insurance Company, Ltd.

- Hudson Specialty

- Red Mountain Casualty Insurance Company

2) Filed for Surplus Lines Eligibility – Eligibility Pending

- None known pending

C. Licensed and Admitted in Texas

- Advocate, MD Insurance of the Southwest
  Writing Physicians and other health care providers

- Professional Liability Insurance Company of America (PLICA)
  DBA in Texas as Medical Liability Insurance Company of America (MLICA)
  Began writing Physicians and other health care providers 12/1/04.

- State Farm
  Writing Dentists

D. Filed for Texas Name Registration

- American Medical Physicians Assurance of Texas
  Filed a name reservation as a licensed insurance company.

- Physicians Insurance Company (PIC) of Florida
  Filed a name reservetion as a licensed insurance company.

E. Filed Application for Charter and License in Texas - License Pending

- None known pending

  (Advocate, MD applied Spring 2004 and completed the licensing process May 28, 2004.)

F. Filed Rates, Rules, and Forms - Approval Pending

- None pending after MLICA approval.

Current Entities Writing Physicians
Medical Professional Liability Insurance

A. Statutory Insurers

- Texas Medical Liability Trust (a self-funded trust for TMA members)
- Texas Medical Liability Insurance Underwriting Association (JUA) (Texas residual market insurer)

B. Licensed and Admitted Insurers (As of January 2005)

- American Physicians Insurance Exchange
- Anesthesiologists' Professional Assurance Company
- Advocate, MD Insurance of the Southwest (new)
- Continental Casualty Company
- Everest National Insurance Company
- The Doctors' Company
- The Medical Assurance Company
- The Medical Protective Company
- Medical Liability Insurance Company of America (MLICA)
- National Union Fire Insurance Company of Pittsburg, PA
- Preferred Professional Insurance Company (limited to physicians in qualifying Catholic hospitals)
- Texas Hospital Insurance Exchange (Limited to hospital-employed physicians)
- Texas Medical Insurance Company

C. Surplus Lines Insurers (As of January 2005)

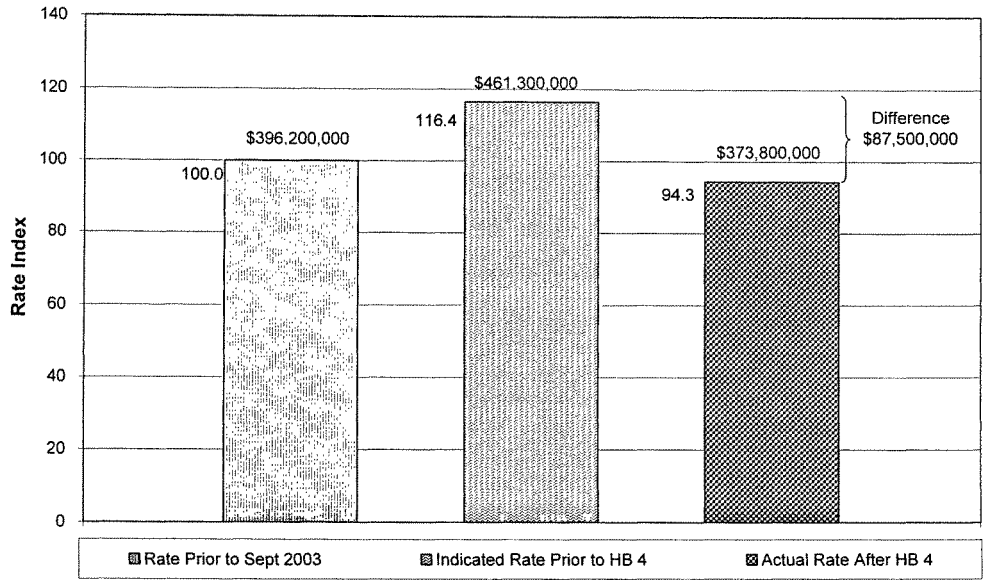
- Admiral Insurance Company
- Catlin Insurance Company, Ltd.
- Evanston Insurance Company
- General Star Indemnity Company
- Hudson Specialty
- Lexington Insurance Company
- Professional Underwriters Liability Insurance Company
- Red Mountain Casualty Insurance Company (new)
- Royal Surplus Lines Insurance Company
- Steadfast Insurance Company

D. Risk Retention Groups (As of January 2005)

- Allied Professionals Insurance Company, RRG
- Applied Medico – Legal Solutions, RRG
- CARE RRG
- Centurion Medical Liability Protective RRG, Inc,
- Eldercare Mutual Insurance Company RRG
- Emergency Medicine RRG, Inc,
- Emergency Physician Ins Co, RRG,
- Green Hills Insurance Company, RRG
- Health Network Providers Mutual Insurance Company, RRG
- Lake Street Risk Retention Group, Inc.

- National Guardian Risk Retention Group, RRG
- Oms National Insurance Company, RRG
- Ophthalmic Mutual Insurance Company RRG
- Preferred Physicians Medical RRG, Inc.

PHYSICIANS and SURGEONS MEDICAL MALPRACTICE
Top Four Writers Filing Rates
Indicated Rate Level vs Actual Rate Level

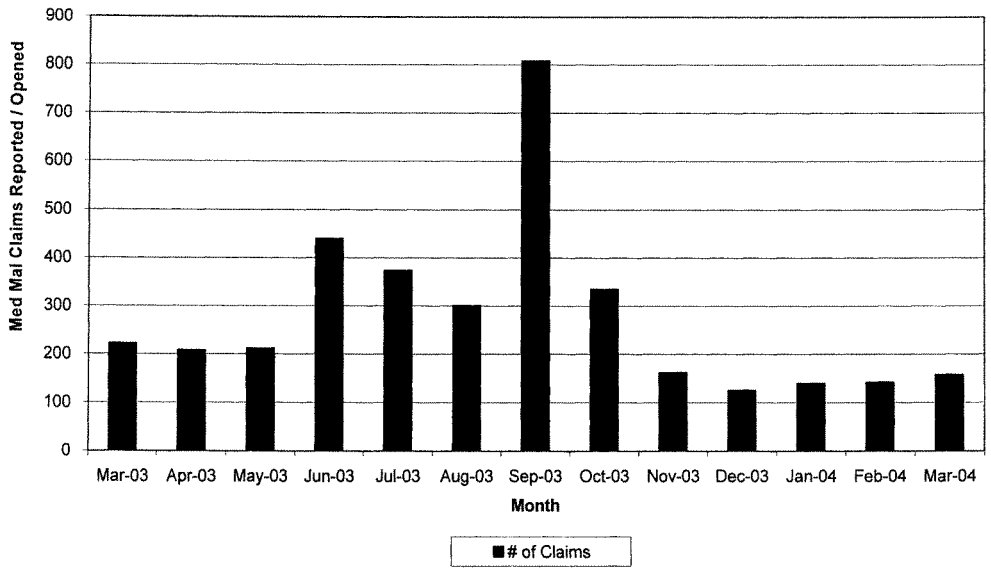


Top Four Writers: Texas Medical Liability Trust, Medical Protective, Doctors Company, and Texas JUA.
Actual rate change includes rates effective January 01, 2005.

TEXAS MEDICAL MALPRACTICE

TMLT and the Texas Medical Liability Insurance Underwriting Association (JUA)

Combined Medical Malpractice Claims by Month



TEXAS MEDICAL LIABILITY INSURANCE UNDERWRITING ASSOCIATION (JUA)

Total Policy Count by Year

Date of Count	Total JUA Policies In Force at Date*	% Change from Previous Year
6/30/1997	242	
6/30/1998	200	-17%
6/30/1999	158	-21%
6/30/2000	139	-12% **
6/30/2001	168	21%
6/30/2002	751	347%
6/30/2003	2,567	242% ***
9/30/2003	2,687	5%
6/30/2004	2,690	0%
9/30/2004	2,688	0%
12/31/2004	2,613	-3%

* Includes policies of all covered providers. Some providers (very few) may have two policies – one primary and one excess coverage. Covered providers include physicians, hospitals, dentists, nursing homes, nurse anesthetists, and other allied health care providers.

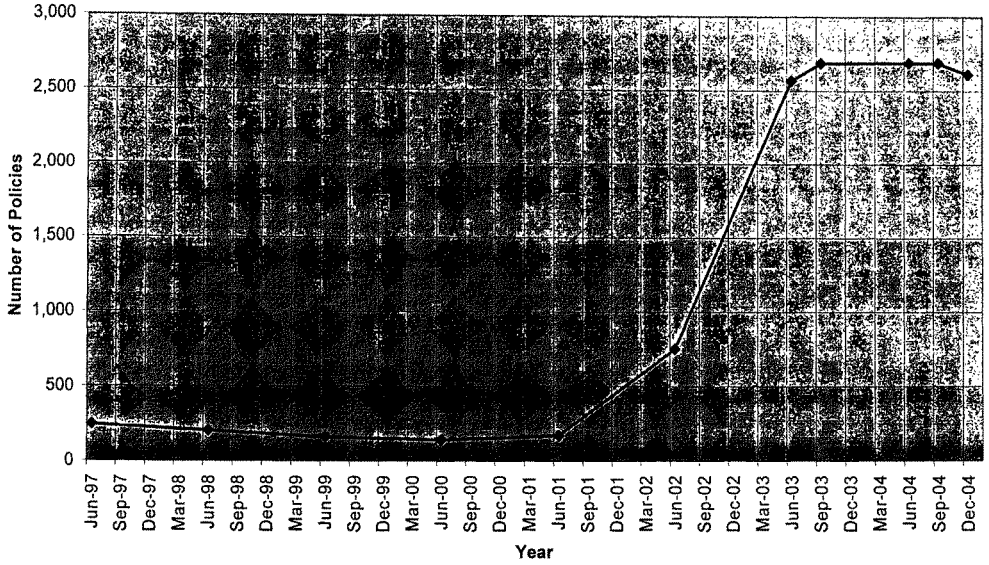
** The all-time low of 139 policyholders occurred in

2000.

*** A twenty-five year high of 2,687 policyholders occurred on September 30, 2003.

TEXAS MEDICAL LIABILITY INSURANCE UNDERWRITING ASSOCIATION (JUA)

Number of Policies

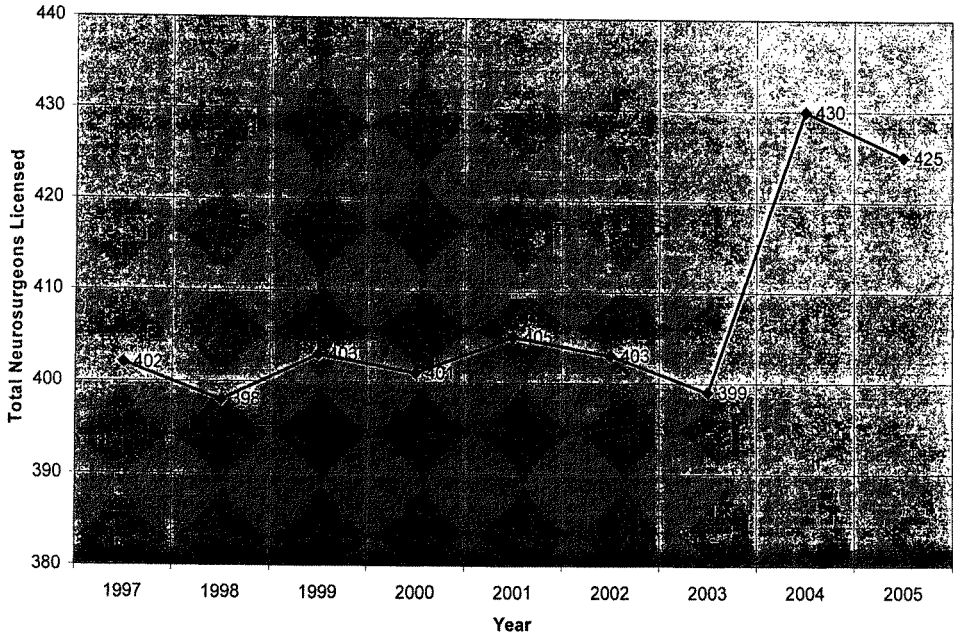


Texas Licensed Neurosurgeons by Year

Date	Number of Texas Licensed Neurosurgeons	Percent Change
Jan-97	402	
Jan-98	398	-1%
Jan-99	403	1%
Jan-00	401	0%
Jan-01	405	1%
Jan-02	403	0%
Jan-03	399	-1%
Jan-04	430	8% *
Jan-05	425	-1%

* The number of Texas licensed neurosurgeons increased 8% in one year following tort reform passage

Texas Licensed Neurosurgeons by Year



Source: Texas State Board of Medical Examiners

Mr. DEAL. I am sorry. I am going to have to cut you off. You have run past our time limit, but we will try to get back and let you expound on some of that.

I would remind everybody that we do have your written testimony that is available and in the record for the members here.

Let me move to Mr. Hunter, Mr. Robert Hunter, Director of Insurance for Consumer Federation of America. We are pleased to have you.

STATEMENT OF J. ROBERT HUNTER

Mr. HUNTER. Thank you, Mr. Chairman.

I am going to be referring to some exhibits—oh, by the way, Mr. Chairman, congratulations on your first hearing.

I handed up some charts, because they are in the—my written statement, but maybe they are easier to follow. There are four I am going to touch on.

[Chart.]

The first chart is the insurance economic cycle. It tells you when and why various hard and soft markets happen. The first was in the mid-1970's. I was the Federal Insurance Administrator under President Ford when the first medical malpractice hard market hit. The White House Domestic Policy staff asked me to look into what was going on and whether or not there was an explosion in medical malpractice claims and verdicts. I dutifully sought the data, wanting to keep my job, and the first thing I discovered was that the medical malpractice statistics were not broken out in the insurance annual reports sent to the insurance department, so we asked the commissioners to do so, which they have done. And that is why we have data today.

We undertook a closed claim study with the States and in due course, I reported back to the White House that there was no explosion in claims, and the cause of the spike was the economics of the insurance industry. Thus, we now know the hard market and the rate shocks that physicians have experienced in the last few years, more than 10 percent between 2000 and 2003, relate to these same economic conditions. The recent rate spike was the very bad news that brings us here today.

The good news is that the cycle has now turned soft. Recent data shows that medical malpractice insurance premium increases have essentially ended. In 2004, A.M. Best reports, malpractice insurance premiums rose by just 4 percent nationwide. The rates are expected to be level for the next few years, as has occurred in each previous soft market phase.

Look at the chart of Federal funds rates. That is the second chart.

[Chart.]

Medical malpractice insurance companies have a huge float on the premiums, since it takes several years for claims to be paid on average from the time they get the premium. Medical malpractice insurers invest heavily in bonds so when interest rates fall, rates must rise. And we have been at historic low rates, which is part of the cause of the rate increases we have witnesses.

Using the data from the medical malpractice insurance company reports, I did the next chart, which is on page six of my written statement.

[Chart.]

The top line of the chart shows premiums collected by insurance companies for medical malpractice on a nationwide, per doctor average, adjusted for medical inflation. Premiums, you will see, go up and down with the cycle, but losses—the bottom, losses paid per doctor are flat. They are not going up. It is—there is no explosion in losses. It is—they are flat. This is the same thing we reported to the White House in 1976 the same thing we reported to the White House in 1986, the same thing that is going on today. Inflation-adjusted payouts producted dropped from 2001 to 2003. The average payment per closed claim over the last decade was under $30,000 from which attorneys were compensated. Few of them, one in four persons, who file a medical malpractice claim, collect any money at all.

The low cost of the medical malpractice system is further evidenced by the final chart at the bottom of page six of my testimony.

[Chart.]

Here, we see the ratio of medical malpractice insurance premiums to the total health care costs. Medical malpractice insurance costs as a proportion of national health care spending is minuscule, 60 cents per $100 spent. If you cap non-economic damages, you will not impact the cost of health care in any meaningful way. Even if you eliminated the entire malpractice system, you would hardly impact the cost of health care.

The good news is this: the worst of the malpractice rate hikes are over. Congress has time to conduct a thorough examination of the problem and proposed thoughtful solutions. You should not rush into changes in the medical liability system harming victims and fail to address insurance failures, which are at the root of these problems.

You should consider and act on insurance reform measures to control the harmful excesses of a business cycle that causes sudden and unjustifiable price spikes and coverage cutbacks every decade or so. I recommend you look at the Proposition 103 system of California or look at Texas. They did pass tort reform, but it wasn't until Jose went after them and disapproved some rate filings that they actually got rates to go down.

You should also assess and enact methods to reduce negligence and medical errors by physicians and medical facilities. And you should evaluate why so few people who are hurt by medical negligence receive any form of compensation. I think you should review a no-fault system, or other methods that maybe could work here. But you shouldn't just do something to victims without looking at other mechanisms. You have plenty of time, now that this cycle has turned, to make sure the action you take does no harm.

Given the return to the soft insurance market, I strongly urge you to use this gift of time to make sure that your action is best for all Americans, and particularly that victims of malpractice would not be harmed by your actions.

[The prepared statement of J. Robert Hunter follows:]

PREPARED STATEMENT OF J. ROBERT HUNTER, DIRECTOR OF INSURANCE, CONSUMER FEDERATION OF AMERICA

Good morning. I am J. Robert Hunter, insurance director for the Consumer Federation of America. I am also an actuary, a former federal Insurance Administrator under Presidents Ford and Carter, and a former Texas Insurance Commissioner. CFA is a non-profit association of 300 organizations founded in 1968 to advance the consumer interest through research, advocacy and education.

I would like to thank Chairman Nathan Deal, Ranking Member Sherrod Brown and the other members of the Subcommittee for the opportunity to offer our comments on this extremely important issue. For the third time in less than thirty years, Congress and state legislators across the country have been grappling with the problem of fast-rising medical malpractice rates. Insurers insist that a sharp increase in large, unwarranted jury verdicts is to blame for the crisis. As a result, lawmakers on this Subcommittee and in a variety of states are considering legislation to place further limits on the legal rights of Americans who have been harmed or killed by medical malpractice.

However, my research over many years shows that insurers are pointing fingers when they should be looking in the mirror. I first studied this issue at the behest of President Ford when, in the mid-1970s, a hard market hit medical malpractice in much the same fashion as we are witnessing today. After doing research similar to what I will present to you today, the Ford White House decided not to push for tort reform since, as today, the sudden surge in prices for doctors was not due to a jump in claims, but was related to insurance industry economics.

It is the "hard" insurance market and the insurance industry's own business practices that are largely to blame for the rate shock that physicians have experienced in the last few years. Recent data also shows that sharp rate increases have ended (in 2004, medical malpractice premiums rose by just four percent) and are expected to level out for the next few years. CFA has also found that:

- The rate problem was caused by the classic turn in the economic cycle of the industry, sped up—but not caused by—terrorist attacks.
- Further limiting patients' rights to sue for medical injuries would have virtually no impact on lowering overall health care costs. Medical malpractice insurance costs as a proportion of national health care spending are miniscule, amounting to 60 cents per $100 spent.
- Insurer losses for medical malpractice have risen slowly in the last decade, by less than the rate of inflation.
- Malpractice claims have not "exploded" in the last decade. In fact, rather than exploding, inflation-adjusted payouts per doctor dropped from 2001 to 2003. The average payment per closed claim over the last decade was $27,524, from which both the plaintiff and defense attorneys were compensated.

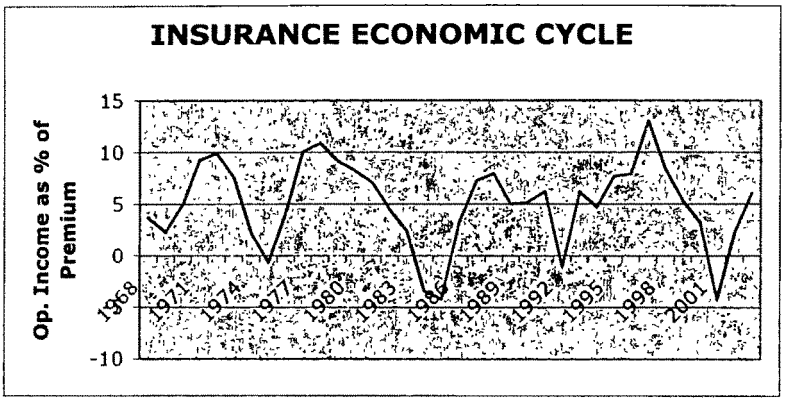
THE GOOD NEWS—STEEP MEDICAL MALPRACTICE RATE HIKES ARE OVER

The insurance industry is a very cyclical business. Insurers make most of their profits from investment income. During years of high interest rates and/or excellent insurer profits, insurance companies engage in fierce competition for premium dollars to invest for maximum return. Insurers severely under price their policies and insure very poor risks just to get premium dollars to invest. This is known as the "soft" insurance market.

But when investment income decreases—because interest rates drop or the stock market plummets or the cumulative price cuts make profits become unbearably low—the industry responds by sharply increasing premiums and reducing coverage, creating a "hard" insurance market that usually degenerates into a "liability insurance crisis."

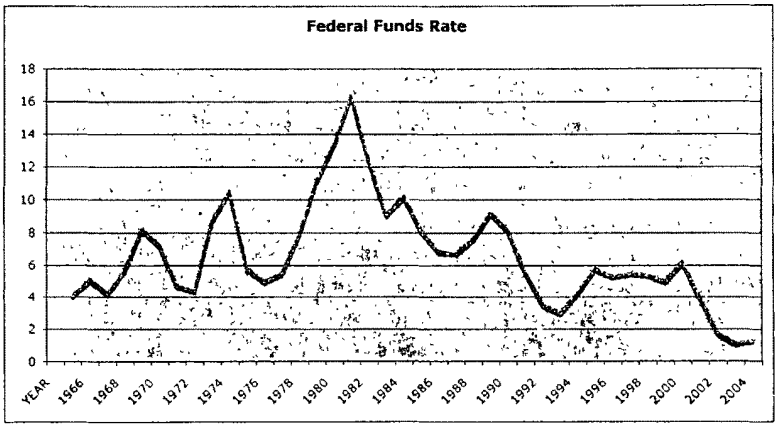
A hard insurance market happened in the mid-1970s, precipitating rate hikes and coverage cutbacks, particularly with medical malpractice insurance and product liability insurance. A more severe crisis took place in the mid-1980s, when most lines of liability insurance were affected. Again, beginning in late 2000, the country started experiencing a "hard market," this time affecting property as well as liability coverage, with some lines of insurance seeing rate increases of 100 percent or more.

The following exhibit shows the national cycle at work, with premiums stabilizing for 15 years following the mid-1980s crisis. (The 1992 data point was not a classic cycle bottom, but reflected the impact of Hurricane Andrew and other catastrophes in that year.)



Prior to late 2000, the industry had been in a soft market since the mid-1980s. The strong financial markets of the 1990s had expanded the usual six- to ten-year economic cycle. No matter how much they cut their rates, insurers wound up with a great profit year when investing the "float" on premiums in an amazing stock and bond market. (The "float" occurs during the time between when insurers receive premium payments and pay out insurance losses. There is about a 15-month lag in auto insurance and a five to ten year lag in medical malpractice.) Further, interest rates were relatively high through the 1990s as the Federal Reserve Board focused on recovery from the recession rather than inflation.

But in 2000, the market started to turn with a vengeance as the Federal Reserve cut interest rates again and again. For medical malpractice insurers, mainly investing in bonds, this sharply reduced future expectations for investment returns and was reflected in their ratemaking by raising rates.



This cut in interest rates began to take place before September 11th, as the chart above shows. The terrorist attacks sped up the price increases that were coming, collapsing two years of anticipated increases into a few months. The increases we witnessed were mostly due to the cycle turn, not the terrorist attack or any other single factor. This was a classic economic cycle bottom.

Fortunately, the hard market is over. Medical malpractice written premiums rose by only 4 percent in 2004 [1], following three years of double digit increases. We anticipate at least eight years of small medical malpractice price increases until the next economic cycle turns hard.

[1] Review and Preview, A.M. Best and Co., January 2005, Page 19.

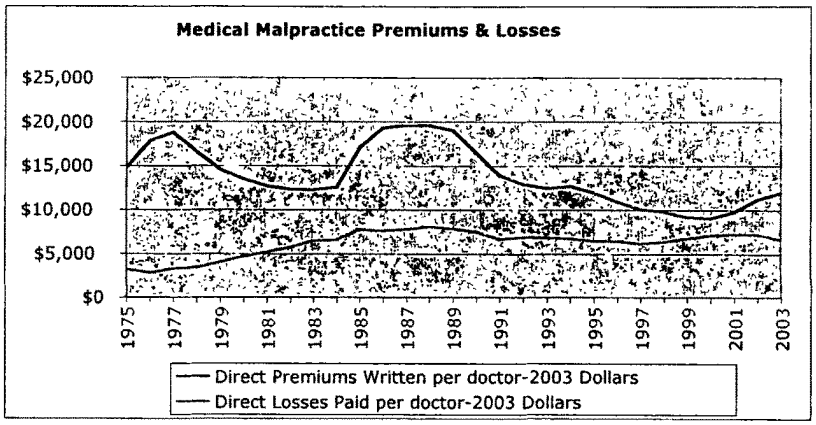
MEDICAL MALPRACTICE WRITTEN PREMIUMS AND PAID LOSSES

I have tested two hypotheses advanced by the insurance industry to justify sharp premium increases in recent years. First, if large jury verdicts in medical malpractice cases or any other tort system costs are having a significant impact on the overall costs for insurers and are therefore the reason behind skyrocketing insurance rates, then losses per doctor should be rising faster than medical inflation over time. Second, if lawsuits or other tort costs are the cause of rate increases for doctors—rather than decreasing interest rates and other economic factors—those losses should be reflected in rate increases in line with such losses, not in ups and downs that instead reflect the state of the economy, the well-documented insurance economic cycle, interest rates, the stock market or the profitability of insurers' investment income.

The data show that both hypotheses are completely false, as demonstrated in the charts below. First, these charts show that since 1975, medical malpractice paid claims per doctor have tracked medical inflation very closely (slightly higher than inflation from 1975 to 1985, and flat since). In other words, payouts have risen almost precisely in sync with medical inflation. Moreover, contrary to what the insurance and medical lobbies have alleged, the years from 2001 through 2003 saw no "explosion" in medical malpractice insurer payouts or costs to justify sudden rate hikes. In fact, rather than exploding, inflation-adjusted payouts per doctor dropped from 2001 to 2003. These data confirm that neither jury verdicts nor any other factor affecting total claims paid by insurance companies that write medical malpractice insurance have had much impact on the system's overall costs over time.

While payouts closely track medical inflation, medical malpractice premiums diverge significantly. They do not track costs or payouts in any direct way. Since 1975, the data show that in constant dollars, per doctor written premiums—the amount of premiums that doctors have paid to insurers—have fluctuated almost precisely with the insurers' economic cycle, which is driven by such factors as investment income, poor insurer business decisions and changing interest rates, not by lawsuits, jury awards, the tort system or other causes. Moreover, medical malpractice insurance premiums rose much faster in 2002 and 2003 than was justified by insurance payouts. This hike is similar to the rate hikes of the past, which occurred in the mid-1980s and mid-1970s and were not connected to actual payouts.

In sum, the results of my analysis are startling; premiums rise and fall with the insurance industry's economic cycle, but paid losses do not[2]:



"Direct Premiums Written" is the amount of money that insurers collected in premiums from doctors during that year. "Direct Losses Paid" is what insurers actually paid out that year to people who were injured—all claims, jury awards and settlements—plus what insurance companies pay their own lawyers to fight claims.

We calculate the paid losses on a per doctor basis to remove from the trend we are studying the effect of the ever increasing number of doctors in America. We ac-

[2] Sources: A.M. Best and Co. special data compilation for AIR, reporting data for as many years as separately available (premiums and losses); American Medical Assoc. (number of non-federal doctors, 1975, 1980, 1985, 1986, 1990, 1992-2002; other years estimated); Bureau of Labor Statistics (CPI).4 See Exhibit 3 for underlying data.

knowledge that the number of doctors includes a certain number of doctors that are retired or otherwise not in the medical malpractice system, but since we are interested in overall loss trends over time, and since the percentage of doctors in that category should not vary much year to year, this fact should not significantly impact our results. "Paid losses" are a far more accurate reflection of actual insurer payouts than what insurance companies call "incurred losses." Incurred losses are not actual payouts. They include payouts but also reserves for possible future claims—e.g., insurers' estimates of claims that they do not even know about yet. While incurred losses do exhibit more of a cyclical pattern, observers know that this is because in hard markets, as we are currently experiencing, insurers will increase reserves as a way to justify price increases. In fact, the current insurance "crisis" rests significantly on a jump in loss reserves in 2001. Historically, reserves have been later "released" to profits during the "softer" market years. For example, according to a June 24, 2002, Wall Street Journal front page investigative article, St. Paul, which until 2001 had 20 percent of the national med mal market, pulled out of the market after mismanaging its reserves. The company set aside too much money in reserves to cover malpractice claims in the1980s, so it "released" $1.1 billion in reserves, which flowed through its income statements and appeared as profits. Seeing these profits, many new, smaller carriers came into the market. Everyone started slashing prices to attract customers. From 1995 to 2000, rates fell so low that they became inadequate to cover malpractice claims. Many companies collapsed as a result. St. Paul eventually pulled out, creating huge supply and demand problems for doctors in many states. Christopher Oster and Rachel Zimmerman, "Insurers" Missteps Helped Provoke Malpractice "Crisis," Wall Street Journal, June 24, 2002.

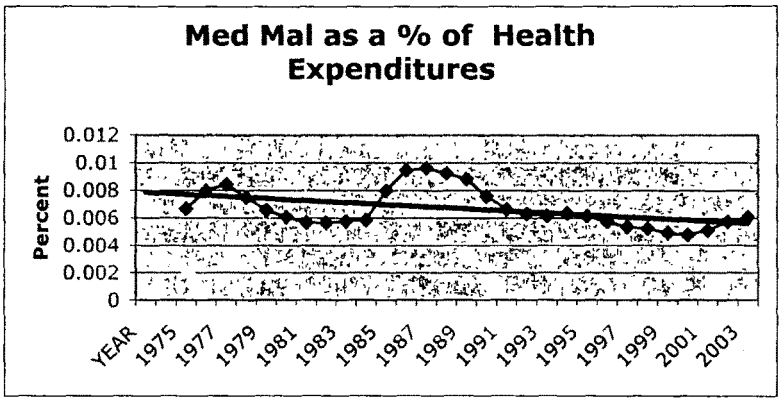
The calculations underlying this chart are attached as Appendix A.

MEDICAL MALPRACTICE HAS LIMITED IMPACT ON HEALTH CARE COST

In last decade, paid malpractice claims totaled $37.8 billion; 1.3 million claims were closed. Thus the average payment per closed claim was $27,524, from which both the plaintiff and defense attorneys were compensated.

Of the 1.3 million claims, only 352,000 received any payment. This means that only 23 percent of claimants got any money. If you were one of the "lucky" ones whose injury was severe enough and the negligence clear enough to qualify you for a payment, your payment averaged $107,000, from which your lawyers were paid. On average, about 35,000 claims per year are paid out in any way.

The relatively low overall cost of this system is shown in the following chart:



Currently, the total premiums paid by doctors and hospitals total $10.1 billion[3], compared to the Health Expenditures of $1,674 billion,[4] which means that medical malpractice premiums represent six-tenths of one percent of Health Expenditures in the nation. Note that the line of best fit shows that this tiny percentage is declining over time.

[3] A.M. Best and Co., special report, run for the Americans for Insurance Reform.

[4] Statistical Abstract of the United States, 2005 Edition, U.S. Census Bureau, 2003 is the Bureau's projection.

So, even if Congress took a step we would never advise and completely immunized doctors and hospitals from legal liability in the event of medical negligence, total health care costs in this country would hardly be affected.

WHAT SHOULD CONGRESS DO?

First, Congress should do no harm. The national problem of serious rate hikes is over for the time being, except perhaps in a couple of states. This gives Congress time to carefully study the situation and not rush to take action that would harm victims of medical negligence.

Unfortunately, medical malpractice legislation passed in 2003 by the House of Representatives, H.R. 5, would do harm to consumers of healthcare and to victims of medical malpractice. The cumulative effect of capping non-economic and punitive damages, shielding liability for some drug manufacturers, and changing joint and several liability and collateral source rules would be to remove key deterrents to dangerous medical practices. Moreover, H.R. 5 does absolutely nothing to deter physician negligence.

Part of a Congressional evaluation of medical malpractice should look at the question of why so few people hurt by medical negligence are recovering compensation for that negligence. Perhaps a review of no-fault and other mechanisms for compensating victims of medical negligence might be considered. How much would alternative systems cost? How can the system be made more efficient while fully protecting the many victims of malpractice in the nation?

Another aspect of this study should be insurance reform, which is a way for the regulators to control the harmful excesses of a business cycle that causes sudden and unjustifiable price spikes and coverage cutbacks every decade or so. We recommend looking at the system passed in California, the Proposition 103 system, which has worked wonders to hold down rates in that state.[5] For example, this system has allowed consumer representatives to successfully intervene in opposition to recently proposed rate hikes by some malpractice insurers, which has led to much lower rates for doctors. Congress should consider creating a national reinsurance facility, which would serve to stabilize the wild swings in rates that characterize the current insurance cycle. A national reinsurance facility would also make insurance more readily available by spreading the cost of large medical injuries to a national base, which does not presently occur.

Congress should also evaluate methods for reducing negligence and medical errors by physicians and medical facilities. It is well known that a very small proportion of doctors cause a very high percentage of the claims for medical malpractice. Yet many states have weak procedures for disciplining dangerous doctors and stopping them from continuing to practice, putting American consumers of health care at risk.

The 1999 report regarding medical errors by the Institute on Medicine (IOM) demonstrates that far too many Americans face the serious possibility of an injury, or even death, due to medical mistakes in the hospital. Using the IOM's low estimate of 44,000 deaths per year, medical errors are the eighth leading cause of death in this country, ahead of breast cancer and AIDS. The IOM's high-range estimate of 98,000 deaths a year would make medical errors the fifth leading cause of death, more than all accidental deaths.[6] Of course, some medical errors are directly attributable to physician negligence and some are not, but the IOM report clearly demonstrates the serious implications of rolling back the legal rights of Americans who have been harmed or killed by malpractice. If Congress gets it wrong, the pain and suffering incurred by many families across the country will only increase.

Before this Committee rushes through tort reform legislation, I urge you to get the facts. As the evidence I've presented you with today shows: (a) insurers have themselves to blame for the predicament they—and physicians and patients throughout the country—face, and (b) you have plenty of time to make sure that any action you take does no harm, given the return of the soft insurance market and very small price increases for doctors.

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[5] See "Why Not the Best," a report on how Proposition 103 works at www.consumerfed.org.

[6] To Err is Human, Building a Safer Health System, Institute of Medicine, National Academy of Sciences; November, 1999.

APPENDIX A

Year	Written Premiums (thousands)	Paid Losses (thousands)	Loss Ratio	Number of Doctors (Non-federal)	Medical Care Inflation (CPI-U)	Direct Premiums Written per Doctor	Direct Losses Paid per Doctor	Direct Premiums Written per Doctor-2003 Dollars	Direct Losses Paid per Doctor-2003 Dollars
1975	$865,208	$190,867	0.221	366,425	47.5	$2,361.21	$520.89	$14,793.63	$3,263.51
1976	$1,187,978	$188,545	0.159	381,000	52	$3,118.05	$494.87	$17,844.85	$2,832.17
1977	$1,423,091	$248,969	0.175	395,575	57	$3,597.53	$629.39	$18,782.87	$3,286.05
1978	$1,412,555	$294,456	0.208	410,151	61.8	$3,443.99	$717.92	$16,584.64	$3,457.17
1979	$1,405,991	$391,800	0.279	424,726	67.5	$3,310.35	$922.48	$14,594.96	$4,067.10
1980	$1,493,543	$521,849	0.349	439,301	74.9	$3,399.82	$1,187.91	$13,508.49	$4,719.91
1981	$1,616,470	$665,570	0.412	455,904	82.9	$3,545.64	$1,459.89	$12,728.37	$5,240.81
1982	$1,815,056	$847,543	0.467	472,507	92.5	$3,841.33	$1,793.72	$12,358.71	$5,770.92
1983	$2,033,911	$1,079,862	0.531	489,109	100.6	$4,158.40	$2,207.81	$12,301.59	$6,531.27
1984	$2,282,590	$1,197,979	0.525	505,712	106.8	$4,513.62	$2,368.90	$12,577.27	$6,600.97
1985	$3,407,177	$1,556,300	0.457	522,315	113.5	$6,523.22	$2,979.62	$17,104.06	$7,812.64
1986	$4,335,863	$1,709,883	0.394	547,222	122	$7,923.41	$3,124.66	$19,327.92	$7,622.12
1987	$4,781,084	$1,905,491	0.399	556,647	130.1	$8,589.08	$3,423.16	$19,647.27	$7,830.38
1988	$5,166,811	$2,128,281	0.412	566,072	138.6	$9,127.48	$3,759.74	$19,598.40	$8,072.85
1989	$5,500,540	$2,273,628	0.413	575,496	149.3	$9,557.91	$3,950.73	$19,051.81	$7,874.99
1990	$5,273,360	$2,415,117	0.458	584,921	162.8	$9,015.51	$4,128.96	$16,480.44	$7,547.78
1991	$5,043,773	$2,423,418	0.480	609,384	177	$8,276.84	$3,976.83	$13,916.31	$6,686.47
1992	$5,228,362	$2,808,838	0.537	633,846	190.1	$8,248.63	$4,431.42	$12,913.17	$6,937.35
1993	$5,469,575	$3,028,086	0.554	648,662	201.4	$8,432.09	$4,668.20	$12,459.73	$6,898.00
1994	$5,948,361	$3,174,987	0.534	661,960	211	$8,985.98	$4,796.34	$12,674.07	$6,764.89
1995	$6,107,568	$3,326,846	0.545	689,121	220.5	$8,862.84	$4,827.67	$11,961.82	$6,515.71
1996	$6,002,233	$3,556,151	0.592	717,335	228.2	$8,367.41	$4,957.45	$10,912.09	$6,465.10
1997	$5,864,218	$3,587,566	0.612	737,263	234.6	$7,954.04	$4,866.06	$10,090.03	$6,172.80
1998	$6,040,051	$3,957,619	0.655	757,865	242.1	$7,969.82	$5,222.06	$9,796.86	$6,419.19
1999	$6,053,323	$4,446,975	0.735	778,491	250.6	$7,775.71	$5,712.30	$9,234.05	$6,783.64
2000	$6,303,206	$4,988,474	0.791	793,211	260.8	$7,946.44	$6,288.96	$9,067.72	$7,176.36
2001	$7,288,933	$5,424,197	0.744	814,776	272.8	$8,945.93	$6,657.29	$9,759.20	$7,262.49
2002	$8,928,252	$5,806,463	0.650	831,645	285.6	$10,735.65	$6,981.90	$11,186.73	$7,275.26
2003	$10,142,575	$5,622,377	0.554	848,514	297.1	$11,953.34	$6,626.15	$11,973.46	$6,637.30

Sources: A.M. Best and Co. special data compilation for AIR, reporting data for as many years as separately available (premiums and losses); American Medical Assoc. (number of non-federal doctors, 1975, 1980, 1985, 1986, 1990, 1992-2002; other years estimated); Bureau of Labor Statistics (CPI).

Mr. DEAL. Thank you, sir.

Our next witness is Mr. James Hurley representing the American Academy of Actuaries. And Mr. Hurley, being from Atlanta, I especially welcome you here today. You are recognized for 5 minutes.

STATEMENT OF JAMES HURLEY

Mr. HURLEY. Thank you, sir.

Good afternoon, Chairman Deal, Ranking Member Brown, and members of the subcommittee. Thank you for inviting me to testify today on behalf of the American Academy of Actuaries.

The Academy is the public policy and professionalism organization for actuaries practicing in all specialties within the United States. It is nonpartisan and it assists the public policy process through the presentation of clear and objective actuary analysis. It also develops and upholds actual standards of conduct, qualification, and practice.

I will start by discussing a recent experience in the medical malpractice line of business.

During the 1990's, the medical malpractice line experienced favorable operating results contributed to by favorable reserve development on prior coverage years and healthy investment returns.

Insurers competed aggressively, health care providers shared in the benefit of improved loss experienced and higher levels of investment income through stable or decreasing charged premiums.

Recently, however, the cost of medical malpractice insurance has been rising. Rate increases have been precipitated in part by the growing size of claims, more frequent claims in some areas, and higher defense costs. The decline in bond yields has exacerbated the need for rate increases. From a financial standpoint, medical malpractice results deteriorated for several years through 2001 and have improved only slightly since then. 2004 data is not yet available but is projected to reflect similar results.

Two indicators of financial results are the combined ratio and the operating ratio. We can obtain these indicators for reporting companies from A.M. Best, a company that offers comprehensive data to insurance professionals and tracks these results. The combined ratio is an indication of how the company is doing in its insurance underwriting. For all companies reporting to A.M. Best, the combined ratio deteriorated to 155 percent for 2001, improving only to 138 percent through 2003. For underwriting, this represents a loss of 55 cents on each dollar of premium written in 2001. Preliminary projections for 2004 are for a combined ratio of 133 percent.

A measure of the overall profitability of a line of business is the operating ratio. The A.M. Best operating ratio adjusts the combined ratio for other expense and income items, primarily investment income. The operating ratio deteriorated to 134 percent in 2001, indicating a loss of 34 cents on every dollar of premium, and stands at 121 percent in 2003. Given lower interest income levels, the 2004 operating ratio will probably not improve as much as the projected improvement in the combined ratio. At these levels, 2001 through 2003 results are the worst they have been in 15 years or more, exceeding levels of the 1980's.

As is clear from this data, the loss in operating environment has deteriorated. Benefits of favorable reserve development appear to be gone, and the available investment income offset has declined. In fact, some observe that reserve liabilities may require increases to cover current ultimate loss obligations. As a result, rates for both insurers and re-insurers have increased to properly align with current loss and investment income levels. Companies failing to do this jeopardize their surplus base and financial health.

My written statement summarizes the two key drivers of financial results and their effects on operating results and surplus for some 30 companies that specialize in this coverage. These companies represent one-third of the experience, approximately one-third of the experience, reported to A.M. Best. The results for these companies are more favorable than the industry in general, but reflect similar deterioration.

In chart B, page seven of my testimony, the total after-tax operating income for these companies is shown. The favorable operating income of the earlier years, 1995—the mid-1990's, is in the 20 percent neighborhood. It declines to a slight profit in 2000, but to a loss of 8 percent in 2001, further to 11-percent loss in 2002, before improving to a 2-percent loss in 2003. Companies who continue to write medical malpractice must interpret the current experience

and determine what rates to charge for perspective coverage in light of this experience.

It should be mentioned that self-insured programs, that is trusts and captives, have also been effected by deteriorating loss and investment circumstances. These entities, insuring their own liability exposure, have experienced increased funding levels and lower yields on assets held to cover these liabilities. The impact extends beyond an insurance company problem.

Tort reform, as discussed, is one means to address the current challenges. The Academy, which takes no position for or against tort reform, has previously reviewed and commented on this subject. The observations include, one, that a package of tort reforms is more likely than individual reforms to impact on losses in premium. The key among reforms is a per medical injury, non-economic cap at a relatively low level and collateral source rule, including introduction as evidence at trial.

You should keep in mind that poorly crafted reforms can increase losses, and therefore rates, rather than decrease them. But we should also have reasonable expectations about what will happen. One is reforms may not yield immediate rate reductions, particularly given the rate increases being implemented, since the actual affect, including judicial confirmation, will not be immediately known. A non-economic cap will not affect the economic component of claim costs, and thus the severity will still likely call for increases in rates but perhaps at some lower level.

Last, such reforms should make the loss environment more predictable, encourage market participation, and reduce concerns about large, subjective, non-economic damage components to claims.

Mr. DEAL. Mr. Hurley, I am going to have to ask you—if you have a sentence or two to summarize, that would be good.

Mr. HURLEY. Just to say that the Academy appreciates the opportunity to be here, and we would be happy to provide any input we can, subsequent to the testimony here.

[The prepared statement of James Hurley follows:]

PREPARED STATEMENT OF JAMES HURLEY, MEDICAL MALPRACTICE SUBCOMMITTEE, AMERICAN ACADEMY OF ACTUARIES

INTRODUCTION

The American Academy of Actuaries appreciates the opportunity to provide comments on issues related to medical malpractice. The Academy hopes these comments will be helpful as Congress considers related proposals.

This testimony discusses what has happened to medical malpractice financial results and its likely effect on rates, tort reform, and some discussion of frequent misconceptions.

MEDICAL MALPRACTICE—WHAT HAS HAPPENED?

The medical malpractice insurance marketplace continues to be in serious turmoil. After an extended period of reported high profitability and competitiveness during the 1990s, this turmoil began with serious deterioration in financial results, continued with some consequences of these results and, still at this point, gives rise to an uncertain future. Industry-wide financial results reflect a 2003 combined ratio (the measure of how much of a premium dollar is dedicated to paying insurance costs of the company in a calendar year) of 138 percent, an improvement relative to the 2001 and 2002 results, but still well above profitable levels. The 2003 operating ratio (reducing the combined ratio for investment income) of about 116 percent extends the several year pattern of losing money after the inclusion of investment

income. Projections for 2004 are for a slightly lower combined ratio (approximately 133 percent) and probable lesser improvement in the operating ratio. This follows 2001 and 2002 operating ratios exceeding 120 percent.

The consequences of these poor financial results are several. Insurers have voluntarily withdrawn from medical malpractice insurance (e.g., St. Paul, writer of approximately nine percent of total medical malpractice insurance premium in 2000) or have selectively withdrawn from certain marketplaces or segments of medical malpractice insurance. In addition, several insurers have entirely withdrawn due to poor financial results (e.g., Phico, MIIX, Frontier, Reciprocal of America, some of which are under regulatory supervision). Overall, premium capacity has been reduced by more than 15 percent. These withdrawals fall unevenly across the states and generally affect those identified as jurisdictions with more severe problems than others.

Capacity to write business would have decreased even more if not for the fact that much medical malpractice coverage is written by companies specializing in this coverage, some that were formed for this specific purpose.

These figures focus on the published insurance industry statistics. Parallel to industry experience is the growing volume of self-insured programs (e.g., deductible programs, trusts and captives), which have significantly increased their share of the medical liability exposure "pie" over time; some would estimate this segment has responsibility for half or more of the exposure today. These self-insured entities, such as hospitals, see the dollars needed to cover their retentions increasing and are having increased difficulty securing excess or reinsurance coverage to manage their exposure.

The future outlook is not positive, at least in the short term. Claim costs are increasing more rapidly now than they were historically. Further, full adjustment to the lower interest rate and tightened capacity environment would drive higher premium rates, even if losses were not increasing. The combined effect is that there are likely to be more poor financial results and additional rate increases.

Background-Market Conditions in the 1990s

The current premium increases are hard to understand without considering the experiences of the last decade. Rates during this time period often stayed the same or decreased relative to the beginning of the period due to several of the following factors:

- Favorable Reserve Development—Ultimate losses for coverage years in the late 1980s and early 1990s have developed more favorably than originally projected. Evidence of this emerged gradually over a period of years as claims settled. When loss reserves for prior years were reduced, income was contributed to the current calendar years, improving financial results (i.e., the combined and operating ratios). That was the pattern during the middle to late 1990s for 29 provider-owned/operated medical malpractice insurers whose results are shown in Chart A. What is evident from that chart is that favorable reserve development (shown as a percentage of premium) was no longer occurring after 2001, as developments in 2002 and 2003 were unfavorable. This unfavorable development contributes to bottom line losses for these companies.
- Low Level of Loss Trend—The annual change in the cost of claims (frequency and severity) through most of the 1990s was lower than expected by insurers, varying from state to state and by provider type. This coincided with historically low medical inflation and may have benefited from the effect of tort reforms of the 1980s. Rates were established using the earlier anticipated higher loss trends and were able to cover these actual lower loss trends for a time. As a result, rate increases were uncommon and there were reductions in several states. This was justified in part because the rates established at the beginning of the last decade proved too high, inasmuch as carriers had assumed higher loss trends.

  Insurers responded to the emerging favorable loss trend in different ways. Some held rates stable and paid policyholder dividends or gave premium discounts. Some reduced filed rates. Others increased rates modestly and tried to refine pricing models to improve overall program equity. In general, however, premium adequacy declined in this period. Collected rates came into line with insurers' costs, but competitive actions pushed rates even lower, particularly in some jurisdictions.
- High Investment Yields—During the 1990s, investment returns produced a real spread between fixed income rates of return and economic inflation. Medical malpractice investment results are based on a portfolio that is dominated by bonds with stock investments representing a minority of the portfolio. Although medical malpractice insurers had only a modest holding of stocks, capital gains

on stocks also helped improve overall financial results. These gains improved both the investment income ratio and the operating ratio.

- Reinsurers Helped—Many medical malpractice insurers are not large enough to take on the risks inherent in this line of insurance on their own. The additional capacity provided by reinsurers allows for greater availability of medical malpractice. Similar to what was happening in the primary market, reinsurers reduced rates and covered more exposure, making the net results even better.
- Insurers Expanded Into New Markets—Given the financial results of the early-to-mid-1990s, some insurers expanded into new markets (often with limited information to develop rates). They also became more competitive in existing markets, offering more generous premium discounts. Both actions tended to push rates down.

What Has Changed?

Although these factors contributed to the profitability of medical malpractice insurance in the 1990s, they also paved the way for the changes that began at the end of the decade.

- Loss Trend Began to Worsen—Loss cost trends, particularly claim severity, started to increase toward the latter part of the 1990s. The number of large claims increased, but even losses adjusted to eliminate the distortions of very large claims began to deteriorate. This contributed to indicated rate increases in many states.
- Loss Reserves are Strengthened—As the losses began to deteriorate, many insurers responded by strengthening their reserves. However, as of year-end 2003, the adequacy of the aggregate loss reserve levels for the industry is still being questioned despite the reserve strengthening recorded during the 2000-2003 period. The statistics for the earlier mentioned 29 companies have been better than the total industry, to date. Some observers suggest that aggregate reserves will require further increases, particularly if severity trends continue or intensify.
- Investment Results Have Declined—Bond yields have declined from 1990's highs. The lower bond yields reduce the amount of expected investment earnings on a future policy that can be used to reduce prospective rates. A one percent drop in interest rates can be translated to a premium rate increase of two to four percent (assuming no changes in other rate components) due to the several year delay in paying losses on average. A 2.5 percent drop in interest rates, which has occurred since 2000, can translate into rate increases of between 5 percent and 10 percent. Note low investment yields may cause an insurer to reduce its market presence and also may discourage new entrants. The recent increases in yields may alleviate some of the pressure from this source.
- The Reinsurance Market Has Hardened—Reinsurers' experience deteriorated as their results were affected by increased claim severity and pricing changes earlier in the decade. Because reinsurers generally cover the higher layers of losses, their results are disproportionately influenced by increases in claim severity. This, coupled with the broadly tightened reinsurance market after Sept.—11 2001, has caused reinsurers to raise rates substantially and tighten reinsurance terms for medical malpractice.

The bottom line is that these changes have required insurers to increase rates if they are to preserve their financial health and honor future claim payments.

The Results

To obtain a better understanding of the effect of these changing conditions, we focus on the results of 29 specialty insurers that are primarily physician owned or operated and that write primarily medical malpractice business. Their results reflect the dynamics of the medical malpractice line. This sample represents about one-third of the insured exposures reported by the insurance industry in the United States.

These insurers, achieving more favorable financial results than that of the total industry, showed a slight operating profit (six percent of premiums) in 2000. This deteriorated to operating losses for years 2001 through 2003 (see Chart B), with 2002 reflecting an 11 percent loss, improving to a 2 percent loss in 2003.

There are two key drivers of these financial results:

- Insurance Underwriting—For these companies, a simplified combined ratio was calculated by dividing calendar year loss and loss adjustment and underwriting expenses by premium. On this basis, the combined ratios peaked at 134 percent in 2001, improving to 129 and 122 percent for 2002 and 2003, respectively. That means in 2003, these insurers incurred $1.22 in losses and expenses for each $1.00 of premium. The five years preceding 2000 were fairly stable, from 110

percent to 115 percent. Deterioration of the loss and loss adjustment expense ratio drove these results; the underwriting expense ratio remained relatively constant (see Chart C).

- Investment Income—Pre-tax investment income (including realized capital gains and losses) emanates from policyholder-supplied funds invested until losses are paid as well as from the company capital ("surplus"). The investment income offset to the underwriting loss is measured as a percentage of earned premiums. This statistic declined during the measurement period from the mid-40 percent level of the mid-1990s to the 20 percent level in 2002 and 2003 (see Chart D).

  This offset will continue to decline because (i) most insurer-invested assets are bonds, some of which were purchased before recent lower yields, and interest earnings do not yet fully reflect these lower yields; and (ii) the premium base is growing due to increased rates and growth in exposure. Invested assets are not increasing as rapidly as premium and, therefore, investment income as a percentage of premium will decline.

The effect of these results on surplus is reflected in Chart E, which shows the percent change in surplus from one year to the next. Surplus defines an insurer's capacity to write business prospectively and to absorb potential adverse loss development on business written in prior years (see Chart E). After three years of declines, the increase in 2003 is in part from external sources (e.g., surplus notes, capital contributions and trust preferreds).

Tort Reform

Some states enacted tort reform legislation after previous crises and in response to the current circumstances as a compromise between affordable health care and an individual's right to seek recompense. The best known is the Medical Injury Compensation Reform Act or MICRA, California's tort reform package. Since MICRA's implementation in 1975, California has experienced a more stable marketplace and lower premium increases than have most other states.

Tort reform has been proposed as a solution to higher loss costs and surging rates. Many are suggesting reforms modeled after California's MICRA, although some have cautioned against modifying the MICRA package. The Academy, which takes no position for or against tort reforms, has previously reviewed and commented on this subject. Based on research underlying the issue, we observe the following:

- A coordinated package of tort reforms is more likely than individual reforms to achieve savings in malpractice losses and insurance premiums.
- Key among the reforms in the package is a cap on non-economic awards (on a per-event basis and at some level low enough to have an effect, such as MICRA's $250,000) and a mandatory collateral source offset rule.
- Such reforms may not assure immediate rate reductions, particularly given the size of some increases currently being implemented. The actual effect, including whether or not the reforms are confirmed by the courts, will not be immediately known.
- These reforms are unlikely to eliminate claim severity (or frequency) changes but they may mitigate them. The economic portion of claims is not affected if a non-economic cap is enacted. Thus rate increases still will be needed.
- These reforms should reduce insurer concerns regarding dollar awards containing large, subjective non-economic damage components and make the loss environment more predictable.
- Poorly crafted tort reforms could actually increase losses and, therefore, rates.

FREQUENT MISCONCEPTIONS

In closing, it might be helpful to address some frequent misconceptions about the insurance industry and medical malpractice insurance coverage.

Misconception 1: "Insurers are increasing rates because of investment losses, particularly their losses in the stock market."

As we have pointed out, investment income plays an important role in the overall financial results of insurers, particularly for insurers of medical professional liability, because of the long delay between payment of premium and payment of losses. The vast majority of invested assets are fixed-income instruments. Generally, these are purchased in maturities that are reasonably consistent with the anticipated future payment of claims. Losses from this portion of the invested asset base have been minimal, although the rate of return available has declined.

Stocks are a much smaller portion of the portfolio for this group, representing about 15 percent of invested assets. After favorable performance up through the latter 1990s, there has been a decline in the last few years, contributing to less favorable investment results and overall operating results. Investment returns are still

positive, but the rates of return have been adversely affected by stock declines and more so by lower fixed income investment yields.

In establishing rates, insurers do not recoup investment losses. Rather, the general practice is to choose an expected prospective investment yield and calculate a discount factor based on historical payout patterns. In many cases, the insurer expects to have an underwriting loss that will be offset by investment income. Since interest yields drive this process, when interest yields decrease, rates must increase.

Misconception 2: "Companies operated irresponsibly and caused the current problems."

Financial results for medical liability insurers have deteriorated. Some portion of these adverse results might be attributed to inadequate knowledge about rates in newly entered markets and to being very competitive in offering premium discounts on existing business. However, decisions related to these actions were based on expectations that recent loss and investment markets would follow the same relatively stable patterns reflected in the mid-1990s. As noted earlier, these results also benefited from favorable reserve development from prior coverage years. Unfortunately, the environment changed on several fronts (loss cost levels increased, in several states significantly; the favorable reserve development ceased; investment yields declined; and reinsurance costs jumped.

While one can debate whether companies were prudent in their actions, today's rate increases reflect a reconciliation of rates and current loss levels, given available interest yields. There is no added cost for past mispricing. Thus, although there was some delay in reconciling rates and loss levels, the current problem reflects current data.

Misconception 3: "Companies are reporting financial losses to justify increasing rates."

This is a false observation. Companies are reporting financial losses primarily because claim experience is worse than anticipated when prices were set. Several companies have suffered serious adverse consequences given these financial results, including liquidation or near liquidation. Phico, MIIX, Frontier, and most recently, the Reciprocal of America, are all companies forced out of the business and in run-off due to underwriting losses. Further, the St. Paul Cos., formerly the largest writer of medical malpractice insurance, has withdrawn from this market. One reason for this decision is an expressed belief that the losses are too unpredictable to continue to write the business.

The Academy appreciates the opportunity to provide an actuarial perspective on these important issues and would be glad to provide the subcommittee with any additional information that might be helpful.

CHART A: LOSS RESERVE DEVELOPMENT AS PERCENTAGE OF PREMIUM

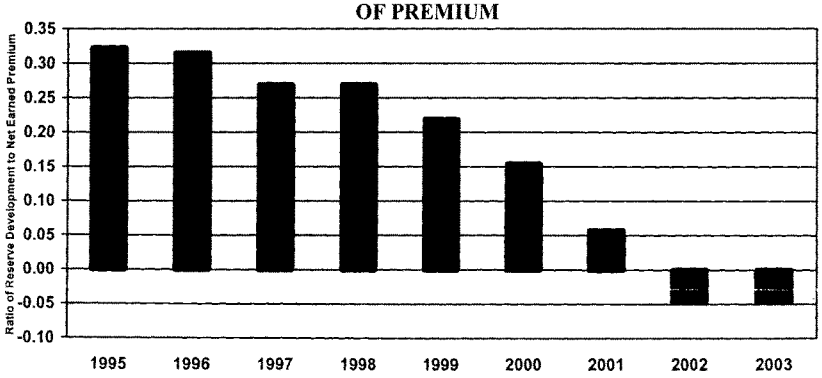


CHART B: CALENDAR YEAR OPERATING RESULTS TURN NEGATIVE

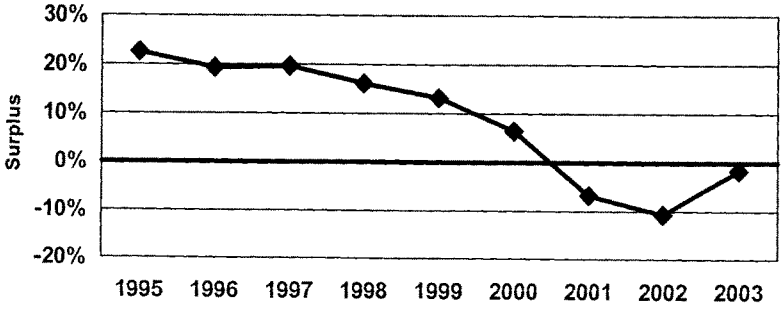


CHART C: COMBINED RATIO

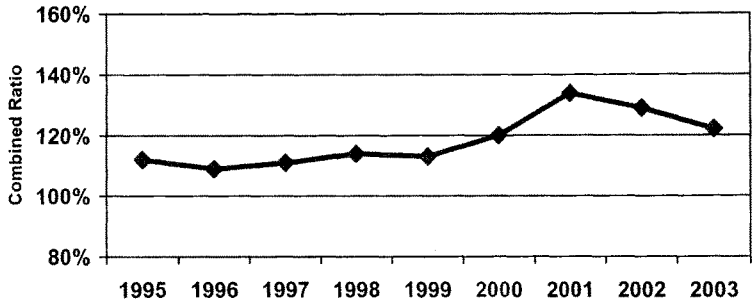


CHART D: INVESTMENT INCOME AS A PERCENTAGE OF PREMIUM DECLINES

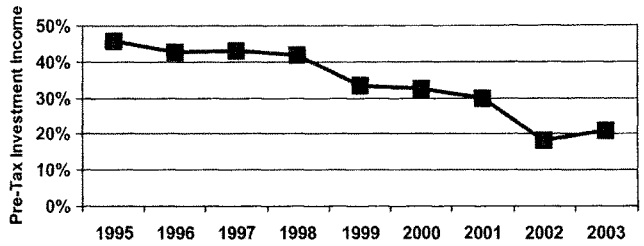
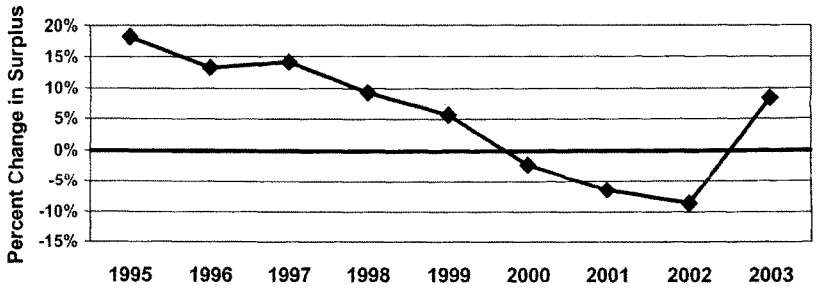


CHART E: SURPLUS CHANGE TURNS NEGATIVE



Mr. DEAL. Thank you very much.

Mr. Brown has asked us to take a break so that we can have Dr. Singh, who is one of the witnesses that is going to be on the video conference, hooked up. So I think that is a reasonable request. We will do that. We will try to do it as quickly as possible.

Mr. BROWN. Thank you. Thank you. And then he will testify after all of you, but he would—he has been at this conferencing center at Stanford for 2 hours. He also has a sick child he is trying to kind of work with, too, but he is—and then he will speak when everyone else is—he would like to listen to the testimony at least from Ms. Rosenbaum on, if possible. Thanks.

Mr. DEAL. Dr. Singh, can you hear me?

Mr. SINGH. Yes, I can hear you.

Mr. DEAL. This is Nathan Deal. I am chairman of the Subcommittee on Health. We are pleased to have you join us by way of this teleconference. We have not arrived at the point of your testimony, but I understood you wanted to hear the other witnesses that have testified. We have two that have already testified on this panel, actually three, and we will proceed in order, and you will be the fourth witness from this point forward. And we will let you know at that point. But if you can hear, you should be able to hear the other witnesses. You can still hear us——

Mr. SINGH. Yes, I can hear you.

Mr. DEAL. All right. Good.

Mr. SINGH. I can hear you, but I can't see anything.

Mr. DEAL. That is the way we like it. We thank you for being with us. If you will just listen and be patient, we will get to you in just a few minutes.

Mr. SINGH. Okay.

Mr. DEAL. Our next witness is Sara Rosenbaum from the Department of Health Policy at George Washington University Medical Center, and we are pleased to have you, Ms. Rosenbaum.

STATEMENT OF SARA ROSENBAUM

Ms. ROSENBAUM. Thank you, Mr. Chairman.

I wanted to focus my observations on H.R. 5 from the last Congress, because I assume that this might be a starting point for the committee's deliberations from here on in. And I want to quickly make just a few points.

The first is that—to the extent that caps on non-economic awards to yield savings, in the intervening 2 years since the bill passed the House, NCSL reports many more States have enacted caps on damages of varying amounts. And so the one cautionary note is simply that the impact of the caps provision probably can be expected to have declined.

A second point is that, as has been mentioned already a couple of times, H.R. 5 lacks any safety or quality provisions, which I think in the intervening 2 years, have become much more important and a much bigger part of the national dialog on health quality. And more importantly, in my view, given the purpose of this bill, the legislation really does nothing to address what I think is the most profound problem for medicine today, which is to have to be on a fault system at all. I think that a fault system, invariably, no matter how you try and deal with the fault system, produces

very poor results for everybody involved, including both the physicians and the injured patients.

The third point goes to the corporation shields that are in this bill. There is a very important shield, which the bill contains, having to do with liability for punitive damages in cases of drugs that have received pre-market approval. First of all, I will just echo the point that has already been made, I am not sure why this corporate shield is in a bill designed to help physicians deal with the high cost of malpractice premiums. More importantly, this kind of shield has been expressly disavowed as reliable evidence by the Supreme Court, in the case of another agency approval standard. And even more importantly, the shield is so large that, as I sat and thought about the magnitude of the shield for today's testimony, it occurred to me that a distributor who is involved in the deliberate tampering with drugs, would, in fact, be shielded, because the drug had FDA approval. That is obviously a complete non-secluder, and yet that is the result of H.R. 5, as it is worded.

A fourth point is that you have elected, in H.R. 5, to use a very narrow statute of limitations for medical negligence actions. Generally speaking, negligence actions do have short statutes of limitations, except in the case of medical negligence under State law, because it often takes a long time for a medical injury to reveal itself, and many States, in fact, use much longer periods than you are allowing. So that is an issue to consider.

Finally, and this is something that I observed 2 years ago when I testified as you were preparing to report H.R. 5, the legislation contains no rule of construction that reconciles its provisions with other Federal laws, and as a result, the bill has the affect of turning every civil action that happens to involve a health care corporation into a health care action. I actually don't think that is what you intend, but the result is that many, many laws that grant civil rights that protect against fraud that give private litigants rights against corporations of various kinds would be converted into health care actions under the terms of this legislation. And so I would recommend, once again, the consideration of a limiting amendment.

Thank you.

[The prepared statement of Sara Rosenbaum follows:]

PREPARED STATEMENT OF SARA ROSENBAUM, HAROLD AND JANE HIRSH PROFESSOR, HEALTH LAW AND POLICY, CHAIR, DEPARTMENT OF HEALTH POLICY, THE GEORGE WASHINGTON UNIVERSITY SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES

Good afternoon Mr. Chairman and Members of this Subcommittee. Thank you for the opportunity to testify before the Subcommittee this afternoon on the important topic of medical liability reform.

I am a professor of health law and policy at the George Washington University School of Public Health and Health Services. I have taught, studied, and written about health law for 20 years following the earlier portion of my career spent in the representation of low income individuals and families. I am the co-author of one of the nation's leading health law textbooks. Over a near-30 year time period, I have testified before Congress on a broad array of topics in health law and policy.

I would like to focus my remarks on the key elements of H.R. 5, The Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2003. It is my assumption that this legislation offers a starting point for the development of legislative policy in the 109th Congress.

The stated purpose of H.R. 5 is to "improve patient access to health care services" and "[reduce] the excessive burden" placed on health care by the current liability system. According to CBO estimates for HR 5, the impact on medical malpractice

premiums would range from 0% liability premium savings in one-fifth of all states (because of state caps already in place) to significantly higher than the 25%-30% savings norm in about a third of the states. It is important to note in the 2 years since HR 5 passed in the House, more states have moved to place limits on non-economic damages. Data available through the National Conference of State Legislatures (NCSL) indicate that as of 2004, only about a dozen states did not impose any limits. Legislative action by the end of the year may have reduced this number further. It is unclear in my view whether more than a handful of states would be affected by the recovery caps in HR 5, were it to be re-introduced at this point.

It is also important to note that HR 5 contains no provisions to either incentivize or require efforts to reduce and report on medical errors, despite the fact that the Institute of Medicine has ranked death from preventable medical errors one of the nation's leading causes of death.

In my opinion, the question thus becomes whether provisions such as those found in HR 5 can be justified in view of the bill's negligible-to-none impact on the cost of malpractice premiums, the absence of any impact on the cost of health insurance premiums, and the absence of any provisions aimed at making recoveries swifter and fairer for individuals killed or injured by preventable errors. Comparing the bill's negligible to no impact on cost and quality against heightened burdens that it places on injured persons and their families, I conclude that the answer is no.

Key Elements of H.R. 5

H.R. 5 would establish strict federal standards, including caps on non-economic damages, statutes of limitations, limits on attorney's fees, damages payouts, collateral source rules, and the procedures and standard of proof necessary to support claims of punitive damages related to malicious intent or willful and wanton disregard of patient wellbeing. Taken together, these standards can be expected to not simply curb limits on non-economic damages, but reduce access to lawyers and the courts because of the procedural constraints and severe limits on recoveries.

The FDA "Shield"

Of particular concern in my view is the shield against recovery of punitive damages (which themselves are severely limited) accorded under the legislation. The Act would prohibit any punitive damages for products that either have received pre-market FDA approval or that are "generally recognized among qualified experts as safe and effective pursuant to conditions established by" the FDA. In other words, the FDA is not required to have weighed in at all for the shield to be triggered; "general recognition" among "qualified experts" (undefined) would suffice to prevent the recovery of even modest punitive damages. Furthermore, the shield would protect not only the manufacturer but also its distributor (§ 7(c)), as well as the supplier of raw input materials in manufacturing the product. Protection would be total no matter how wanton, willful, and intentional the misconduct. *It appears that the Act would shield even negligible punitive damages, even were the claim to involve intentional product tampering by a distributor of an FDA approved drug.*

The rationale underlying the provisions such as the FDA shield in (§ 7(c))—which is irrebuttable and unprecedented in its breadth—has been explicitly rejected by the United States Supreme Court. In *Bragdon v Abbott* 524 U.S. 624 (1998), the Court refused to recognize CDC universal safety precaution guidelines as irrebuttable proof of the existence of a safety standard for professionals treating patients with HIV. The majority noted in their opinion that treating federal agency action as irrebuttable evidence of what is reasonable is unwarranted, since standards may either be incomplete or rest on an incomplete record and therefore must be independently validated by a court, through the use of objective evidence. Here, the FDA standard in question is the very pre-marketing standard that has been the subject of enormous controversy in recent months, as Vioxx and other drug approval scandals have come to light. The conflicts of interest that have emerged in these scandals undermine any notion in my view that an FDA pre-market review standard would constitute conclusive—or potentially even persuasive—evidence of reasonableness.

Statutes of Limitations

The Act imposes a three-year statute of limitations in all but the narrowest of circumstances. Many states currently use longer statutes of limitations precisely because it can take far longer for the true consequences of medical negligence to manifest themselves. As a result, many states provide for statutes of limitations substantially longer than the typical three year time period granted for ordinary negligence.

The Eclipsing of Federal Civil Rights and Other Rights

The Act contains no rule of construction reconciling its provisions with other federal laws. In essence, any claim, regardless of its underlying theory, arising out of any civil action involving health care and involving a health care provider would be subject to the limitations of the Act.

The term "health care lawsuit" is defined as

> any health care liability claim concerning the provision of health care goods or services or any medical product affecting interstate commerce, or
>
> any health care liability action concerning the provision of health care goods or services or any medical product affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, or market, promoter or seller of a medical product, regardless of the theory of liability on which the claim is based or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim. Such a term does not include a claim or action which is based on criminal liability; which seeks civil fines or penalties paid to Federal State or local government; or which is grounded in antitrust. * * * § 9(7)

A "health care liability action" means

> A civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim. § 9(8)

A "health care liability claim" means

> A demand by any person, whether or not pursuant to ADR against a health care provider, health care organization, or the manufacturer, distributor, supplier, marketer or promoter or seller of a medical product * * * which are based on the provision of, use of, payment for (or the failure to provide, use or pay for) health care services or medical products, regardless of the theory of liability on which the claim is based * * * § 9(9)

THE TERM "HEALTH CARE GOODS OR SERVICES" MEANS

> Any goods or services provided by a health care organization, provider or by any individual working under the supervision of a health care provider that relates to the diagnosis, prevention or treatment of any human disease or impairment or the assessment of the health of human beings. § 9(12)

The popular understanding of this legislation, as reflected in press coverage, is that it is intended to shield individual clinical practitioners against punishing liability judgments. However, the bill's actual reach is breathtaking because the Act contains no limiting language.

The sweep of the above-cited definitions effectively means that any claim against any health care corporation becomes a health care liability claim, thereby permitting a defendant to invoke the bill's numerous protections. The law's protections would appear to be triggered even in cases that do not involve medical injuries in the medical negligence context, simply because the defendant is a health care corporation: claims involving alleged civil rights violations; claims involving alleged acts of fraud and corruption on the part of health care companies, brought by ERISA plans or health care suppliers; and any claim that can be characterized as a "demand" against a "provider."

Mr. DEAL. Thank you. You did good on time.

Our next witness is Mr. Sherman Joyce from the American Tort Reform Association. Mr. Joyce, we will recognize you for 5 minutes.

STATEMENT OF SHERMAN "TIGER" JOYCE

Mr. JOYCE. Thank you, Mr. Chairman, Ranking Member Brown, and members of the subcommittee.

The American Tort Reform Association believes very strongly, as many of you have echoed, that the case for comprehensive medical liability reform to cover not just an individual State's, which has been referenced, but to be national in scope is very, very strong.

The American Medical Association has stated that currently 20 States in the United States are in a crisis as a result of our current medical liability system. And further, 25 more are certainly moving in that direction and very much in jeopardy of reaching that status as well.

The reason why this is happening has already been discussed, and I will just add a couple of pieces of data.

The Physician Insurers Association of America, which is the association of physician and dentist-owned mutual liability insurers that provide coverage for health care providers, has found that between 1997 and 2003, the median jury award in a medical liability case nearly doubled from $157,000 to $300,000. Over roughly the same timeframe, settlements also roughly doubled from $100,000 to $200,000. Further, in a large number of cases as the PIA has noted, actually resulted in no verdict, yet the average defense costs in these cases, because they are very complex, is nearly $88,000, which is a very high price to pay in terms of costs.

As you have discussed and has been widely reported, access to health care is threatened, and President Bush made a point of highlighting this when he visited southern Illinois last week. He was in Madison County. Madison County, a county that my organization has identified as what we call judicial hellholes. It is the worst litigation jurisdiction in the country. Its neighboring count, in St. Claire, together, in the last 2 years of seeing over 160 physicians leave their practice, and it is particularly pronounced, as you heard, very much along the lines of what the earlier panel talked about with high-risk specialties.

The American Hospital Association concluded recently that 45 percent of hospitals have reported losses of physicians, with a particular emphasis on emergency room coverage and emergency medicine coverage. You heard of the very tragic case of the young woman on the previous panel. I think that was probably the most tragic example of that particular kind of problem.

But the problems go beyond these quantifiable costs and situations. The problem of defensive medicine is a very, very real problem for us as consumers, and also particularly for the Federal Government, which expends large numbers of our tax dollars to pay for our health care system. And we see estimates of upwards of $28 billion or more could be saved in defensive medicine costs by some estimates, if we pass good medical liability legislation.

The solution, as you have heard, we believe, is on hand. It has been the law in California for nearly 30 years. And the experience there has been very, very positive. According to the National Association of Insurance Commissioners, between 1976 and 2002, insurance premiums rose for physicians outside of California three times as fast during that timeframe as they did in California. Cases settle faster, which is good for people who have claims. And the costs are lower. We think it is good for all involved.

The Medical Liability Monitor provide even more compelling data, highlighting current liability costs—liability insurance costs for physicians in Los Angeles, Chicago, and Miami. For an ob-gyn, the insurance averages to about $66,000. In Chicago, it is $147,000. And in Miami, it is $277,000. I think you can—we can all agree that that is a very serious matter. Commissioner Montemayor

talked about what is happening in Texas. They passed legislation, as have the good people in Mississippi, in response to a very real crisis there. More needs to be done at the State level.

Let me conclude by making two final points.

The first is that State reform is essential, and we certainly support, but the opportunities are somewhat limited, and a number of States have actually overturned—State courts have overturned tort reform and medical liability reform proposals on the basis of State constitutions. That alone, it seems to me, is an invitation for the Congress to address this issue.

The final matter that I would point out is that litigation generally does not involve a single plaintiff and a single defendant. It generally involves multiple parties, sometimes on both sides. We believe that the rules should apply equally to all parties. We don't think that there should be one set of rules with respect to coverage and compensation for one party and a different set for others. A fair and balanced set of rules based on what works, we think, is good public policy and encourage you to take those steps to enact that.

Thank you.

[The prepared statement of Sherman "Tiger" Joyce follows:]

PREPARED STATEMENT OF SHERMAN JOYCE, PRESIDENT, AMERICAN TORT REFORM ASSOCIATION

Mr. Chairman, Representative Brown, and Members of the Subcommittee, thank you for inviting me to speak today on behalf of the American Tort Reform Association (ATRA).

ATRA is a Washington, DC-based membership association of more than 300 large and small businesses, physician groups, nonprofits, and trade and professional associations having as its mission the establishment of a predictable, fair, and efficient civil justice system through the enactment of legislation and through public education.

INTRODUCTION

There is no doubt that the American healthcare system is the finest in the world. We have the best doctors, hospitals, and medical schools. American pharmaceutical companies are the engine of innovation in creating life-saving medicines. America has conquered polio, developed cures for serious diseases that were once death sentences, and created technologies and therapies that have not only improved the American people's health, but also the world's.

Unfortunately, we also know that our healthcare system costs are a major issue for consumers and elected officials, with annual costs increasing at double digit rates. This increase threatens the very greatness of our healthcare system, and ultimately the American people's access to world class medical care. While elected officials at the federal and state level discuss possible solutions to this problem, be they medical savings accounts or a single-payer healthcare system, one of the contributing factors to the healthcare cost problem is the crisis in our medical liability system. ATRA believes that Congress should consider reforms to our medical liability system as one of the critical elements to reform our healthcare system.

THE PROBLEM: THE CURRENT MEDICAL LIABILITY SYSTEM IS INADEQUATE

An effective medical liability system should provide predictability and fairness, guided by the over-arching principle of fairly compensating those who are truly injured by medical negligence.

Unfortunately, our medical liability system comes up short.

In our system, costs are escalating astronomically. According to the Physicians Insurers Association of America, a trade association composed of 50 insurance companies owned by doctors and dentists, the median medical liability jury award nearly

doubled from $157,000 in 1997 to $300,000 in 2003.[1] The average award also increased from $347,134 in 1997 to $430,727 in 2002.[2] The growth in settlements followed this trend, with the median settlement increasing from $100,000 in 1997 to $200,000 in 2002.[3] Average settlements increased from $212,861 in 1997 to $322,544 in 2002.[4]

In addition to sharp escalation in costs, however, the medical liability system is highly inefficient.[5] Prompt and full compensation to injured plaintiffs are the exception and not the rule. A full 70 percent of medical liability claims result in no payment to the plaintiffs.[6] Of the 5.8 percent of claims that do go to a jury verdict, defendants won 86.2 percent of the time, with an average cost to defend such lawsuits of $87,720 per claim.[7]

In addition to being expensive and inefficient, the system does a poor job of promoting patient safety. Only 1.53 percent of patients injured by medical error file claims and most claims that are filed do not involve medical malpractice.[8] Such a system plainly fails to serve the interests of all parties to litigation.

NEGATIVE POLICY IMPLICATIONS OF THE STATUS QUO

Doctors routinely order unnecessary tests and procedures to guard against the possibility of litigation in the aftermath of a bad outcome. According to a study published in the *Quarterly Journal of Economics,* the excess cost of defensive medicine contributes $50 billion annually to the cost of our healthcare system.[9] Through programs such as Medicare and Medicaid, the federal government pays tens of billions of dollars to pay the costs associated with defensive medicine. According to a recent HHS report, between $28.6 and $47.5 billion per year in taxpayer funds is spent indirectly subsidizing this system.[10] These increased costs in a financially overburdened healthcare system reduce both the access to and quality of healthcare. The root of this problem is an unpredictable litigation system in which the volatile nature of jury verdicts provides no clear signals and predictability to healthcare providers and insurers.

IMPACT ON PHYSICIANS

The current costs of the litigation system impose burdens on taxpayers and individual physicians. This compromises innovation in delivering improvements to patient safety. The result is a medical liability system that is too costly, offers little deterrent value, and, at best, does little to promote improvements in patient safety. For example, the American Hospital Association has reported that 45 percent of hospitals have lost physicians and/or reduced coverage in emergency departments due to the medical liability crisis.[11] Stories about individual physicians are equally compelling. For example, after serving 30 years as medical director for Forsyth County Emergency Medical Services of North Carolina, Dr. Lew Stringer resigned his position in 2003 due to the lack of availability of affordable malpractice insurance.[12] And in Missouri, family physician Dr. Donald Maples closed his practice after serving the community of Kirksville for 14 years because of the high cost of his medical liability insurance. Commenting on his experience, Dr. Maples said, "I expected to be here until I was in my mid-60s, but the reality is that I can no longer really truly afford to do this."[13]

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[1] PHYSICIANS INSURERS ASSOCIATION OF AMERICA, PIAA CLAIM TREND ANALYSIS: 2003 ed. (2004) [hereinafter "PIAA TREND ANALYSIS" (2004)].

[2] *Id.*

[3] *Id.*

[4] *Id.*

[5] Fifty-eight cents from every dollar recovered goes to administrative and defense costs, as well as attorneys' fees. *See* COUNCIL OF ECONOMIC ADVISERS, WHO PAYS FOR TORT LIABILITY CLAIMS? AN ECONOMIC ANALYSIS OF THE U.S. TORT LIABILITY SYSTEM 9 (April 2002).

[6] *See* PIAA TREND ANALYSIS (2004), *supra* note 1.

[7] *Id.*

[8] *See* OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CONFRONTING THE NEW HEALTH CARE CRISIS: IMPROVING HEALTH CARE QUALITY AND LOWERING MEDICAL COSTS BY FIXING OUR MEDICAL LIABILITY SYSTEM 11 (Jul. 24, 2002) [hereinafter "HHS REPORT (2002)"] .

[9] David Kessler and Mark McClellan, *Do Doctors Practice Defensive Medicine?* QUARTERLY JOURNAL OF ECONOMICS, May 1996, at 387-388.

[10] *See* HHS REPORT (2002), *supra* note 8, at 7.

[11] AMERICAN HOSPITAL ASSOCIATION, PROFESSIONAL LIABILITY INSURANCE SURVEY (2003).

[12] WINSTON-SALEM JOURNAL, June 3, 2003.

[13] KTVO, April 30, 2004.

PATIENT ACCESS TO HEALTHCARE IS COMPROMISED BY CURRENT LIABILITY SYSTEM

A survey of physicians showed that over 76 percent believed malpractice litigation affected their ability to provide quality healthcare.[14] According to the American Medical Association (AMA), 20 states are in the midst of a healthcare liability crisis, while another 25 states show problem signs that indicate a crisis is imminent. ATRA believes that this litigation environment has resulted in many physicians stopping the practice of medicine, abandoning high-risk parts of their practices, or moving their practices to other states. The public has taken notice, as well. According to a nationwide survey commissioned by the Health Coalition on Liability and Access, 82 percent of Americans believe doctors are leaving their practices due to unaffordable malpractice premiums caused by excessive litigation.[15]

For example, on January 10, 2005, Mercy Hospital of Wilkes-Barre, Pennsylvania, stopped delivering babies because of the retirement of several OB/GYNs due to the high cost of medical liability insurance.[16] Pennsylvania has been hit hard by the medical liability crisis, with a 2004 poll suggesting that one in four patients have changed doctors in the Keystone state due to the medical liability crisis.[17]

In early January, President Bush visited Southern Illinois to discuss the medical liability crisis. The President pointed out that Madison and St. Clair Counties[18] had lost about 160 doctors over the last two years due to the medical liability crisis.[19] High-risk specialists have been particularly hard hit; in 2004, the last two brain neurosurgeons in Southern Illinois resigned their posts at Neurological Associates of Southern Illinois because their malpractice insurance premiums were approaching $300,000.[20]

SOLUTION

Fortunately, there are proven policy changes that Congress can enact to abate this liability crisis. These laws can ensure Americans will continue to enjoy high quality medical care. At the same time, these reforms will protect the rights of patients in cases of true medical negligence. As Congress contemplates a legislative remedy, ATRA believes that any such legislation should apply to all defendants in healthcare actions. Doing so will ensure that all parties in a claim are treated equitably in the civil justice system.

The solution to the medical liability problem was devised over 25 years ago in California with reforms called the Medical Injury Compensation Reform Act, better known as MICRA. Like much of the United States today, California experienced a medical liability crisis in the early 1970s. By 1972, a sharp increase in litigiousness ensured that California medical malpractice insurance carriers were paying claims well in excess of dollars that they collected in premiums. The crisis continued to worsen. By 1975, two major malpractice carriers in Southern California notified physicians that their coverage would not be renewed. At the same time, another insurer announced that premiums for Northern California physicians would increase by 380 percent.[21] In response to the crisis, then-Governor Jerry Brown called the California Legislature into special session to develop solutions. The result was MICRA.

Signed by Governor Brown in 1975, MICRA's centerpiece is a single cap of $250,000 on noneconomic damages.[22] Other provisions of MICRA include: (1) allowing collateral source benefits to be introduced into evidence; (2) permitting the peri-

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[14] *See* HHS REPORT (2002), *s*upra note 8, at 4.

[15] *See* Health Coalition on Liability and Access, available at http://www.hcla.org/factsheets/2004-HCLA-Poll-(Fact%20Sheet).pdf.

[16] WILKES-BARRE CITIZENS VOICE, January 8, 2005.

[17] *See* Pennsylvania Economy League, available at http://www.issuespa.net/polls/point/10295/10281/.

[18] The American Tort Reform Foundation published an analysis of the worst trial court jurisdictions in the country, known as "Judicial Hellholes®" where the law is applied in a systematically unfair and unbalanced manner, generally against defendants. Madison County is ranked as the number one Judicial Hellhole in the United States, with Saint Clair County being ranked as number two. The 2004 Judicial Hellholes report is available at http://www.atra.org/reports/hellholes/report.pdf.

[19] *President Discusses Medical Liability Reform,* available at http://www.whitehouse.gov/news/releases/2005/01/print/20050105-4.html.

[20] UPI, February 25, 2004.

[21] *See* Californians Allied for Patient Protection, MICRA Information, July 1, 1995, at 10.

[22] Noneconomic damages are monetary awards intended to compensate the plaintiff for subjective losses such as physical pain and suffering, mental anguish, loss of body function, disfigurement, or emotional distress. This differ from economic damages which are monetary awards intended to compensate the plaintiff for objective quantifiable losses such as property loss, medical expenses, lost wages, or lost or impaired future earnings capacity.

odic payment of judgments in excess of $50,000; (3) allowing patients and physicians to contract for binding arbitration; and (4) limiting attorney contingency fees according to a sliding scale.

CALIFORNIA—A COMPARISON

Evidence indicates that MICRA's success has stabilized insurance rates in California by limiting overall damages and by substantially diminishing the unpredictability—the volatility—of judgments. For example:

- From 1976 through 2002, malpractice premiums in California rose 245 percent. In the rest of the country, premiums increased 750 percent;[23]
- Medical liability lawsuits in California settle on average in 1.8 years, while the same lawsuits in states without limits on noneconomic damages settle on average in 2.4 years—33 percent longer;[24] and
- Medical liability lawsuits in California settle for an average of $15,387; the same lawsuits in states without limits on noneconomic damages settle for an average of $32,714—53 percent more.[25]

While these figures make the case that MICRA has worked, an even more compelling argument for its success can be made by comparing malpractice rates for California physicians with their counterparts in other major metropolitan areas of states without MICRA-style reforms.[26] For example:[27]

- A Los Angeles area internist pays $13,808; an internist in Chicago pays $38,424, and in Miami pays $69,310;
- A Los Angeles area general surgeon pays $40,436; a general surgeon in Chicago pays $102,700, and in Miami pays $277,241; and
- A Los Angeles OB/GYN pays $66,100; an OB/GYN in Chicago pays $147,540, and in Miami pays $277,241.

MICRA has ensured that those injured by medical negligence receive fair compensation, but it also has ensured that the market for medical liability insurance has remained stable and affordable. As a result, California has been largely immune from the liability crisis endemic to other states.

RECENT EXAMPLES OF REFORMS: MISSISSIPPI AND TEXAS

Over the last two years, Mississippi and Texas passed significant medical liability reform legislation to rein in skyrocketing malpractice premiums. In July 2004, Mississippi Governor Haley Barbour signed House Bill 13, comprehensive civil justice reform legislation, which contained significant medical liability reform provisions. One of the key provisions was a $500,000 limit on noneconomic damages in medical liability cases. Positive results are already being seen as the Medical Assurance Co. of Mississippi, which insures approximately 60 percent of doctors in Mississippi, did not raise base premium rates for 2005.[28] The story is much the same in Texas. In the summer of 2003, Governor Rick Perry signed House Bill 4, comprehensive civil justice reform legislation containing meaningful medical liability reform, including a $750,000 limit on noneconomic damages ($250,000 per healthcare provider). As a result, the largest medical malpractice provider in the state, the Texas Medical Liability Trust, lowered rates by 12 percent for 2004 and an additional 5 percent for 2005.[29] According to Lieutenant Governor David Dewhurst, 13 new companies have started writing policies in Texas.[30] The recent experiences of both Misssissippi and Texas confirm that MICRA-style reforms have a positive impact in reining in medical malpractice rates.

OPPONENT ARGUMENTS ARE INCOMPLETE

Opponents of medical liability reform claim that the "access to healthcare" problem is a myth and that MICRA-style reforms are not the solution to rising mal-

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[23] *See* American Medical Association, Medical Liability Reform-Now!, December 3, 2004, at 40.

[24] See The Doctors' Company, What is MICRA?, available at http://www.thedoctors.com.

[25] *See* Californians Allied for Patient Protection, MICRA: A Successful Model for Affordable and Accessible Health Care, available at http://www.micra.org.

[26] The Florida Legislature passed medical liability reform, CS SB 2-D, during special session in August 2003. The bill contained a high cap on noneconomic damages. CS SB 2-D became effective on September 15, 2003.

[27] Rates are for 2004, $1/$3 million coverage as reported by Medical Liability Monitor. Los Angeles rates reported from SCPIE Indemnity Co., Chicago rates reported from Illinois State Medical Ins. Services, Inc., and Miami rates reported from First Professional Insurance Company.

[28] *See* HATTIESBURG AMERICAN, October 10, 2004, at 8.

[29] *See* HOUSTON CHRONICLE, September 21, 2004, at 5.

[30] *Id.*

practice premiums. One of the most common arguments they advance is that malpractice rates are increasing because insurance companies are making up for investment losses suffered in the stock market bubble in the late 1990s. They further argue that insurance carriers are gouging doctors with rate increases to boost profits.

A brief examination of the evidence, however, suggests otherwise. A report by the investment and asset management firm Brown Brothers Harriman examined the investment mix of medical liability insurance carriers and the effect those investments had on premiums. The Brown Brothers report found no relationship between losses suffered by carriers in the stock market and rising premiums, "As medical malpractice companies did not have an unusual amount invested in equities and since they invested these monies in a reasonable market-like fashion, we conclude that the decline in equity valuations is not the cause of rising medical malpractice premiums." [31]

In addition, more than 60 percent of physicians obtain insurance through physician owned and operated companies.[32] These companies began to form in the 1970s when commercial carriers were exiting the medical liability insurance market due to unexpected losses, leaving healthcare providers no other options but to form their own insurance companies. These companies compete with commercial carriers and return excess revenue to policy holders, the owners of the companies. The contention that malpractice premiums are increasing in an effort to boost profits is, in essence, asking us to believe that a majority of doctors are "gouging" themselves and picking their own pockets. A reasonable examination can reach only one conclusion: medical liability insurance premiums are increasing because of higher costs and instability of our current litigation system, which does not allow carriers to accurately predict future losses and provide reasonable pricing of liability policies. Insurers price their product on cost and risk. It is logical to infer that a medical liability system that is more expensive and more volatile will necessarily be more expensive to insure.

A 2003 Government Accounting Office (GAO) study examined the impact of the medical liability system on access to healthcare. The report acknowledged that states that limit noneconomic damages have enjoyed a lower rate of increase in medical liability insurance rates than states with more limited reforms.[33] As our opponents are quick to point out, however, the report also alleged that there is little evidence to suggest that states with no limits on damages have a healthcare access problem. [34]

The report is incomplete. GAO examined only a limited number of states, 5, and not the entire 18 then in crisis, as identified by the AMA at the time that the GAO conducted its examination. It has never been ATRA's position that the effects of the medical liability crisis are uniform. Many variables drive the crisis, including the type of medical specialty, the physician's location (urban, rural, or suburban), and the overall litigation environment of a particular region. In some areas and among some specialties, the effects of the current crisis are minimal; in other areas, and many other specialties, the effects of the crisis are profound.

CONCLUSION

Members of Congress should examine the medical liability system and assess the effects that current cost escalation and litigation will have on the future. ATRA believes such an examination inevitably leads to the conclusion that the costs associated with the current system are unsustainable and that MICRA-style reforms must be enacted. Such reforms are in the best interests of patients, taxpayers, physicians, and plaintiffs. And these reforms should apply to all defendants in litigation. As Californians can attest, strong medical liability reforms create a system that strikes the correct balance between fairly compensating victims of medical negligence with a liability market that stabilizes premiums for physicians. This reform will go a long way toward enhancing and protecting access to healthcare. Lawmakers should not wait to act until a full-blown crisis is verified by a government report. It is the responsibility of elected officials to take remedial and, if necessary, preventive action to ensure that such a crisis never occurs.

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[31] Raghu Ramachandran, Brown Brothers Harriman & Co., Did Investment Affect Medical Malpractice Premiums? (January 2003).

[32] *See Patient Access: The Role of Medical Litigation Before a Joint Hearing of the United States Senate Judiciary Committee and Health, Education, Labor and Pensions Committee* (Feb. 11, 2003) (statement of Lawrence E. Smarr, President, Physician Insurers Association of America).

[33] *See* GOVERNMENT ACCOUNTING OFFICE, MEDICAL MALPRACTICE: IMPLICATIONS OF RISING PREMIUMS ON ACCESS TO HEALTH CARE 5 (August 2003) [hereinafter "GAO Report" (2003)].

[34] *See* GAO Report (2003), *supra* note 33, at 5.

Thank you for your attention, and I would be happy to answer any questions.

Mr. DEAL. Thank you.

Our next witness is Dr. Joseph Glenmullen from the Harvard Law School. Dr. Glenmullen, we are pleased to have you, and you are recognized for 5 minutes.

STATEMENT OF JOSEPH P. GLENMULLEN

Mr. GLENMULLEN. Thank you, Mr. Chairman.

I am here particularly to talk about the pharmaceutical company shield that is under discussion. I am a psychiatrist who practices at the Harvard Law School Health Services and also in private practice. I am on the faculty at Harvard Medical School and the author of two books on antidepressant side effects: "Prozac Backlash" and "The Antidepressant Solution." I am very much a moderate in the debate about antidepressants, because I prescribe the drugs to many patients who have reported their benefits, but I have been a critic of patients not being adequately warned about their side effects.

I am sure you are aware of the historic 2005 FDA warning. It is a black box warning that antidepressants can make children and adolescents suicidal, especially whenever the dose changes, and that this is suicidality over and above any that results from the underlying illness. Numerous families testified at the FDA hearings last year about losing children or having children survive this terrible side effect, and I am here because I have witnessed this side effect firsthand in patients who I was treating and know full well how important it is for doctors to be well educated about how to differentiate antidepressant-induced suicidality from the suicidality that can occur in depression.

Unfortunately, both the FDA and the pharmaceutical industry knew over a decade ago about this side effect. Shortly after Prozac, the first of today's antidepressants, was introduced in the early 1990's, there were multiple reports in prominent medical journals and media attention greater than there is today. The FDA held a hearing in September 1991 at which, unfortunately, the issue was swept under the carpet. Numerous conflicts of interest among the committee members the FDA appointed. But despite that, one-third of them voted in 1991 for a warning and repeatedly called for additional research.

I have given you some documents in the slide preparation of internal Eli Lilly documents that came out of lawsuits against the company, showing that Eli Lilly agreed in the early 1990's to do the gold standard research, developed a full protocol for the study, involved as many as 100 scientists, and as part of the effort, developed a more sensitive scale for assessing antidepressant-induced suicidality. Unfortunately, once the media attention died down, Eli Lilly never did the study, saying in a later lawsuit that it was mooted by the FDA hearing, but anyone who reads the transcript of that hearing would know how untrue that is.

The FDA not only failed to get the study done, but it failed to have other companies that had new antidepressants in the pipeline adopt the more sensitive scale for assessing antidepressant-induced suicidality.

These are just a few of countless internal company memos that have literally changed health care, literally changed the way doctors and I can diagnose antidepressants' side effects and treat them and, therefore, save lives and also contributed to the momentum that resulted in the 2005 warnings. Without these lawsuits, we would be without a vital avenue for protecting the public.

The FDA has still not done enough to protect American children. It hasn't adequately filled out the warning in terms of the relationship between antidepressant-induced suicides and antidepressant withdrawal reactions. It hasn't done enough to limit off-label prescribing of the drugs. Only Prozac is approved for depression in children, and yet a million American children are taking all kinds of other antidepressants for everything from shyness to headaches to school anxiety to attention deficit disorder. I don't understand how the FDA can let this happen after acknowledging that these drugs can make children suicidal.

The FDA has also failed to adequately educate the public and doctors about the meaning of this side effect and how to differentiate it from underlying suicidality of depression. In fact, the most dangerous scenario is when neither doctors nor patients are well informed about this side effect. Patients get it, deteriorate, and think, "Oh, my God, the miracle cure that has worked for millions of people is not working for me," and are at serious risk to kill themselves.

This side effect can happen to anyone on an antidepressant, even people doing well on a stable dose. The research shows that most patients will forget to take their antidepressant for 2 or 3 days, and with many of these drugs, that is all it takes to be in severe antidepressant withdrawal, which can make people suicidal.

I really think that the issue of the pharmaceutical company shield—I hope you will think of it as a very personal question. What if one of your children or one of your grandchildren was under consideration for an antidepressant? Would you want the doctors treating them to have all of the information that the pharmaceutical companies have about these drugs, or would you prefer that the pharmaceutical companies control access to that information and withhold much of it, as we have learned in the last decade? If you would want doctors treating your family members to have access to this information, please do not vote along partisan party lines. Instead, vote to protect this vital source of protection for the American public.

Thank you very much.

[The prepared statement of Joseph P. Glenmullen, follows:]

Antidepressant-Induced Suicide and Tort Reform

Joseph Glenmullen, MD
Congressional Hearing
Energy and Commerce Committee
February 10, 2005

Joseph Glenmullen, MD

- Psychiatrist at the Harvard University Health Services
- Psychiatrist in private practice
- Clinical Instructor in Psychiatry, Harvard University
- Author of *Prozac Backlash (2000)*
- Author of *The Antidepressant Solution (2005)*

A Moderate in the Antidepressant Debate

- I prescribe antidepressants to countless patients who have reported their benefits
- I have been a critic of the drugs being over-prescribed for mild, even trivial conditions
- And of patients not being adequately warned about their side effects

FDA's Historic 2005 Black Box Warning

- Antidepressants can make children and adolescents suicidal "especially at the beginning of therapy or when the dose either increases or decreases," i.e. whenever the dose *changes*

FDA's Historic 2005 Black Box Warning

- The over-stimulating side effects of antidepressants that can make children suicidal include: "anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania"

According to the FDA

- Antidepressant-induced suicidality "is beyond the suicidality as a result of the disease."

The FDA Warning on Adults

- Adults may also be vulnerable to antidepressant-induced suicidality but the FDA is not yet finished studying the adult data
- Much of the FDA warning applies to adults, but the black box only applies to children and adolescents

Numerous Families Testified at the 2004 FDA Hearings on Antidepressant-Induced Suicide

- Many of the families have lost children to this side effect
- Others have children who survived
- The testimony was dramatic, moving, and demonstrated that distinct pattern of over-stimulating side effects leading to suicide and violence

I Have Witnessed This Side Effect First Hand in Patients Who I Treat With Antidepressants

Doctors Need to Be Well Educated about Antidepressant-Induced Suicidality in Order to Distinguish it from the Suicidality of Depression

FDA's Historic 2005 Warning

- Covers all 32 antidepressants currently on the American market including
- Prozac, Zoloft, Paxil, Celexa, Lexapro, Effexor, Cymbalta, Wellbutrin, Remeron, Luvox

The FDA and Pharmaceutical Industry Knew About This Side Effect Over a Decade Ago

In the Early 1990s Shortly after Prozac Was Introduced

American Journal of Psychiatry

New England Journal of Medicine

Archives of General Psychiatry

Journal of Family Practice

Journal of the American Academy of Child and Adolescent Psychiatry

Human Psychopharmacology

Journal of Family Practice

FDA Held a September 1991 Hearing on Prozac-Induced Suicide

But...

- The FDA waived its own standards for conflicts-of-interest for 5 of the 9 committee members and 4 of the 6 consultants because of their ties to the pharmaceutical industry

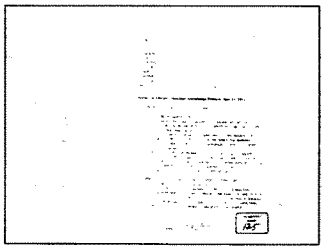
Despite the Conflicts-of-Interest

- One-third of the committee members voted for a warning back in 1991

The 1991 Committee Repeatedly Called for More Research

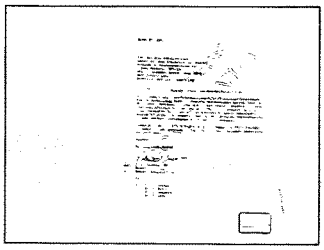
Eli Lilly Agreed to Do the Gold Standard Research

- May 13, 1991 internal Eli Lilly memo
- On meeting with FDA and agreeing to do the research
- Obtained in Prozac suicide lawsuit



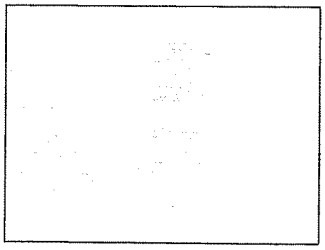
Lilly Developed the Study Protocol

- March 29, 1993 internal Eli Lilly memo
- Full protocol for the study
- Obtained in Prozac suicide lawsuit



Lilly Submitted the Protocol to the FDA

- Deposition of Dr. Charles Beasley, Lilly scientist
- In Prozac suicide lawsuit
- November 8, 2000

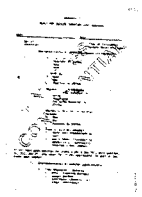


Lilly Involved as Many as 100 Scientists

- Deposition of Dr. Charles Beasley, Lilly scientist
- In Prozac suicide lawsuit
- November 8, 2000

Lilly Developed a More Sensitive Scale for Assessing Antidepressant-Induced Suicidality

- As part of the study protocol
- March 29, 1993 internal Eli Lilly memo on the protocol
- Obtained in Prozac suicide lawsuit



Once the Media Attention Died Down Lilly Never Did the Study

Lilly Claimed the Study Was "Mooted" by the 1991 FDA Hearing

- Eli Lilly interrogatory
- Obtained in Prozac suicide lawsuit

FDA Failed to Get the Study Done

FDA Failed to Have Other Companies with New Antidepressants in the Pipeline Adopt the More Sensitive Scale for Assessing Antidepressant-Induced Suicidality

Countless Internal Pharmaceutical Company Documents

- Obtained in lawsuits involving antidepressant-induced suicide and violence
- Are responsible for the momentum leading up to the FDA's historic 2005 warning in which the agency finally admitted this side effect

The Internal Company Documents

- Have allowed researchers like myself who were writing about this side effect long before the FDA finally acknowledged it in 2005

The Internal Company Documents

- Have saved people's lives
- Because they have changed the way doctors like myself diagnose and treat these severe antidepressant side effects

In 2003 the FDA Lagged Behind the British MHRA Which Virtually Banned Many Antidepressants for Children and Adolescents

Without Lawsuits Against the Pharmaceutical Industry, a Vital Avenue for Protecting the Public Would Be Lost

The FDA Has Still Not Done Enough to Protect American Children

The FDA's Warning Does Not Adequately Spell Out the Link to Antidepressant Withdrawal Reactions

- The warning describes changes in the dose as the most dangerous period but falls short of spelling out the link to antidepressant withdrawal reactions

Mosholder Report

- Internal FDA report originally suppressed in 2004 by the FDA but leaked to the media
- Specifically said the link to antidepressant withdrawal reactions needs to be further investigated
- The FDA has apparently not pursued this key link

The FDA Has Not Done Enough to Limit Off-Label Prescribing of Antidepressants to Children

- A recent study showed that as many as 89% of antidepressant prescriptions for children are "off-label"

Only Prozac Is Approved by the FDA for Depressed Children

All Other Antidepressants Studied Have Failed to Be More Effective than Placebo (Dummy) Pills for Depressed Children

The FDA Failed to Tell Doctors in the Drug Labels that They had Been Studied and Failed

One Million American Children Are on Antidepressants for Everything from Shyness to School Anxiety to Headaches to Attention Deficit Disorder

How Can the FDA Allow This to Happen When It Has Acknowledged That the Drugs Can Make Children Suicidal?

The FDA Has Failed to Adequately Educate Doctors and the Public

- Family doctors write 70% of prescriptions for antidepressants and know little about how to diagnose and treat antidepressant-induced suicidality

The Most Dangerous Scenario:

When Neither the Doctor Nor the Patient Knows How to Recognize Antidepressant-Induced Suicidality

This Side Effect Can Happen to Anyone, Even People Doing Well on a Stable Dose

- The research shows the majority of patients routinely forget to take their antidepressant
- Missing just one or two day's doses may throw patients into severe withdrawal that can lead to suicidality and violence

What if Doctors Were Considering an Antidepressant for Your Child or Grandchild?

- Would you want the doctors to be informed about this side effect and how to keep your child safe?
- Or, would you want pharmaceutical companies to control all the information and keep it out of public view?

If You Would Want Doctors to Know...

- Please do not vote along partisan lines
- Instead, use your power as legislators to preserve lawsuits against pharmaceutical companies, a vitally important check and balance in the system

Mr. DEAL. Thank you.

Have we got Dr. Singh's microphone turned on on the other side? Dr. Singh, you can still hear me?

Mr. SINGH. Yes, I can hear you.

Mr. DEAL. All right. Well, we are to your point in the testimony. And Dr. Singh is an adjunct professor of medicine at Stanford University, and we are pleased to have you, and we thank you for your patience in waiting on us to get to you.

Now you have the feeling that most politicians have when they are being interviewed. That is, you can't see us, but we can see you.

We are pleased to having you recognized for 5 minutes.

STATEMENT OF GURKIRPAL SINGH

Mr. SINGH. Thank you very much, chairman, ladies, and gentlemen.

I am a rheumatologist by clinical training with research interests and expertise in drug safety and epidemiology. My complete background, as well as my complete testimony, are made available to you, and you should have photocopies of those. I am not going to read all of it in—because I only have 5 minutes, and I would only highlight some important significant features of my testimony. But I would be happy to answer questions on any of the points that I have raised in my written testimony.

I have been specifically asked to comment on the notion that the FDA represents an effective, concerned, and independent regulatory entity that can be relied upon to require and accurately analyze, in a timely manner, all information necessary to assess a drug or a device's safety and efficacy profile and that it promptly informs the prescribing and patient community through complete and accurate and understandable labeling.

I will use the case example of Vioxx to illustrate some of the points made in this particular statement.

First of all, let me start by stating for the record my admiration for the FDA scientists and medical reviewers. They are clearly some of the smartest individuals in the medical field and have dedicated their lives to public service. They work long hours in jobs that are mostly invisible to the public they try to protect for salaries that are a fraction of what they could make outside the FDA. But they work within a system that is far from perfect, witness the Vioxx and antidepressant episodes.

The first problem is that clinical trials designed before the approval of a drug are not designed to study drug safety. They are designed, in the current system, only to look at drug efficacy. This means that there are a small number of patients who are followed for short periods of time in selected populations and therefore you would be very likely to miss early safety signals.

To assess safety, we need to do studies after the drug's approval, the so-called post-marketing studies, but these are rarely completed. You saw an example from the previous speaker as well. In the current system, a drug is considered safe until proven otherwise. While this system does bring rapid drug approval, it raises the possibility of sometimes causing serious harm.

No. 2, and this is the problem, the system is designed for rapid drug approval, not a careful review of drug safety. For example, in the case of Vioxx, you will see medical testimony that I will quote these reviewers from the Food and Drug Administration who pointed out that there were already significant problems with heart attacks, a threefold increase in the risk of heart attacks, seen in the data that Merck submitted to the FDA for the approval of the drug. And the reviewer went on to say that this available data, the studies are still very small, and it is impossible to answer, with complete certainty, whether the risk of cardiovascular and thromboembolic events is increased in patients on Rofecoxib. And she says a larger data base will be needed to answer this and other safety comparison questions.

So what happens next? Does the FDA require Merck to conduct larger and more definitive studies? No. Remember, the system is designed for rapid drug approvals. So the drug is approved quickly by the FDA and applied to review within 6 months with no discussion of the heart attack tradeoff. The system works at a cost that we will all know many years later.

No. 3, there is no mechanism for conditional or time-limited approval. Once a drug is approved, the FDA has little power to force a drug company to do safety studies. Again, I will give you repeated examples in my written testimony when this happened with Rofecoxib. The FDA repeatedly noted that adequately powered and prospectively designed studies are necessary to address the cardiovascular safety issues with Vioxx. But Merck would not do that and, in fact, canceled the only study that could have provided an answer in 2002, and the reason is because they said it would send the wrong marketing and public relation signal. Why ask the question if you do not want to know the answer? Instead, they proposed a pooled analysis of ongoing clinical trials, which is not a very effective way to look for these signals. And the FDA recognized that, but really did not have any way of forcing the drug company to do safety studies.

So life goes on, millions of people keep on taking the drug, the drug company makes billions of dollars of profits, nobody knows what is happening, and the band plays on.

No. 4, there is no good mechanism of informing the prescribing physician or the public of FDA's concerns. Again, to look at the Vioxx example, the drug company had unlimited resources, millions and millions of dollars to launch a direct to consumer campaign, held physician meetings, you know, do scientific presentations to point out their view of the safety of the drug. The Food and Drug Administration differed in their views, but there was no way for the public to know about that. I mention in my written testimony many instances when written published material from the drug company were in direct conflict with what the FDA had found, but everybody only heard one side of the picture. We did not know what the FDA was thinking. Why does the FDA not publish its own findings in medical journals? Why do the FDA reviewers not go to scientific meetings and present their data, their interpretation of the data, so that we understand better both sides of the picture?

[The prepared statement of Gurkirpal Singh follows:]

PREPARED STATEMENT OF GURKIRPAL SINGH, ADJUNCT CLINICAL PROFESSOR OF MEDICINE, DEPARTMENT OF MEDICINE, DIVISION OF GASTROENTEROLOGY AND HEPATOLOGY, STANFORD UNIVERSITY SCHOOL OF MEDICINE

Chairman Barton, Congressman Dingell, and Ladies and Gentlemen:

Thank you for inviting me to testify before the Subcommittee on Health of the Committee on Energy and Commerce.

I am a rheumatologist by clinical training with research interests and expertise in drug safety and epidemiology. My group and I at Stanford University were instrumental in pointing out the risks of painkillers such as ibuprofen (Motrin) and Aleve (a class of drugs called NSAIDs). Our NIH sponsored research over the years has allowed us to identify patients who have a high risk of serious stomach bleeding from such drugs and potential ways to avoid such risks. I have been working in this research area of drug safety and outcomes research for almost 15 years, and have published extensively in the medical literature. I am currently working with large public datasets such as Medicare and Medicaid to study early safety signals of medications. I lecture medical students, residents and other physicians, both at Stanford, and in conferences worldwide, on many of these issues.

I have been asked to comment on the notion that FDA represents an effective, concerned and independent regulatory entity that can be relied upon to require and accurately analyze in a timely manner all information necessary to assess a drug or device's safety and efficacy profile and that it promptly informs the prescribing and the patient community through complete and accurate and understandable labeling. I will use the example of the approval and withdrawal of rofecoxib (Vioxx) as a case-study. It is not my intention to catalogue all the errors made, but rather to highlight the lessons that we have learnt and the knowledge that we can derive from this episode so that early signals are not missed again with another drug.

First of all, let me start by stating for the record my admiration for the FDA scientists and medical reviewers. They are some of the smartest individuals in the medical field, and have dedicated their lives to public service. They work long hours, in jobs that are mostly invisible to the public they try to protect, for salaries that are a fraction of what they could make outside the FDA. But they work within a system that is far from perfect—witness the Vioxx and anti-depressant episodes.

1. PRE-APPROVAL CLINICAL TRIALS ARE NOT DESIGNED FOR STUDYING DRUG SAFETY

In a clinical trial, patients are assigned randomly to receive the study drug or the comparison treatment, and they are followed for the health outcomes of interest. The clinical trial is the optimal method of assessing the efficacy of medications, but often not its safety. For example, clinical trials to study the efficacy of an arthritis pain medicine can be conducted in a few hundred patients who are followed for 6 weeks. But such a study is too small to evaluate the effects of a medication on health outcomes such as heart attack or stroke. Studies of thousands of patients followed for several years are often needed to provide confidence in the evaluation of these outcomes. And therein lays a problem. The current system of drug approval at the FDA relies on clinical trials designed for efficacy—while these trials provide information to evaluate if the drug works, there are very often not sufficient to assess its safety.

Another problem is the fact that many clinical trials are performed in an "optimal" population, and exclude people who may be at risk for suffering the maximum harm from a drug—such as those with a weak heart or the elderly or pregnant women. So, there is little safety data collected in these high-risk populations.

In the current system of drug approval, trials designed to assess the safety of a drug are often performed after its approval—the so-called post-marketing studies. But these are rarely completed. A drug is considered "safe" unless proven otherwise. While this system brings rapid drug approvals, it does raise the rare possibility of sometimes causing serious harm from side-effects not discovered in clinical trials.

2. THE SYSTEM IS DESIGNED FOR RAPID DRUG APPROVAL, NOT A CAREFUL REVIEW OF DRUG SAFETY—THE VIOXX EXAMPLE.

The first principle of medicine is primum, *non nocere*—first do no harm. It is extremely important that clinical trial data be carefully studied and if there is any indication—even a small one—that there is a possible risk of serious harm, the approval of the drug should be deferred till appropriate large-scale data is collected. How well equipped are we to do that today? Let me illustrate with the Vioxx example.

When Merck filed for the approval of Vioxx in the US, it submitted data on 58 studies (that included 3629 patients treated with Vioxx) to the FDA. However, only

371 and 381 patients had received doses of 12.5 mg or 25 mg for more than 1 year, and only 272 had received doses of 50 mg for at least 6 months. These studies were adequate to study the efficacy of Vioxx on pain relief, but did not have enough power to look at serious adverse vents such as heart attacks and strokes. Nevertheless, there were early signs of serious problems. In a careful FDA review of Merck's new drug application for Vioxx, Dr. Villalba (exhibit 10) noticed (and I quote) that "thomboembolic events [such as heart attack and stroke] are more frequent in patients receiving VIOXX than placebo . . ." [page 105]. Among 412 patients taking placebo, 1 had a cardiovascular event (0.24%). In contrast, among the 1631 patients receiving 12.5 mg or more of VIOXX daily, 12 had a cardiovascular event (0.74%) (6)—a three-fold increase in risk. Many scientists would consider this three-fold difference as an early warning sign. But at that time, there were no adequate data to make a firm conclusion one way or another. In fact, the FDA reviewer went on to point out that: "With the available data, it is impossible to answer with complete certainty whether the risk of cardiovascular and thromboembolic events is increased in patients on rofecoxib. A larger database will be needed to answer this and other safety comparison questions" [page 105].

What happens next? Does the FDA require Merck to conduct larger and more definitive studies? After all, the drug was no more effective than any other available pain-killer in the US—and there were nearly 30 such drugs available in the US. Further, another drug—the cox-2 inhibitor celebrex—which had no such signal for heart attacks had been already available in the US market 6 months prior. A combination of two older drugs—a pain-relieving drug such as motrin with a drug that protects the stomach such as prilosec—is as effective and almost as safe on the stomach as Vioxx, with no heart attack risk. There was certainly no emergent need to approve Vioxx without further studies if there were lingering safety concerns. The trade-off of heart attacks for the rare instances of stomach bleeds is not a reasonable one. Remember, primum non nocere—first, do no harm. Instead, the drug was approved by the FDA in a priority review within 6 months—with no discussion on the heart attack trade-off. The system that is designed to approve drugs rapidly works—at a cost that we all know now.

3. THERE IS NO MECHANISM FOR CONDITIONAL OR TIME-LIMITED APPROVAL.

Once a drug is approved, the FDA has little power to force a drug company to do safety studies. Let us look at Vioxx. From the time the NDA was filed to the ultimate withdrawal of the drug, FDA medical reviewers repeated noted the increase in heart problems with the drug, in multiple studies. The signals were not definitive because there were no large safety studies. FDA reviewers repeatedly noted the need for such studies. On March 12, 2002, Dr. Villalba wrote to Dr. Goldkind (Deputy Division Director): "Adequately powered and prospectively designed studies are necessary to definitively address cardiovascular safety issues with Vioxx". Merck would not do any, and in fact, cancelled the one study that could have provided the answer in 2002. The New York Times recently reported that Merck decided a cardiovascular outcome study would send the "wrong" marketing and public relations signal. Why ask a question if you do not want to know the answer? Instead Merck proposed a pooled analysis of ongoing clinical trials for new indications. On December 19, 2002, the FDA sent a letter to Merck stating that this approach ". . . might not be sufficient to address the ongoing cardiovascular safety concerns surrounding Vioxx."

Four years before the withdrawal of Vioxx, the FDA had "ongoing cardiovascular safety concerns surrounding Vioxx". Concerns that had started before the drug was approved. Yet, the sponsor would not do definitive studies to address these safety concerns. So what happens—life goes on, millions of people take the drug, blissfully unaware of "ongoing cardiovascular safety concerns' of their regulatory agency. And the band plays on . . .

It is my recommendation that a system of conditional or time-limited approvals should be instituted. This way, if there are any emerging safety problems with a drug after its approval, the FDA can require companies to do large safety studies within a certain time period.

4. THERE IS NO GOOD MECHANISM OF INFORMING THE PRESCRIBING PHYSICIANS OR PUBLIC OF FDA'S CONCERNS.

In my opinion, this is the single most important problem of communication with the system. While the drug companies spent hundreds of millions of dollars in touting the benefits of their drugs in direct-to-consumer advertisements and sales calls to physicians, the FDA has no way to inform the public of its concerns, except through a process of label change.

Again, let us look at the Vioxx example. Multiple studies published by Merck in medical journals underplayed the risk of serious cardiovascular complications. The VIGOR trial was published in the New England Journal of Medicine, once of the most reputed medical journals in the world. However, the publication under-reported the true number of heart attacks in patients on Vioxx. (Four years later, Merck would say that those were preliminary numbers—but did the publication say that at that time?). While it prominently discussed the 50% reduction of stomach bleeds in patients taking Vioxx, it did not mention that in spite of this, patients on Vioxx had more serious adverse events, more hospitalizations and more deaths than patients on Naproxen. In addition, the true rates for cardiovascular thrombotic adverse events (a prespecified study endpoint in the protocol), hypertension and congestive heart failure, factors that may contribute to heart attacks and which were all higher in the Vioxx group—were not shown in the paper at all. The FDA knew the truth—but these concerns were never communicated to the prescribing physicians or public. In February 2001, the FDA put the correct numbers on its website—but how many physicians know how to navigate the FDA website? Why could the FDA not publish its own findings in the New England Journal?

In March 2000, Merck sent a letter to all its investigators to encourage the use of aspirin in patients on Vioxx who may be at risk for cardiovascular complications. For the next 4 years, Merck sales force would tell prescribing physicians that the use of aspirin would eliminate the increased heart attack risk seen with Vioxx. But studies that the FDA reviewed suggested that this was simply not true. For example, in a document released to public last week, Dr. Villalba's review of the ADVANTAGE study on November 28, 2001 states: "the use of low dose ASA for cardiovascular prophylaxis may not eliminate the excess of cardiovascular events on rofecoxib 25 mg compared to naproxen . . ." The FDA knew, but the prescribing physicians and the American public remained blissfully unaware—and the band played on . . .

Merck has repeatedly insisted that prior to the APPROVe study, there was no evidence of Vioxx's toxicity. In multiple scientific meetings and other communications with physicians, Merck presented data from Alzheimer's disease studies to claim that there was no heart attack risk from Vioxx. However, FDA memos released last week show that the FDA "never accepted the results from the Alzheimer's studies as a replacement for prospectively designed, placebo-controlled studies. Furthermore, the FDA repeatedly requested that these data be updated." Yet, it took more than a year from FDA's first request on December 9, 2002 to when it finally received the updated data on December 17, 2003. As early as 2001, the FDA already knew that in two Alzheimer's Disease studies, patients on Vioxx were almost twice as likely to die as those on placebo; updated safety data confirmed these findings. Yet, the FDA never released their analysis in any scientific meeting or any other communication to the public. Once again, the drug company continues to claim safety of its drug, the FDA knows otherwise, but the prescribing physicians and patients remain blissfully unaware. And the band plays on . . .

5. THE LABEL PROCESS IS ONE OF NEGOTIATIONS—LET US MAKE A DEAL . . .

There needs to be an open public discussion of the role of FDA in approving drugs and labels. The label is the practically the only way through which the FDA communicates with physicians. Last week, the FDA released a document titled "Sequence of Events with Vioxx, since opening of IND". I would encourage all of you to read it—and see for yourself how this process can be manipulated. Some quotes from this document:

"The sponsor rejected FDA proposed labeling."

"The division requested that the sponsors reconsider their proposal . . ."

"Merck cancelled the January 09, 2002 meeting."

And many more.

The current process of labeling is one of negotiations—if the "sponsor" does not agree with what the FDA wants, it can continue to stall or worse. In the meantime, it can continue to sell its drug and promote its cardiovascular safety in the scientific and lay media. And the band plays on.

Finally, one side gives in—the label is approved. A label that mostly supports Merck's position.

This process needs to be corrected, if need be, by new legislation. The FDA should be given the authority that is accorded to our judicial system—to make unilateral decisions on issues of public health safety, after appropriate public hearings, without having to negotiate and reach agreement with drug companies. The FDA should regulate the drug companies, not collaborate or negotiate with them if there is any question of public safety.

6. ABSENCE OF PUBLICLY-AVAILABLE INFORMATION

The FDA approval process needs to be more open and subject to public scrutiny. Once a drug is approved, all the data supporting such approval should be put in the public domain. If this had been done with Vioxx, perhaps independent scientists would have been able to spot early signals. Similarly, all clinical study data submitted to the FDA should be available to the public after the drug is approved. Claims of "trade secrets" should not take precedence over public health and safety. Pharmaceutical companies should not be allowed to selectively disseminate only positive data.

The FDA should encourage its scientists to publish their findings—even if these findings challenge currently-held opinions. In fact, it is more important to hear views of dissent—only through an open discussion of all issues does science advance. Scientists like Dr. Graham and Dr. Mossholder should be encouraged to discuss their findings in public, and publish in the scientific literature.

7. EMPHASIS ON DRUG SAFETY

It is important for life-saving medications to be approved in a rapid fashion. However, there needs to be a renewed focus on drug safety as well. Current standards regard every drug as safe—even one that has multiple safety signals in clinical trials—unless it can be proven with 95% certainty that it is not. Such certainty requires large trials, which are not done—and the band plays on—If there is conditional approval, this will change.

An independent office of drug safety which does not report to the FDA new drug approval section should be established. Safety data on all new drug approvals must be vetted through this office. Such independent office should have the authority to conduct safety studies on approved drugs, or require that such studies be conducted if there are safety signals. Only then will be able to adhere to the principle of "Primum, Non Nocere"—First, Do No Harm.

Thank you.

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Mr. DEAL. Dr. Singh, I am going to have to stop you at this point since we have exceeded the 5 minutes, but we will, I am sure, expound on this as we get to the question stage. Thank you very much.

Mr. SINGH. Thank you.

Mr. DEAL. And our next witness is Mr. Richard Kingham from here in Washington, DC of Covington & Burling. We are pleased to have you, Mr. Kingham.

STATEMENT OF RICHARD F. KINGHAM

Mr. KINGHAM. Thank you, Mr. Chairman.

I was asked to address the specific provision relating to punitive damages for products that are approved by FDA, particularly drugs, and that is what I will do.

I have looked at the language that was in H.R. 5, though I recognize, of course, that there is no specific language before us today in this hearing.

I note the following things. First, it is a very limited defense. It applies only to punitive damages. It does not, in its terms, limit the ability of a plaintiff to recover for economic damages, including pain and suffering. Now there are other issues in the bill, but this provision does not affect that. So it affects only punitive damages.

What is more, it applies only if the product went through an FDA approval system and if the FDA actually looked at the aspect of the product that is the subject of the litigation and made it affirmative decision with respect to it. And it does not apply if the manufacturer withheld anything from the FDA during the approval process or afterwards, nor does it apply if anything improper was done in the way of payments to FDA officials.

So it is a narrow and limited provision. It is not unprecedented. Not only have eight States passed legislation like this over the last 20 years, but Congress passed a provision very similar to this in 1986, which I was involved in negotiating, the National Childhood Vaccine Injury Act of 1986, which includes a provision that significantly limits the right to get punitive damages for products that are approved by FDA and are within the scope of that legislation. So we have ample precedent for this having been done.

Now what is its rationale? The rationale ultimately is that if you have given all of the information to FDA that it needs to make benefit risk judgments about a product and if the FDA has made that judgment, then you can not be held liable for having engaged in the kind of egregious misconduct that warrants punitive damages. This does not mean that courts and juries can not second-guess, in the context of compensatory damages, whether the right decisions were made by manufacturers. They can, indeed.

Now the fact is, all drugs, that I am familiar with, entail risks, and the approval of every drug is a benefit risk judgment. FDA officials, in my experience, and it is 31 years of experience, make a good faith effort to perform that function. Yes, they make decisions that well-intentioned people disagree with. They may even sometimes make mistakes. I do not believe there is any evidence that FDA officials engage in the kind of egregious misconduct that would warrant the imposition of punitive damages for the decisions they make and which manufacturers comply with.

Let me switch now and just respond to a couple of things that have been said.

Professor Rosenbaum suggests in her written testimony, and she suggested in her oral testimony, that there may be some constitutional problem with this proposed legislation. Well, let me say, first, there has never been a serious constitutional issue about a very similar provision included in the childhood vaccine legislation in 1986. That problem has never occurred.

Second, a much stronger limitation on liability with respect to drug products, vaccines, was enacted by Congress 10 years before that in the swine flu episode and that actually was tested in the courts and was determined not to violate the constitution. I don't think there is a serious constitutional argument here.

I also don't think this legislation protects against a situation in which someone deliberately introduces poison, or otherwise tampers, with a product. In fact, it has provisions that expressly require compliance with tamper-evident packaging regulations as a condition of protection against punitive damages.

Dr. Singh has made a number of points, and I won't deal with all of them, but I would say two things to respond to him.

First of all, the FDA does have the power to require manufacturers to engage in post-marketing inquiries. There were regulations passed in the 1970's that give the agency that authority, if it wishes to use it. The agency does communicate with doctors. It does publish, in medical journals and other places, information concerning its findings from post-marketing safety evaluation and other activities that the agency engages in. The agency does communicate with the profession in other ways than through the drug approval process.

There are, clearly, things that can be improved about FDA, about the pharmaceutical industry. There are always areas of improvement that can be identified. I simply do not see, in what has been presented here today, evidence of the kind of misbehavior on the FDA's part that would justify the imposition of punitive damages on people who comply with its requirements and fully disclose the information they have that is relevant to the imposition of those requirements.

Thank you.

[The prepared statement of Richard F. Kingham follows:]

PREPARED STATEMENT OF RICHARD F. KINGHAM, PARTNER, COVINGTON & BURLING

Mr. Chairman, thank you for inviting me to testify before this Subcommittee. My name is Richard F. Kingham. I am a partner in the law firm of Covington & Burling, where I have practiced in the area of food and drug law for more than 31 years. During this time, I have represented pharmaceutical companies and industry associations in numerous proceedings before the Food and Drug Administration and other federal agencies. I have also advised clients with respect to product liability actions and the relationship between tort liability and the FDA drug approval process. I have served on committees of the National Institutes of Health and the Institute of Medicine of the National Academy of Sciences and have taught food and drug law and related subjects at the University of Virginia School of Law, the Georgetown University Law Center, and the University of Wales in the UK. I am testifying in my personal capacity at the request of the Committee, and am not representing any client.

My statement addresses the proposal to provide a defense to punitive damages for manufacturers and distributors of drugs, biological products, and medical devices that have been subject to premarket approval, licensure, or clearance by FDA. Language to enact this type of protection included in section 7(c) of H.R.5 as passed by the House in the 108th Congress. I support the passage of legislation creating a carefully worded, narrow defense that is based on the language in that bill.

A defense like that proposed in H.R.5 will protect against the imposition of punitive damage judgments against manufacturers, but only under very limited circumstances. The defense will not prevent any person from bringing a claim against a drug or device manufacturer. Injured patients will continue to be able to have their day in state court. Furthermore, the defense is narrowly crafted so that it will not prevent an injured patient from being awarded full compensation in any case. The full range of compensatory damages, including substantial awards for pain and suffering, will still be available to plaintiffs. The bill will provide only a narrow defense to the award of punitive damages.

Moreover, only defendants that have complied in all relevant respects with FDA requirements are eligible to use this defense. FDA not only conducts a demanding and comprehensive safety assessment before each product reaches the market, but also continues to review the product's safety over its life on the market. Although the need for certain changes and reforms in FDA's review process recently has been

the subject of debate, the agency's current structure and processes do support the goal of providing a comprehensive review. To facilitate this review, FDA imposes extensive reporting requirements on the manufacturers of drugs, biological products, and medical devices. Any manufacturer that knowingly misrepresents or withholds required information from FDA, and thus potentially distorts or subverts the FDA review process, will be unable to use this statutory defense against punitive damages.

A review of even a few steps of the FDA review process for prescription pharmaceutical products reveals both the scope of the information that manufacturers must submit to FDA and to the breadth and depth of FDA's product review. I choose to focus on prescription drugs today because these products have been the topic of much discussion in recent months. The requirements for medical devices and biological products, including vaccines, are similar in breadth.

In applying for FDA approval of a new prescription drug, the manufacturer is required to submit to FDA all known safety information about the drug, including information obtained in clinical trials in the U.S. and in foreign countries. As part of this application, the manufacturer must submit the results of affirmative large-scale studies of the drug's safety and effectiveness. These studies often involve several thousand patients at multiple locations. New Drug Applications (NDAs) literally can reach hundreds of thousands of pages in length.

As part of a drug's approval, FDA may require the manufacturer to conduct additional studies and submit reports. These postmarketing studies provide additional data and may allow the manufacturer and the agency to identify rarely-occurring adverse events that could not have been identified in clinical trials of even thousands of patients.

Whether or not postmarketing studies are required, the drug manufacturer must report to the agency a wide range of information about each marketed drug on an ongoing basis. For instance, the manufacturer must report to FDA adverse events that occur anywhere in the world, whether or not the company thinks that the event is caused by the drug. Any issues arising in the manufacturing process must be reported, as well. For instance, if even one batch of a distributed drug fails to meet a single manufacturing specification, FDA must be notified within 3 days. In annual reports to FDA, the manufacturer must submit the reports of any clinical trial conducted inside or outside of the U.S. The manufacturer also must notify FDA of any significant regulatory decision that affects the drug by any regulatory agency in the world.

FDA's structure and processes allow the agency to review this information thoroughly and to update potential safety concerns continuously. In its reviewing Divisions, FDA employs hundreds of doctors, each qualified in the relevant scientific discipline. These doctors review individual data points for each drug, as well as the universe of data for similar products, to determine whether the product's benefit-risk ratio has changed and if additional product warnings or limitations are required. To assist in this assessment, FDA employs epidemiologists, statisticians, and microbiologists and has developed technology tailored to the reviewers' needs such as adverse event databases. Moreover, the agency's advisory committees, of which there is one for each category of drug, are composed of prominent specialists that are not employed by FDA and are required to comply with FDA requirements regarding conflicts of interest. FDA regularly refers technical issues to these committees for additional input.

The combination of mandatory reporting by manufacturers and careful agency review allows FDA to identify immediate and unusual safety issues such as manufacturing errors, as well as long-term issues such as rarely-occurring but serious adverse events. The manufacturers clearly play an essential and irreplaceable role in the process.

Manufacturers that act lawfully and in good faith with FDA's requirements—that submit all required information to FDA and that comply with any limitations that FDA imposes on the product's marketing—still may be exposed to tort claims of negligence and strict liability under the proposed statutory language. They still may be required to pay compensatory damages. This bill properly would recognize, however, that these manufacturers cannot be deemed to have engaged in the sort of egregious misconduct that would justify punitive damages. Their good faith compliance with the regulatory requirements cannot be viewed as the kind of behavior that would "shock the conscience" of the community and thus deserve to be subject to punitive damages.

Indeed, commentators have urged for years that regulatory compliance be deemed a defense to claims for punitive damages. In 1991, a very distinguished panel writing the Reporter's Study on Enterprise Responsibility for Personal Injury for the American Law Institute asserted that, "If a defendant has fully complied with regu-

latory requirements and fully disclosed all material information relating to risk and its control, it is hard to justify the jury's freedom to award punitive damages." The panel argued specifically that "Pharmaceuticals present a special combination of circumstances justifying such a [limited] defense."

Congress itself took that view in passing the 1986 National Childhood Vaccine Injury Act. That Act creates a limited defense to punitive damages for manufacturers of certain vaccines. That provision's limitations are similar to those in the proposed language, in that vaccine manufacturers may invoke the defense only if they can demonstrate their compliance in all material respects with the relevant requirements of the Federal Food, Drug, and Cosmetic Act (FDCA). That legislation has successfully achieved the goals that led to its enactment. Companies developing or testing vaccines for many new uses are not covered by that Act, however.

A large number of states also have taken the view that manufacturers should be able to defend themselves from punitive damages on the basis of their compliance with FDA requirements. Since New Jersey first enacted such a defense nearly 20 years ago, at least seven additional states have created a statutory defense either for FDA-approved products or for all products that comply with mandatory state or Federal government standards. In addition, six other states either prohibit claims for punitive damages more generally or make no provision for the award of punitive damages. Michigan goes even further, providing a complete defense to tort liability for products that are FDA-approved and compliant.

Thus, at least 15 states provide defenses that are at least as generous as the language of the proposed bill. There has been no suggestion that these state laws have precluded injured patients from successfully litigating cases of negligence and strict liability against companies manufacturing and distributing drugs, biologics, and medical devices. In fact, the legal scholars that endorse a limited regulatory compliance defense acknowledge that the defense will affect a relatively limited number of cases.

The language of H.R.5 also appropriately makes the defense unavailable where a person illegally paid or bribed an FDA official to obtain or maintain the approval, clearance, or licensure for the product at issue. Although no innovative pharmaceutical manufacturer has been accused of bribery, and although the concerns regarding generic manufacturers appear to have been resolved, this language remains a necessary and wise precaution.

In summary, this House should enact a carefully crafted, limited defense to punitive damages for products that are subject to and compliant with FDA premarket approval requirements. Under such a provision, no injured person will go uncompensated. No person will receive less than complete compensation. At the same time, the defense will encourage reporting by FDA-regulated companies and will further strengthen the already comprehensive FDA review process for drugs, biological products, and medical devices.

Mr. DEAL. Thank you, sir.

Our next witness is Dr. Sidney Wolfe, Director of the Health Research Group at Public Citizen.

Dr. Wolfe.

STATEMENT OF SIDNEY M. WOLFE

Mr. WOLFE. Thank you.

In keeping in this whole idea of a medical defense and if something is approved by the FDA it must be okay is the idea that the FDA is doing a good job. We surveyed physicians in the FDA in 1998 because a number of drugs that shouldn't have come on the market were coming on, and then they were being taken off. And they told us that there were 27 drugs, which they had thought were too dangerous, which were approved over their head. Seventeen of them told us that the standards for safety and efficacy had—were lower than they had been prior to 1995, and several said they had been silenced against talking about drug dangers at Advisory Committee hearings.

The FDA itself followed up our study several years later, and they found that a third of the medical officers didn't feel comfortable expressing different scientific opinions, and a number of

reviewers said decisions should be based more on science and less on corporate wishes.

And then finally, just a year and a half ago, the Inspector General of HHS did another study on the same topic and found that 18 percent of the physicians in the FDA felt pressure to recommend that drugs be approved for sale, despite their reservations. The conclusion of the inspector general is overall, these findings represent a significant safety warning.

I am now going to quickly go through seven examples of drugs: two have been taken off of the market much too late, five are still on the market. The five that are still on, we have filed petitions with the FDA with all of them to be banned.

Rezulin, a diabetes drug, approved in March 1997, and within a few months, it was taken off the market in the United Kingdom because of liver damage largely in the United States. Six deaths from liver damage. We petitioned the FDA to ban this drug. A few months later, by then, 26 liver deaths. The FDA held an Advisory Committee meeting. Another couple of years later, 43 liver deaths. And finally, after FDA physicians complained not for attribution that the drug should be taken off the market, it was taken off the market several years later than it had been in the United Kingdom. By then, 63 liver deaths, 7 transplants.

Trovan, an antibiotic, was taken off the market everywhere in the world because of liver damage. Liver damage had shown up before it was approved in the United States in 10 percent of men who were tested with this Pfizer drug. When the FDA finally decided what to do, instead of banning the drug, as the rest of the world had done, they banned it except for people in nursing homes and in hospitals. When we filed the petition in 1999 to ban the drug, there were eight cases of liver failure, including five deaths and three transplants. This morning, we looked at the most recent data: 56 cases of liver failure, including 29 deaths and 9 transplants. This drug is still in the market, only in the United States because of the FDA's incompetence, I think.

Baycol, a cholesterol-lowering drug, was taken off the market a year after the FDA had enough information to be aware that it was much more dangerous than the other cholesterol-lowering drugs. By the time it was taken off the market, there were 1,899 cases of this life-threatening muscle destruction, called rhabdomyolysis. Many of these had occurred in the year between when the FDA knew and when the FDA acted.

A somewhat chemically related cousin to Baycol is a drug we tried to stop from getting on the market in the United States called Crestor, another cholesterol-lowering drug. Before approval, it looked like it had more cases of this same rhabdomyolysis than any drug ever, even Baycol, which came off the market, hadn't shown any of these cases prior to its approval. An FDA medical officer looking at some kidney damage said, "This may represent an unacceptable risk since the other cholesterol-lowering drugs don't have these effects." We tried to stop it, but since it came into the market, there have been 100 cases of this life-threatening rhabdomyolysis muscle destruction and more than 40 cases of renal failure, a rate 75 times higher per million prescriptions than the other statins combined.

Vioxx has been mentioned before. Four years before it came off the market, a published study showed a four to fivefold increased risk in heart attacks. We asked the FDA to put a black box warning on it. Had that been done, hundreds of thousands of people—millions of people who took the drug wouldn't have taken it, and according to FDA's own estimates, tens of thousands of heart attacks would have been prevented, including Mr. Huggins' wife we heard about before.

Bextra, another drug in this family, still on the market. We had to sue the FDA, because Pfizer and the FDA didn't want us to see the internal reviews on this drug, which showed an FDA physician concerned about the blood clotting properties of this drug and the similarity between it and Vioxx.

And finally, Meridia, sibutramine, a weight-reduction drug. The FDA physician and the Advisory Committee thought it was too dangerous. It shouldn't have been approved. It came on the market. At this point, 56 cardiovascular deaths in people using the drug, many under the age of 50.

Not counting Vioxx or Baycol, we are talking about hundreds, if not thousands, of people who have died unnecessarily because of drugs the FDA should have taken off the market. We have a book called "Worst Pills, Best Pills," which lists 170 other drugs that we say do not use, also on our website, worstpills.org. The FDA clearly is not doing a good job, and it is adding insult to injury to try and immunize drug companies because they pass the so-called FDA gold standard.

[The prepared statement of Sidney M. Wolfe follows:]

PREPARED STATEMENT OF SIDNEY M. WOLFE, DIRECTOR, PUBLIC CITIZEN'S HEALTH RESEARCH GROUP

Chairman Deal and Members of the Subcommittee, thank you for the opportunity to testify today. Under the most perfect circumstances, if the FDA were actually doing as good a job as possible at preventing the approval of drugs and other medical products whose benefits are known to be outweighed by their risks and, as expeditiously as possible, removing such products when such risks are discovered after approval, this legislation would still unfairly punish patients and their families.

I will focus on substantial evidence, based on our more than 33 years of oversight over the agency, demonstrating that the FDA is far from doing an adequate job protecting the public from such products, making the impact of this legislation even more disastrous to potential victims.

HRG MEDICAL OFFICER SURVEY/FDA STUDY/INSPECTOR GENERAL STUDY

In late 1998, prompted by many drugs with clear evidence of dangers not being adequately regulated, we surveyed FDA medical officers who were the primary reviewers in the Center for Drug Evaluation and Research (CDER) for new drug applications. The responses, from 53 FDA physicians, included 27 instances cited in which the FDA medical officer thought a drug too dangerous to be approved but approval occurred over their objection. Seventeen medical officers described the current standards of FDA review for safety and efficacy as "lower" or "much lower" compared to those in existence prior to 1995. And several medical officers said they had been instructed by their superiors to censor their reports or presentations.

A study in 2001 by the FDA itself, precipitated by high turnover rates among scientists and physicians in the agency, showed that about one-third of medical officers did not feel comfortable expressing differing scientific opinions, and a similar number felt that decisions adverse to a drug were stigmatized within the agency. A number of reviewers said that decisions should be based more on science and less on corporate wishes.

A subsequent study by the HHS Inspector General in 2003 confirmed that decisions concerning drug safety and effectiveness were being overturned. Eighteen percent of surveyed FDA physicians and scientists felt pressure to recommend that

drugs be approved for sale despite their reservations about the drug's safety, efficacy or quality. The report concluded: "Overall, these findings present a significant warning signal."

SPECIFIC EXAMPLES OF DANGEROUSLY POOR FDA REGULATION

Rezulin (troglitazone-diabetes drug)

- March, 1997: U.S. Rezulin marketing begins
- Dec, 1997: drug withdrawn in UK after 130 cases of liver damage including six deaths, mainly in the US
- July, 1998: Health Research Group petitions FDA to ban Rezulin after 560 cases of liver damage, including 26 liver deaths
- March, 1999: FDA advisory committee meeting: now 43 liver deaths
- early, 2000: Some FDA physicians state drug should be banned
- March, 2000: Rezulin is withdrawn in the US; by then, 63 liver deaths, seven liver transplants

Trovan (trovafloxacin-antibiotic) Like two other drugs also approved in 1997, the painkiller Duract (bromfenac) and the diabetes drug Rezulin (troglitazone), (now both off the market) there was also clear evidence of liver damage caused by Trovan (in animals and in humans) before the drug was approved in December 1997. In one study prior to approval in which the drug was used to treat prostatitis, almost 10% of the men (14 out of 140) given the drug developed evidence of liver toxicity. With eight other drugs in the fluoroquinolone antibiotic family available in the U.S, as well as dozens of other safer and equally or more effective drugs for infections, the removal of Trovan from the market would not have deprived doctors or patients of a drug that could possibly be considered indispensable. Instead of banning Trovan as was done everywhere else in the world, the FDA chose to "limit" its use in the United States to patients who were either hospitalized or in nursing homes. At the time of our petition in 1999 to ban the drug, there were eight cases of liver failure, including five deaths and three liver transplants. There are now a total of 56 cases of liver failure, including 29 deaths and nine people requiring liver transplants.

Baycol (cerivastatin-cholesterol lowering) Approximately one year before Baycol was removed from the market in August 2001, its manufacturer Bayer, using FDA data on other statins found that Baycol had 20 times more reports of rhabdomyolysis (an often-fatal destruction of muscle) per million prescriptions than Lipitor. An FDA official, feebly excusing FDA's belated ban, stated that "We weren't aware at that point of the difference between Baycol, and the other similar [drugs]. Our expectation is when a company becomes aware of a specific problem with their drug, they come to us." By the time Baycol was banned, there were 1,899 cases of rhabdomyolysis, a significant number having occurred between the time there was unequivocal evidence that FDA should have banned the drug and when it was actually banned a year later.

Crestor (rosuvastatin-cholesterol lowering) Despite the Baycol disaster, and some chemical similarity between Baycol and Crestor, the FDA approved Crestor in August 2003, knowing that prior to approval there had already been 7 cases of rhabdomyolysis in clinical trials, compared to none in clinical trials prior to Baycol's approval (or that of any other statin). In addition to this risk, which AstraZeneca (Crestor's manufacturer) and the FDA wrote off as limited to the highest (80 mg) dose that was subsequently not approved, the drug also causes unique kidney toxicity, even in people who did not have rhabdomyolysis that can lead to secondary kidney damage. An FDA medical officer reviewing dozens of cases of blood and protein in the urine and several cases of renal insufficiency/renal failure in people using Crestor before approval said "if they [these findings] are the signals for the potential progression to renal failure in a small number of patients, this may represent an unacceptable risk since currently approved statins do not have similar renal effects." Since Crestor came on the market, there have been more than 100 cases of rhabdomyolysis reported to the FDA, a rate per million prescriptions that is higher than any of the other statins still on the market. In addition, there have been approximately 40 cases of renal failure in people without rhabdomyolysis, a rate approximately 75 times higher per million prescriptions than that of the other statins combined.

Vioxx (rofecoxib-NSAID) A study published more than four years ago showed a four to five-fold increase in heart attacks in people using Vioxx compared to those using naproxen. As a result, we asked FDA for a black box warning four years ago. Although such a warning would have greatly reduced the toll of tens of thousands of heart attacks occurring between then and Vioxx's withdrawal, the agency, to the pleasure of Merck, rejected a black box and chose not to adequately warn the public. Many lives were thus lost.

Bextra (valdecoxib-NSAID) When we learned almost two years ago that FDA had rejected Pfizer's application for a new pain indication for Bextra, the agency, in collaboration with Pfizer, denied our freedom of information request for the FDA review as to why the application had been rejected. We thus had to sue the FDA to obtain these data. The medical officer who reviewed the study stated that "The excess of serious cardiovascular thromboembolic [blood clots] in the valdecoxib arm of the CABG [Coronary Artery Bypass Graft] trial is of note as the entire study population received prophylactic low dose aspirin as part of the standard of care in this setting to minimize just such events. Given the emerging concern over a possible pro-thrombotic action of certain agents in the COX2 class, these data are of concern."

Meridia (sibutramine-weight reduction) Both the FDA medical officer who reviewed the new drug application for the amphetamine-like weight reduction drug Meridia and the FDA advisory committee were opposed to the drug's approval because of safety concerns such as increased blood pressure. Since approval, there have been reports of a total of 56 cardiovascular deaths in people using Meridia, a large proportion of whom were under the age of 50.

If this legislation is enacted, it will represent the third prong of a three-pronged attack on patients' safety involving the FDA and the drug and device industries:

The two prongs involving the FDA are, as discussed in the above examples, inadequate regulation over the introduction and market removal of unsafe drugs and a sharp (85%) decrease from 1998 through 2004 in FDA enforcement actions concerning illegal prescription drug ads—distorting the power of information into misleading doctors and patients about risks and benefits of drugs. The third prong, reducing the "regulation" of drug and device companies by lessening their liability for injuries and deaths to patients, is all the more onerous in the face of such lax FDA activities. Unless all three forms of "regulation" are allowed to operate in a maximal way, patients will not be adequately protected.

In addition to the four drugs discussed above that are still on the market in this country, all of which we have petitioned the FDA to ban, the newly published edition of our book, Worst Pills, Best Pills and our web site, WorstPills.org both list 176 other prescription drugs that we and our consultants urge that people DO NOT USE and discuss safer alternatives to each of these.

Comments Regarding Draconian Limits the House Proposes to Placed on Patients' Medical Malpractice and Products Liability Lawsuits

Ensuring safe drugs for Americas' consumers is not just predicated on a strong regulatory system at the FDA. The role of the civil justice system is equally important. Without strong state laws that enable patients and consumers to hold medical providers accountable for negligence or errors, the medical industry—including the drug companies—will have much more incentive to cut corners in pursuit of profits and will have much less incentive to be vigilant about patient safety.

For this reason, Public Citizen strongly objected to the two identical omnibus medical malpractice bills voted approved by the House last Congress (H.R. 5 and H.R. 4280). As it is likely that the same legislation will soon be before this committee and the entire House, I would like to provide our perspective on how inadvisable it is.

This legislation is remarkable in that its provisions not only apply to medical malpractice lawsuits against doctors, hospitals and HMOs, but also to pharmaceutical companies and medical device companies when their products injure or kill. In this way, the legislation is also a product liability bill.

The cumulative effect of the provisions would be to limit the ability of patients to recover for serious injuries and also to limit the ability of patients to find lawyers willing to take their cases. As a result, drug and device companies would have less incentive to ensure that their products are as safe as possible and that adverse effects are known before the products are marketed—a consequence that will threaten the health and well-being of us all.

The two bills introduced in the last Congress proposed to cap non-economic damages at $250,000. Non-economic damages compensate people for pain and suffering—sometimes a lifetime's worth—resulting from permanent and significant injury such as brain damage, paralysis, disfigurement, or lost childbearing ability. For example, this cap would affect patients with significant kidney damage from a drug such as Rezulin, permanent incapacitating back injury caused by a broken spinal screw, or children who lost their young father from a heart attack induced by a CoX-2 pain reliever. Cases seeking compensation for such injuries are not "frivolous" cases—the usual justification offered by President Bush and others for imposing a damages cap. And a $250,000 cap will have it s biggest impact on the cases that are the most deserving of large compensation—something the legislation's pro-

ponents claim they do not intend. Moreover, because the bill would not allow the damages to account for inflation, its arbitrary limits would become more unjust with each day.

In addition, the two bills introduced in the last Congress would have virtually eliminated the ability of injured patients to recover punitive damages. Punitive damages are awarded to punish and deter serious and wanton wrongdoing. Although they are awarded in only a small fraction of civil cases, the threat of punitive damages is important to deter reckless disregard for patient safety. Last year's legislation would have eliminated punitive damages entirely in cases against drug and medical device companies or restricted them to instances in which the plaintiff could show that the company had marketed the product without FDA approval or that it had committed fraud to get FDA approval. Because prescription drugs and medical devices cannot be sold legally without FDA approval, this latter proposal effectively bans punitives.

Litigation against Merck is still in its early stages, but it may unearth very incriminating documents showing that the company knew Vioxx posed a serious danger to a significant number of patients, that the company knew that Vioxx had limited, if any, improved efficacy over ibuprofen, but that, to protect the company's investment, the company engaged in a cover-up of information that would have saved lives. If what I have posited about Merck is true, would the American public support sparing a company that engages in such unethical conduct from punitive damages? I can't imagine it.

The proposal to apply a one-year statute of limitations, running from discovery of the injury, will provide another hurdle to the ability of injured consumers to bring suit. The law in most states starts the limitation period running from the discovery of the malpractice, not discovery of the injury. This distinction is important because an injury will frequently manifest itself well before its cause is known. For example, the association between the anti-depressant Serzone and liver toxicity was not widely known until 2002, years after the drug came on the market in 1995. The injured party should not have to twice bear the cost of this defective product.

The two medical malpractice bills also would have changed state rules of joint and several liability, leaving patients with no recovery for the share of damages assigned to an uninsured, underinsured, or bankrupt defendant. The doctrine of joint and several liability says that when two defendants, such as a doctor and a hospital, are both found liable for negligence, a plaintiff may collect the entire award from either defendant if the other is unable to pay its share. In essence, the legal system recognizes that the wrongdoing could not have occurred without the participation of all parties and, therefore, that all parties should be accountable for making the victim whole.

Next, by instituting a "periodic payment rule" for future damages over $100,000, the legislation would allow defendants and insurance companies to string out payments for future damages over the life expectancy of the victim, rather than having to pay up front. Thus, even after the civil justice system has determined that the money rightfully belongs to the plaintiff, defendants and insurers would be able to invest and earn interest on a large piece of the plaintiff's damages award. Victims would be left to cope with new and unexpected expenses attributable to their injury, such as changing medical costs or increased transportation costs. The bill would provide no protection to the victim if his or her needs change or if the defendant drug manufacturer's insurance company becomes insolvent.

Finally, the cap on plaintiffs' attorney fees payable under contingent fee arrangements will drastically cut back on the ability of patients with limited means to get qualified legal counsel. As a result, patients' ability to bring product liability cases against drug and device companies, which have massive resources to defend themselves, will be reduced significantly.

Medical malpractice and product liability cases are very risky for plaintiffs' attorneys for three reasons: the costs are especially high, the likelihood of prevailing is quite low compared with other types of tort actions, and the lawyers do not get paid unless they win. But limiting plaintiffs' attorney fees will create an enormous imbalance in favor of the defendant. While we may disagree on the need for damage caps, we should all be able to agree that our legal system should remain a fair and balanced forum accessible to all Americans.

Mr. DEAL. Thank you.

Our last witness is Victor Schwartz of Shook, Hardy & Bacon here in Washington, DC.

Mr. Schwartz, we are pleased to have you.

STATEMENT OF VICTOR E. SCHWARTZ

Mr. SCHWARTZ. Okay. Thank you.

I think I am the last of 15 witnesses here that as a prominent politician who had married a woman who was her sixth husband, and I once heard him say he knew what the challenge was, he just had to find a way to make an interest——

Mr. DEAL. I haven't started the clock yet, sir.

Mr. SCHWARTZ. I know. They always let me—you have one line that is not on the clock.

Mr. Chairman, thank you for inviting me and Ms. DeGette, is that how you pronounce it, actually, I was in—down in Illinois in that hellhole of Madison County, and they had a woman doctor, an ob-gyn, who was moving to Colorado because her insurance would be reduced by 80 percent. And it is just something to think about. I think that doctors should actually practice where they are needed and not be hopscotching around the country to find better tort laws.

But I am going to briefly talk about punitive damages and this somewhat controversial provision in your bill.

Punitive damages, plain and simple, are there to punish people who have done something wrong. And anybody, and I have won punitive damage cases, the first one in Ohio, actually. And I had the State in back of me to enforce that judgment. And there is really very little difference between a punitive damage award, which is strictly punishment, and the State going after somebody and punishing them for something wrong that they have done.

And in Texas, when I was down there, the Texas trial lawyers had signs up all over the place. And I like those signs. They said, "Punitive damages are needed to punish corporate criminals." Well, if somebody has followed the law, they are not a criminal. This body, a few years ago, passed legislation that raised the speed limit. My friend Ralph Nato was aghast. He thought it was a very bad thing. If a person today drives at 65 miles an hour, a clear day, they are driving carefully, and they have an accident, and an expert comes in, and this can happen, and that expert testifies, "Well, if he had driven 55, there wouldn't have been an accident." Should that person be punished?

FDA, we hear it today, and we are going to hear it again and again, is in controversy. And whether their rules are right or their rules are wrong, that is something for this body to decide. But if somebody is following the law, the exact letter of the law, it is very difficult to see, under our system of justice, why that person should be punished.

Now that is the FDA defense, properly construed. And there is something else that hasn't been mentioned by any other witness. First, in Ohio, when this bill was—the same provision was put into law in 1988, I was there. And I was told by opponents that Ohio would become the dumping ground for bad drugs, that this would create very bad incentives, it would be Sodom and Gomorra. And in 2005, the legislation was considered. What happened? None of that. In fact, it worked very well. There has been no dumping ground. There have been no problems whatsoever. And we have actual experience with this provision and these horrible tales that are told have not come true.

And Mr. Brown, good to see you. I didn't get a chance to say hello.

My role as counsel to pharmaceutical companies, and the law is not just made of carrots and sticks. It has both aspects to it. And just hitting somebody over the head all of the time doesn't always bring about a good result. Mr. Stewart of NYU, the ALI Enterprise study showed the same thing that is my experience. If you have a provision in the law that says if you report, you do not have to be punished, that creates an incentive on that marginal piece to have the drug company report. And that is one of the benefits of this type of defense. It has incentives as well as punishments. And they also know that if they don't, a jury is told about the defense, and the jury is told that if you don't comply with all of the regulations, there is no shield. And that jury hears in its head that if there is noncompliance, punishment is appropriate.

So I don't see the controversy, really, on policy over this type of defense. There is a controversy about whether the FDA rules should be changed. But if one follows the law, it is very difficult, under our system of justice, to justify punishment.

Thank you very much.

[The prepared statement of Victor E. Schwartz follows:]

PREPARED STATEMENT OF VICTOR E. SCHWARTZ, GENERAL COUNSEL, AMERICAN TORT REFORM ASSOCIATION

Chairman Deal, Ranking Member Brown, and Members of this Distinguished Subcommittee, I thank you for your kind invitation to testify today about whether it is appropriate to preclude punitive damages from being awarded against manufacturers of medical products, when the products were subject to pre-market approval by the Food and Drug Administration (hereinafter "FDA").

BACKGROUND

By way of background, the subject of tort law has been of interest to me throughout my career. I was a law professor and acting dean of the University of Cincinnati College of Law, and have taught at the University of Virginia, Georgetown, and American University Law Schools. I continue my affiliation with Cincinnati as an Adjunct Professor and a Member of the Board of Visitors.

I am co-author of *Prosser, Wade & Schwartz's Torts* (10th ed., 2000), the most widely used torts casebook in the United States. For the first fourteen years of my practice, I represented only injured persons and assisted in obtaining the first punitive damages verdict in the State of Ohio against a product manufacturer.

I have served under both President Ford and President Carter as Chair of the Federal Inter-Agency Task Force on Product Liability. That Task Force explored the product liability crisis that arose in the late 1970s and 1980s. It also developed the Model Uniform Product Law Act, which has been used as a basis for state legislation and the development of law by courts. I have had the privilege of working with Members of Congress from both parties on numerous federal liability issues, including the successful enactment of the Biomaterials Assurance Access Act of 1998, the General Aviation Revitalization Act of 1994, and the Paul D. Coverdell Teacher Protection Act of 2001.

For the past two decades, I have worked at law firms whose principal practice has been on the defense side. Currently, I chair Shook, Hardy & Bacon's Public Policy Group. Approximately two hundred articles that I have authored or co-authored have been published in learned journals. I have been fortunate to have many of them cited by courts as a basis for rulings of law. I serve, and I am speaking today, as General Counsel to the American Tort Reform Association (hereinafter "ATRA"), but the views are solely my own, based on my practice and experience. No one, other than my Public Policy Group colleagues at Shook, Hardy & Bacon, has changed or modified my testimony.

HISTORY OF PUNITIVE DAMAGES IN A NUTSHELL

Punitive damages evolved in England in the development of common law. They served, and continue to serve, an important function. They were an auxiliary to the criminal law to help assure that persons who committed wrongful criminal acts paid a price for their conduct, even if the government did not prosecute these acts. The purposes of punitive damages are to punish the defendant, deter him from committing future wrongful acts and to deter others who might be similarly inclined, so that such acts are less likely to occur in the future.

It should be absolutely clear to this Subcommittee that punitive damages are not compensatory. Compensatory damages include paying people for their out-of-pocket losses in the past and in the future, and also damages for pain and suffering, emotional loss, and other harms that do not readily translate to a precise monetary value.

Punitive damages are, in effect, punishment by the state. State means are used to enforce punitive damages, the same way state means are used to enforce the criminal law or government action and civil fines. As a practical matter, there is no difference. The state will use its official mechanisms to enforce such awards, and the sting is the same. Sometimes it is more so, because punitive damages—especially when they are large—generate quite a bit of publicity. Most constitutional rights that protect criminal defendants, however, do not apply to defendants who are subject to punitive damages. This is one basic reason why this body should work to assure that the punitive damages system is fair.

THE CHANGE IN PUNITIVE DAMAGES

During oral argument of a major punitive damage case, *Pacific Mut. Life Ins. Co. v. Haslip,* 499 U.S. 1 (1991), Justice Scalia asked a lawyer for a petitioner who was seeking to overturn a punitive damages award, "Who whispers in my ear what was constitutional in 1789 is not constitutional today?" I attended that argument and Justice Scalia, at least in my view, did not receive a clear answer to his question. Here is the answer.

In 1789, punitive damages were confined solely to purposeful, wrongful acts, such as battery, assault, and wrongful imprisonment. They also were never larger than compensatory awards, and usually less. They dealt with a wrongful act and were imposed once on a defendant. In the past three decades, punitive damages have undergone substantial change in all three of these areas. Punitive damages are not at all the same as they were in 1789.

First, the standard for awarding punitive damages has been attenuated in a number of states, and mere gross negligence as contrasted with purposeful conduct, could be a trigger for making an award. Second, the types of acts for which punitive damages may be imposed have become less clear and harder to define or predict. Finally, punitive damages awards might be awarded multiple times, especially against manufacturers where each plaintiff against the company may seek an award and a jury has absolutely no idea that awards were previously made.

This is by way of background to evaluate whether it is appropriate to allow the state to punish a defendant—who has marketed a drug or medical device, and has fully complied with FDA pre-market approval and post-market rules and regulations. Of course, every Member of this Subcommittee knows, and most Americans know, that the FDA and its procedures have been under question in recent times. Not long ago, I remember when the FDA was challenged because it was not moving quickly enough in providing the American public with drugs that were needed to fight serious diseases. Now, among many, there is a contrary feeling—that the FDA may be moving too quickly and not carefully enough in the drug approval process. That debate is an important one to have in Congress, but it is not relevant for a core public policy decision about whether someone should be punished who has complied with the law.

Let me give you an example. A number of years ago, Congress decided to allow states to raise the speed limit on automobile driving. My friend, Ralph Nader, and others, strongly decried the charge, stating that it would lead to more accidents and more fatalities. Nevertheless, it was the view of Congress that the states should be permitted to allow drivers to go drive much faster than 55 mph—65, 75 or even 85 mph. Consider a motorist going 65 mph on a clear day that tries to drive carefully but nevertheless has a collision. The facts indicate that if he had been driving more slowly, he may have avoided an accident. In our legal system, that drive may be subject to civil liability. Rational thought clearly suggests, however, that a driver going at or below the legal speed limit should not be punished by the state. If the law needs to change, this body or state legislature should do it. Punishment is not

appropriate for totally lawful acts that have been specifically considered by Congress.

Even prominent members of the personal injury bar agree with this concept. For example, in a trip to Texas not long ago, I noticed advertisements on the highway, placed by the Texas Trial Lawyers Association, which is composed of some of the toughest, most effective personal injury lawyers in America. The advertisement stated, "Punitive damages are needed to punish corporate criminals." This may be true because law enforcement mechanisms are sometimes overwhelmed with more serious cases and do not have time to punish wrongful, criminal corporate acts. If a corporation has complied with the law, and a company that manufactures pharmaceuticals or medical devices has met the standards of pre-market approval for the FDA, it is difficult, as a matter of public policy, to see why they should be punished. If the FDA standard needs to be changed (just like the situation with the speed limit, which may need to be changed), it is the responsibility of this body to make the change. No matter how emotional the arguments might be, it is not sound public policy to punish a company that has complied with the legal rules.

EXPERIENCE WITH FDA COMPLIANCE PUNITIVE DAMAGES DEFENSE

Compliance with FDA standards defenses have been enacted in a number of states, including Arizona, Michigan, New Jersey, Oregon, Utah and Ohio (copies of laws attached hereto). The Michigan law goes further than the bill you are considering—it provides that a product is not defective or unreasonably dangerous, and the manufacturer or seller is therefore not liable in a product liability action, if the product at issue was approved by the FDA for safety and efficacy.

I was personally involved in the development of the law in Ohio, which was enacted in 1987. Those who opposed it predicted that the drug companies might treat Ohio as part of Sodom and Gomorra and dump dangerous drugs in the state. They said drug warnings might disappear, and defective drugs would be heaped upon the good citizens of Ohio. As a member of the Ohio Bar, former dean and currently an Adjunct Professor at Cincinnati, I certainly did not wish to be part of such mayhem, but I believed, for the policy reasons I have outlined today, that punishment should not be imposed against people who follow the law. The FDA compliance punitive damages defense would be sound policy and do no harm. Well, that provision has now been law for more than 15 years. Recently, the issue was reviewed again by the Ohio legislature, and the legislation kept that law in place there has been not a scintilla of evidence that any wrongful conduct was caused by this defense. In fact, in December 2004, the Ohio legislature amended the law to extend the FDA compliance punitive damages defense to over-the-counter drugs and medical devices, in addition to prescription drugs.

Pharmaceutical companies in Ohio and a number of other states have been treated with fairness in not being subject to punishment when they follow the law. They still may be subject to liability for compensatory damages. In pharmaceutical cases, these damages are substantial, but they should not be punished.

The experience in Ohio can be revealing, because sometimes there may be factual questions as to whether a particular defendant withheld material information or made misrepresentations to the FDA regulators; in other words, a question of fact. When such an issue goes to a jury, it is told that punitive damages are not to be awarded if a company met the standards of pre-market approval and did not withhold material information or misrepresent the facts. What a jury sometimes hears is that it should award punitive damages if a defendant did not comply with FDA regulations. For that reason, in this type of defense there is a certain danger to companies who are reckless or negligent and fail to meet FDA requirements. It exerts a powerful pressure to follow the law.

MOTIVATION IS NOT SIMPLY BY STICKS, BUT CARROTS

Incentives to follow the law can be positive. Motivation is not brought about by sticks; carrots help too. In the past twenty years of practice, I have worked with pharmaceutical companies in a counseling role. I would share with you that a good, well-drafted FDA punitive damage defense can help bring about good conduct.

FDA rules sometimes are precise, but do leave room for judgment at times. When client conduct can be assured, going to the ultimate to meet every requirement and turn over all pertinent information to the FDA (such as adverse risk reports) will prevent punishment; it can be a factor in motivating conduct that is positive and goes far beyond the requirements of the black letter of the law. Life experience teaches us that carrots as well as sticks can motivate good results. A properly constructed FDA defense can do just that, a point that is overlooked or perhaps not appreciated by those who opppose such provisions because those opponents of a

sound public policy idea are not and have not been in a position of providing counsel.

CONCLUSION

If one places the words "Food and Drug Administration" into Google(on the Internet, hundreds of thousands of hits come up now because it is very controversial. This body can and will regulate FDA procedures and rules. What is important to appreciate today is that state punishment—and that is punitive damages—should be reserved for unlawful conduct. If a company in good faith comports with the rules and regulations, and meets the requirements of the organization established by federal law to govern its behavior, monitor it and review it on a national basis, punishment is totally and entirely inappropriate.

I thank you very much for your kind attention, and would be pleased to answer any questions.

APPENDIX:

STATE FDA REGULATORY

COMPLIANCE DEFENSE STATUTES

Arizona Revised Statutes Annotated
Title 12. Courts and Civil Proceedings
Chapter 6. Special Actions and Proceedings by Individual Persons
Article 11. Drugs and Pharmaceuticals

→§ 12-701. Drugs; exemplary or punitive damages; definition

A. The manufacturer or seller of a drug is not liable for exemplary or punitive damages if the drug alleged to cause the harm either:

1. Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the food, drug and cosmetic act (21 United States Code § 301, et seq.) or the public health service act (42 United States Code § 201, et seq.) or

2. Is generally recognized as safe and effective pursuant to conditions established by the federal food and drug administration and applicable regulations, including packaging and labeling regulations.

B. Subsection A does not apply if the plaintiff proves, by clear and convincing evidence, that the defendant, either before or after making the drug available for public use, knowingly, in violation of applicable federal food and drug administration regulations, withheld from or misrepresented to the administration information known to be material and relevant to the harm which the plaintiff allegedly suffered.

C. In this section, "drug" means the same as provided in § 201(g)(1) of the federal food, drug and cosmetic act (21 United States Code § 321(g)(1)).

CREDIT(S)
Added by Laws 1989, Ch. 172, § 1.

Michigan Compiled Laws Annotated
Chapter 600. Revised Judicature Act of 1961
Revised Judicature Act of 1961
Chapter 29. Provisions Concerning Specific Actions

→600.2946. Product liability actions, admissibility of evidence; liability, burden of proof; presumption; drugs

Sec. 2946. (1) It shall be admissible as evidence in a product liability action that the production of the product was in accordance with the generally recognized

and prevailing nongovernmental standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the initial purchaser or user.

(2) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a production defect, the manufacturer or seller is not liable unless the plaintiff establishes that the product was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller and that, according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others. An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was economically feasible for use by the manufacturer. Technical, medical, or scientific knowledge is not economically feasible for use by the manufacturer if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability.

(3) With regard to the production of a product that is the subject of a product liability action, evidence of a philosophy, theory, knowledge, technique, or procedure that is learned, placed in use, or discontinued after the event resulting in the death of the person or injury to the person or property, which if learned, placed in use, or discontinued before the event would have made the event less likely to occur, is admissible only for the purpose of proving the feasibility of precautions, if controverted, or for impeachment.

(4) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller. Evidence of compliance or noncompliance with a

regulation or standard not relevant to the event causing the death or injury is not admissible.

(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

CREDIT(S)
Amended by P.A.1995, No. 249, § 1, Eff. March 28, 1996.

New Jersey Statutes Annotated
Title 2A. Administration of Civil and Criminal Justice
Subtitle 6. Specific Civil Actions
Chapter 58C. Products Liability

→2A:58C-5. Punitive damages

a. (Deleted by amendment, P.L.1995, c. 142.)

b. (Deleted by amendment, P.L.1995, c. 142.)

c. Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or

licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded. For purposes of this subsection, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

d. (Deleted by amendment, P.L.1995, c. 142.)

CREDIT(S)
L.1987, c. 197, § 5, eff. July 22, 1987. Amended by L.1995, c. 142, § 8.

Baldwin's Ohio Revised Code Annotated

Title XXIII. Courts--Common Pleas
Chapter 2307. Civil Actions
Product Liability Claims
2307.80 Effect of recall notification

Underlines and strikethroughs represent amendments enacted in 2004 in 2004 Ohio Laws File 144 (S.B. 80) (Am. Sub. S.B. 80). The changes are effective on April 7, 2005.

(A) Subject to ~~division~~ divisions (C) and (D) of this section, punitive or exemplary damages shall not be awarded against a manufacturer or supplier in question in connection with a product liability claim unless the claimant establishes, by clear and convincing evidence, that harm for which the claimant is entitled to recover compensatory damages in accordance with section 2307.73 or 2307.78 of the Revised Code was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question. The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product.

(B) Whether the trier of fact is a jury or the court, if the trier of fact determines that a manufacturer or supplier in question is liable for punitive or exemplary damages in connection with a product liability claim, the amount of those damages shall be determined by the court. In determining the amount of punitive

or exemplary damages, the court shall consider factors including, but not limited to, the following:

(1) The likelihood that serious harm would arise from the misconduct of the manufacturer or supplier in question;

(2) The degree of the awareness of the manufacturer or supplier in question of that likelihood;

(3) The profitability of the misconduct to the manufacturer or supplier in question;

(4) The duration of the misconduct and any concealment of it by the manufacturer or supplier in question;

(5) The attitude and conduct of the manufacturer or supplier in question upon the discovery of the misconduct and whether the misconduct has terminated;

(6) The financial condition of the manufacturer or supplier in question;

(7) The total effect of other punishment imposed or likely to be imposed upon the manufacturer or supplier in question as a result of the misconduct, including awards of punitive or exemplary damages to persons similarly situated to the claimant and the severity of criminal penalties to which the manufacturer or supplier in question has been or is likely to be subjected.

(C) ~~If~~ (1) Except as provided in division (C)(2) of this section, if a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug or device that allegedly caused the harm satisfies either of the following:

(a) It was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301-392, as amended, or the "Public Health Service Act," 58 Stat. 682 (1944), 42 U.S.C. 201-300cc-15, as amended~~, unless it is established~~.

(b) It was an over-the-counter drug marketed pursuant to federal regulations, was generally recognized as safe and effective and as not being misbranded pursuant to the applicable federal regulations, and satisfied in relevant and material respects each of the conditions contained in the applicable regulations and each of the conditions contained in an applicable monograph.

(2) Division (C)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and

relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type. ~~For~~

(3) For purposes of ~~this division, "drug~~ divisions (C) and (D) of this section:

(a) "Drug" has the same meaning ~~given to that term~~ as in the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 1041 (1938), 21 U.S.C. 321(g)(1), as amended.

(b) "Device" has the same meaning as in the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 1041 (1938), 21 U.S.C. 321(h), as amended.

(D)(1) If a claimant alleges in a product liability claim that a product other than a drug or device caused harm to the claimant, the manufacturer or supplier of the product shall not be liable for punitive or exemplary damages in connection with the claim if the manufacturer or supplier fully complied with all applicable government safety and performance standards, whether or not designated as such by the government, relative to the product's manufacture or construction, the product's design or formulation, adequate warnings or instructions, and representations when the product left the control of the manufacturer or supplier, and the claimant's injury results from an alleged defect of a product's manufacture or construction, the product's design or formulation, adequate warnings or instructions, and representations for which there is an applicable government safety or performance standard.

(2) Division (D)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer or supplier of the product other than a drug or device fraudulently and in violation of applicable government safety and performance standards, whether or not designated as such by the government, withheld from an applicable government agency information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to an applicable government agency information of that type.

(E) The bifurcated trial provisions of division (B) of section 2315.21 of the Revised Code, the ceiling on recoverable punitive or exemplary damages specified in division (D)(1) of that section, and the provisions of division (D)(3) of that section apply to awards of punitive or exemplary damages under this section.

1987 H 1, § 3, eff. 1-5-88.

West's Oregon Revised Statutes Annotated
Title 3. Remedies and Special Actions and Proceedings
Chapter 30. Actions and Suits in Particular Cases
Product Liability Actions

→30.927. Drug manufacturer liability for punitive damages; exceptions

(1) Where a drug allegedly caused the plaintiff harm, the manufacturer of the drug shall not be liable for punitive damages if the drug product alleged to have caused the harm:

(a) Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration under the Federal Food, Drug and Cosmetic Act or the Public Health Service Act; or

(b) Is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(2) Subsection (1) of this section does not apply if the plaintiff proves, in accordance with the standard of proof set forth in ORS 30.925 (1), that the defendant, either before or after making the drug available for public use, knowingly in violation of applicable federal Food and Drug Administration regulations withheld from or misrepresented to the agency or prescribing physician information known to be material and relevant to the harm which the plaintiff allegedly suffered.

(3) Nothing contained in this section bars an award of punitive damages where a manufacturer of a drug intentionally fails to conduct a recall required by a valid order of a federal or state agency authorized by statute to require such a recall.

(4) For the purposes of this section, the term "drug" has the meaning given to the term in section 1201 (g)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321(g)(1).

Laws 1987, c. 774, § 5.

West's Utah Code Annotated
Title 78. Judicial Code
Part II. Actions, Venue, Limitation of Actions
Chapter 18. Punitive Damages Awards

→§ 78-18-2. Drug exception

(1) Punitive damages may not be awarded if a drug causing the claimant's harm:

(a) received premarket approval or licensure by the Federal Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301 et seq. or the Public Health Service Act, 42 U.S.C. Section 201 et seq.;

(b) is generally recognized as safe and effective under conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(2) This limitation on liability for punitive damages does not apply if it is shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug Administration under its regulations, which information was material and relevant to the claimant's harm.

Laws 1989, c. 237, § 2.

Mr. DEAL. Thank you.

We will now go to the question phase, and I will start it off.

You have all presented very interesting testimony, although some of it is somewhat contradictory with the other, but we expect that because this whole issue is controversial.

Let me start out, Mr. Hurley, if I might, Ms. DeGette had the slide that was up earlier showing the in and out on premiums from insurance malpractice premiums versus the payouts. From what little I understand about the insurance industry, and I must admit you are really the expert there, on cases of this type in malpractice, especially where you have injuries that may not present themselves for many years, where you have statutes that give a statute of repose before the bringing of actions from an actuarial standpoint, we are not talking about just an in and out proposition, are we? We are talking about having to maintain reserves for unknown claims. We are talking about just the general insurance industry requirements of reserves, are we not?

Mr. HURLEY. Certainly, Chairman Deal, they—the need is that insurance companies carry reserves for the liabilities that they have as of a point in time. It is not simply just in and out as of a point in time. For example, if an insurance company, particularly a malpractice insurance company, provides coverage in a given year or in a given number of years and then stops collecting premiums, stops providing coverage prospectively, it will be years before that company is finished making the payments for which it is obligated as of the point in time it stopped collecting premium. The reserves that company carries are the amounts of money set aside in order to allow it to make that payment, that subsequent payment activity. So when the company stops collecting premium, it doesn't stop making payments. It must have reserves in order to make good on the promises related to the policies that it already issued.

So yes, it must carry reserves. It is not simply just comparing today's payments with today's premiums. That is a mismatch.

Mr. DEAL. One of the statements, Mr. Hunter, that I gathered from you was with regard to returns that the insurance companies have recognized. Obviously, an insurance company receiving premiums, like any other business receiving revenue, must invest that revenue in order to stay in business and, hopefully, make a profit. Would you acknowledge that during the good years where those investments were being very profitable for the insurance companies that, in fact, the malpractice premiums were given a break in terms of the premiums that were being charged simply because the investments were profitable?

Mr. HUNTER. Yes, I believe that is correct. The investment income does impact the rates. If the investment income goes up, the rates go down. If the investment income goes down, the rates go up. But it is true that paid losses over the last 30 years, if you add them up, are about half—less than half of the premiums that were collected. And that includes 30 years, so you have caught up with the lags. So that—I think her chart was——

Mr. DEAL. Did you——

Mr. HUNTER. Even over the long poll.

Mr. DEAL. Did your calculations on that include litigation expenses?

Mr. HUNTER. No, I am talking now about payouts——

Mr. DEAL. Oh, payouts.

Mr. HUNTER. [continuing] to victims. Yes.

Mr. DEAL. Just to victims.

Mr. HUNTER. But that includes the litigation, the expenses of the victims but not of the defense.

Mr. DEAL. So if, in fact, most of the cases that are litigated are, in fact, won, there may not be a payout to the victim, but there is significant defense costs that are not calculated in your figures?

Mr. HUNTER. Yes, I think of the claims brought against insurance companies, only 23 percent actually result in a payout. Some are closed with almost no expense, but others are closed with a significant expense, if they go all of the way to a trial, and that would—that is not in the paid losses, but it is in the total data.

Mr. DEAL. But it is a real outgo in terms of making an insurance business work?

Mr. HUNTER. Oh, sure.

Mr. DEAL. All right.

Mr. Hurley, did you wish to comment about this further?

Mr. HURLEY. Well, it is hard for me to comment on the comments that Mr. Hunter has made. But one thing that I—it is not clear to me is whether, when he says they are comparing premiums and—premiums to the payouts over time, whether, in fact, he is including the fact that those companies had—are going to stop collecting premium are still going to be responsible for future payments if they never collect another nickel in premium.

Mr. DEAL. Right.

Mr. HURLEY. You just can't compare premium payments and loss payments. You just can't compare the two. You do reserves——

Mr. HUNTER. You can over the long pull. You can't in the short—over 1 year. I agree.

Mr. DEAL. Dr. Singh, I don't want to keep you there sitting in the dark again. I am going to ask you a really quick question, and I have got 5 seconds.

You have testified on one aspect of this legislation that is proposed, but on the side of recognizing the need for medical malpractice reform, do you agree we need to do something?

Mr. SINGH. Yes, I agree with that. As a practicing physician, I think I agree. You need to do something with medical malpractice reform.

Mr. DEAL. Thank you.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. Thank you for your patience. Thank you all for being here so long and waiting through all of this.

I am going to request to enter into the record a letter from the Insurance Commissioner of California, John Garamendi, and also that any members on either side could submit written questions since so many people had to leave today.

Mr. DEAL. Without objection.

Mr. BROWN. Thank you.

And I have just a couple of real quick things.

Mr. Garamendi said that there are three reasons that California rates have stabilized. MICRA is one of them. Proposition 103 insurance reforms one of them. And what has happened with State, local, and private programs to eliminate bad practitioners and adequate care. In the like he said, "It is incorrect to attribute California's lower medical malpractice rates to any single factor. It is incorrect to use California's MICRA law as an argument to support the broad range of actions contemplated in the bill." He said, "The bill overreaches and gives wrongdoers protection that is not appropriate." So if I could enter that into the record.

[The letter follows:]

INSURANCE COMMISSIONER
STATE OF CALIFORNIA
February 9, 2005

The Honorable JOHN D. DINGELL
Member, United States Congress
2328 Rayburn House Office Building
Washington, D.C. 20515

DEAR CONGRESSMAN DINGELL: You asked why California's medical malpractice rates are lower than the average rates in America. I believe three things account for this:

1. MICRA: The Medical Injury Compensation Reform Act (MICRA) of 1975, reformed the medical malpractice insurance system in California through implementation of a $250,000 cap on non-economic damages, a limit on attorney fees, and full disclosure of collateral sources of compensation and periodic payments for awards over $50,000.
2. Proposition 103 and the resultant rate regulation that has been in effect since 1992.
3. State, local and private programs that eliminate bad practitioners, inadequate care, and underperforming hospitals and providers. Included in this category are licensing boards for medical professionals, hospital accreditation, peer review, and group practice peer review.

It is incorrect to attribute California's lower medical malpractice rates to any single factor. It is incorrect to use California's MICRA law and the relative advantageous rates in California as an argument to support the broad range of actions contemplated in the bill before you. MICRA is limited to those issues discussed in Item 1 above.

I believe that the bill before you overreaches and gives wrongdoers protection that is not appropriate and may well result in the proliferation of products, services and procedures that are truly harmful to the public. For example, creating a safe harbor from product liability for pharmaceutical manufacturers who receive FDA approval makes no sense in the face of recent mistakes by the FDA and subsequent recalls of commonly prescribed drugs. If evidence can be produced in a court of law that establishes that a pharmaceutical is unsafe, and penalties levied against the manufacturer, this will help to protect patients who suffer when the FDA makes the wrong call. Recent revelations of conflicts of interest and hiding relevant data should warn you away from this ill-conceived proposal.

As for the nation and this state, the best way to bring medical malpractice rates under control is to eliminate the possibilities for malpractice. This must be our focus.

Sincerely,

JOHN GARAMENDI

Mr. BROWN. Thank you, Mr. Chairman.

Dr. Singh, since both the chairman and I feel bad that you have had to sit there by yourself, my questions are going to you and for more than 5 seconds, I hope.

You and Dr. Graham with the FDA, my understanding is, have conducted a large study of heart attacks and COX-2 drugs. Tell us, briefly, what your conclusions from that study were.

Mr. SINGH. We have conducted a large study in the California Medicaid population of heart attacks and the COX-2 drugs. It is,

by far, the largest study ever done and is—and studies more heart attacks than all of the studies that have been done up so far. The results of the study were submitted to the FDA about 3 weeks ago, and it was our expectation that these results would be presented in a scientific forum during the FDA Advisory Committee meetings next week. But I have been informed that Dr. David Graham has been told that he can not present the results of these studies of this particular study during that meeting. And that is very unfortunate, I think.

Mr. BROWN. But why is that? Why are you and Dr. Graham not allowed to?

Mr. SINGH. I do not know. I do not know the answer. No reasons were given. The FDA has had, now, 3 weeks to look at the results. It followed a protocol that was very similar to the Kaiser Permanente FDA protocol that was done, a very carefully done study. It has meaningful data that answers very important questions that are going to be discussed next week. But Dr. Graham has been told he can not present the data.

Mr. BROWN. And you have, Dr. Singh, significant concern about Celebrex, as others have had about Vioxx, correct?

Mr. SINGH. That is hard to say. You know. There is a lot of data in the study, and I would probably not go on record and tell about the results of our study on any one given drug. But our data on Celebrex, as well as on other drugs, puts it into perspective of what is going on in the whole field with, also, the non-COX-2. And this is important information that the public, as well as the FDA's Advisory Committee, needs to hear. And I would rather discuss it in a scientific forum. And we have given the FDA the opportunity, shown them all of the results. Dr. Graham is a core investigator on this study. He knows exactly what was done, how it was done, what the results are, and he is not being allowed to present it at the FDA.

Mr. BROWN. Yes, I am just incredulous what has happened to what I thought was perhaps our government's best agency, the Food and Drug Administration. And with this government so awash in drug company money, the FDA appears more and more to be a wholly owned subsidiary of the drug industry. And I just am amazed at the behavior of something like this, not allowing two scientists, two scientists who have very good reputations, one of whom works for the FDA, not to who have made national news with their work, not being allowed to testify. And I—it is just one more example of the FDA failing to represent the public, in my mind.

Mr. Chairman, I will yield back the balance of my time.

Thank you, Dr. Singh, for being with us, and thank you all on the panel.

Mr. DEAL. Thank you, Mr. Brown.

Dr. Norwood.

Mr. NORWOOD. Thank you very much, Mr. Chairman.

I am glad to see so many people that we have seen in here before at other hearings. We are glad that you are back. And I think, Mr. Chairman, that if you wish to do an FDA hearing, you have got a lot of witnesses here that want to testify or, in fact, if you want to go over H.R. 5, you probably have got a lot of witnesses here who

wish to testify. But I want to remind us all, that is not what this hearing is about. And I am so happy to hear your remarks on FDA, but that is not why we are here.

Now I don't believe there are many people in Congress, in fact, I am certain a majority, who don't believe that we have to do something about medical liability. I—the majority believe that. Now there is, and always will be, contention on how we best get to that.

I am going to vote for H.R. 5, if I ever see it again, but it is not because I love it. It is not because I agree with everything in it. It is not because I don't believe it can be made better. It is because it may be the only vehicle where we have a possibility to ever try to bring these premiums in line and correct a serious problem for which my—one of my constituents today was right here talking about and the fact that access to care is getting out of hand. We have just lost, in Augusta, Georgia, one of the finest neurosurgeons in the Southeast, because he can't practice anymore because of frivolous lawsuits, because of what is going on with liability and lack of reform in controlling the premiums.

I don't know whether $250,000 is right. I will debate that and have a discussion with anybody about that. But that is not the point. The point is, there has to be a known number, a known amount of liability, for people to be able to function in the real world and practice medicine. And that doesn't even, Dr. Burgess, take into consideration for the very costly business of practicing medicine or practicing law, as physicians do, rather than medicine for fear of being sued. Now it is clear to me, those of you who want to have some type of reform, have given us numbers that suit that. Your studies all show we should. Those of you that don't want to have any type of reform have given us another study that refutes everything that, basically, we are saying needs to be done.

I don't know why I am surprised. Lawyers don't agree on things. And they tend to—one lawyer says it says this and another lawyer says it says that, and that is sort of what has come out of this hearing. What we need out of this hearing is some good ideas from smart people like you how to get this problem under control. And I am sorry, I don't believe we got that data today.

I am just curious, and I will conclude, Mr. Chairman. Would each of you tell me, do you really—do you believe that Congress should deal with this problem of medical liability that is out of hand? I know Mr. Hunter says it is not. Somebody else says it is. All I know is my doctors I live with at home tell me it is out of hand. And I see it being out of hand in my District. Now does anybody here think Congress ought not to try to come to a solution? And if you do, speak up.

Mr. HUNTER. I think Congress should take their time and not just do a knee-jerk bill. I think you should—you have time because the premiums last year just rose by 4 percent. We are not in a crisis mode at this point.

Mr. NORWOOD. That is a matter of opinion.

Mr. HUNTER. It is not a matter of opinion. That is reported by A.M. Best and Company.

Mr. NORWOOD. That is not a matter of opinion.

Mr. HUNTER. It is not.

Mr. NORWOOD. There are plenty of people who think——

Mr. HUNTER. That is a fact.

Mr. NORWOOD. [continuing] we are in a crisis.

Mr. HUNTER. That is a fact.

Mr. NORWOOD. That is a fact because you believe——

Mr. HUNTER. Oh, no, no, no. There were serious rate increases at—the 3 previous years, but last year, 4 percent, and the rates are pretty much flat right now.

Mr. NORWOOD. Is 4 percent correct?

Mr. HUNTER. Yes, 4 percent is correct.

Mr. NORWOOD. I want to hear somebody else tell me that——

Mr. HUNTER. Okay.

Mr. NORWOOD. [continuing] or tell me it is not.

Yes, sir.

Mr. HURLEY. Well, I don't have the report that Mr. Hunter is referring to, but I think it would be worth investigating. I think it would be worth checking. Four percent sounds low in light of the—I see this report.

Mr. NORWOOD. Right. We see reports from everybody, and——

Mr. HUNTER. I didn't make it up. This is A.M. Best.

Mr. HURLEY. A.M. Best is quoting on the total aggregate premium. The problem with total aggregate premium is it doesn't count self-insured programs that are diminishing the amount of money that is being reported to A.M. Best——

Mr. NORWOOD. Which is my point. If you are not for this, you can sure as hell come up with a report that allows you to say you are not for this. I just want to know if there is anybody here that thinks that the Congress should not deal with this critical problem in the United States today. I am not asking you whether you believe there ought to be a shield in it or not. I am not asking you whether you believe it ought to be $250,000 or $1 million. I am asking you do you believe—anybody not believe that the Congress must deal with this and it must deal with it now? And maybe we do have a lot of time, but we have spent my entire career in Congress trying to get here. Now I think we have spent enough time. I don't like H.R. 5 either, but I am going to vote for it, because we need to establish in law there is a limitation to what these juries can give out or otherwise you are not going to have people to deliver your babies and take care of your child when they hit their head.

And with that, Mr. Chairman, unless somebody says they think we ought not to do it, well——

Mr. DEAL. Let us give Dr. Wolfe a real quick response and——

Mr. WOLFE. About 20 seconds. I worked this op-ed in the New York Times a couple of years ago on the fact that 5 percent of the doctors account for over half of the malpractice payouts. I think that there is a crisis of doctor discipline, and I think that one of the things that Congress here could do is conduct enough research to figure out why so many medical boards are doing such a bad job preventing medical malpractice. I think if we prevented a significant chunk of it, that, in and of itself, would bring down the payouts and premiums.

Mr. NORWOOD. Well, you—I don't totally——

Mr. DEAL. I am going to have to call time.

Ms. DeGette is anxious to get her testimony—her questions in.

Ms. DEGETTE. Thank you.

Like all of the other members, Mr. Chairman, I have got a plane to catch, and like the witnesses. So I will be quick.

I want to ask you a question, Mr. Kingham, because I have been sitting here all day, and I have been sitting here for 8 years listening about the malpractice insurance crisis that we have that is forcing doctors to leave the practice of medicine, particularly in lots of different subspecialties, neurosurgeons, ob-gyns, and others. And the problem we are grappling with in Congress and in this committee is what, if anything, should Congress do to deal with these rising medical malpractice insurance rates? I appreciated your testimony today because, frankly, it is the first testimony I can remember hearing about the caps for the pharmaceutical industry. And I guess I want to ask you a question, because I have been puzzling for a long time, why are we putting these—if the problem is medical malpractice insurance rates, why have we included the pharmaceutical industry in this bill? What is the looming problem for the—are the—is the pharmaceutical industry going to get out of the business of making drugs if we don't put these caps on?

Mr. KINGHAM. Well, no, obviously, people are going to stay in the pharmaceutical business. What has been suggested in a number of reports by the Institute of Medicine and other organizations over the years, is that the standardless award of punitive damages and the possibility that they will be awarded and the risk environment that that creates discourages research in certain key areas, for——

Ms. DEGETTE. And does that——

Mr. KINGHAM. [continuing] example——

Ms. DEGETTE. Does that affect what happens to physicians then?

Mr. KINGHAM. Yes, it does.

Ms. DEGETTE. Okay. If you could explain that.

Mr. KINGHAM. If it doesn't—if you don't have a drug to administer to somebody when they are pregnant because nobody is willing to develop a drug for use in pregnant women, because of liability risks, yes. If you don't have the latest research in oral contraceptives because people are afraid to go in the oral contraceptive business and develop new products, yes.

Ms. DEGETTE. Okay.

Mr. KINGHAM. If you don't have a vaccine to prevent a disease in a person because people are afraid to be in the vaccine business, yes, it does affect the practice of medicine.

Ms. DEGETTE. Okay. So my question is, then, is there a risk right now, under current law, with punitive damages that the pharmaceutical companies are going to stop making all of those drugs? And if so, could you supplement your testimony to give us that evidence?

Mr. KINGHAM. I would be happy to, but there are——

Ms. DEGETTE. Thank you.

Mr. KINGHAM. There have been studies over the years, which suggest that it does have a perverse influence on willingness to do research and development in key areas.

Ms. DEGETTE. Now——

Mr. KINGHAM. There is no question about that.

Ms. DEGETTE. [continuing] let us see. Is this Dr. Wolfe here? You are shaking your head. Can you respond?

Mr. WOLFE. Yes. The idea that the pharmaceutical industry, with its, roughly, 18-percent profit margin, can't afford to do research for whatever reason, I mean, that is the—it is the we won't do research if you control drug prices, something that the Administration seems to have lied about in the Medicare bill. So every time there is any kind of "cap" to the industry, they say, "If you don't behave, we are not going to do any research." I think it is just a preposterous kind of statement to make. There is no basis whatsoever for it, as far as I have been able to see, and I have been watching this for even slightly longer than you have.

Ms. DEGETTE. Thank you.

I want to ask a quick question to Mr. Hunter and Mr. Hurley.

And this is sort of what we were talking about on the last panel, too. The issue of insurance company rates is a very complex issue. I think you would both agree with that. And it is something the committee is struggling with. Is that right?

Mr. HUNTER. Yes, it is complex. Sure.

Ms. DEGETTE. Would either one of you—and if you can both answer for the record, would either one of you have any objection to, in this bill, including, as part of any bill Congress passed, a study of insurance—malpractice insurance rates pricing in risk pools?

Mr. HUNTER. I wouldn't, absolutely not.

Ms. DEGETTE. Mr. Hurley?

Mr. HURLEY. I, professionally, don't have any view about that. I mean, I am here for the American Academy, and I am——

Ms. DEGETTE. The Academy doesn't have a position on that, but they wouldn't object to it, would they?

Mr. HURLEY. I don't know. I would have to check.

Ms. DEGETTE. Okay. Would anybody here object to that kind of study being included? Okay. I guess that—I take that as a no, just like Mr. Norwood asked for his response.

Again, I want to thank all of you. I would like to note, Mr. Schwartz, I noticed in your written testimony you helped write the tax book I studied tort law from at NYU Law School, so you have——

Mr. SCHWARTZ. And you are still awake, so that means that there was something——

Ms. DEGETTE. Well, it was quite a few years ago.

Mr. SCHWARTZ. Yes. Don't remind me. I am in the 11th edition.

Ms. DEGETTE. Thank you. Thank you, Mr. Chairman. I yield back.

Mr. DEAL. Thank you, Ms. DeGette.

Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. And I appreciate everyone's indulgence through what has been a long afternoon.

I have got a number of questions, and I will go through them as quickly as I can with the time that is available.

First off, Mr. Hunter, on the table that you have provided us, and I will just have to tell you what—I started to look through this. I was afraid you were going to show us fetal heart rate tracings, but actually they were insurance cycles, so I was relieved about that.

If I just look at this appendix A, and again, I will confess to you that I am not very bright about this sort of stuff. But if I just do

the simple math of the last two columns, direct premiums per doctor 2003 dollars and the paid doctor 2003 dollars and you go from 1975, which was my second year in medical school, up until the present day, it looks like we went from a ratio of about $4.73 being paid in for every dollar that was paid out in losses in 1975. Fast forward to the present and in present-day dollars of $2 in premiums for every dollar paid out. Is that—am I reading that correctly? Am I doing the math——

Mr. HUNTER. That would be right.

Mr. BURGESS. [continuing] right on that? But then these are direct costs——

Mr. HUNTER. Yes.

Mr. BURGESS. [continuing] so the costs that Medical Protective or Texas Medical Liability Trust spent defending me through these processes in each of the—any time you are sued, as the young man testified, it takes a long time to get through the process. So we are typically talking about several years for one of these cases, if it, in fact, comes to trial. So there are significant costs on the defensive side, which we don't even know about in this form, is that correct?

Mr. HUNTER. That is correct.

Mr. BURGESS. So I guess my take-away from that is the insurance companies probably aren't overcharging? They may have been overcharging in 1975 when you were the—Gerald Ford's Insurance Commissioner, but they are not overcharging at the present date. Am I drawing the correct conclusion from your data?

Mr. HUNTER. I don't conclude anything about overcharging. I—that is not the point of this. The point of this is that the premiums go up and down with the cycle and the losses have stayed flat over the years.

Mr. BURGESS. Well, yes. I would just—in a simple-minded way, doing the calculations and not being smart enough to calculate cycles, it looks like the insurance companies are doing a whole lot worse in 2003, in 2003 dollars, than they were the first or second year I was in medical school.

Let me go——

Mr. HUNTER. Well, except that you—it is the data that underlies the chart on the top of my page 6, which shows that the losses are flat.

Mr. BURGESS. And then again, we have heard other testimony, and in response to Dr. Norwood's question, that that—there perhaps is another school of thought on that.

Mr. Schwartz, I did appreciate your remarks. I thank you for being so thorough. I would just ask a question. You made the point that punitive damages are designed to punish, and obviously, we want to punish behavior that we don't want to see again. And these are—this is a civil proceeding, but these, in fact, are quasi-criminal—it is a punishment. It deals in a quasi-criminal sense. But for criminals, for drug dealers, we have got sentencing guidelines. With punitive damages, and I have never understood this, we don't. The sky is the limit. You get whatever you guys or the people on the other side, actually, can prove, you get—is what you get to take home that day. Do I understand that correctly?

Mr. SCHWARTZ. You do. The——

Mr. BURGESS. And why are there not sentencing guidelines for punitive damages? What is the problem with structuring a settlement so that if someone is, in fact, harmed and you don't want to see that behavior again, why can the judge not make a recommendation to a jury?

Mr. SCHWARTZ. There are problems for a judge to do that under the common law. This is a legislative matter, and it is something that this body or State legislature should do. You have put your finger on a key point. You have a criminal justice system where there are certain protections for a substantial fine being levied against you. In a civil system where the fines could be a billion dollars or a million dollars, there is no structure whatsoever. And I have had discussions with people who, on the criminal side, want to be more fair to criminal defendants. But oops, when you are on the civil side, they just want to—just imagine, in a criminal case, you said to a jury, "Okay. You can sentence, and look how you feel, what your emotions are," and the person's sentence would be whatever the jury wanted to render. I think that is why this legislation should include some guidelines like you are suggesting for what punishment is appropriate.

Mr. BURGESS. Thank you. My time is about expired. Dr. Wolfe, you mentioned doctor discipline is a problem, and Ms. Rosenbaum, you indicated that—did I understand you right? You said you would favor a no-fault system?

Ms. ROSENBAUM. Yes.

Mr. BURGESS. And I truly believe, too, that that is the only way to really get the issue of patient safety. But, ma'am, we are having a dickens of a time with the $250,000 cap because of the contingency fees that are present from the plaintiff's bar in this country. Do you think we could ever get a no-fault system where you just took the plaintiff's bar completely out of the equation? A yes or no answer will be fine. I have always wanted to do that to a lawyer.

Ms. ROSENBAUM. Yes, I actually think, going back to the question that Dr. Norwood raised, that it is that issue that actually really is worth Congress's time and patience.

Mr. BURGESS. Correct, but the—and Mr. Brown is no longer here, but he impugned the President's activity of this field because he said the President is getting campaign contributions. I don't know if anyone cares to do a study on campaign contributions on that side for the American Trial Lawyers Association, but I suspect they were pretty evident in the last election as well. You are talking about a system, a no-fault system, which I, in fact, would embrace, but a no-fault system is going to remove the contingency fee award to plaintiffs' lawyers across the country. I think they will be pretty upset to read about that.

I will yield back.

Mr. DEAL. Thank you, Dr. Burgess.

Mr. NORWOOD. Mr. Chairman.

Mr. DEAL. Yes, Dr. Norwood.

Mr. NORWOOD. I would like to ask unanimous consent for just 1 minute to sort of finish my statement, if that is agreeable.

Mr. DEAL. Without objection.

Mr. NORWOOD. I thank you, sir.

Mr. Wolfe, I don't know—Dr. Wolfe. Pardon me. I don't know if your figures are right that 4 percent of the doctors cause all of the malpractice awards, but assuming you are, it makes me very happy that 90 percent—96 percent of that profession is doing everything it can to help people. They are also doing everything they can to keep from being sued, which is why we see so much—I don't require a comment, so much—why we see so much defensive medicine being practiced.

I don't know whether the people in my District, who had a frivolous lawsuit brought against an ob-gyn clinic of five doctors and then they had to shut their place down because nobody would sell them any malpractice insurance. I don't know if they fit in the 4 percent or the 96 percent. I don't know if the doctors in Athens, Georgia, who closed the emergency room clinic there because they couldn't get any malpractice insurance because of a frivolous lawsuit, I don't know whether they fit in the 4 percent or 96 percent. What I do know is that we absolutely have to deal with this problem, and even if we don't get it right, we have got to limit liability to some number.

Mr. Chairman, I appreciate your opportunity to finish that up.

Mr. BURGESS. Mr. Chairman.

Mr. DEAL. Yes.

Mr. BURGESS. May I ask for unanimous consent that we ask Dr. Singh to send us the data that he has provided to the FDA and has not been allowed to speak on?

Mr. DEAL. Yes, without objection.

And anyone else that has any further information that you wish to submit would be appropriate as well.

This is, indeed, a very distinguished panel, and we do appreciate your——

Mr. BURGESS. Mr. Chairman.

Mr. DEAL. Yes.

Mr. BURGESS. May I ask, the same as Dr. Norwood, for the indulgence of an additional minute. We have assembled these——

Mr. DEAL. Without objection. Yes.

Mr. BURGESS. Dr. Singh, just briefly, how many doses of Vioxx were taken during the time that drug was on the market?

Mr. SINGH. I am sorry. I don't have the number here with me. We have done a study on that.

Mr. BURGESS. Okay. How——

Mr. SINGH. It has been hundreds of millions. Hundreds of millions.

Mr. BURGESS. And how many—let us just leave it with fatal heart attacks. How many fatal heart attacks do you estimate were caused by Vioxx?

Mr. SINGH. That is a very difficult number to reach, and Dr. David Graham has done calculations based on his study——

Mr. BURGESS. And you are going to share that data——

Mr. SINGH. [continuing] and he estimates is at about 130,000.

Mr. BURGESS. 130,000. And you are going to share that data with us.

Mr. SINGH. But that is Dr. David Graham's data. That data is out in the public domain.

Mr. BURGESS. Okay. And your—but you are going to share your data with us as well.

Mr. SINGH. Yes, our data we didn't look at the total number of heart attacks——

Mr. BURGESS. Okay.

Mr. SINGH. [continuing] caused. We just looked at what the different drugs do in comparison to each other.

Mr. BURGESS. Very well.

Mr. Kingham, finally, you talked about the vaccine injury compensation fund, and I think that was a wonderful thing that was done and did allow vaccines to be available without the costs being exploded, but we saw what happened with that in the—when you can't sue the vaccine manufacturer, sue the guy that puts the preservatives in the bottle. And that was kind of an unfortunate result of that. I think your testimony that you have to—the protections have to extend across the spectrum or there are no protections at all, I think that you really underscored that point, and I thank you for bringing it to us. I think I understood a little better today than I have ever understood it before.

The psychiatrist, Dr. Glenmullen left. I would just make the point about psychiatry and antidepressants and suicide. When I was in medical school in the 1970's, we didn't have selective seratonin reuptake inhibitors like he was talking about today. We had a class of compounds called the tricyclic antidepressants. Even back then, way back in the dark ages of psychiatry, we were told that if you start a patient on a tricyclic antidepressant, watch out, because within the first couple of weeks, they are likely to become more suicidal as they start to feel better. Initially, they are so depressed they can't think about suicide. As they start to feel a little better, it starts to cross their mind again, and maybe they feel good enough to act upon it.

So that has been in the psychiatric jargon for—and domain for a long, long period of time. I don't dispute what he is saying about the SSRIs in children, and I think, certainly, the managed care has done nothing for the practice of psychiatry in this country. It simply underscores that a child on a selective seratonin reuptake inhibitor needs to be under the care of a board-certified psychiatrist, and preferably a child psychiatrist. These are potent medications. But when used as—in the proper way, they may provide a great deal of benefit.

Thank you, Mr. Chairman, for your indulgence.

Mr. DEAL. Well, thank you all.

Thanks especially to our panel members, and thank you for your indulgence in the time delays that we have had today. We thank you very much and look forward, perhaps, to seeing some of you again.

[Whereupon, at 5:13 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

AMERICAN ACADEMY OF ACTUARIES
February 22, 2005

The Honorable NATHAN DEAL
Chairman, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

DEAR CHAIRMAN DEAL: As a representative of the American Academy of Actuaries [1], I am writing this letter as a clarification to information provided to your subcommittee during the February 10 hearing on medical liability issues. In discussions of medical malpractice premium, Mr. Robert Hunter quoted a four percent (4%) medical malpractice premium growth from AM Best's Review and Preview. Because this statistic was inconsistent with my experience and expectations, I contacted AM Best and asked for an explanation of the relatively small change considering all the premium rate increases implemented by many of the reporting companies. According to AM Best, the calculation was not adjusted for the fact that some companies stopped reporting information in 2004. Ordinarily this would not have been a significant problem except that one of the largest writers of medical malpractice in the United States stopped reporting data in 2004 causing the premium increase of 2004 over 2003 to be distorted. Mr. Hunter's observation that "...the cycle has turned and the crisis is over," at least based on this statistic, seems unsupported.

Although aggregated Best premium data is sometimes used as an indicator of increases in rates, it can only be an approximation. Increases in self-insured retentions, deductibles and captive formations erode the year-to-year growth in premium and make this statistic less effective as an indicator of increasing rates. In the case of 2004, the change in reporting companies has also distorted the comparison. In my experience, the rate increases implemented in 2004, at least for most jurisdictions, were substantially more than four percent.

It was a pleasure to have met you and if the Academy can provide additional information, please let us know.

Sincerely,

JAMES D. HURLEY ACAS, MAAA
Member, Medical Malpractice Subcommittee

AMERICAN BAR ASSOCIATION
GOVERNMENTAL AFFAIRS OFFICE
February 16, 2005

The Honorable NATHAN DEAL
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

DEAR MR. CHAIRMAN: I am writing to you on behalf of the American Bar Association regarding the February 10, 2005 Subcommittee's hearings on medical liability to present ABA views on federal proposals to pre-empt state medical liability laws.

The ABA, which has over 400,000 members throughout the country has long opposed legislation that would pre-empt the state tort laws and impose federal medical professional laws on the states.

It has been suggested by some that enactment of such legislation would help the uninsured. This is simply not the case. Limiting compensation to those who have been inured by medical malpractice will not help the uninsured gain access to health insurance. While limiting medical malpractice awards would have a major impact on those patients most severely injured by malpractice, it would have only a minor impact on national health care costs. According to the Congressional Budget Office, malpractice costs make up less than 2 percent of overall health care spend-

[1] The American Academy of Actuaries is the public policy organization for actuaries practicing in all specialties within the United States. A major purpose of the Academy is to act as the public information organization for the profession. The Academy is non-partisan and assists the public policy process through the presentation of clear and objective actuarial analysis. The Academy regularly prepares testimony for Congress, provides information to federal elected officials, comments on proposed federal regulations, and works closely with state officials on issues related to insurance. The Academy also develops and upholds actuarial standards of conduct, qualification, and practice, and the Code of Professional Conduct for all actuaries practicing in the United States.

ing. The CBO also reports that even if malpractice costs were reduced by 25 to 30 percent, it would only lower health care costs by 0.4 to 0.5 percent would likely have a comparably small effect on insurance premiums.

The ABA is especially concerned about proposals that would place a cap on pain and suffering awards in states that have no such cap for patients that have proved in their state courts that they were harmed by malpractice or a defective medical product. Those affected by caps on damages are the patients who have been most severely injured by negligence of others. No one has stated that their pain and suffering injuries are not real or severe. These patients should not be told that, due to an arbitrary limit, they will be deprived of the compensation they need to carry on. Yet legislation to cap pain and suffering awards, if enacted, would result in the most seriously injured persons who are most in need of recompense receiving less than adequate compensation.

The reallying cry of proponents of this type of legislation has been that doctors have experienced significant increases in their insurance premiums. Insurance premiums in a number of areas are up significantly. Pre-empting the state tort laws and limiting the rights of patients to be compensated for malpractice and harm caused by defective medical products will not solve this problem. Caps on non-economic damages have failed to prevent sharp increases in medical malpractice insurance premiums, according to a white paper comparing states with caps to states without caps that was released June 2, 2003, by Weiss Ratings, Inc., an independent provider of ratings and analyses of financial services companies, mutual funds and stocks.

For over 200 years, the authority to promulgate medical liability laws has rested with the states. The system, which allows each state autonomy to regulate the resolution of medical liability actions within its borders, is a hallmark of our American justice system. Because of the role they have played, the states are the repositories of experience and expertise in these matters. Thus the ABA urges your subcommittee not to approve Legislation that would pre-empt the states' medical liability laws.

In addition to the policy reasons why this long- and effectively-functioning liability system should not be altered by the U.S. Congress, it should be noted that the constitutionality of the amendment will surely be challenged based on constitutional separation-of-powers grounds. The Supreme Court, in the decisions of *Pegram et al. v. Hendrich,* 120 S.Ct. 2143 (2002), and *Rush Prudential HMO, Inc. v. Moran,* 122 S.Ct. 2151 (2002), continued to recognize that it is appropriate for the states to handle health accountability matters because health care is an area traditionally left to the states to regulate. In addition, a number of states have constitutions that prohibit caps on damage awards in personal injury cases.

Currently, states have the opportunity to enact and amend their tort laws, and the system functions well. Congress should not substitute its judgement for the systems which have thoughtfully evolved in each state over time. To do so would limit the ability of a patient who has been injured by medical malpractice or by defective medical products to receive the compensation he or she deserves.

The ABA is concerned about those in America who are without health insurance. Since 1772, the ABA has been on record supporting access to quality health care for every American regardless of the person's income. In February, 1994, the ABA's House of Delegates reaffirmed its support of legislation calling for universal coverage for all through a common public or public/private mechanism through which all contribute. But federal legislation to pre-empt state liability laws would not help the situation.

We request that you include this letter in the record of your February 10 hearings. Thank you.

Sincerely,

ROBERT D. EVANS

Cc: Members of the Subcommittee on Health

PREPARED STATEMENT OF THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS

The Joint Commission on the Accreditation of Healthcare Organizations is pleased to submit testimony for the record to the House Energy and Commerce Health Subcommittee's hearing on medical malpractice reform, held on February 10th. The Joint Commission is the nation's oldest and largest standard setting and accrediting body in health care. Approximately 15,000 health care organizations are currently accredited by the Joint Commission, including the preponderance of U.S. hospitals. Our mission is to continuously improve the safety and quality of care provided to

the public. Under its Public Policy Initiatives—which focus on broad issues that have the potential to seriously undermine the provision of safe, high-quality health care and, indeed the health of the American people—the Joint Commission's convened an expert roundtable to address strategies for improving the medical liability system and preventing patient injury.

On February 10, 2005, the Joint Commission released the results of the roundtable discussions in a white paper entitled "Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury." Its recommendations center around one very basic fact: there is a fundamental dissonance between the medical liability system and the patient safety movement. While patient safety depends on transparency of information as the basis for improvement the current system drives too much of that information underground. As a result, neither patients nor providers benefit.

The paper is a call to action for those who influence, develop or carry out policies that will lead the way to resolution of the issue. For the Committee's consideration, we have attached the conclusions and recommendation presented in the white paper. The complete document can be found at http://www.jcaho.org/about+us/public+policy+initiatives/tort—resolution.htm.

RECOMMENDATIONS FROM "HEALTH CARE AT THE CROSSROADS: STRATEGIES FOR IMPROVING THE MEDICAL LIABILITY SYSTEM AND PREVENTING PATIENT INJURY"

Recommendation I: Pursue Patient Safety Initiatives that Prevent Medical Injury

When the Institute of Medicine (IOM) released its landmark report, To Err Is Human,[1] the frequent occurrence of medical error went public. Now, five years after the IOM report, error remains ubiquitous in health care delivery. To be sure, activities and initiatives aimed at improving patient safety have been and continue to be pursued. However, there are obstacles within health care organizations that stymie improvement—most notably, lack of will, resources and knowledge.

The axiom, "you learn from your mistakes" is too little honored in health care. Near-miss and error reporting is an essential component of safety programs across safety-conscious industries. Within health care, though, many physicians are often reluctant to engage in patient safety activities and be open about errors because they believe they are being asked to do so without adequate assurances of legal protection.[2] The stifling specter of litigation results in the under-reporting of adverse events by physicians and avoidance of open communications with patients about error.[3]

The IOM report suggests that 90 percent of medical errors are the result of failed systems and procedures that are poorly designed to accommodate the complexity of health care delivery. If properly designed, these systems and procedures could better prevent inevitable human errors from reaching patients. But understanding the root causes of errors requires their divulgence in the first place. In sharp contrast to the systems-based orientation of the patient safety movement, tort law targets individual physicians.[4]

I.a *Strengthen oversight and accountability mechanisms to better ensure the competencies of physicians and nurses*

As the IOM reports make clear, multiple broken systems can be identified in the majority of cases in which a serious adverse event has occurred. However, there remains today too little effort to unveil the specific contributory factors to such occurrences. That said, a systems-based approach to quality improvement does not preclude individual accountability. Accountability mechanisms—licensure, certification, and peer review—also need to be strengthened to ensure an optimally qualified health care workforce. The tort system should not be the net to snare incompetent physicians, and it cannot be effective, when it is cast so wide.

The American Board of Medical Specialties (ABMS) is now in the process of implementing encompassing new requirements for the maintenance of board certification for the 24 medical specialties it represents. These requirements would eventually apply to over 90 percent of practicing physicians. Following suit, the Federation of State Medical Boards is also pursuing an agenda for the maintenance of physician licensure.

While the legal system is often maligned by physicians, some physicians do not hesitate to use it to stave off loss of hospital privileges and licensure. Going forward, to avoid the quagmire in which hospitals often find themselves when they attempt to curtail or remove privileges, these institutions need to be thorough and deliberate in their initial granting of privileges, to consider granting new privileges for shorter periods of time, and to apply objective measures of performance before renewing privileges. This approach would be synchronous with the movement of certification

boards to grant time-limited board certification, and to undertake rigorous competency assessment on a continuing basis.

Administrative and clinical leadership must also take greater initiative to ensure the competency of their nurses. Nurse staffing shortages have made the hiring of new nurses a priority, but newly graduated nurses typically receive far too little training before assuming clinical responsibilities, and the monitoring of clinical performance is uneven at best. The growing use of external staffing agencies to fill staffing gaps only makes this problem worse.

I.b *Allow health care researcher access to open liability claims to permit early identification of problematic trends in clinical care*

One of health care's principal patient safety success stories is anesthesiology. The American Society of Anesthesiologists uses case analysis to identify liability risk areas, monitor trends in patient injury, and design strategies for prevention. Today, the ASA Closed Claims Project—created in 1985—contains 6,448 closed insurance claims. Analyses of these claims have, for example, revealed patterns in patient injury in the use of regional anesthesia, in the placement of central venous catheters, and in chronic pain management. Results of these analyses are published in the professional literature to aid practitioner learning and promote changes in practices that improve safety and reduce liability exposure.

Closed claims data analysis is the one way in which the current medical liability system helps to inform improvements in care delivery. However, reliance on closed claims for information related to error and injury is cumbersome at best. It may take years for an insurance or medical liability claim to close. These are years in which potentially vital information on substandard practices remains unknown. Providing patient safety researchers with access to open claims, now protected from external examination, could vastly improve efforts aimed at identifying worrisome patterns in care and designing appropriate safety interventions.

I.c *Encourage appropriate adherence to clinical guidelines to improve quality and reduce liability risk*

Adherence to clinical guidelines has long been touted as an effective way in which to improve quality, reduce variation in care, and improve financial performance.[5] In court, clinical guidelines are increasingly invoked to prove or disprove deviations from the standard of care. But there is a more significant relationship between medical liability and clinical guidelines. A new study has shown that adherence to clinical guidelines can have a significant role in reducing legal risk.[6] The study, which focused on obstetrical patients, found a six-fold increase in risk of litigation for cases in which there was a deviation from relevant clinical guidelines.[7] Further, one-third of all obstetric claims analyzed in the study were linked to non-compliant care.[8]

I.d *Support teamwork development through team training, "Crew Resource Management," and high-performing microsystem modeling*

Teamwork—indeed, team training—has been identified by patient safety experts as an essential factor in reducing the risk of medical error. In aviation, "Crew Resource Management" (CRM) is the methodology used to guide team development among pilots, flight attendants and other crew. In this context, predefined roles and responsibilities for various scenarios help to assure the safety of every flight. Consistently applying such an approach to health care delivery could increase the timeliness and accuracy of communications—breakdowns of which are commonly implicated sources of serious adverse events. This could also help to enlist clinicians and support staff in committing to a common goal—safe and effective care—in the often high-pressure and chaotic environments of health care. Unfortunately, health care professionals are not educated and trained to work as teams or even team members. Recreating the culture of health care delivery to value team-based care must begin at the earliest point of intervention—health care professional education—and be continuously reinforced in practice.

Clinical units that successfully foster strong team-based approaches to health care delivery do exist. In their research, Nelson, Batalden *et al* identified high-performing, front-line clinical units called microsystems.[9] A microsystem is further defined as a small group of people who regularly work together to provide care to discrete sub-populations of patients, and share business and clinical aims, linked processes, and a common information environment.[10] Microsystems are often embedded in larger organizations—the "macrosystem."

High-performing microsystems produce superior outcomes and cost-effective care, and at the same time, provide positive and attractive working environments.[11] These units are also characterized by the high value placed on patient safety, as well as compliance with policies and other requirements.

I.e *Continue to leverage patient safety initiatives through regulatory and other quality oversight bodies*

A study recently published in *Health Affairs* by Devers et al concludes that the major driver for hospital patient safety initiatives is Joint Commission requirements.[12] The majority of hospitals surveyed as part of the study explicitly noted that they were working to meet Joint Commission requirements—developing better processes for reporting, analyzing, and preventing sentinel events; meeting patient safety standards, including acknowledgement of leadership's accountability for patient safety and the creation of a non-punitive culture; and meeting the specific national patient safety goals.[13]

In the Devers *et al* study, the description of hospital patient safety initiatives also highlights the influence of other third parties in driving patient safety improvements. The Leapfrog Group was frequently mentioned by study participants, particularly with regard to its influence in driving the adoption of Computerized Physician Order Entry (CPOE) systems.

I.f *Encourage the adoption of information and simulation technology by building the evidence-base of their impacts on patient safety, and pursue proposals to offset implementation costs*

In its *Crossing the Quality Chasm* report, the IOM underscores the importance of information technology as a key factor in meeting several of its quality aims. Since then, the momentum toward widespread adoption of information technology has accelerated. Leading proponents include the National Alliance on Healthcare Information Technology, the Markle Foundation's Connecting for Health initiative, and now the Department of Health and Human Services (HHS) itself, with the appointment of a national coordinator for IT initiatives last year.

I.g *Leverage the creation of cultures of patient safety in health care organizations*

The pressures on health care leaders today are great. Increasing costs, increasing demand for services, and unfavorable reimbursement policies mean that patient "throughput"—the time in which patients move into, through, and out of the health care setting—must be accelerated to maintain revenues. This acceleration of the care process heightens the risk of medical error, and compromises effective patient-practitioner communications.[14] Yet, in this environment, a culture of patient safety must be created and emulated from the top down. This responsibility lies both with individual health care organizations and practitioners, and with those who set health care policy in this country.

I.h *Establish a federal leadership locus for advocacy of patient safety and health care quality*

Until this country both elevates the importance of quality and safety problems and engages in a coordinated approach to solutions, it will be difficult to make significant strides in addressing the foundational patient safety problems that persist today. Creation of an Office of Health Care Quality in HHS could provide a powerful platform for setting priorities and direction for improving patient safety and health care quality. Such an office could also coordinate and enhance the efforts of established private and public sector bodies already engaged in patient safety and quality improvement activities.

I.i *Pursue "pay-for-performance" strategies that provide incentives to focus on improvements in patient safety and health care quality*

New public and private sector payer initiatives designed to "pay for performance" may provide a new opportunity to align incentives for increasing safety and improving quality and patient outcomes. In 2003, CMS launched a demonstration project in partnership with Premier Inc. to test the effectiveness of paying hospitals more for better performance according to selected measures. In 2005, a new demonstration project was initiated for large medical group practices. Small but symbolically significant bonuses are to be based on results in the management of specific clinical conditions and procedures. The pay-for-performance concept essentially envisions rewards for desired behaviors and outcomes.

Recommendation II: Promote Open Communication Between Patients and Practitioners

Lack of disclosure and communication is the most prominent complaint of patients, and their families, who together have become victims of medical error or negligence. Years of expensive and wounding litigation often ensue when families are sometimes only seeking answers.

II.a *Involve health care consumers as active members of the health care team*

Health care consumers are playing an important role in the patient safety movement—as educated advocates for change based on their own experiences. When individuals' stories reach the right audience, listeners pay heed. Health care consumers can specifically help to prevent adverse events by being active, informed, and involved members of the health care team. For patients and family members, the physical and emotional devastation of medical error cannot be easily overcome. What they want most out of their ordeal is honest and open dialogue about what went wrong, and a "legacy"—having their experience serve as a lesson for prevention in the future.[15] Seldom are such communications and assurances forthcoming.

II.b *Encourage open communication between practitioners and patients when an adverse event occurs*

An unintended consequence of the tort system is that it inspires suppression of the very information necessary to build safer systems of health care delivery. When it comes to acknowledging and reporting medical error, there is too often silence between practitioners and patients; practitioners and their peers; practitioners and the organizations in which they practice; and health care organizations and oversight agencies.

One of the basic principles of patient safety is to talk to and listen to patients.[16] Several elements are fundamental to any disclosure effort. These include a prompt explanation of what is understood about what happened and its probable effects; assurance that an analysis will take place to understand what went wrong; follow-up based on the analysis to make it unlikely that such an event will happen again; and an apology.[17]

The Joint Commission's accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients, and to their family members when appropriate. A recent study confirms that many hospitals—half of those surveyed—are reluctant to comply with this standard for fear of medical liability suits.[18] If disclosure is taken a step further to the offer of an apology, hospitals and physicians are even more likely to gravitate to traditional "defend and deny" behaviors. But there is increasing awareness that openness has the potential to heal, rather than harm, the physician-patient relationship. A growing number of hospitals, doctors and insurers are coming around to the idea that apologies may save money by reducing error-related payouts and the frequency of litigation.[19]

II.c *Pursue legislation that protects disclosure and apology from being used as evidence against practitioners in litigation*

Today, some prominent medical centers have adopted policies that urge doctors to disclose their mistakes and to apologize.[20] Insurers, too, are increasingly urging apologies.[21] And, a growing number of states are passing laws that protect an apology from being used against a doctor in court.[22] More such protections will be needed in order for most caregivers and organizations to feel comfortable with apologies, despite the ethical imperatives underlying such disclosure.

II.d *Encourage non-punitive reporting of errors to third parties that promotes sharing of information and data analysis as the basis for developing safety improvement strategies*

Few caregivers and health care organizations voluntarily break through the wall of silence to report life-threatening medical errors beyond the walls of their institutions. The Joint Commission has had a voluntary reporting system since 1996, but its Sentinel Event Database receives only about 400 new reports of events each year—well below the 44,000 to 98,000 deaths related to medical error estimated by the IOM to occur each year.

A number of states now have mandatory error reporting systems of various types.[23] One of the most active, the New York State Patient Occurrence Report and Tracking Systems (NYPORTS), logged approximately 30,000 reports in 2003.[24] A new reporting system in Pennsylvania captures reports of near-misses as well as actual errors. Reporting systems can capture enormous volumes of data, but without the requisite resources to analyze and translate data into useful information, their potential is far from being fully realized. Other types of external reporting systems include voluntary reporting systems tailored to specific health care segments and medical specialty-based reporting systems.[25]

There remains a substantial lack of clarity as to whether error analyses reported to a third-party, such as a state agency or the Joint Commission, are afforded legal privilege protections. This lack of certainty of protection continues to hamper reporting efforts that could otherwise yield essential information for making breakthrough improvements in health care safety.

II.e *Enact federal patient safety legislation that provides legal protection for information reported to designated patient safety organizations*

Patient safety legislation—under consideration by the Congress for several years and currently pending reintroduction in the current Congress—proposes legal protection for information reported to any Patient Safety Organization, as defined in the legislation. Passage of patient safety legislation of this nature would provide the cornerstone for effective reporting systems that assure confidentiality and encourage the sharing of lessons learned from the analyses of adverse events.

Recommendation III: Create an Injury Compensation System that is Patient-Centered and Serves the Common Good

Only a small percentage (2 to 3 percent) of patients who are injured through medical negligence ever pursue litigation, and even fewer ever receive compensation for their injuries.[26] Those who are awarded compensation wait an average of five years to receive it.[27] Clearly, the current tort system falls short in compensating injured patients. As for exacting justice, there is often little correlation between court findings of negligence and actual negligence.[28] And rather than deterring negligence, there is a common refrain among physicians that the current tort system "keeps us from doing things that we, as good professionals, would naturally do."[29]

A central question is how the medical liability system can be restructured to actively encourage physicians and other health care professionals to participate in patient safety improvement activities.[30] The goal of any such restructuring should be to reduce litigation by decreasing patient injury, by encouraging open communication and disclosure among patients and providers, and by assuring prompt and fair compensation when safety systems fail.

III.a *Conduct demonstration projects of alternatives to the medical liability system that promote patient safety and transparency and provide swift compensation to injured patients*

Numerous proposals have been suggested for improving the medical liability system. These proposals center on three broad approaches: (1) creation of alternative mechanisms for compensating injured patients, such as through early settlement offers; (2) resolving disputes through a so-called "no-fault" administrative system or through health courts; and (3) shifting liability from individuals to organizations.[31] Though these approaches are distinct, they are not in conflict. One could imagine an injury resolution system that incorporates the characteristics of all three.

Inherent in any alternative to the current tort system must be a high priority for disclosure—an acknowledgement of the error or injury, an apology, and assurances that steps will be taken to avoid such an error in the future.

A 2003 IOM report calls for demonstration projects to test the feasibility and effectiveness of alternative injury compensation systems that are patient-centered and focused on safety.[32] Such demonstration projects are needed to begin the process of mitigating the periodic medical liability crises that, aside from economic factors, result from the delivery of unsafe care, unreliable adjudication of claims, and unfair compensation for injured patients.

III.b *Encourage continued development of mediation and early-offer initiatives*

Some states and liability insurance companies are already pursuing reforms to reduce reliance on litigation as a means to resolve injury claims. In 2002, Pennsylvania became the first state to require hospitals to disclose, in writing, adverse events to patients or their families.[33] Nevada and Florida have since followed Pennsylvania's lead.[34] Pennsylvania is also the site of a Pew-sponsored demonstration project that encourages mediated dispute resolution.[35] As part of this model, physicians are encouraged to disclose adverse events to their patients and to apologize.[36] Patients or their families are provided with an early and fair offer of compensation, and the opportunity for mediation to resolve disputes.[37] It is too soon to know the full ramifications of the Pew-sponsored project, but early indications are that it has been successful in mitigating litigation.[38]

COPIC Insurance Company, a physician-owned liability insurer in Colorado, initiated its "3Rs" (respect, respond and resolve) program in 2000. Under this program, each insured physician is encouraged to communicate openly with the patient if an adverse event occurs, and to offer an apology when warranted.[39] COPIC pays for patient expenses, and also reimburses for lost wages.[40] Importantly, patients are not asked to waive their rights to litigation.[41] Since its inception, none of the cases addressed through the 3Rs program has gone to litigation.[42]

Comprehensive medical liability reform is the long-term solution for resolving the issues inherent in today's system, but there are actions that can be taken in the

intermediate term that would bring greater integrity and transparency to the process.

III.c *Prohibit confidential settlements—so-called "gag clauses"—that prevent learning from events that lead to litigation*

Medical liability claims are often settled before they reach trial, or before the trial ends in judgment. Terms of these settlements typically include a "gag clause" that requires the confidential sequestering of all information related to the case. Such confidential settlement offers may encourage quick resolution, but this is achieved at the cost of forever barring access to potentially important information that could be used to improve the quality and safety of care.

III.d *Redesign or replace the National Practitioner Data Bank*

Physicians named in medical liability judgments and settlements, as well as disciplinary actions, are reported to the National Practitioner Data Bank (NPDB). The primary reason for the existence of the NPDB is to permit hospitals and licensing boards to track incompetent physicians. Since its inception, questions have continued to be raised about the validity and reliability of the NPDB.[43] A 2000 General Accounting Office (GAO) report cited a multitude of NPDB problems, including underreporting of disciplinary actions, which, the report states, is a far better expression of physician competence than medical liability claims.[44] In fact, medical liability claims data constitute 80 percent of the information contained in the NPDB.[45] The information the data bank contains is also characterized in the GAO report as substantially incomplete—lacking,, for example, any information as to whether the standard of care was considered when a claim was settled or adjudicated.[46]

There is a need for a centralized information or sources that reliably capture important inputs about the performance of physicians and other practitioners, but other options than the NPDB exist. For instance, the Federation of State Medical Boards (FSMB) regularly makes information on disciplinary actions taken against physicians publicly available. It has now been five years since the release of the GAO report critical of the NPDB, and no substantial progress has been made to implement its recommendations. Given the relative ineffectiveness of the NPDB, it either needs to be substantially redesigned or its responsibilities need to be reassigned to other more reliable information repositories.

III.e *Advocate for court-appointed, independent expert witnesses to mitigate bias in expert witness testimony*

Accountability for health care professional competency lies with the individual and his or her licensing and certification boards, and employers. This accountability should increasingly extend to the conduct of physicians who act as expert witnesses in medical liability cases. As many who have participated in a medical liability case can attest, expert opinion is subject to substantial potential bias when that opinion is paid for by either the defendant or the plaintiff in a case.[47] According to the Federation of State Medical Boards, expert witnesses who give false or misleading testimony are subject to disciplinary action.[48] In the long term, court-appointed experts that are independent of either plaintiffs or defendants are more likely to provide objective support to the litigation process.

It is clearly time to actively explore and test alternatives to the medical liability system. The goal of such alternatives is not to legally prescribe "blame-free" cultures. Rather, the goal is to stimulate the creation of "just cultures," that is, health care environments that foster learning—including learning from mistakes—but that also emphasize individual accountability for misconduct. Inherent in any viable alternative for addressing medical liability claims should be the potential for fairly compensating greater numbers of injured patients, while allowing health care practitioners and providers the opportunity to reveal error, learn from such errors, and ensure that they are not repeated.

Redesigning the medical liability system will necessarily be a long-term endeavor. Meanwhile, more and continued efforts aimed at fostering transparency among provider organizations, practitioners, and patients; seeking alternatives to litigation; leveraging the development of patient safety cultures; treating health care providers fairly; and honoring patients are both noble goals and practical necessities that must be actively pursued.

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Statement for the Record

of the

American Medical Association

to the

Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives

RE: Current Issues Related to Medical Liability Reform

February 10, 2005

Division of Legislative Counsel
202 789-7426

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RE: Current Issues Related to Medical Liability Reform

February 10, 2005

On behalf of our physician and student members, the American Medical Association (AMA) appreciates the opportunity to submit our statement for the record examining the risk a dysfunctional medical liability system bears on patient access to care. In his annual State of the Union Address, President Bush said that solving the medical liability crisis continues to be one of the nation's top priorities. The President called on Congress to pass medical liability reform that "will reduce health-care costs and make sure patients have the doctors and care they need." As we have done in the past, the AMA will work with the President and Congress to pass common sense medical liability reform legislation this year so that patients have greater access to health care and physicians can practice medicine more effectively.

In the course of the past year there were several significant developments relating to the medical liability crisis. For example, going into 2004 the AMA had identified 19 states in crisis.[1] In June 2004, however, the AMA announced that Massachusetts had become the 20th state in a full-blown medical liability crisis due to its deteriorating medical liability climate and the growing threat of patients losing access to care. Data from the Massachusetts Medical Society show how patients' access to care may be in jeopardy as increased medical liability costs force physicians to restrict the services they provide, especially high-risk specialists such as neurosurgeons, orthopedic surgeons, obstetricians, and general surgeons. The situation outside of Boston is particularly worrisome, as the most recent data show there are only 23 neurosurgeons based outside of Metro Boston to serve 39 hospitals and the time to recruit a neurosurgeon has increased from 23 months in 2002 to 30 months in 2004.

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[1] Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Mississippi, Missouri, New Jersey, Nevada, New York, North Carolina, Ohio, Oregon, Pennsylvania, Texas, Washington, West Virginia, and Wyoming (see attached map).

There was also significant activity at the state level with legislatures passing medical liability reform bills in Iowa, Mississippi, Missouri, Oklahoma, and Wyoming.[2] In Iowa and Missouri, however, the efforts of the legislatures proved to be in vain as the governors of those states vetoed their respective legislature's liability reform measures. Also in 2004, the citizens in four states (Florida, Nevada, Oregon, and Wyoming) voted on ballot measures related to medical liability reform. While the efforts in these states (and the states with existing liability reforms) are indicative of the severity of the problems in the medical liability system and the desire to find effective solutions, the goal of stabilizing medical liability insurance premiums may prove elusive in the short term as legal challenges continue to work their way through the respective state court systems. As discussed below, this is one reason the AMA believes that it will take a federal approach to resolve the liability crisis.

THE CRISIS

What defines a crisis? In medicine, a crisis is defined as a sudden intensification of symptoms in the course of a disease. For the past several years, we have seen numerous symptoms that tell us our nation is facing a crisis because of a broken medical liability system. The symptoms are unmistakable: patients having to leave their state to receive urgent surgical care; pregnant women who cannot find an obstetrician to monitor their pregnancy and deliver their babies; community health centers reducing their services or closing their doors because of liability insurance concerns and the increasing fear of litigation; efforts to improve patient safety and quality being stifled because of lawsuit fears, just to name a few.

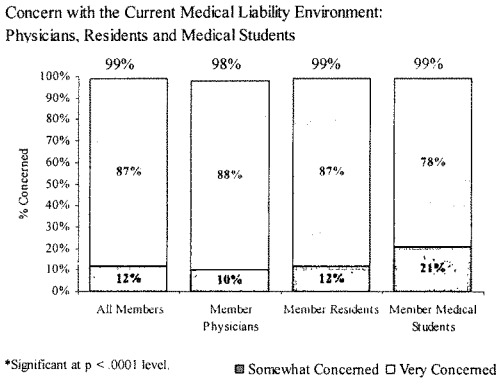
Escalating jury awards and settlements, and the high cost of defending against lawsuits, even those without merit, are driving medical liability insurance premiums to unprecedented levels. As insurance becomes unaffordable or unavailable, physicians are being forced to relocate, close their practices or drop vital services—all of which seriously impede patient access to care. Emergency departments are losing staff and scaling back certain services, such as trauma units, while some advanced and high-risk procedures (such as neurosurgery) are being postponed because physicians can no longer afford or even find the liability insurance they need to practice. Many young physicians and medical students are opting out of high-risk specialties even before their careers begin, while other physicians are choosing to retire from practice altogether.

The AMA believes the time for action is past due. Physicians across the country are making decisions now about the future of their practice, and patients are increasingly recognizing that the current litigation system jeopardizes access to quality health care services. We must act now to fix our broken medical liability system. We must bring common sense back to our courtrooms so patients have access to their physicians—whether in emergency rooms, delivery rooms, or operating rooms. This is why the AMA has worked hard to seek passage of federal legislation that includes reasonable reforms that have proven effective at keeping medical liability insurance premiums stable, and why we continue to join with numerous other members of broad-based coalitions such as the Health Coalition on Liability and Access

[2] In addition, in 2003 seven states passed laws to avert falling further into crisis (Arizona, Florida, Idaho, Mississippi, Ohio, Texas, and West Virginia).

(HCLA) and the American Tort Reform Association (ATRA) to seek passage of critical reform legislation.[3]

As seen in the chart below, an outstanding 99 percent of AMA members are very or somewhat concerned about the current medical liability environment, with 87% being very concerned.[4]



Physicians and patients across the country are realizing more and more every day that the current medical liability situation is unacceptable. The AMA has nearly 100,000 physicians who are actively participating in a grassroots network to call attention to the problem and effectuate change. Patients are involved, too. Our AMA Patients' Action Network currently has over 350,000 patients advocating for effective reforms by way of well over a million communications to their respective Members of Congress. By the second quarter of this year, we estimate that there will be 600,000 patients involved in the effort, and we are on track to exceed that goal.

ACCESS TO CARE IS AT RISK

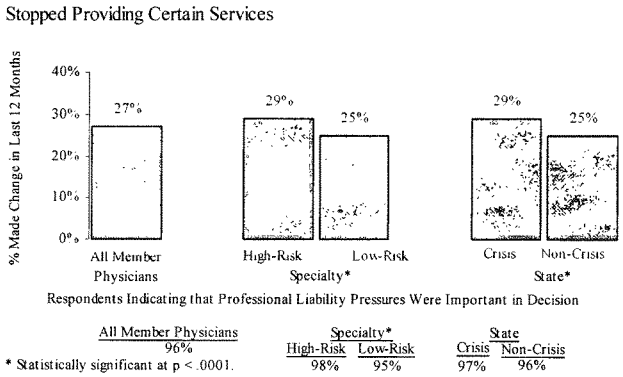
The most troubling aspect of the current medical liability litigation system is its impact on patients. Unbridled lawsuits have turned some regions of our country—and in several cases entire states—into risky areas to be sick, because it is so risky to practice medicine.

Throughout 2004, the medical liability crisis only got worse. Access to health care is now seriously threatened in 20 states, up from 12 states in 2002.[5] In many other states a crisis is

[3] A compendium of facts supporting medical liability reform and debunking arguments against reform is available on the AMA Web site at http://www.ama-assn.org/go/mlrnow.
[4] American Medical Association, Division of Market Research and Analysis, May 2004.

looming—a crisis that not only threatens access to quality medical care, but also stifles medical and scientific innovation, inhibits efforts to improve patient safety, discourages new treatments and procedures, heaps billions of dollars in additional costs upon a health care system already strained to the breaking point, and places lives at risk. Virtually every day for the past three years there has been at least one major media story on the plight of American patients and physicians as the liability crisis reaches across the country. A sample of media reports that illustrate the problem faced by patients and physicians is available at http://www.ama-assn.org/go/crisismap.

A recent survey of AMA members shows that physicians in high-risk specialties (29%) are more likely than member physicians in low-risk specialties (25%) to have stopped providing certain services in the last 12 months.[6] Member physicians in crisis states (29%) are more likely than member physicians in non-crisis states (25%) to have stopped providing certain services in the last 12 months.



A look at several states provides a grim picture of the future of medicine if effective tort reforms are not enacted.

FLORIDA

- In Florida, emergency neurosurgery patients are increasingly being transported from Palm Beach County to hospitals in Broward and Miami-Dade counties, and sometimes as far as Tampa and Gainesville. In March, one of those patients, Mildred McRoy, died six days after being transferred to a hospital in Broward County because no

[5] See attached map of medical liability crisis states.
[6] American Medical Association, Division of Market Research and Analysis, May 2004

neurosurgeon was available to treat her in Palm Beach County. (*Palm Beach Post*, March 9, 2004)

- Lee Memorial Health System officials announced they were giving the state a required six-month notice to close the trauma center after two neurosurgeons quit, leaving only two to handle 24-hour on-call duty. The center treats more than 1,000 trauma-alert patients a year. Recruitment efforts to bring neurosurgeons to Lee County have been disappointing. "The fact is, three trauma centers in Florida have notified the state that they can't hang on much longer," according to Lee Memorial's government consultant. (*The News-Press*, December 14, 2003)

- 100% of South Florida neurosurgeons have been sued, according to surveys of area physicians, and physicians in South Florida can expect to be sued 1.44 times in their career. Further, 31% of physicians have limited their practice in hospital settings. (Floridians for Quality Affordable Healthcare, December 2002)

- At least seven Florida hospitals have closed their obstetrics units due to insurance concerns, and four other hospitals have reduced or limited obstetrics services. In addition, ten hospitals have eliminated, reduced or limited neurological services. (Florida Hospital Association, January 2, 2003)

GEORGIA

- Georgia's ongoing crisis has negatively affected patient access for children, women and families throughout the state. Only seven pediatric neurosurgeons are left in the state. Women in Statesboro often wait between 6 - 9 months for routine mammogram since fewer radiologists are willing to read mammograms. Nine Macon obstetricians have stopped delivering babies or will soon do so. Two of three obstetricians in Eastman have left the state, leaving the remaining obstetrician to deliver nearly 200 babies without backup coverage. (Medical Association of Georgia)

- Gainesville obstetrician-gynecologist Linda Harrell, 49, learned in November that her insurance premiums had more than doubled in two years and she's now contemplating retirement. "How can you budget for increases like that?" Harrell asked. "I wanted to retire on my own terms. I didn't want to be run out." (*The Atlanta Journal-Constitution*, February 8, 2004)

- The Athens Women's clinic, which has offered obstetrics services for 35 years, announced May 21 that the state's medical liability crisis was forcing it to no longer deliver babies. It will continue to offer gynecological services. (*Athens Banner-Herald*, May 21, 2004)

- More than two dozen medical liability insurers have left Georgia, according to MAG Mutual, one of the state's remaining carriers. Since 1995, MAG Mutual's average payout in jury awards and settlements has increased from $215,000 a case to

$465,300. Last year, it paid claims in 20 cases of more than $1 million. (*Atlanta Journal-Constitution*, February 8, 2004)

ILLINOIS

- One physician relocated from Chicago to Centura Parker Adventist Hospital near Denver after her liability insurance premiums more than doubled, from $75,000 to $170,000. In Colorado, she pays only about $25,000. (*Denver Post*, March 4, 2004)

- Dr. Stephanie Skelly, an obstetrician-gynecologist in Belleville, is considering a move to her home state, Louisiana, where liability costs are about half compared to Illinois. The combined premium for Skelly and her partner, Dr. John Hucker, doubled to $200,000 from $100,000. They took out a loan to pay a one-time $250,000 for tail coverage. "We have to work for free this year," Hucker said. (*St. Louis Post-Dispatch*, October 6, 2002)

- In 2002, non-economic damages comprised 91% of the average total monetary value awarded by a jury. In 1997, it was 67%. (Illinois State Medical Society, February 9, 2004)

- When three obstetrician-gynecologists on staff at Advocate Lutheran General Hospital in Park Ridge learned their 2004 liability insurance premiums would climb from $345,000 to $510,470, they decided to take their practice to Kenosha, Wisconsin, where during their first year their combined insurance will cost $50,018. "This state is like the Titanic," said one of the doctors. "A year ago, we saw the iceberg. Now we've already hit." (*Chicago Tribune*, March 12, 2004)

MASSACHUSETTS

- Cape Cod lost its only board-certified neurosurgeon when Robert Leaver, MD, retired early rather than face insurance premiums that reached $115,000. Dr. Leaver, who said he would have to perform about 100 operations just to pay his insurance bill, had no intention of retiring. (*Cape Cod Times*, October 6, 2003)

- The number of jury awards topping $2 million has quadrupled over five years, according to ProMutual's chairman, Barry M. Manuel, MD, a surgery professor at Boston University. Dr. Manual also said that ProMutual's investments are not behind rising insurance premiums: "In the past 10 years, there's not one year that we've shown a negative return on our investments. It's the severity of awards that's driving this situation." (Associated Press, May 17, 2004)

- A majority of Massachusetts patients believe patients bring too many lawsuits against physicians, and they strongly support reforms advocated by the state medical society. 85 percent of voters said they supported legislation that would assess liability based on a doctor's or nurse's level of responsibility, and nearly 70 percent favor limiting non-

economic damages ("pain and suffering") when economic damages (such as child care costs, lost wages, benefits, etc.) are fully covered. (*Boston Herald*, June 7, 2004)

- Large jury awards and settlements continue to occur in Massachusetts, putting further pressure on the liability system. In 2003, there were jury awards of $3.18 million and $1.8 million. Settlements were reported for $3.75 million and $3.25 million, eight settlements between $2 million and $3 million, and eight settlements between $1 million and $2 million. (*Mass. Lawyers Weekly*, January 19, 2004)

MISSISSIPPI

- Days before Mississippi's new reforms went into effect (January 1, 2003), several counties saw a rush of lawsuit filings. Hinds County saw a 200-300 case increase; Holmes County had at least 30 additional lawsuits filed; Rankin County's increase went from less than 300 to nearly 400. (Associated Press, December 30, 2002)

- Pediatric specialist Kurt Kooyer, MD, left the small town of Rolling Fork after getting fed up with a legal system that allowed lawyers to file suit against him without the patients knowledge they were suing their physician. Dr. Kooyer, the only pediatrician among three physicians in town, arrived in 1994 and was responsible the infant mortality decreasing from an average of 10 deaths per 1,000 live births to 3.4. Dr. Kooyer now lives in North Dakota. (*Clarion Ledger*, August 23, 2003)

- Only two neurosurgeons remain in practice in the Gulf Coast-area of Mississippi, and general surgeons are in short supply because of the state's medical liability crisis. "Everybody is reduced to the same low level of trauma care that we had 20 years ago," said Steve Delahousey, vice president of operations at American Medical Response ambulance service. (*Biloxi Sun Herald*, January 29, 2003)

- Mississippi's only Level I trauma center, the University of Mississippi Medical Center in Jackson, is concerned it may not be able to handle its increased patient load now that so many towns have lost their neurosurgeons. Towns including Columbus, Greenwood and Meridian have lost their sole neurosurgeon, and the Gulf Coast region has gone from five to one. (*Modern Healthcare*, September 9, 2002)

- Fifty-one of Mississippi's 82 counties face doctor shortages, according to a report by the Mississippi Health Policy Research Center. Starkville physician Steve Parvin, president-elect of the Mississippi State Medical Association, said a major reason for Mississippi's depleting work force of physicians is the high cost and scarcity of medical malpractice insurance. (*Health & Medicine Week*, December 29, 2003)

- Rural obstetric care is in serious jeopardy. Cleveland has lost three of six Ob-gyns, Greenwood has lost two of four, and Yazoo City-with 14,550 residents, has no one practicing obstetrics. (Associated Press, November 19, 2003)

- Dr. Paul Mace, a general surgeon in Gulfport, said his premium could reach $170,000 if he continues to handle trauma and other high-risk procedures. (*Biloxi Sun Herald*, November 7, 2003)

- Dr. Ron Graham, an orthopedic surgeon in Gulfport, received a retroactive premium increase in May of $36,000, then another increase in September. He said he's already been informed that when renewal time comes next year, it will double. That means in 10 years he's seen a 400 percent increase, he said. He may be forced to close his practice and put his four employees out of work. (*Biloxi Sun Herald*, November 7, 2003)

- Although there are several companies licensed to write medical liability insurance policies, state insurance commissioner George Dale said few new policies are actually being written. "A lot of the companies still perceive that Mississippi is not a good place to do business," he said. (Associated Press, April 28, 2004)

MISSOURI

- St. Anthony's Health Center in Alton will lay off 50 to 75 employees in coming months. William E. Kessler, president and CEO of St. Anthony's, blamed the layoffs on declining revenue associated with increased medical liability insurance premiums and the resulting exodus of doctors from the community. (*St. Louis Post-Dispatch*, June 26, 2004)

- Dr. Al Elbendary, a gynecological oncologist, left a group practice and eliminated a rural outreach clinic because of rising professional liability premiums. "Women with gynecologic cancers in Ste. Genevieve, Carbondale and Chester now have to drive over a hundred miles to see a gynecologic oncologist and receive the care they deserve," said Elbendary. (*St. Louis Post-Dispatch*, October 31, 2002)

- Dr. Scot Pringle, a Cape Girardeau obstetrician, said he has delivered approximately 8,000 babies during his 23 years, and his premiums will likely exceed $85,000 if he continues to practice. "A lot of us have been practicing long enough we are near retirement," Dr. Pringle said. "Frankly, I don't want to put up with this mess anymore." (*Southeast Missourian*, April 26, 2004)

- After obstetrician Jamie Ulbrich's liability insurance carrier stopped doing business in Missouri, the best coverage he and three colleagues at their Marshall clinic could find would have cost them double what they paid in 2003. The four doctors decided they couldn't each afford the $50,000 liability insurance premium, so they decided to stop providing obstetric service and instead work solely as family physicians in 2004. (Associated Press, January 3, 2004)

NEVADA

- The people of Nevada overwhelmingly support comprehensive medical liability reforms. A May 2003 poll conducted by the "Keep Our Doctors In Nevada" initiative found that more than 80 percent of Republicans and Democrats said they would support candidates who supported reforms, including a limit on non-economic damages and trial-lawyer contingency fees. (BestWire, September 15, 2003)

- "I left Nevada because the litigation climate had driven medical liability premiums to astronomical heights," obstetrician-gynecologist Shelby Wilbourn, MD, testified before a Congressional subcommittee. Dr. Wilbourn, whose premiums increased to $108,000, moved to Maine this year and still receives calls from some of the 8,000 patients he saw during his 12 years in Nevada. "Liability isn't about fault or bad practice-it's about hitting a jackpot. Even the best obstetrician-gynecologists have been sued, many more than once." (Associated Press, February 12, 2003)

- Mary Rasar's father died in Las Vegas after the only Level 1 trauma center was forced to [temporarily] close due to skyrocketing medical liability costs. Jim Lawson was injured July 4 in a traffic accident and rather than being rushed to the Level 1 trauma center at nearby University Medical Center, which had been forced to close, Lawson was taken to a hospital that did not have the resources necessary to save his life. He died while physicians tried to stabilize him for airlift to Salt Lake City. (PR Newswire, April 21, 2003)

- The ongoing crisis has caused one of the few remaining liability insurers, American Physicians Assurance, to pull out of Nevada, a move that will leave about 125 doctors looking for new coverage to continue their practices. Dr. Fred Redfern, president of the Nevada Orthopedic Society, said the withdrawal of another insurance carrier should alarm Nevadans. He said APA is his third insurance carrier to decide to leave Nevada because of the high cost of fighting medical liability claims. "This is not a good place to practice medicine. That's the message doctors are getting," he said. (*Las Vegas Review-Journal*, January 29, 2004)

NEW JERSEY

- A New Jersey Hospital Association survey shows that 100% of New Jersey hospitals saw an increase in liability insurance premiums in 2002, with the average hospital experiencing a 50% increase. Liability insurance has increased 203% from 1999. (New Jersey Hospital Association, January 29, 2003)

- One out of every four hospitals-nearly 27 percent-has been forced to increase payments to find physicians willing to cover the Emergency Department. Physicians are increasingly reluctant to take on such assignments because of the greater liability exposure. (New Jersey Hospital Association, January 28, 2003)

- Dr. Stephen Smith says that part of the reason costs are going up is the doctors are now forced to practice defensive medicine. "What bothers me so much is that element of -- of fear and doubt that is created by this system we're in. What we're doing now is we practice [defensive] medicine. His father, also a physician, is worried that the legal climate could cause a future shortage of high-risk specialists: "the best students are not going into high-risk fields, they're not going into OB, they're not going to neurosurgery." (*60 Minutes*, March 9, 2003)

- An eight-physician ophthalmology practice, which treats premature babies born with retinopathy-a condition that can lead to blindness-will no longer offer the procedure due to the high-risk and liability exposure. (Medical Society of New Jersey)

NEW YORK

- Dr. John Cafaro, 45, an obstetrician-gynecologist in Garden City, said some doctors are paying $130,000 for only $1 million worth of protection. "But we are getting sued for $85 and $90 million at a time," he said. "You do the math. Every time I walk into an operating room I put my family's life savings on the line." (*New York Times*, May 25, 2003)

- Of the 13 largest medical negligence lawsuits in the United States in 2002, seven were in New York state, according to the National Law Journal, including a $94 million verdict from a Brooklyn jury. (*Albany Business Review*, March 21, 2003)

- Awards greater than $1 million are three times more frequent in New York than in California, a state that has had reforms since 1975, according to the Insurance Information Institute. (*Poughkeepsie Journal*, April 1, 2003)

- Many young doctors won't specialize in obstetrics. They fear the threat of lawsuits and wince at liability insurance costs, which can be as much as $200,000 per year. Last summer, Manhattan's Elizabeth Seton Childbearing Center, which practiced natural childbirth, had to close when its medical liability insurance premiums rocketed to $2 million. (*New York Daily News*, February 12, 2004)

NORTH CAROLINA

- Dr. David Pagnanelli, a neurosurgeon, said he moved to Hendersonville, North Carolina in 2002 because liability costs were too high in Pennsylvania. But they shot up here too - to nearly $190,000 a year - even though there've been no successful claims against him, he said. Following his insurance carrier's advice, Pagnanelli stopped seeing trauma cases. But neurosurgeons are in short supply in Hendersonville, so his decision means patients with life-threatening head injuries have been transferred to other hospitals. (*Charlotte Observer*, February 11, 2004)

- The annual number of settlements greater than $1 million for medical liability cases has more than tripled between 1993 and 2002 from 6 to 19. (*N.C. Lawyer's Weekly*, April 21, 2003)

- Hospitals in North Carolina have had insurance premiums go up 400 percent to 500 percent in the past three years, the North Carolina Medical Society says. Small, rural hospitals were hit hardest. (*Winston-Salem Journal*, March 9, 2004)

- "If we remain in North Carolina we will likely be forced to make the decision to limit procedures which carry high risks (but also are often life-saving)," said K. Stuart Lee, M.D. of Eastern Neurosurgical and Spine Associates Inc. Dr. Lee's practice saw their medical liability premiums increase 116 percent last year. (*The News and Observer*, January 26, 2003)

OHIO

- Dr. William Hurd, chairman of the department of obstetrics and gynecology at the Wright State University School of Medicine, said the liability crisis already is driving young doctors out of the Dayton area. "In the last two years, not a single one of our (obstetrical-gynecological) residents has set up a practice in Dayton, or even Ohio," Hurd said. (*Dayton Daily News*, August 28, 2002)

- "My wife and I are both physicians and just arrived in Wausau [Wisconsin] in March. We fled the crisis in Ohio after spending our whole careers in that state," said Christopher J. Magiera, a gastroenterologist. Magiera and his wife, Pamela G. Galloway, a general surgeon, gave up their 15-year-old practice when their medical liability premiums that were projected to reach $100,000 apiece. In Wisconsin, they pay a fraction of that. (*Journal Sentinel*, April 20, 2003)

- From 2001-02, Ohio physicians faced medical liability insurance increases ranging from 28 to 60 percent. Ohio ranked among the top five states for premium increases in 2002. General surgeons pay as much as $74,554, and obstetrician-gynecologists pay as much as $152,496. Comparatively, Indiana general surgeons pay between $14,000-$30,000; and obstetrician-gynecologists pay between $20,000-$40,000. (*Medical Liability Monitor,* October 2002)

- Dr. Rebecca Glaser, a popular breast cancer specialist, will retire from surgery on April 1 because of high liability insurance premiums. "I think it's horrifying when we lose a physician who has literally a one-of-a-kind practice," said Donna Buchheit, one of Glaser's breast cancer patients. She continues, "It is literally a life and death issue. The legislature needs to understand that. It is not melodramatic to say that there will be women who die this year because of this. I certainly hope I won't become one of them." (*Dayton Daily News*, February 28, 2004)

PENNSYLVANIA

- In 2000, Philadelphia accounted for 82 percent of the $415 million in medical-liability awards in Pennsylvania, and 14 of the 19 awards that exceeded $5 million, according to the Pennsylvania Trial Lawyers Association. (*The Wall Street Journal*, January 28, 2003)

- More than two out of three medical residents in six medical specialties chose to leave Pennsylvania after completing their training, according to the Philadelphia Daily News, which examined data from the city's major teaching hospitals between 1998-2002. "The resident brain drain is greatest among doctors going into high-risk specialties: ob-gyns, orthopedic surgeons and neurosurgeons. These doctors, not surprisingly, are most likely to be sued for malpractice, and pay some of the highest malpractice insurance premiums." (*Philadelphia Daily News*, May 28, 2003)

- A good example of Pennsylvania's lawsuit culture came in early 2004 when juries returned $15 million and $20 million verdicts on the same day. (Associated Press February 4, 2004)

- According to Grand View Hospital President Stuart Fine, the medical liability crisis is a main reason why patient access problems are occurring throughout the state and "has caused experienced doctors to leave the area, especially neurosurgeons, orthopedic and general surgeons, obstetricians and cardiologists. Few young doctors are coming in to take their place, and the result is a shortage of doctors." (*Morning Call* (Allentown, PA), January 23, 2004)

TEXAS

- David Gray is an emergency medical physician who has been thinking about moving to Colorado for several years to avoid lawsuits in Corpus Christi. His group of 16 emergency room doctors were sued six times in the last 30 days, as lawyers rushed to the courthouse to file cases before [recent] lawsuit caps went into effect. (*Corpus Christi Caller-Times*, September 16, 2003)

- Claims against Texas physicians doubled from approximately 16 per 100 physicians in 1996 to more than 30 in 2000. In the Lower Rio Grande Valley, the number of claims filed is growing at 60 percent a year. (Texas Department of Insurance)

- A pregnant woman showed up in Dr. Lloyd Van Winkle's Castroville office in South Texas, less than 10 minutes from delivery. Her family doctor in Uvalde had recently stopped delivering babies, citing malpractice concerns, and the woman was trying to drive 80 miles to her San Antonio doctor and hospital. (*Fort Worth Star-Telegram*, January 26, 2003)

- Fifty-two percent of all Texas physicians had medical malpractice claims filed against them in 2000, which is about twice the national average. (*The Battalion*, October 28, 2002)

WYOMING

- The loss of even one physician can have dire consequences for Wyoming patients, yet the liability crisis has forced the loss of obstetricians in Wheatland, Cheyenne and Newcastle. Surgeons have disappeared from Casper and Gillette, and more may leave Jackson. And all remaining Fremont County anesthesiologists have left their practice. (Wyoming Medical Society)

- Emergency and trauma care also is in jeopardy in Jackson Hole and Gillette. Without trauma services in the popular ski town, patients' lives will be compromised by the long distance to the next open center-travel that can take several hours in good weather. (Jackson Hole News&Guide, June 11, 2003 and Buffalo Bulletin, May 15, 2003)

FEDERAL SOLUTION

The medical liability crisis is a growing national problem that requires a national solution. If the crisis was just a matter of physicians obtaining or affording medical liability insurance in one state, we might agree that a national approach would not necessarily be required. However, the problem goes far beyond physicians and other health care professionals and institutions. The medical liability crisis has become a serious problem for patients and their ability to access health care services that would otherwise be available to them, including services provided to Medicare and Medicaid patients.

Also, the premise that it is within the ability of every state to enact legislation to effectively resolve their respective medical liability crisis has been shattered by the fact that many state liability reform laws have been nullified by activist state courts or stripped of their most effective provisions under state constitutions that limit reforms. Taking into consideration that studies show the litigation system to be an ineffective, and often unfair, mechanism for resolving medical liability claims, we believe that the time is ripe for a uniform, federal approach to resolving the liability crisis.

Moreover, there is a direct and compelling federal interest in reforming our outmoded medical liability system. According to estimates by the U.S. Department of Health and Human Services (HHS), altogether medical liability adds $70 billion to $126 billion to the cost of health care each year. These are the costs attributed to defensive medicine, which could be significantly reduced by effective medical liability reforms. These costs mean higher health insurance premiums and higher medical costs for all Americans, and especially for the federal government given that one-third of the total health care spending in our country is paid by the Medicare and Medicaid Programs. Further, HHS estimates that excessive medical liability adds $47.5 billion annually to what the federal government pays for Medicare, Medicaid, the State Children's Health Insurance Program, Veterans' Administration health care, health care for federal employees, and other government programs. Recent data from the agency shows that reasonable limits on non-economic damages would reduce the amount of taxpayers' money the federal government spends by up to $50.6 billion per year.

A PRACTICAL SOLUTION

The AMA recognizes that injuries due to negligence do occur in a small percentage of health care interactions, and that they can be as devastating for patients and their families as injury due to natural illness or unpreventable accident. When injuries occur and are caused by a breach in the standard of care, the AMA believes that patients are entitled to prompt and fair compensation. This compensation should include, first and foremost, full payment of all out of pocket "economic" losses. The AMA also believes that patients should receive reasonable compensation for intangible "non-economic" losses such as pain and suffering and, where appropriate, the right to pursue punitive damages.

Unfortunately, our medical liability litigation system is neither fair nor cost effective in making a patient whole. Transformed by high-stakes financial incentives, it has become an increasingly irrational "lottery" driven by open-ended non-economic damage awards. It is also an extremely inefficient mechanism for compensating claimants where court costs and attorney fees often consume a substantial amount of any compensation awarded to injured patients.

To ensure that all patients who have been injured through negligence are fairly compensated, the AMA believes that Congress must pass fair and reasonable reforms to our medical liability litigation system that have proven effective. Toward this end, we strongly support legislation that is based on the successful California law known as MICRA (Medical Injury Compensation Reform Act of 1975). In the 108th Congress, the House of Representatives passed two bills (H.R. 5 and H.R. 4280) that include language similar to MICRA. The major provisions in these bills would benefit patients by:

- awarding injured patients unlimited economic damages (e.g., past and future medical expenses, loss of past and future earnings, cost of domestic services, etc.);
- awarding injured patients non-economic damages up to $250,000 (e.g., pain and suffering, mental anguish, physical impairment, etc.), with states being given the flexibility to establish or maintain their own laws on damage awards, whether higher or lower than those provided for in these bills;
- awarding injured patients punitive damages up to two times economic damages or $250,000, whichever is greater;
- establishing a "fair share" rule that allocates damage awards fairly and in proportion to a party's degree of fault; and
- establishing a sliding-scale for attorneys' contingent fees, therefore maximizing the recovery for patients.

These reforms are not part of some untested theory. They have been proven to stabilize the medical liability insurance market in California—increasing patient access to care and saving

more than $1 billion per year in liability premiums—and have reduced the time it takes to settle a claim by 33 percent. MICRA is also saving California from the current medical liability insurance crisis brewing in many states that do not have similar reforms. In fact, the gap between medical liability insurance rates in California and those in the largest states that do not limit non-economic awards is substantial and growing. Data from the National Association of Insurance Commissioners (NAIC) shows that aggregate premiums in California increased by 245 percent over the 1975 to 2002 period, while premiums in the rest of the United States increased by 750 percent.

Studies and expert opinions confirm that MICRA reforms lower costs and improve access. In a study on the effect of reforms, Stanford University researchers Kessler and McClellan concluded that direct reforms, including caps on non-economic damages, reduced the likelihood that a physician will be sued by 2.1 percent. Within three years, premiums in direct reform states declined by 8.4 percent.[7] Another study by Stephen Zuckerman *et al.* looked at several types of reforms and concluded that capping medical liability awards reduced premiums for general surgeons by 13% in the year following enactment of that reform and by 34% over the long term. Premiums for general practitioners and obstetrician-gynecologists were impacted similarly.[8]

When liability insurance premiums are lower, more physicians are able to remain in practice, and the access to quality care is improved. A July 3, 2003, study from the Agency for Healthcare Research and Quality (AHRQ) looked at the distribution of physicians across states with and without caps on non-economic damages since 1970.[9] After adjusting for multiple factors, AHRQ found that by 2000, states with damage caps averaged 12 percent more physicians per capita than states without damage caps.

In a study released in May 2003, the Joint Economic Committee of the U.S. Congress stated: "Some of the key reforms proposed at the federal level, including the cap on pain and suffering damages, have proven successful at producing savings when implemented."[10] The study points to California, praising MICRA as "perhaps the most successful example of reform at the state level," and noting its slower rate of growth in medical liability premiums.[11]

Furthermore, there is strong public support for continued efforts to fix our broken medical liability system. A January 2005 survey by Public Opinion Strategies/Frederick Polls (for the AMA) shows that 73 percent of voters support a national law to limit the amount a jury can award in damages to compensate for pain and suffering in a medical liability lawsuit. These findings are consistent with the results of a Gallup poll released on February 4, 2003, which show that 72 percent of those polled favor a limit on the amount patients can be awarded for pain and suffering.

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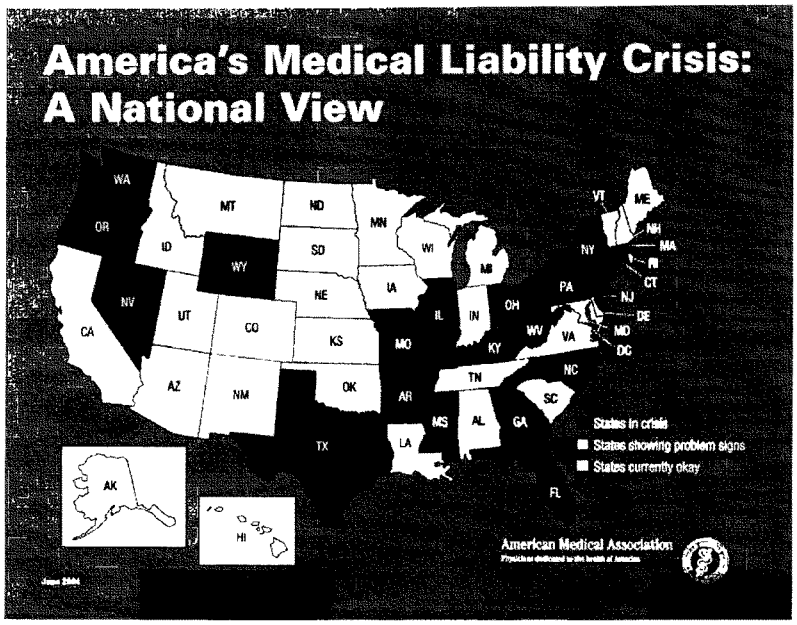
[7] Daniel P. Kessler & Mark B. McClellan, *The Effects of Malpractice Pressure and Liability Reforms on Physicians' Perceptions of Medical Care*, 60 LAW & CONTEMP. PROBS., 81-106 (1997).
[8] Stephen Zuckerman, Randall R. Bovbjerg & Frank Sloan, *Effects of Tort Reforms and Other Factors on Medical Malpractice Insurance Premiums*, 27 INQUIRY 167-182 (1990).
[9] FRED HELLINGER & WILLIAM ENCINOSA, U.S. DEP'T OF HEALTH AND HUMAN SERVS., THE IMPACT OF STATE LAWS LIMITING MALPRACTICE AWARDS ON THE GEOGRAPHIC DISTRIBUTION OF PHYSICIANS (2003).
[10] JOINT ECON. COMM., 108TH CONG., LIABILITY FOR MED. MALPRACTICE: ISSUES & EVIDENCE 19 (2003).
[11] *Id.*

CONCLUSION

Unless the hemorrhaging costs of the current medical liability system are addressed at a national level, patients will continue to face an erosion in access to care because their physicians can no longer find or afford liability insurance. The reasonable reforms embodied in H.R. 5 and H.R. 4280 (108th Congress) have brought stability in those states that have enacted similar reforms.

By enacting meaningful medical liability reforms, Congress has the opportunity to increase access to medical services, eliminate much of the need for medical treatment motivated primarily as a precaution against lawsuits, improve the patient-physician relationship, help prevent avoidable patient injury, and curb the single most wasteful use of precious health care dollars—the costs, both financial and emotional, of health care liability litigation. The modest proposals highlighted in this statement answer these issues head on and would strengthen our health care system.

The AMA appreciates the opportunity to submit this statement on the impact of medical liability issues on patient access to care and urges Congress to pass legislation that would bring about meaningful reforms.



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D.O.s: Physicians Treating People, Not Just Symptoms

February 10, 2005

The Honorable Joe Barton
Chairman, Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Barton:

On behalf of the American Osteopathic Association (AOA), I want to thank you for your continued efforts to reform the nation's broken medical liability system. We appreciate the priority you have placed upon this issue and for holding a hearing to examine it in greater depth. Today's hearing will demonstrate the negative impact this crisis has upon patient access to timely and quality health care.

The AOA, which represents the nation's 54,000 osteopathic physicians practicing in 23 specialties and subspecialties, has made reform of the medical liability system our top legislative priority. We stand ready to work with you and the Committee on the enactment of meaningful reforms. The medical liability crisis represents one of the greatest challenges to our nation's health care delivery system. It adversely impacts patient access to physician services, the physician-patient relationship, the overall costs of health care, and the training of the future physician workforce.

The impact of the crisis is growing worse, not better as many would lead us to believe. Since this crisis knows no geographic boundaries, physicians across the country are facing the reality that they will need to make significant changes in their careers. These changes range from altering or limiting the services they provide their patients, to relocating their practices to a state with more favorable medical liability laws. In far too many cases, physicians have no choice but to change careers altogether.

Limits Patient Access to Health Care Services—As a result of the decreased availability and increased costs of professional liability insurance, our members face the necessity of altering their professional careers. Many are forced to limit the services they offer their patients in an attempt to secure affordable medical liability coverage. Others are forced to relocate to states with more favorable medical liability laws. Many depart the practice of medicine altogether. Regardless of the reason for the decision, patients face decreased access to health care services. Additionally, since hospitals rely upon physicians to provide services within their institutions, a loss of physicians or decrease in physician services limits their ability to provide care to patients. This results in closures of trauma centers and OB units, and the elimination of other "high-risk" services.

Economic Impact Upon the Health Care System—The economic impact is both well documented and growing worse. In a 2002 report, the Department of Health and Human Services estimated that medical liability adds $60 to $100 billion to the costs of health care each year. The Congressional Budget Office (CBO) estimates that the enactment of comprehensive medical liability reforms would save the Federal government $14.9 billion over ten years. The trends in medical liability cases show no sign of improving. The average jury award, according to Jury Verdict Research, has increased 176 percent since 1994. The average jury award is now $3.9 million. Fifty-four percent of all awards are for $1 million or more.

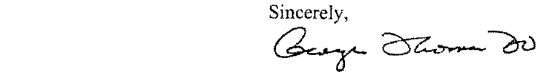
Influence Upon Physician Workforce—The influence of the medical liability crisis upon future generations of physicians is an area of great concern. In March 2004, the AOA surveyed osteopathic medical students to determine the impact of the crisis upon their career decisions. The results were startling. Eighty-two percent told us that the crisis would influence the type of practice they would pursue, while 86 percent stated that it would influence future practice locations. Additionally, 98 percent told us that they were very concerned about the medical liability crisis. These statistics demonstrate the significant negative impact the crisis has upon medical students and their future career choices.

AOA Position on Medical Liability Reform—The AOA supports comprehensive reforms, similar to those included in the "Help, Efficient, Accessible, Low-cost, Timely Health Care Act" approved by the House of Representatives during the 108th Congress. These reforms include: limitations on non-economic damages, collateral source reform, joint and several liability reform, periodic payment of damages, limitations on attorney contingency fees, and the establishment of uniform statute of limitations. We believe that when enacted together, these provisions have demonstrated the ability to stabilize the medical liability system, ensure patient access to health care services, increase the availability and affordability of professional liability insurance for physicians, while preserving access to courts for injured or harmed patients.

We fully support the ability of patients to access the legal system and to receive compensation for their economic losses. However, we believe that the nature of the medical liability system often leads to the pursuit of cases that lack merit in hopes of securing a quick settlement or a substantial jury award. This trend has led to increased costs of professional liability insurance for our members and, in some cases, a complete lack of available coverage.

Mr. Chairman, we recognize that significant steps should be taken to improve the quality and safety of health care delivered. These steps should not deflect attention from the very serious problems in the medical liability system. The AOA and our members stand ready to assist you with these efforts.

Sincerely,



George Thomas, D.O.
President

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