SMARTER HEALTH CARE PARTNERSHIP FOR AMERICAN FAMILIES: MAKING FEDERAL AND STATE ROLES IN MANAGED CARE REGULATION AND LIABILITY WORK FOR ACCOUNTABLE AND AFFORDABLE HEALTH CARE COVERAGE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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THURSDAY, MARCH 15, 2001

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

The subcommittee, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Greenwood, Burr, Whitfield, Ganske, Wilson, Shadegg, Bryant, Buyer, Pitts, Tauzin (ex officio), Brown, Strickland, Barrett, Capps, Pallone, Engel, Wynn, Green, and Dingell (ex officio).

Staff present: Nandan Kenkeremath, majority counsel; Yong Choe, legislative clerk; and Bridgett Taylor, minority counsel.

Mr. BILIRAKIS. I call the hearing to order.

As most of you know, many members of this committee and the Congress as a whole have been grappling with the issues involved in the managed care debate for a number of years now.

Today I think we are closer than we ever have been to finding common ground on several key issues.

Although some of the players have changed, the goal is the same; that is, a piece of legislation that can be passed by both the House and the Senate and signed into law by the President.

Managed care is no longer a new method of health care delivery. It has become an integral part of our national system of health coverage.

In the public and private sectors, millions of Americans participate in managed care plans.

Clearly, opinions differ on this sensitive subject. Some patients are pleased with the type of benefits and treatment they have received, while others have had difficulty obtaining the type and quality of care they need.

Most lawmakers are in general agreement on some of the basic issues of concern regarding managed care.

This hearing will focus on two issues which still bedevil us: the Federal and State regulatory roles for scope and liability.

Many stakeholders are particularly concerned about new causes of action that may increase litigation and uncertainty, thereby driving employers away from providing the health coverage many Americans depend upon.

I am hopeful that we can also tackle the difficult issue of medical malpractice this year, and we may hear from some of our witnesses on that issue.

I would like to welcome our witnesses and thank you all for joining us today. I want to extend a particular welcome to a fellow Gator fan, Steve deMontmollin, who is the Vice President and General Counsel for AvMed, a managed care organization based in Gainesville, Florida, which operates throughout the State.

I greatly appreciate the time and effort of all of our witnesses who will share their views on these important issues.

I look forward to using the information gained today as we work with the President and our colleagues in the Energy and Commerce Committee to enact responsible managed care legislation in this Congress.

Members of this subcommittee have worked for over 6 years to craft and enact responsible managed care reforms that do not impede access to health insurance. Our current system utilizes a confusing patchwork of Federal and State regulatory and enforcement relationships, and we do not want to make that situation worse.

Recognizing that new legislative mandates could add to that complexity, we must be informed and precise in all of our actions.

I am pleased that the President has taken a leadership role in outlining principles in support of a broad set of patient protections to a system that provides deference to State laws and the traditional authority of States to regulate health insurance.

The White House principals also State employers should be shielded from unnecessary and frivolous lawsuits and should not be subject to multiple lawsuits in State court.

I believe there is a general consensus on this point and we should ensure that any legislation accomplishes this result.

Stakeholders on all sides of this thorny issue have found areas of consensus in the President's Principles. As a result of his leadership, I am optimistic that we can enact responsible legislation this year.

Of course, before any measure can be presented to the President for signature, the House and Senate must first reach agreement. The role of Congress is critical in this process and we must work together to find bipartisan solutions to the Nation's health care problems.

I now yield to my good friend, the ranking member, Mr. Brown.

Mr. BROWN. I thank you, Mr. Chairman. I thank our distinguished witnesses, especially my friend Ron Pollack, and Sara Rosenbaum and others, thank you all for being here.

Beyond jurisdiction, there is another good reason for this subcommittee to hold a hearing on the Patients' Bill of Rights.

Our subcommittee is fortunate to include the policymakers in this Congress who have led the fight for managed care reform.

Ranking Member Dingell, Charlie Norwood, Greg Ganske, Frank Pallone, John Shadegg, all of them. These lawmakers have already

brought about beneficial changes in the health care system and they are poised to finish the job.

It would be difficult to underestimate their contribution and achievement.

We owe, the Nation owes a particular debt of gratitude to Charlie Norwood and John Dingell and Greg Ganske. They supported patient protections when the political barriers seemed insurmountable. They supported patient protections, whether their colleagues stood with them or not.

They supported patient protections, despite continual pressure from powerful and firmly entrenched interest groups in Washington. They supported patient protections because health insurance is meant to allay worry, not to compound it. And they supported patient protections until, finally, a majority in Congress saw things their way.

Their efforts have brought us closer than we have ever been to enacting meaningful patient protections. The key word is meaningful. If we enact rights that can't actually be exercised, they are simply not rights.

I want to focus on the right to sue. As I see it, the goals are, one, to deter irresponsible coverage decisions; two, to provide an appropriate judicial forum for settling health plan contract disputes; three, to provide genuine resource for individuals who have been materially harmed by a health plan's medical decision; and, four, to prevent frivolous lawsuits.

A related goal is to make sure that the right party is being sued. In other words, an employer should never be held liable unless that employer does something employers don't do; that is, he or she takes over the role of medical examiner, reviewing individual claims and making explicit medical decisions.

How do we achieve these goals? If we can enact legislation that includes a strong independent external appeals mechanism and timely bona fide access to the appropriate court system, we have knocked off the first four goals. If we write explicit language into this legislation that protects employers from exposure to liability when a third party is making medical decisions, we have accomplished the fifth goal.

The President believes all suits should go through Federal courts. Unfortunately, that approach fails to meet two key goals associated with the right to sue, deterring irresponsible treatment decisions and providing genuine recourse when individuals have been materially harmed by a treatment decision.

Obviously, simply ensuring individuals access to a court, even if it is the wrong one, is no real deterrent to reckless health plan behavior and it certainly doesn't provide a legitimate remedy when health plan decisions cause serious harm to enrollees.

Ranking Member Dingell and Mr. Ganske, along with Senators Edwards and McCain, have introduced legislation that bifurcates lawsuits into categories that reflect the court system best suited to hearing them.

Contract disputes would and should be resolved in Federal courts. Personal injury cases would and should be heard in State courts.

Their bill also includes a specific prohibition on suing employers for actions that the health plan takes.

With these provisions, the bill's authors have done a stellar job meeting, I believe, all five goals, and I commend them for it.

This is not a legislative hearing, per se, but it would be foolish to ignore good ideas that are already on the table.

I hope we can continue to look to the members that have led on this issue as a source of very good ideas.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. The remaining opening statements will be limited, in concert with the rules, to 3 minutes.

The Chair recognizes Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman. In today's Roll Call, there is a two-page ad, "Quality Health Care, Not Frivolous Lawsuits: President Bush, We Couldn't Agree with You More," and a long list of companies.

And you know what? You can put my name on that, too. There's a lot of myths out there, and I want to talk a little bit about the Ganske-Dingell bill.

Myth No. 1, that our bill would lead to a flood of litigation. The Ganske-Dingell bill's legal liability provisions will not create a widespread rush to the courthouse.

We ensure that the vast majority of disputes between managed care plans and patients would be resolved without the need for legal intervention, because we have a strong appeals process, both internal and external.

Under the bill, the patients would have to complete the internal and external appeals process before proceeding to court, unless there is danger of immediate and irreparable harm, or death has already occurred.

The Texas experience shows that over the last 4 years, external appeals, internal appeals work. There have only been 10 lawsuits.

Myth No. 2, employers can be sued under the Ganske-Dingell bill. Fact: employers cannot be held liable unless they have directly participated in the actual making of the decisions about the patient's care.

You know what? That is what Van-Hillary was proposing in one of the substitutes 2 years ago. We made a good faith effort to move toward employers on this and, once again, they have stepped away and moved that goalpost.

The Ganske-Dingell bill provides that an employer only can be held legally accountable when it directly participates in the actual making of the decision or the actual exercise of control in making the decision were in the conduct constituting the failure.

In those rare instances, employers should be held accountable, and I will talk about a few cases on that.

Further, the bill expressly states that employers cannot be sued for, A, picking the plan; B, picking the third-party administrator; C, conducting a cost-benefit analysis of the plan; D, modifying or terminating the plan; E, designing the plan benefit; or, F, advocating for coverage, additional coverage for an enrollee, and defining medical necessity in a certain way also does not constitute direct participation.

Myth No. 3, with a strong appeals process, there is no need for legal accountability with managed care. Well, fact: although you need a strong and independent appeals process and it is essential, it won't suffice. Let me give one example.

Mr. BILIRAKIS. Mr. Ganske, your time has expired.

Mr. GANSKE. Thirty seconds, Mr. Chairman.

Mr. BILIRAKIS. Without objection. I don't want that to be the start of something here.

Mr. GANSKE. Thank you. A patient sustained injuries to his neck and spine from a motorcycle accident, after he was taken to the hospital.

The hospital's physicians recommended immediate surgery, but the health plan, the HMO, refused to certify the procedure. Soon afterwards, the patient was paralyzed.

That patient didn't have a chance to go through an internal and external appeals process. Are you going to continue with ERISA, which says the only liability, the only remedy is the cost of care denied? I think that is not justice.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Dingell, for an opening statement.

Mr. DINGELL. Mr. Chairman, your courtesy is appreciated. I commend you and Chairman Tauzin for your interest in this very important matter of the Patients' Bill of Rights.

I want to say that I hope my colleagues and our audience were listening to Dr. Ganske, my co-sponsor and good friend, and I want to commend him and Mr. Brown and, also, my very special friend, Dr. Norwood, for the fine leadership that they and so many others have given on this particular piece of legislation.

There are a number of things that need to be addressed. First of all, we have to see to it that the rights in the Patients' Bill of Rights go to all people who are covered by plans of this kind and not just to a portion.

Second of all, we have to address the problem of liability fairly and to see to it that we, in fact, have a liability system which assures that the patient gets what he wants and what he thinks he is getting under the plan of which he is a part.

I would note that we didn't include such device in the Kennedy-Kassebaum bill and, as a result, that bill is largely nugatory in its impact.

I would note that last year Dr. Ganske and I co-sponsored a bill with the help and the leadership and participation and counsel of Dr. Norwood that provides some middle ground on the question of liability.

It says that traditionally cases which have gone to State court, i.e., medically reviewable decisions, will continue to go there; that contract cases will, of course, go to Federal courts.

This whole question of lawsuits is a red herring, as has been observed, as also is the unfortunate question of the other unfortunate questions that are raised.

I would note that when you are hurt by wrongdoing, you ought to have some remedy. Denial of that remedy is clearly wrong. ERISA provides shelter for wrongdoing and there are only two categories of persons in this Nation who can absolutely escape liability

for their wrongdoing. One is foreign diplomats and the other is HMOs under the ERISA situation.

I think we have the capacity to get at least one crowd of wrongdoers, and I think it would be a splendid idea that we did so.

Having said this, I have a superb opening statement, Mr. Chairman, that I know you and the other participants in this matter will enjoy reading. I would ask unanimous consent that it be inserted in the record, and I believe I have made my statement conclude in a timely fashion, and I thank you.

[The prepared statement of Hon. John D. Dingell follows:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

I am pleased Chairman Tauzin has taken an interest in the Patients' Bill of Rights, an issue that many of us on this Committee have worked on for some time now. I am also pleased that Chairman Bilirakis has called this hearing. Today, we are going to hear about scope and liability, both critical components of a patient protection bill.

I am not quite sure why we are even talking about scope. I don't think there is anyone here, on this Committee or in the audience, who would say that we shouldn't protect all patients. It's the right thing to do, and it's what we will do—ensure that all Americans are guaranteed basic, minimum protections. Some will propose loopholes and escape clauses, but those will not stand public scrutiny.

But on the question of liability, the differences are significant, and the key question remains: will consumers have a real remedy that offers them meaningful recourse, or will consumers be left with only an illusory solution to their current plight? We have a President who is calling for a federal liability scheme, one that would preempt state laws currently on the books. But the House passed a bill last year that allowed state courts to continue their work without federal interference. How can and should these be resolved?

This year, Dr. Ganske and I co-authored a bill, with the help and counsel of Dr. Norwood, that provides a middle ground. We preserve ERISA's uniformity for benefit decisions—which is what many employers have expressed concern about—yet at the same time, we allow states to continue their work without the federal interference of ERISA by reinstating the states' traditional purview over personal injury tort cases. This approach is balanced, sound, and fair.

Whether consumers will go to Federal court or state court when they are injured, is not just quibbling over which court to go to. It is the difference between a workable and meaningful remedy and a remedy so riddled with roadblocks, hurdles, and complications that it is of no use to anyone. The federal remedies I've seen offered thus far are so narrow in scope as to be practically meaningless.

Moreover, a federal remedy for medical cases ignores the traditional role of state courts in addressing personal injury matters. Whether you have been hurt by slipping on the floor in Wal-Mart or by a doctor or hospital, these are personal injury cases. A federal remedy, therefore, duplicates the work of state courts and doubles the number of lawsuits—patients would be forced to hold their doctor accountable in state court and their HMO accountable in Federal court. And, it leaves patients vulnerable to an HMO's "empty chair" defense, as HMOs in Federal court will always blame the doctor or hospital, who will not be there. Finally, it delays patients' ability to get a remedy. Why should injured patients have to wait in line behind drug dealers and criminals before they can get their case heard? I don't know about you, but I put injured patients before criminals any day.

Not only that, but restricting consumers to a federal remedy is worse than an empty promise. The Supreme Court recently ruled that medical decisions that cause injury could appropriately be heard in state court. To provide an exclusively federal remedy would undo what patients have already gained through that Supreme Court decision. It's no wonder some health plans and employers are interested in a federal remedy—they can escape the current trend in state courts to hold them accountable for their actions. We cannot let this Trojan horse within the city walls. Our goal is to provide meaningful remedies for consumers, not take them away.

I am pleased this hearing focuses on the important issue of liability, and I look forward to hearing our witnesses. I hope this can be the year all Americans receive effective and enforceable patient protections.

Mr. BILIRAKIS. I can't even respond to that. Without objection, the opening statements of all members of the subcommittee will be made a part of the record.

The Chair now recognizes Mr. Buyer for an opening statement.

Mr. BUYER. Thank you, Mr. Chairman. I have an opening statement I'd like to submit for the record.

Mr. BILIRAKIS. Without objection.

Mr. BUYER. And in response, I would say that the issue over the litigation provisions is not a red herring. It is more like a whale for trial lawyers.

I would also say that just the mere allegation of the immediate irreparable harm means that it is the access to litigation.

So I am very concerned about that, Dr. Ganske. I respect your medicine, but being a trial lawyer myself, I would love what you're trying to do. But if you believe in reducing the litigation in our society, we are such a litigious society, I am stunned that a doctor would advocate that.

Great praise and gratitude should be offered to Mr. Shadegg and Dr. Coburn. Why? Because they sought to find the middle ground, and I believe that they found that middle ground, and I would like to yield the balance of my time to Mr. Shadegg.

[The prepared statement of Hon. Steve Buyer follows:]

PREPARED STATEMENT OF HON. STEVE BUYER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. Chairman: I thank you for having this hearing which focuses on two areas of contention in the debate on protecting patients in managed health care settings. Before moving into that, however, I think it is important to first mention the areas in which there is a great deal of agreement.

There is really not much dispute that in the event of a medical emergency, patients should be able to access the emergency room. If an individual thinks a heart attack is occurring, that person should have no hesitation in going to the emergency room.

Patients who need specialized treatment should have access to specialists.

Women should have direct access to obstetricians and gynecologists.

Parents should have peace of mind and be able to choose a pediatrician for their children, if that is their desire.

Plans should provide clear and concise information to consumers about the coverage in the health plan.

The focus of this hearing is on the areas of disagreement: the extent of the federal role into what has traditionally been a State regulated environment; and the ability of patients to sue employers for decisions related to health benefits.

This subcommittee and this Congress need to recognize that employers have provided access to quality health care to millions of Americans. And many of these people like the coverage they get through their employer. It is reliable, it is hassle free, and it is affordable.

I agree that those who make medical decisions should be held accountable when the patient is harmed by that decision.

However, we must tread carefully and not simply accuse employers of medical malpractice simply because they provide health insurance to their employees. Increasing litigation will result in less health care, not more.

Finally, I applaud the President for stepping forward in this debate. He has given us a viable set of principles. We need to work with the President to turn these principles into legislation that can be signed into law.

Mr. SHADEGG. I thank the gentleman for yielding, and I will be brief.

I was going to say in my own opening statement, and I will say it now, that this has been an issue characterized by two polar extremes.

On the one hand, you have a position which says that HMOs which injure people will enjoy absolute immunity when they do so, and I couldn't agree more with my colleague, Mr. Dingell, that no one in this society should be absolutely immune for the consequences of their conduct.

The reality of that public policy is that it simply encourages bad decisions, and it does not encourage care, and at the end of the day, we need a system that encourages care.

So for my friend, Dr. Ganske, and my friend, Dr. Norwood, who have led in this fight, I commend them. The policy of allowing an HMO to injure or kill a patient by the result of their decision and go without paying any consequence, other than the cost of care denied, which is a joke, is, I think, clearly wrong.

But sadly, at the other end of this pendulum is the other extreme, and the other extreme says we ought to be able to sue any plan anytime over anything, and the sad fact is that that kind of a public policy will have consequences.

And in my opening statement, I will talk about the specific provisions of the language that is in the current legislation that has been discussed here today, the Edwards-Kennedy legislation, Dr. Ganske's legislation, which I don't believe is seriously intended, because it will, in fact, open a floodgate of lawsuits and enable, for example, employers to be sued and held into that lawsuit all the way to the end of the litigation, merely because they bought the health insurance and offered it to their employees.

I would urge us as a committee to do what my friend Mr. Brown talked about and what the chairman referred to, and that is seek to find common ground. Enough of the extremes of this debate. Enough of the trial advocates at the one end of the spectrum and enough of the pure HMO interests at the other end of the spectrum asking for immunity.

We have to, for the sake of the American people, find middle ground on this issue and pass a bill which will, in fact, improve health care in America for all Americans.

And I yield back.

Mr. BILIRAKIS. I thank the gentleman. Mr. Pallone.

Mr. PALLONE. Mr. Chairman, let me say, first of all, that I think we've found the middle ground, and it disturbs me to hear of those who think that we haven't.

I want to start by commending progressive Republicans like Mr. Ganske and Mr. Norwood and in the Senate, Senator McCain, because they introduced a bill which I co-sponsored a few weeks ago or a month ago that basically is similar to the Patients' Bill of Rights that was passed in the State of Texas and that is on the books in Texas, and was a very middle ground approach.

It even limited punitive damages a little more than what we passed by a majority in the House last year, and I thought that we had a bill that we could fly with and all of a sudden to hear President Bush saying, "Oh, that is not good enough, that doesn't meet my principles," and now those in the Senate, the Frist-Breaux people who are now trying to go down a slippery slope and say that it is not good enough and whittle away more at patients' rights, it is very, very disturbing to me.

We are simply saying, and I think all of us who are progressive agree that the scope of this should be all-encompassing, everybody should be included, and that you should have a legitimate viable right to sue if all else fails.

And what we are seeing now, I know the hearing isn't a legislative hearing today, but what we are seeing now is the President and the Republican leadership, who never supported the Patients' Bill of Rights, who appointed people who were against the Patients' Bill of Rights to the conference last year, so we were never able to get a bill out, basically trying to whittle down the scope and the liability provisions.

If you read, although we don't have a bill, what the Frist-Breaux is basically saying, with regard to the scope, they are trying to do something where you can opt out for States, which I am very concerned about, basically limits the scope, and they are trying to say with regard to the right to sue that it should be a Federal, limited Federal right to sue, which, again, eliminates options for people who need to sue in State courts.

And I just think that what we are going to see is that the people who were against the Patients' Bill of Rights last year are now trying to use these two issues and, again, whittle away from what we have essentially agreed on.

We have a consensus. This passed in the House, with almost every Democrat, maybe every Democrat and about a third of the Republicans.

President Bush, on the campaign trail, said he supported the Texas law. He didn't sign it, but he said he supported it and it was doing a good job.

That is what Dr. Ganske and Mr. Dingell did. They basically took the Texas law and they made it into Federal law.

What's wrong with it? It is working. As Dr. Ganske said, what have you had, like 10 suits so far? This is just an effort to kill this bill, to wear us all down, to drag out this process.

I am not suggesting, Mr. Chairman, you shouldn't have the hearing today. I think the hearing is a good idea. But we need to pass the Dingell-Ganske bill. It has got bipartisan support. It can pass both houses if it is put up.

I call upon the Republican leadership to put it up and to sign it into law as quickly as possible.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. The Chair recognizes now, for his time, Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Chairman. It is regrettable that this has a tendency to deteriorate into a partisan debate.

I think it is vitally important that we resist that in every way.

The reality is the American people deserve legislation in this area and it is incumbent upon this Congress and upon this President to find common ground.

It is true that the debate has been characterized by the extremes to this point in time and it is sad that that is so.

The chairman said in his opening remarks that our task is to find common ground, and he felt we were closer to finding common ground than we ever have been.

I think that is right. Contrary to the comments of my colleague just a moment ago, for example, the basic patient protections in both the Ganske-Dingell, Kennedy-Edwards legislation, and in the alternative legislation that Dr. Coburn and I offered last year, those basic patient protections are nearly the same and they would extend to patients across America the fundamental rights that need to be extended to them.

But there are critical differences and there are certain concerns where the two sides have to give up their extremes, and I'd like to begin by talking about some of the issues that have already been discussed.

I think and I think it is worth noting that no one, no one in this city can plausibly believe that it is realistic to propose legislation on this topic which will allow employers to be sued, and yet the Edwards-Kennedy legislation clearly allows employers to be sued.

Here is the language of the bill. We have copies of it for anybody who wants. It begins with a blanket statement that lawsuits against employers are precluded and then there is a large exception.

It says a cause of action may arise, and here is where it says it may arise. It may arise if the employer directly participated in the final decision to deny care.

Now, that sounds reasonable. And if the employer did participate in the final decision to deny care, they ought to be held liable. But the problem with this structure is that it creates a fact question—that is, did the employer participate in the final decision.

That fact question goes all the way to the jury, which means every employer in America can be sued and can be held in that lawsuit all the way through the jury verdict, based on a mere allegation that they directly participated.

There is an alternative structure that is well-known in this town called the designated decisionmaker, and that is a structure that says every employer could designate a health care decisionmaker, which is the entity that will make the health care decision and that entity may be sued and only that entity, although the employer, if they fail to designate such an entity or if they chose to retain the decision to make the health care decision, then the employer could be sued.

That is a structure that protects all employers, and I don't think anybody can credibly say that structure isn't viable and shouldn't be the preferred alternative.

Second, let's look at this issue of exhaustion. Exhaustion is vitally important right now because today health care plans in America today have a structure where they are being told how to practice medicine by HMOs.

Well, HMOs don't have doctor's degrees and they shouldn't be telling doctors how to practice medicine.

The reverse of that should be true. You should have a panel that tells the plan how, a panel of doctors that tells the plan how to practice medicine and what the standard of care ought to be in America.

Unfortunately, the Kennedy legislation, the Edwards legislation creates two large exceptions for that. It is not death that is the issue. It creates an exception for late manifestation of injury and

it creates an exception, as my colleague, Mr. Buyer pointed out, for immediate irreparable harm.

But the key is it is a mere allegation of late manifestation of injury or a mere allegation of irreparable harm.

Now, all that means is that any trial lawyer who wants to go directly to the court can cut out external review and that means doctors won't set the standard of care in America. That means trial lawyers will.

You don't have to prove the late manifestation of injury. You simply have to allege it.

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

Mr. SHADEGG. You don't have to prove immediate irreparable harm. You merely have to allege it.

We need to get beyond these points and get to some common ground.

Mr. BILIRAKIS. Mrs. Capps.

Mrs. CAPPS. I want to thank the chairman for holding this hearing. It is an important topic and many on this committee have worked very hard to address the need for patient protection in managed care.

I particularly tip my hat to Mr. Dingell, Mr. Norwood, Mr. Ganske, and Mr. Brown. Their diligence and leadership throughout the last Congress led to a reasonable and bipartisan piece of legislation to protect patients and these efforts should serve as an example to us now, particularly in the area of liability components.

Most managed care organizations want to give their beneficiaries adequate care, but they are operating in an environment designed to keep costs low. Not a bad thing, unless the pressures to cut corners are too severe.

When this pressure is excessive and leads to bad decisions, abuse of patients' rights and quality health care are the result, there needs to be a counter force on the side of quality care, on the side of the patients, and that counter force is the threat of the courts.

Access to the courts will help restore balance to the scales, will prevent the need for efficiency from outweighing the need for quality care.

My constituents don't want to go to court to get their health care that they need, but sometimes HMOs don't want to provide that care. HMOs don't want to go to the courts either, but the threat of appropriate litigation is how average Americans will keep the HMOs honest. We need to give patients that tool.

I am so pleased to see that the President has also recognized the need for patients to have access to the courts. I know there are differences between his position and the Ganske-Dingell-Norwood bill, but it seems to me they should be resolvable.

In fact, I think this legislation meets the requirements the President laid out in his State of the Union on February 27, in which he said, "We will ensure access to the courts for those with legitimate claims, but first let's put in place a strong independent review so we promote quality health care, not frivolous lawsuits."

I hope the President will see that this sounds exactly like the Ganske-Dingell bill and will sign this legislation when we pass it.

Now, I know the President believes the right to sue should be left to the Federal court, but this flies in the face of common sense and

the advice of leading legal experts, including Chief Justice Rehnquist, who has stated that Federal courts should be reserved for cases that cannot be adequately handled by the State courts.

For more than 200 years, State courts have been able to handle these types of personal injury and wrongful death cases. The experience and the precedent that the Federal bench lacks on these matters. Even so, the Ganske-Dingell bill includes a compromise on this issue in which matters of medical judgment are dealt with at the State court level and matters regarding benefits are addressed at the Federal level.

And it is my hope that the President will see the wisdom of this compromise and accept it.

Mr. Chairman, although this committee did not hold hearings on the Patients' Bill of Rights last year, its members have been very active on it. We know the issues, the background, the challenges we face, and we know how to overcome them.

We know it is the right thing to do and we know it is what we will ultimately pass.

Mr. Chairman, I look forward to working with you to move us quickly on these issues for these goals.

If I have any remaining time, I will yield a few seconds to Mr. Brown.

Mr. BILIRAKIS. By all means.

Mr. BROWN. I thank my friend from California. I just want to emphasize that the employer liability issue that we, on our side, and on both sides that support this issue have, we only want the employer to be liable when that employer itself, himself or herself, denies treatment, and that ends in injury or death for the patient.

We have constructed it very narrowly. We have made repeated requests, we on the committee, we supporters of this bill. We have negotiated this issue and made repeated requests to employers, consumer groups have made repeated requests to employers, physician organizations have made repeated requests to employer organizations that say give us some language that keeps it that narrow.

Mr. SHADEGG. Will the gentleman yield?

Mr. BILIRAKIS. The gentleman's time has long expired. The chairman of the full committee, Chairman Tauzin.

Chairman TAUZIN. Thank you, Mr. Chairman. Let me commend you for holding this important hearing.

It is no secret that in the years passed, this committee was essentially bypassed on this critical issue of managed care reform. I hope all the visitors today will know that this committee is now meeting this issue head on. That is a marked departure from the past and I hope it is well received and well respected by all of you who have come here to testify and to help educate us on the issue.

While the names of members of this committee, Mr. Norwood, Mr. Dingell, Mr. Ganske, Mr. Shadegg, Mr. Burr, Mr. Bilirakis, the chairman of the Health Committee for the past years of this Congress, have all been involved in the debate on the floor on this issue, this is the first time we will actively engage the issue and hopefully process this issue in months ahead at this committee level.

We are moving relatively fast. There were efforts, as you know, for us to delay this hearing and not to process, and Mr. Bilirakis,

the chairman of this committee, has correctly stood his ground and is moving forward with these hearings.

And he has my full support and, by the way, the support of the Speaker in these hearings.

On the other hand, at the request of the White House, we have excused a representative who was scheduled to be with us reorienting HCFA, who was going to testify on the limited area of dual accountability under the 1996 HIPAA Act, accountability for enforcement between State and Federal authorities, to give us some sense of how those systems currently work.

At the request of the administration, we have excused that witness, because the administration correctly indicates that Secretary Tommy Thompson has not yet even announced nor received clearance on his designee as head of that agency and has asked for some time before his agency testified, and we have voluntarily agreed to that request today.

Nevertheless, we are going to hear some important perspectives on either side of this issue today, and I want to thank the chairman for moving forward and for involving our committee as it is.

This is an issue that has been around for at least 6 years and many of the members that I pointed out of this committee have been part and parcel of the debate, and it is one that we are anxious to settle this year.

We want doctors to make medical decisions. We want insurance companies to provide useful insurance products, and we want health care costs that are reasonable, and we want a system of coverage that works for patients and their families, and patients are going to always be the focus of our efforts here on the health care issues.

We do not want legislation whose cure is worse than the problem. Current regulation of employee benefit plans in health insurance is already a confusing patchwork of Federal and State regulatory enforcement relationships, which we are going to explore somewhat today.

We have the Department of Health and Human Services, Department of Labor, the Internal Revenue Service, State Insurance Commissioners, all in a regulatory and enforcement mix.

HHS is still working through many of the provisions of the Health Insurance Portability and Accountability Act and State children's health insurance programs, how those laws will affect the States.

We are having hearings on some of these problems and we are seeing huge problems at HCFA and we are going to, as you know, examine the whole operations of that agency over the next several months.

Any version of managed care will likely add to the complexity in varying degrees. We need to be very thoughtful and careful as we move forward.

The White House is taking a leadership role, with principles that support a broad set of patient protections, through a system that provides deference to State patient protection laws, and to the traditional authority of States to regulate health insurance.

We need to respect those principles, both because they are right and because we need legislation the President will sign in the end.

Neither the Federal Government nor the States can afford anymore excessive bureaucracy. We must minimize the potential for disruption, complexity and uncertainty for those who provide coverage and we must realize that there are few resources for Federal agencies to administer and enforce regulations where States choose not to do so. We had better create a flexible system.

And when it comes to liability issues, Federal remedies are generally the exclusive remedies for wrongful denial of benefits under private employee insurance plans.

The standard of conduct for such administration has been for 25 years Federal law. Federal law provides employers nationally uniform and cost-effective standards of conduct for the administration of plans, including the system for improving and denying claims for coverage.

As stated in the White House Principles, we should not disturb this fundamental linkage of Federal stands of conduct and Federal remedies for breach of such conduct.

A contrary approach would allow unlimited and inconsistent theories. The law is challenge all aspects of administration of benefits and, I think, would create uncertainty and inconsistency.

We do not want to raise the cost of providing health insurance benefits. We don't want to increase unnecessary legislation. On the other hand, President Bush is providing leadership on this subject.

His principle states that patients should have the right to appeal a health care decision, to deny health care through both internal and independent binding external review.

This is an important new innovation upon which there is broad agreement. An independent external appeal process will really make a difference for patients and their families, and we all know that.

The White House Principles further state that Federal remedies should be expanded to hold health plans accountable specifically. After an independent review decision is rendered, patients should be allowed to hold their health plans liable in Federal court if they have been wrongfully denied needed medical care.

That would be a substantial addition to current Federal law. At the same time, the White House principles state that employers should be shielded from unnecessary and frivolous lawsuits and should not be subject to multiple lawsuits in both State and Federal courts.

Now, that should be a bedrock principle. Employees need to be protected, but employers, too, from unnecessary and frivolous litigation. Damages, likewise, should be subject to reasonable caps.

Mr. Chairman, we are going to make every effort to do this right.

In my own State of Louisiana, the failure to have reform of medical malpractice liability is costing the people of my State in higher costs, less insurance coverage, and unnecessary litigation.

I have heard from many physicians in my State about the need to reform medical malpractice laws, and this is an important issue for us to think about and to address.

When we craft this managed care legislation, I hope we don't do anything to compromise our principles on medical malpractice reform.

Mr. Chairman, this is an incredibly important first step. There are many steps to follow. I want to commend you for taking this first step and all the ones that will come as we go forward.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the chairman. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I appreciate you holding this hearing on a number of issues which have the support not only of our country, but also the constituents I represent. We need to reform our country's managed care system.

More than 161 million Americans are enrolled in some form of managed care plan. Unfortunately, many of these Americans feel that they have less access than ever before to the health care they want and need.

They often feel powerless under many medical plans, believing they have no resource should something go wrong.

It is time for Congress to take action and I am a proud co-sponsor of, this year, H.R. 2526, the Bipartisan Patient Protection Act.

This important legislation will do a number of things, such as provide access to emergency room care, access to specialty care, direct access for women to OB/GYNs, direct access for children to pediatricians, and a fair and independent internal and external review process, and, also, eliminate of the gag orders.

Most importantly, however, the legislation makes sure that HMOs are held accountable for damages if their denials or coverage decisions harm patients. I know this is a controversial provision and one that we will discuss at great length today, but if you can't tell, I represent a district in Texas and in the last few years, Texas did pass, in 1997, a Patient Protection Act that has an external review, and allows patients to go to the courthouse for accountability.

But we have only had, at least at last count, five lawsuits in the last 4 years. The external and internal review system is working very well.

There has not been a flood of lawsuits and, in fact, like I said, we had less than five lawsuits filed.

There are several reasons for so few lawsuits. One, it has an independent external appeals process and I believe it takes care of the threat of lawsuits.

People feel like they have an avenue for grievances. In most of those cases, the rulings run from the internal and external appeals process, fall a little over 50 percent, for the patient.

So I always say we need better than the flip of a coin when someone decides on health care for not only us, but our constituents, and that is why I think if we model something after the Texas plan for managed care reform, it will have success. But you have to have accountability and we don't have the experience of lawsuit abuse that our chairman fears we might get to that point.

I think it is time Congress follow the States' lead and we can enact bipartisan managed care reform.

I yield back my time, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. Mr. Whitfield.

Mr. WHITFIELD. Mr. Chairman, thank you very much. I also would like to congratulate Dr. Ganske and Mr. Dingell and Dr.

Norwood and others who have been pursuing a Patients' Bill of Rights.

However, I voted against the bill on the floor last time, and the reason I voted against it was because of the liability issues.

Now, everyone says that we don't want frivolous lawsuits against employers, and I think all of us are realistic enough to know that today trial lawyers are very innovative, and Dr. Ganske said that employers are not going to be sued unless they directly participated in making a decision about the health treatment of a patient.

And as Mr. Shadegg said, that is an allegation, that is a fact situation that a jury will determine. And I think we have a responsibility to move slowly on this, as we have, to be sure that we address that issue in a comprehensive way.

Right now, there are more than 30 class action lawsuits pending against a number of health plans in a Federal district court in Florida about policy issues, about purchasing issues.

And we want a health care system that does not sap the resources available for health care for the benefit of a few talented trial lawyers.

And I think all of us want a health care plan that protects patients, but we also have a responsibility to make sure that there are not these humongous class action lawsuits, with these multibillion dollar awards in today's marketplace.

I would also say that I personally would like to see us conclude not only a Patients' Bill of Rights, but a citizen's right to health insurance, because in the Patients' Bill of Rights, we are talking about 139 million people and there are about 44 million people or 43 million people who don't have any health insurance at all.

So I would like to see, as a part of this bill, including health marts or some pooling arrangements or some incentives to help people who can't afford to pay their premiums for their health insurance.

And unlike the people in this factual situation, their employers do not provide their health care.

So with that, Mr. Chairman, I will yield the balance of my time to Mr. Shadegg.

Mr. SHADEGG. Mr. Chairman, I will be very brief. I simply want to respond to the comments of my colleague, Mr. Brown. He said that there had been active efforts to seek language to protect employers.

The question of protecting employers from frivolous lawsuits, while still allowing those entities that make negligent health care decisions to be sued and to be held liable is a critical question and is it at the heart of this dispute, because if employers can be sued, we will never pass this legislation, if they can be sued for merely buying insurance.

The language that has been offered, Mr. Brown, and I'd be happy to give you a copy, is a concept called designated health care decisionmaker. It precludes a lawsuit against an employer for simply buying an insurance policy.

The problem with the language proffered in the Ganske, Kennedy, and Edwards bill is that that language, as my colleague, Mr. Whitfield, has just pointed out, allows an employer to be named as a defendant and held in the lawsuit.

What that means is if Joe Jordan's Mexican Food Restaurant, a small Mexican food restaurant in my home town, where my family goes to eat, were simply buying insurance, it can be named in the lawsuit and because it is a fact question whether it directly participated in the decision to deny care, it can be held in that lawsuit all the way through a jury trial.

Imagine the cost to Joe Jordan's Mexican Food Restaurant, which only employees about 12 people, to defend that lawsuit.

Mr. BILIRAKIS. Mr. Whitfield's time has long expired.

Mr. SHADEGG. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Barrett.

Mr. BARRETT. Thank you very much, Mr. Chairman. I appreciate you holding this hearing. I assume everything I was going to say has been said.

I simply want to respond very quickly to the statement Mr. Shadegg made.

I have long thought that there are three legitimate issues—or two legitimate issues in terms of this debate. One is the liability issue. Second is the ERISA coverage. The third issue, which I consider the boogeyman issue, is the issue that the previous speaker just spent a considerable amount of time on.

That, to me, is an issue that is just thrown out there to throw mud on the wall, and I don't know a single person on this side of the aisle or anybody who is moving and pushing this legislation who is interested in having employers held liable.

I think that that is an issue that we can certainly address with language, but I don't think it advances the debate at all to throw out this boogeyman issue.

Mr. BILIRAKIS. I don't want to have a debate now during opening statements. It isn't fair to the witnesses, for crying out loud, and I've let it go long enough.

Mr. GANSKE. Would the gentleman yield? The gentleman from Wisconsin.

Mr. BARRETT. I will certainly abide by the chairman's wish and if you want me to stop there, Mr. Chairman, I will stop. If you want me to yield to your fellow Republican, I'd be happy to do so.

Mr. BILIRAKIS. You are welcome to yield to my fellow Republican, but I am not at all happy with the way these opening statements are going.

Mr. BARRETT. Thank you very much. I would yield to Mr. Ganske.

Mr. GANSKE. I appreciate your yielding. I will be very brief, Mr. Chairman.

I would be happy to get the voting records from this committee on the number of Republicans who voted for the Hillary substitute back in 1999, which used a direct participant standard.

I will yield back.

Mr. BARRETT. And I will yield back to the chairman.

Mr. BILIRAKIS. Thank you, sir. Mrs. Wilson.

Mrs. WILSON. Thank you, Mr. Chairman. I have found these opening statements to be interesting for the amount of heat, if not light, and I find myself in a situation where I come from a State that has a fairly strong patients' protection law and a very robust and competitive managed care market.

I actually have read the legal arguments, and I am not a lawyer, and some lawyers are good for writing for people who aren't lawyers and some aren't, but I have read the legal briefs on both sides, the ones that support Dr. Ganske's view and the concerns written by the lawyers for businesses who are worried about whether their companies will be able to continue to provide health insurance for their employees.

For me, I am not a lawyer. I am married to one. It always ruins my reputation when I mention that, but I don't think this is about lawsuits and I think that the attorneys who wrote those briefs and the people who are arguing these positions firmly believe what they are saying and believe that they will have to advise their senior executives in their companies that they can no longer afford the risk to provide health insurance.

I think the last thing we want to do is to pass a law to protect patients that results in making it even harder than it already is to get health insurance or for a small business to just feel as though, golly, I just can't take the risk of offering health insurance, and we have an increase in the uninsured.

I don't think that is a red herring. I think it is a legitimate issue and a real fear among those who are trying to make these decisions on behalf of their companies and their employees, and we have to resolve it, while, at the same time, recognizing the change in health care.

That is that insurance companies used to just make one decision, does the plan cover it or not cover it. They did not involve themselves in, yes, it is covered, but this is the preferred method of treatment.

That is more of a medical decision, and what we are struggling with is what to do in that gray area when a doctor doesn't use his best medical judgment because an administrator with the HMO, who may be a medical doctor, as well, says, no, our statistics show that the best course of treatment is this one and, oh, by the way, it may also be less expensive to the HMO.

Those are the things we are trying to square here and I think it is possible to find a way to do it in a way that gives patients protections, gives people access to the care they need for themselves and their families, and allows companies to continue to offer health insurance for their employees.

Thank you, Mr. Chairman.

Mr. BURR [presiding]. The gentlelady's time has expired. The Chair would recognize Mr. Pitts for an opening statement.

Mr. PITTS. Mr. Chairman, I want to thank you for holding this important hearing today.

As a new member of the committee, I look forward to taking part in the managed care discussion.

I believe that you have chosen an appropriate title for this hearing, A Smarter Health Care Partnership for American Families, and I look forward to examining the Federal and State roles and regulation of managed care and how these two can become a healthy partnership.

I realize that many managed care proposals have been introduced today. However, I believe that the Health Subcommittee, by carefully evaluating the issues that will come before us today, can

both improve the quality of any final legislative product and help come to a fair and reasonable compromise.

Allow me to say for the record, I want to improve the quality and reliability of health care services, and I want to increase patient access to these services.

Further, I want to be sure that doctors make medical decisions, that health care costs are reasonable, and that our health care system works for our patients.

However, I do not want a legislative solution whose cure is worse than the problem. I would like to avoid legislation that would create unnecessary bureaucracy and litigation, which, in turn, would significantly raise the cost of health care.

I am gravely concerned about the 42 million Americans who currently lack health insurance. Employers in my district have told me that if a few of the current managed care reform proposals were to become law, they would drop employee coverage immediately and provide their employees with a lump sum payment for them to shop around for their own insurance.

This gives me pause. I wonder what percentage of employees would actually use that money for health insurance? Not enough, I am afraid.

If we allowed this to happen, it would only drive up the number of uninsured in America. That is why it is important that we carefully examine these issues today.

Again, Mr. Chairman, thank you for this hearing. I look forward to hearing the testimony today so that I can learn more about this important issue.

I yield back.

Mr. BURR. The Chair thanks the gentleman. The Chair would recognize Mr. Bryant for purposes of an opening statement.

Mr. BRYANT. Thank you, Mr. Chairman. I would be brief by associating myself with the remarks of my colleague from Arizona, Mr. Shadegg, as well as my colleague from New Mexico, Mrs. Wilson.

I agree with those comments, and I don't think anyone here has any less concern for access to health care than I do or I think probably everybody on this committee.

Access is very important, but having come from a practice of medical malpractice defense, I think that issue of medical malpractice is one of the biggest cost drivers in the health care system.

Of course, the doctors have to purchase medical malpractice insurance because they are the ones that see the patients. That is because you've got litigation involved in that, and what we are doing in some of these bills that Mr. Shadegg has mentioned specifically by name is inviting this type of litigation into this part of the system, and here the employer has other options that the doctors don't have.

The doctors have to play in that game and buy insurance. The employer has additional options, and that is, as has been mentioned several times, they don't have to provide the insurance. If there is a risk that they are going to be sued, if their lawyer tells them you are exposed here, why put up with that?

It is already very expensive and if you can get out of it easily and without furnishing that benefit, you will do that. And in the end, we are defeating our issue of access by putting more and more

people off onto the uninsured rolls. So we all want access, we all want quality health care, accountability, those good things, and my view has been all along that the Shadegg-Coburn bill is the best bill that meets all of these standards.

I would, again, thank the chairman for his holding this hearing as we talk about insurance and families.

We have to deal with these kinds of issues, and I suspect all these witnesses that are waiting very patiently to testify today are imminently qualified to talk about the different parts of this.

With that, I would yield back the balance of my time.

Mr. BURR. The Chair thanks the gentleman from Tennessee.

The Chair would recognize himself for the purposes of an opening statement at this time.

Let me just say that as our audience can tell, there is tremendous passion on both sides of this issue. The sad part is we can't display the same type of passion on other health care issues. If we could, we would solve many of the problems that patients face today as they are delayed, waiting for technology to receive reimbursement codes before they can get treatment or whether they are elderly and don't currently have prescription drug benefits.

I must be an exception to the rule. In every debate, there is one.

I am a member of an HMO in North Carolina. My children go to a pediatrician. My wife goes to an OB/GYN. Whenever we have an emergency, we know exactly what the cost is of the option of going to the emergency room versus trying to get in the pediatrician's office, and we make a decision in our household whether it is urgent enough that we seek that additional cost of care or whether, in fact, we go through the burden of a possible delay in that pediatrician's office.

I welcome the opportunity to make that decision. I know that all Americans don't want to make tough choices.

In that case, we get involved where government tries to get new rules. Maybe that is what we are here to do as we debate this piece of legislation.

My last two colleagues that spoke talked about a very important population in this country. They talked about the employers that aren't under a Federal obligation to offer, to extend to their employees coverage, health care coverage, one of the single most expensive things that we have in society today.

We continue to try to find the balance of the appropriate role of Federal mandates, while still maintaining this base of employee offered health care.

Most of the health care debates focus around the 44 or 42, depending upon which figure you look at, million people without insurance.

My question at the end of this debate is if we force employers, whether they are employers who purchase insurance options for their employees, or if it is the large pool of self-insured companies out there, both public and private, that cannot withstand the pressure from their board of potential exposure, exposure that many up here have said we have taken care of in the language, none of us know until the courts interpret how exposed they are.

In North Carolina, I can see a self-insured company that would be brought up for making coverage determinations because they ex-

panded the scope of coverage to take care of one of their employees who they value.

Well, the question is, who are we going to sue when these people have no health insurance anymore? Who are we going to blame? We should blame ourselves, if we do the wrong thing.

I want to thank our witnesses for coming. I want to thank the members of this panel on both sides for the passion that they have on this issue, and my hope is, at the end of the day, we will learn just a little bit more about what to do that is the right thing.

At this time, I think all members have had an opportunity for opening statements.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WYOMING

Today's hearing will help guide us in understanding federal and state roles in regulating health plans. It will also give us the opportunity to learn more about the complexities surrounding the federal law known as ERISA that governs employer-sponsored health plans.

Without a thorough understanding of these issues, I believe we will have difficulty crafting a universally acceptable liability provision within any managed care legislation.

I always keep in mind one very simple thing as I try to better understand the intricacies of regulating health plans—patients want good medical care, and they want to know that some remedy is available to them if that care is not rendered properly.

My difficulty with this issue is two fold. I have many individuals in my district who have problems with their health plans and they want a state cause of action available to them—but ERISA is not permitting that.

On the other hand, I must be very conscious of the small business community in my state because it is a driving force in Wyoming's economy. These small businesses voluntarily provide health coverage for their employees.

If these employers did not have the liability protections afforded them by ERISA, as they currently do, they would drop coverage immediately. The number of uninsured in my state would then increase dramatically. That is unacceptable to me.

I am hoping the testimony of our witnesses today will shed some light on this particular aspect of the liability debate because I know that I am not the only one with such concerns.

Thank you, Mr. Chairman. I yield back the balance of my time.

PREPARED STATEMENT OF HON. ELIOT ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. Chairman, I would like to thank you for having this hearing today and providing an opportunity to highlight HR 526, the Ganske/Dingell Patient's Bill of Rights, of which I am a cosponsor. Patient protection is a key issue in this Congress. The American people have asked Congress to provide adequate protections and we must respond. We will be discussing crucial aspects of patient protection legislation, scope and liability. The Ganske/Dingell bill addresses these issues in the proper manner.

Ganske/Dingell leaves no individual behind. Everyone with insurance coverage is protected by the bill. To do anything less would be irresponsible. Managed care providers should be held to the same standards as physicians and hospitals across the country. HR 526 would ensure that all Americans enjoy the benefits of a patient's bill of rights. I am also pleased the Ganske/Dingell bill includes the "substantially equivalent" provision in determining whether or not state laws are adequate, and allows states to prove that its laws meet or exceed the federal standard. The process improved upon the HIPAA model and should prove to be an efficient method.

The question of liability has been the subject of much debate. The Ganske/Dingell model has evolved to provide a compromise to the federal/state jurisdiction question. It has established that state courts are the proper venue in instances of medical decisions and federal courts are the proper venue for administrative or coverage questions. States have traditionally held jurisdiction in tort law and medical liability should be no different. Federal courts have neither the time nor the resources to

handle the case load and injured patients should not be left to languish while waiting to have their case heard.

Mr. Chairman all Americans deserve a strong, enforceable patient's bill of rights. I believe the Ganske/Dingell bill is good for the American people and I look forward to moving this legislation.

Mr. BURR. Let me then call up the first panel and welcome the Honorable Steven Larsen, Insurance Commissioner, Maryland Insurance Administration; the Honorable Angela Monson, Senator, State of Oklahoma; Mr. Ron Pollack, the Executive Director, Families USA.

At this time, I would extend to Mr. Larsen the opportunity for his opening statement. Welcome.

STATEMENTS OF HON. STEVEN B. LARSEN, INSURANCE COMMISSIONER, MARYLAND INSURANCE ADMINISTRATION; HON. ANGELA MONSON, SENATOR, STATE OF OKLAHOMA; AND RONALD F. POLLACK, EXECUTIVE DIRECTOR, FAMILIES USA

Mr. LARSEN. Good morning and thank you, Mr. Chairman and members of the subcommittee. It is a pleasure to be here.

I am Steve Larsen, the Insurance Commissioner for the State of Maryland, and I am also the Chairman of the NAIC's Health Insurance and Managed Care Committee. Again, thank you for inviting us to testify.

As you know and as we have heard, under ERISA's dual regulatory structure, State regulators are currently enforcing many of the patient protection provisions that are being considered by Congress and that have been included in the President's Principles, and I have included in my written testimony a comprehensive list of some of the things that the NAIC has developed and that the States have adopted.

There are just three particular points that I would like to make to the subcommittee.

First, in considering the patient protection proposals, we ask that States be given the greatest amount of flexibility in preserving and enforcing the existing State patient protection laws.

I think it was noted in his principles, President Bush says that deference should be given to the States as patient protection laws and to the traditional authority of the States to regulate insurance, and the members of the NAIC also want to preserve and enforce these State laws and we prefer a Federal approach that gives us the flexibility in how we meet those requirements.

Some of the proposals that have been discussed save the State laws by using the HIPAA standard, which prevents the application standard, and, under this standard, State laws are preempted only if they prevent the application of the Federal standard.

This approach essentially establishes what is a Federal floor for patient protections.

If you are going to use this approach, we ask that language be added to clarify specifically that State laws and regulations that are stronger than the Federal requirements or more protective of the consumer than the Federal requirements are not preempted.

Without this clarifying language, I think disputes will arise as to whether stronger State laws still somehow prevent the application

of what, in some cases, maybe a less protective, weaker Federal standard.

In this regard, we are also supportive of the concepts of State certification and substantial equivalents, as these will give particular deference to the States and their laws. Under this approach, the States would determine whether their patient protection laws, as a whole, are substantially equivalent to the Federal standards and the State would then certify that the State meets the goals of the new Federal requirements.

This also would prevent disputes over whether the State language is exactly the same as the Federal bill, and instead the focus would be on whether the intent and the outcome of the State and Federal laws were similar.

The second point I would like to emphasize, and, again, I think this point was referred to in a number of the opening statements, is that the State internal and external review processes are the most fundamental and important patient protections, and it is particularly important that these State laws are preserved.

It is through these processes that we enforce all of the other State patient protection laws. Almost every State has an internal review law and about 38 States and the District of Columbia have independent external review laws, and, simply stated, we think that these laws work.

In Maryland, where I am Commissioner, we have what I think is one of the most consumer-friendly external review laws in the country.

During the 2000 calendar year, we issued 68 orders to health plans, requiring coverage of medically necessary care under our external review process, including a tonsillectomy for an adult in order to treat obstructive sleep apnea.

We ordered 24-hour professional in-home care for a 77-year-old man with ALS, on a ventilator; a foot orthotic for a 15-year-old competitive cross-country runner who had a stress fracture; an inpatient detox and rehab for a woman with a 4-year addiction to medication for chronic severe back pain.

All of these had been denied by the health plan and through the external review process, we reversed that and ordered the health plan to provide the care.

Recognizing and preserving the State external review laws is particularly important, because some Federal courts have recently concluded that State external review laws conflict with ERISA's exclusive remedy provisions.

These cases fundamentally threaten the ability of the States to regulate the external review process and although not all the courts have adopted this construction, the Supreme Court is deciding whether to resolve this. The best solution here would be for Congress to clarify that State internal and external review laws, as well as other complaint or grievance processes, are not preempted and we have, in the written testimony, offered some suggested language.

Third and finally, Congress, we hope, will recognize that patient protection laws require an infrastructure to enforce them.

State insurance departments currently have established regulatory infrastructures and if these State laws were preempted,

along with the State infrastructure, we think that consumers would lose.

Any Federal standard should be linked to Federal resources to enforce the patient protections.

Thank you very much.

[The prepared statement of Hon. Stephen B. Larsen follows:]

PREPARED STATEMENT OF HON. STEVEN B. LARSEN, COMMISSIONER OF INSURANCE, STATE OF MARYLAND ON BEHALF OF THE NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS

I. INTRODUCTION

Good morning, Mr. Chairman and Members of the Subcommittee. My name is Steve Larsen. I am the Insurance Commissioner for the state of Maryland. Also, I am the chair of the NAIC's Health Insurance and Managed Care (B) Committee. I would like to thank you for providing the NAIC [1] with the opportunity to testify about the states' role in managed care regulation and the need for state flexibility in any federal legislation that is drafted.

As state regulators, the members of the NAIC have been regulating health insurers and managed care entities and protecting consumers for many years. Most states have enacted almost all of the same provisions that Congress is currently considering. We believe our experience in this area and the infrastructure that has been established in the states to ensure these patient protections are critical factors that Congress needs to consider carefully when crafting any federal patient protection legislation.

Today, I will focus on four areas that Congress specifically should examine should the federal government and the states become partners in providing patient protections. These areas are: (1) Congress should recognize that the states have already enacted patient protection laws; (2) the states should be given the greatest amount of flexibility in preserving and enforcing these protections; (3) state internal and external review processes, the most fundamental and important patient protections, should not be preempted by federal law and should be given the same amount of state deference as the other patient protections; and (4) Congress should recognize that the states have an extensive infrastructure in place to protect consumers, and if federal legislation were to preempt state laws, the federal government does not have the resources or the infrastructure to enforce these new patient protections.

II. THE STATES' ROLES AND ACTIVITIES IN MANAGED CARE REGULATION

The enactment of the Employee Retirement Income Security Act of 1974 (ERISA) created a dual federal-state regulatory structure in this country for health insurance and health benefits. Under ERISA, the federal government has jurisdiction over all employer-sponsored group health plans, but state laws that regulate the business of insurance are saved from preemption by virtue of the saving clause (Section 514 of ERISA). The saving clause was enacted to preserve the states' traditional role of regulating insurance, including the regulation of insurance policies purchased by ERISA plans (fully insured plans).

The states have taken this role seriously. They have enacted patient protections for consumers in individual and group plans under their authority to regulate the business of insurance, and they have an established infrastructure to enforce these rights. State regulators are presently enforcing many of the patient protection provisions that are being considered by the Congress and that are included in the President's "Principles for a Bipartisan Patients' Bill of Rights" ("President's Principles").

To assist the states in this work, the NAIC has established a comprehensive regulatory structure that includes the following patient protections as reflected by the NAIC's Model Acts:

- Using a "prudent layperson" standard and prohibiting prior authorization requirements for emergency care. (*Managed Care Plan Network Adequacy Model Act; Utilization Review Model Act; Model Regulation to Implement Rules Regarding Contracts and Services of Health Maintenance Organizations.*)

[1] The NAIC, founded in 1871, is the organization of the chief insurance regulators from the 50 states, the District of Columbia, and four of the U.S. territories. The NAIC's objective is to serve the public by assisting state insurance regulators in fulfilling their regulatory responsibilities. Protection of consumers is the fundamental purpose of insurance regulation.

- Requiring continuity of care where a provider is terminated from the plan. (*Managed Care Plan Network Adequacy Model Act; Health Maintenance Organization Model Act; Model Regulation to Implement Rules Regarding Contracts and Services of Health Maintenance Organizations.*)
- Requiring network adequacy. (*Managed Care Plan Network Adequacy Model Act.*)
- Establishing utilization review requirements. (*Utilization Review Model Act.*)
- Providing quality improvement and measurement standards. (*Quality Assessment and Improvement Model Act.*)
- Requiring that plan information be given to patients. (*Individual Accident and Sickness Insurance Minimum Standards Model Act; Health Maintenance Organization Model Act; Small Employer Health Insurance Availability Model Act.*)
- Establishing privacy requirements for patient medical records. (*Insurance Information and Privacy Protection Model Act; Health Information Privacy Model Act; Health Maintenance Organization Model Act; Privacy of Consumer Financial and Health Information Model Regulation.*)
- Requiring plans to establish specific procedures for determining enrollee coverage and payment for services, and to meet defined time frames for standard and expedited coverage determinations. (*Utilization Review Model Act; Health Carrier Grievance Procedure Model Act; Model Regulation to Implement Rules Regarding Contracts and Services of Health Maintenance Organizations; Health Maintenance Organization Model Act.*)
- Requiring and establishing standards for an internal review process, including time frames for routine and expedited cases. (*Health Carrier Grievance Procedure Model Act; Utilization Review Model Act; Health Maintenance Organization Model Act.*)
- Requiring and establishing standards for an external review process, including time frames for routine and expedited cases. (*Health Carrier External Review Model Act.*)
- Prohibiting restrictions on physician-patient communications (anti-gag rule). (*Managed Care Plan Network Adequacy Model Act.*)

In addition to enacting the specific provisions above, many states have enacted additional consumer protections, some of which are included in the President's Principles and in Congressional legislation, such as requiring access to obstetricians, gynecologists and pediatricians without referral from a primary care provider. Although not every state has enacted every protection,[2] these protections are just a part of the many services that the state insurance departments provide for consumers in their states.

III. PRESERVE STATE LAWS AND ALLOW FOR STATE FLEXIBILITY

President Bush in his principles says that since "many states have passed patient protection laws that are appropriate for their states, deference should be given to these state laws and to the traditional authority of states to regulate health insurance." The members of the NAIC are also interested in preserving the state-enacted consumer protections and the states' authority to ensure that consumers have their questions, claims and grievances addressed. State systems that are working should not be preempted by Congressional action that cannot guarantee the enforcement of these protections. Congress should recognize the states' efforts and expertise in developing these protections and give the states the greatest amount of flexibility in preserving and enforcing these protections through the effective and user-friendly consumer complaint and appeals systems in place around the country.

A. Preserve State Laws and State Authority to Regulate Insurance

There is an attempt in some current proposals to save many state laws by using the "prevents the application" standard established in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This standard provides that federal law "shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relat-

[2] Not all of the states have enacted all of the above provisions for a variety of reasons. Some states have no managed care penetration or very limited managed care penetration, although it is important to note that many states with limited managed care penetration have enacted these reforms for consumers in managed care and other health care arrangements. Other states have not had the problems that particular provisions are meant to address or have found other solutions. To require all states to adopt the same blanket regulation for all situations would only result in over-regulation of and unneeded expense to the marketplace. State legislatures are sensitive to their marketplaces and consumer concerns, and when needed, they have been proactive in establishing consumer protections that are tailored to the needs of their states' health care markets.

ing to health insurance issuers (in connection with group health insurance coverage or otherwise) except to the extent that such standard or requirement prevents the application of a federal requirement." Basically, this structure establishes what is commonly referred to as a "federal floor" (federal minimum standard), and it only preempts state laws that are weaker than the federal proposal. Equal or stronger state laws would continue in effect. If Congress is going to establish a federal minimum standard, we offer the following suggestions to improve implementation of the legislation and to ensure that state consumer protections are not preempted.

First, Congress should reinforce the saving clause and not preempt existing state patient protection laws. Due to the uniqueness of each state's marketplace and the effective framework already in place, we ask Congress to respect the existing state consumer protections and allow states to continue to regulate fully insured plans and enact consumer protections based on the needs of the individual states' marketplaces. We urge that Congress not preempt state laws that already address the patient protections Congress hopes to enact.

In this effort, we ask that Congress add the following legislative language that reinforces the continued state authority to regulate the business of insurance under the McCarran-Ferguson Act and ERISA's "Saving Clause": *"This legislation shall preserve and shall not interfere with the states' authority granted under 15 U.S.C. sec. 1011 et seq. (McCarran-Ferguson Act) and under ERISA Section 514 to regulate the business of insurance."*

Second, Congress should include clarifying language in any federal patient protection bill that uses the "prevents the application" standard. From a state's perspective, HIPAA's "prevents the application" standard is problematic because it is unclear and difficult to use in comparing state laws to the relevant federal law. If the "prevents the application" standard is used, we suggest that clarifying language be added to give states more guidance when implementing the standard. Therefore, after the usual "prevents the application" standard language, we offer the following language suggestion: *"A State statute or regulation that establishes standards, requirements or administrative processes does not prevent the application of a requirement of this title if the protection the state statute or regulation affords any person is equal to or greater than the protection provided under this title and the amendments made by this title."*

B. Give Deference to State Laws and Allow for State Flexibility

Although the current legislative proposals generally attempt to save state laws that are equal to or more protective than the proposed federal standards, the President's Principles seek to preserve state authority beyond the federal floor. The President wants to give deference to state laws that are tailored to the state health insurance market and to the traditional authority of states to regulate health insurance. So far this year, the concepts of "state certification" and "substantial equivalence" have been included in the federal legislation that will give greater deference to the states and preserve more of their laws.

Using these concepts, the states would determine whether their patient protection laws as a whole meet the goals of the new federal requirements. Deference should be given to the states in their analysis that their state laws meet the requirements of the federal proposals. The states then would certify that their statutory and regulatory patient protections taken as a whole are "substantially equivalent" or are comparable to the federal standards and that the state laws should remain in force. This approach would prevent the debate from getting bogged down in whether the state language is exactly the same as the federal bill, especially if the intent and the outcome are similar.

While this is the prevalent approach that has been introduced so far in this year's patient protection debate, other approaches may be developed that also would preserve and give deference to state laws. We welcome any approach that allows states to continue to enact reforms based on their state markets and gives states maximum flexibility in how they meet the federal requirements, while ensuring that all individuals have a basic level of protection.

IV. INTERNAL AND EXTERNAL REVIEW

Internal and external review processes are the most fundamental and important of the patient protections. President Bush stated as one of his Principles that patients should have the right to appeal a health plan's decision to deny care through internal and independent external review. The NAIC and the states could not agree more. We recognize the importance of internal and external review as fair and quick processes for resolving issues for consumers. The NAIC has model laws on each process, almost every state has internal review laws in place, and 38 states and the District of Columbia have independent external review laws in place. There has

been a sharp increase in the number of states adopting these laws over the last few years.[3] As such, we believe state internal and external review processes should not be preempted by federal law and should be afforded the same level of deference as the other state patient protection laws.

While we are supportive of the inclusion of internal and external review processes in any federal legislation (so that all individuals are afforded this protection, not just those covered by the state laws), Congress should keep in mind three points: (1) internal and external review are the heart of any patient protection legislation; (2) the state external review laws are working; and (3) internal and external review is a process, not a remedy.

A. Internal and External Review are the Heart of Patient Protections

In passing a patients' bill of rights, Congress is setting minimum standards in a variety of areas designed to ensure a basic level of protection for consumers. However, enforcement of those standards, through internal and external review processes, is crucial to ensure that the consumer actually benefits from those standards. States presently enforce internal and external review laws and thus ensure that consumers get the benefits to which they are entitled. Enforcement of patient protections by way of internal and external review is what makes those protections real, rather than illusory rights on paper. For example, letting states maintain their emergency room prudent layperson standard, but taking away the state process to ensure that standard is used, results in an empty right for patients.

It is crucial that Congress extend the same deference to state internal and external review laws as it does to other state patient protections. Internal and external review standards are the heart of patient protections; enforcement of those standards is what makes all patient protections meaningful. For the federal government to preempt state laws in this area would be to preempt state insurance departments from responding to consumer complaints by eliminating an effective method or process which states use to assure that consumers receive basic protections under their health plan. To give states the ability and flexibility to keep their other patient protection laws but to take away the patient protection process to ensure delivery of these other protections at the very time that those protections come into play would be a serious mistake.

B. State External Review is Working, So Do Not Disrupt It

Most of the states have enacted external review laws already and the appeals process is working in these states. In fact, President Bush praised the Texas independent external review law as a desirable way to resolve disputes and for consumers to get the care to which they are entitled. He even endorsed the Texas law as a model for any federal legislation. This endorsement combined with his desire for deference to state law would support the preservation of the Texas law and other state external review laws from being preempted by any federal legislation.

Texas is not the only state that has recognized the success and the importance of external review as a fair and quick process for resolving issues for consumers. For example, in Maryland last year, the Insurance Administration reviewed 137 complaints about the denial of health care by insurers. The agency upheld the denials 69 times, but reversed or modified them 68 times.[4] Similar figures have been found in other states, with the reviewer finding for the consumer in half of the cases

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[3] The Kaiser Family Foundation updated its November 1998 study of independent review laws in May 2000 documenting a doubling in the number of such state laws. Geraldine Dallek and Karen Pollitz, Institute for Health Care Research and Policy, Georgetown University *External Review of Health Plan Decisions: An Update,* May 2000, at 1.

[4] The Maryland legislature created the appeals procedure in a 1998 law, and the Insurance Administration began hearing appeals in 1999. In 1999, the regulators conducted 91 full reviews, upholding the insurer about half the time. In 1999 and in 2000, about half the complaints involved patients wanting to get a service, while the rest involved patients who have received care but the insurer declined to pay. The Insurance Administration can have cases reviewed by independent medical specialists to decide whether care is appropriate.

In 2000, most of the 1,526 complaints received by the Maryland Insurance Administration did not result in a full investigation (similar to 1999). A large majority of cases drop out of the process for various reasons. In 120 cases, the insurer reversed itself during the review process. In about a third of the cases, the Insurance Administration did not have jurisdiction because the patient was covered by Medicare, Medicaid, employer self-insured plans, or state and federal employee plans. All these are outside the appeals procedure. Nearly half the complaints did not go to investigation because the dispute was not about medical necessity, because the patient had not first tried the insurer's internal appeals process, or because there was not enough information.

and for the insurer in the other half.[5] The high percentage of reversals by state independent reviewers proves both the wisdom and importance of preserving these state laws from federal preemption. The states believe this review process has been and continues to be very successful; it is a way for people to challenge a denial of their claims and a way of holding HMOs accountable.

B. Internal and External Review—A Process not a Remedy

When drafting any federal patient protection legislation, Congress needs to give special consideration to the internal and external review processes in terms of their construction and scope and their placement within the ERISA statute. The NAIC members are concerned about how these provisions are drafted for two reasons.

Some federal courts have interpreted the remedy provision in ERISA--the filing of a civil suit in court--as an "exclusive remedy" that preempts state laws addressing claims handling by insurers. These cases fundamentally threaten the enforcement authority of state insurance regulators. Not all courts have adopted this construction, and the Supreme Court is deciding whether to resolve this conflict between federal courts.

A related issue is the scope or definition of "grievance and appeals processes." Last year the patient protection bills in both chambers included grievance and appeals processes that went beyond resolving disputes concerning coverage decisions. In fact, the bills established grievance and appeals processes to handle any question, complaint or concern a consumer may have. If a court were to determine that the grievance and appeals section of any new federal law conflicts with the so-called "exclusive remedy" under ERISA, then state insurance departments would be preempted from handling *any* consumer complaints.

Congress must clarify that it intends for state internal and external review laws, as well as other complaint or grievance processes, not to be preempted and must amend ERISA accordingly. The following suggested language will clarify that internal and external review are "processes" not "remedies" and ensure that states can continue answering consumers' questions and complaints. *"Nothing in this title shall be construed to supersede any provision of State law or regulation which establishes, implements, or continues in effect any standard, requirement or administrative process solely relating to health insurance issuers (in connection with group health insurance coverage or otherwise) except to the extent that such standard, requirement or administrative process prevents the application of a requirement of this title. State laws or regulations that establish standards, requirements or administrative processes comparable to or more protective of consumers than federal requirements of this title, including those that address the resolution of claim or coverage disputes, do not prevent the application of a requirement of this title."*

V. INFRASTRUCTURE AND ENFORCEMENT

As Congress drafts legislation, we urge you to consider how critical an infrastructure is for enforcing any new patient protections. Not only has each state established a statutory framework of patient protections, but also each state has a regulatory structure in place that is able to handle and quickly respond to consumers' complaints and grievances.[6] This regulatory structure includes: consumer representatives and market conduct reviewers who respond, investigate and enforce the patient protection standards; toll-free consumer telephone lines and Internet access; and on-site representatives to respond to complaints. State insurance departments have established their regulatory infrastructures based on their markets and have allocated significant resources to respond to consumers. Consumers throughout the

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[5] The 1998 Kaiser Family Foundation Study compiled disposition statistics of state independent review laws. The study found that independent reviewers reversed nearly as many health plan decisions as they upheld, overturning health plan decisions between 32 and 68 percent of the time. The following is a list of states, their effective dates and the percentage of cases that were decided in favor of the consumer. Connecticut-January 1998-66%; Florida-1985-60%; Michigan-1978-39%; Missouri-1994-50%; New Jersey-1997-42%; New Mexico-March 1997-50%; Pennsylvania-1991-37%; Rhode Island-1997-68%; Texas-November 1997-48%; Vermont mental health law-November 1996-33%. Karen Pollitz, Geraldine Dallek and Nicole Tapay, Institute for Health Care Research and Policy, Georgetown University, *External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare,* Nov. 1998, note 11, at vii-viii.

[6] Just to quantify the level of state resources (time, money and people-power) that is necessary to regulate the business of insurance and to successfully handle consumer concerns, in 1999 state insurance departments responded to more than 3.3 million consumer inquiries and followed-up on more than 448,000 consumer complaints or grievances. State Departments of Insurance employed 1,045 financial examiners, 345 market conduct examiners, 384 financial analysts, 786 complaint analysts, and 75 consumer advocates. The examiners conducted 1,562 financial exams, 1,122 market conduct exams, and 554 combined financial and market conduct exams.

country have easy access to a network of assistance. State systems that are working should not be preempted by Congressional action that cannot guarantee the enforcement of these protections.

We are concerned by the potential impact of any federal patient protection legislation on consumers. If the federal legislation preempts state laws and state infrastructure, the federal government does not have the resources (money and staff) or the infrastructure to enforce these new protections. The members of Congress should ask themselves the following questions as they draft and debate patient protection legislation:

(1) Are we ready to eliminate a state system and a structure that is already working?
(2) Do we really want consumers all across the country calling Washington D.C. to ask a question, register a complaint or ask for a review of a denial of their claim?
(3) How long will it take for the federal government to set up an infrastructure that replicates what all 50 states and the District of Columbia have had in place for decades to assist consumers?
(4) Do we really think that legislation that would preempt state laws will protect patients from the managed care abuses that we seek to resolve through a federal patients' bill of rights?

With all due respect, we do not think consumers benefit from the preemption of state law or state infrastructure. As such, we ask Congress to recognize the effective state infrastructure already in place and to preserve it so that consumers in insured plans continue to enjoy the benefits of state oversight.

Even with state laws and enforcement preserved, there is still the question of how these new standards will be enforced against self-funded plans, which are not regulated by the states. As noted, there is no federal infrastructure in place such as there is in the states to enforce patient protections. Congress should give the Department of Labor (DOL) the authority to contract with those states that want to enforce the federal patient protection standards for all group plans, including self-funded ERISA plans. This contract arrangement would be voluntary on the part of those states that want this enforcement authority and would be done on a state-by-state basis. The DOL-state contract structure would function like other federal arrangements that give federal grants to the states to implement and enforce federal programs.

VI. CONCLUSION

ERISA provides for both federal and state regulation of group health plans. State insurance regulators are presently shaping and upholding state consumer protection laws and enforcing many of the protections being considered by Congress, including internal and external review. State systems that are working should not be preempted by Congressional action that cannot guarantee the enforcement of these protections. As such, when drafting federal patient protection legislation, we ask Congress to preserve and give deference to state laws that are tailored to the state markets and to give states as much flexibility as possible in meeting the federal requirements.

Mr. BILIRAKIS. Thank you very much, Mr. Larsen.

Senator from the State of Oklahoma, Angela Monson, is here on behalf of the National Conference of State Legislatures.

Please proceed, ma'am.

STATEMENT OF HON. ANGELA MONSON

Ms. MONSON. Thank you, Mr. Chair, members. I am very pleased to be with you this morning.

I am Angela Monson, a member of the Oklahoma State Senate, where I serve as Senate Finance Committee Chair.

Today I have the pleasure of wearing the role as Vice President of the National Conference of State Legislatures, and it is within that context that I provide these remarks to you today.

Let me express my appreciation again for your hard work and your interest given to what is an extremely important issue to

State legislatures across the country, to our constituents, obviously, your constituents, as well.

NCSL has, over the years, supported various means to expand coverage, to increase access to health care services. We have also done so in our States and, of course, the utilization of managed care, managed care products, has been one of those means to further the development of delivery systems, to improve access, to increase coverage throughout our States.

While we use these means to expand coverage, to increase access, we also, in our States, have recognized a need to enact State laws that protect individuals, to ensure that persons who receive their coverage, who receive their care through HMOs, through other managed care arrangements are protected.

NCSL has continuously recognized and supported efforts to protect the interests of patients, to protect the quality of care being received through managed care entities, and we also recognize that there is a need for a national floor.

However, we quickly hasten to add that we oppose any effort to preempt State laws, to expand ERISA preemption, as well. We have, through our States, I think, demonstrated the ability to provide protections, to establish the means necessary, that patients are protected and, of course, we will continue to support that those efforts be maintained.

We believe that the ultimate approach, of course, is the appropriate balance between State and Federal law.

There is a Federal role, though, that we want to emphasize. We think that legislation certainly should ensure that individuals and federally regulated plans enjoy protections similar to those already available in most States. We think it is important that you, as Congress, establish a floor of protections, so that anyone in any managed care entity would be provided the protection that is necessary.

We think maximum State flexibility, however, is important. Preservation of State laws that provide patient protections that are equal to, substantially equivalent to, or more protective than those established in Federal laws should be honored.

We also want to emphasize that it is necessary to provide adequate resources for monitoring and enforcing federally regulated provisions.

So if and when there are provisions that are federally regulated provisions, it is important that the resources are there to appropriately enforce and monitor that law.

The Federal bill being proposed, being discussed today is a step in the right direction. It is very similar in many instances to State law.

We, again, emphasize the need that there is a recognition and a support for State laws that are substantially equivalent to those that we have in place.

We also want to throw another idea out to you today that you might consider when there is Federal law that has to be administered, monitored at this level, at the Federal level, that you consider the utilization of State processes, the internal and external review laws that we have in place are appropriate mechanisms that might be used to actually enforce, to deliver the regulatory level that your laws provide.

The Department of Labor, your U.S. Department of Labor and our State Insurance Commissioner offices and other state-based regulatory entities are more than willing to enter into a cooperative relationship with you so that we can have the appropriate enforcement on all levels.

We want you also to give State legislatures adequate time necessary to implement, to change laws, or to develop implementation procedures that might be necessary for new Federal law.

There are clear procedures or there should be clear procedures for Federal enforcement. So if mechanisms are put in place that continue or expand Federal enforcement of patient protection laws, we know that those procedures must be clear.

That does require some public education, public information; therefore, we, again, offer to assist you in that opportunity by using certain State mechanisms that are already in place.

Much of your discussion today is focused on HMO liability. There are seven States, and I am from one of those States, that have passed laws which allow HMOs to be held accountable through the court system for decisions made.

NCSL, however, has not taken a position on that at this time.

Let me just conclude by saying we are more than willing to sit with you, to work with you to ensure that appropriate balance is maintained between State legislatures and our authority, the traditional authority given to our State, to the States to enforce these kinds of laws, as well as maintain and identify the appropriate role for Federal Government.

Thank you very much. Be happy to, at the appropriate time, answer questions.

[The prepared statement of Hon. Angela Monson follows:]

PREPARED STATEMENT OF HON. ANGELA MONSON, OKLAHOMA STATE SENATE, VICE-PRESIDENT, NCSL, ON BEHALF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES

Chairman Bilirakis and distinguished members of the subcommittee: My name is Angela Monson. I am a state senator in Oklahoma where I chair the Senate Finance Committee. I am also the Vice-President of the National Conference of State Legislatures (NCSL). It is a pleasure to be here today on behalf of NCSL to talk about moving forward on a national effort to enact a Patients' Bill of Rights.

NCSL supports the establishment of consumer protections for individuals receiving care through managed care entities. We also support the development of public and private purchasing cooperatives and other innovative ventures that permit individuals and groups to obtain access to affordable health coverage.

States have taken the lead in providing needed regulation of managed care entities and these state initiatives have enjoyed bi-partisan support and have been successfully implemented. Individuals who receive their health care through federally regulated ERISA plans have not benefited from the state laws enacted to provide needed protections for individuals who receive care through managed care entities. It is appropriate and necessary for the Congress to address the needs of these individuals. Individuals and families who receive health care benefits through federally regulated plans should enjoy the same protections as their neighbors who receive care through entities subject to state regulation. NCSL strongly supports the efforts here in Washington to establish a federal floor that sets a national level of protection for everyone who receives care in a managed care environment.

As we move toward this goal, it is important to preserve the traditional role of states as insurance regulators. NCSL strongly opposes preemption of state insurance laws and efforts to expand the ERISA preemption.

We believe federal legislation should:

- ensure that individuals in federally-regulated plans enjoy protections similar to those already available in most states;

- establish a floor of protections that all individuals who receive care through managed care entities should enjoy;
- preserve state laws that provide patient protections that are equal to, substantially equivalent to, or more protective than those established in federal law; and
- provide adequate resources for monitoring and enforcing federally-regulated provisions.

THE BI-PARTISAN PATIENT PROTECTION ACT OF 2001 (H.R. 526)

This bi-partisan bill is moving in the right direction. Most of the patient and provider protections included in the bill are similar to those that many of the states have already enacted. The bill would preserve state laws with patient and provider protections that are "substantially equivalent to" provisions in the bill. This is a very important issue for NCSL and state legislators across the country. The concept of "substantial equivalence" is one we have been pursuing for some time. The inclusion of this provision will go far to facilitate a more immediate implementation of the protections that we all believe are important.

As you know, federal law supercedes state law unless there is legislation that clearly preserves state law. State insurance commissioners can only enforce state law. Without the inclusion of the substantial equivalence standard, state law that would provide essentially the same protections provided for in the federal law would be preempted. State legislatures would then have the option of enacting state laws that mirror the federal statute or handing over the enforcement of those provisions to the U.S. Department of Labor and the Health Care Financing Administration.

There are three issues regarding substantial equivalence that I would like to emphasize during my short time with you today. NCSL urges you to:

(1) apply the substantial equivalence standard to all of the provisions of Title I, including those related to grievances and internal and external appeals.
(2) provide adequate transition time to permit state implementation.
(3) establish a clear process for enforcement should a state opt not to enact state law to facilitate state enforcement.

Apply the substantial equivalence standard to all of the provisions of Title I, including those related to grievances and internal and external appeals.

There are currently conflicting court decisions on whether or not the ERISA preemption applies to state laws regarding internal and external appeals. We would like to work with the members of this subcommittee to craft language that would clarify that for the purposes of implementing patient protections for individuals receiving care through managed care networks, that state laws establishing internal and external appeals processes would not be preempted by ERISA.

The establishment of effective internal and external appeals processes is critical to the implementation and effectiveness of patient protections. We believe that these functions are best provided at the state and local level. NCSL urges you to explore options that would permit federally-regulated plans to participate in appeals processes established in the states where they are located. This could be done through cooperative agreements between the states and the Department of Labor.

Provide adequate time for state legislatures to take necessary actions to implement the federal law.

State legislatures are often out of session when major federal legislation is enacted. In cases where state legislative action is desired or required, that action is delayed until the legislature reconvenes for its next regular session. We believe it is helpful to recognize this reality and to make accommodations for it in federal legislation. NCSL recommends that states should have at least one regular session of the legislature to make changes in state law and regulation related to this legislation that may be required to maintain state enforcement.

Establish a clear procedure for the establishment of federal enforcement of some or all provisions of the Act in cases where a state opts for federal enforcement of any of the provisions of the Act.

In the event that sufficient transition time is not provided for or that a state opts to have federal enforcement of some of the provisions of this legislation, NCSL recommends the Act establish a mechanism for notifying patients regarding what enforcement authority is responsible for enforcing the various patient protections.

HMO LIABILITY

NCSL has not taken a position on the inclusion of HMO liability provisions in Patients' Bill of Rights legislation. I am from one of the seven states (Arizona, Cali-

fornia, Georgia, Maine, Oklahoma, Texas and Washington) that have laws that specifically permit HMO enrollees to sue for malpractice. Our law in Oklahoma became effective July 1, 2000. These laws are all relatively new. The Texas law that became effective September 1, 1997 is the oldest and the Washington law does not become effective until July 1, 2001. Of the seven states, two (Georgia and Maine) do not allow the plaintiff to collect punitive damages.

IN CONCLUSION

NCSL looks forward to working with this committee and your colleagues in both the House and the Senate to enact Patients' Bill of Rights legislation this year. I believe it can be achieved and achieved in a way that preserves the traditional role of states in regulating insurance and at the same time provides needed protections for all HMO enrollees.

I thank you for this opportunity to discuss these important issues with you today and would be happy to answer questions.

Mr. BILIRAKIS. Thank you very much, Senator.

We will see if we can get through Mr. Pollack. We have a couple of votes on the floor. So why don't we have you start, at least, Mr. Pollack, and see how far we can go.

STATEMENT OF RONALD F. POLLACK

Mr. POLLACK. Thank you, Mr. Chairman. Mr. Chairman, members of the committee, thank you for holding this hearing and for inviting me to it.

One of the things I think that is missed in terms of the debate about Patients' Bill of Rights is the crazy quilt pattern that exists today throughout the Nation in terms of regulating managed care, and it does not serve consumers well, it doesn't serve the managed care industry well.

When I say there is a crazy quilt pattern, what I mean is people have different rules that govern then, depending on what State they are in, and even for people in the same State, there are very different rules.

One set of rules for people who purchase coverage independently, another set of rules for people who get their coverage from an employer who insures, and yet another set of rules for those people that get coverage from an employer who self-insures.

For consumers, it is baffling, it is very difficult to understand.

Now, I was asked, as part of this panel, to talk about scope of protection. There are three types of variation by State in terms of the coverage in protection that people get.

First, if you look at the chart that is attached to my testimony, Chart A, you will see that there is a wide disparity in the areas covered by consumer State protections.

Of the ten areas of consumer protections analyzed in that appendix, only one State, the State of Illinois, has adopted protections in at least nine of those areas.

Two of the States, Wyoming and Mississippi, have adopted only one such protection. The most common number of protections enacted is six out of the ten that we analyzed that are in virtually all the Federal bills.

If I may just take the States of Florida and Ohio, where the chairman and the ranking minority member come from. Ohio has adopted the prudent layperson standard for emergency care and provides access to drugs prescribed by physicians that are not on a health plan's formulary.

Florida does neither of those things. However, Florida enables patients with disabling or life-threatening illnesses to continue receiving transition care from physicians dropped from a health plan. Ohio does not.

Second, even the States that have adopted specific patient protections, those laws are not applicable to many of the people in those States.

With respect to the substantive protections established by some of these States, these rules do not apply to people in self-insured plans.

About 43 percent of all employees who get their health coverage through their employer are not covered by any of these protections, irrespective of what the State has enacted.

Approximately 56 million people are in that situation. To make matters worse, it appears that State laws relating to remedial processes ranging from the right to sue to the right to independent external appeals may be inapplicable to the vast majority of people, approximately 124 million Americans who get their coverage from a self-insured or a fully insured ERISA plan.

Third, even in the States that have established specific consumer protections, the details of these protections vary considerably from one State to the other.

The laws that provide access to emergency rooms are an excellent case in point. In States, some States have enacted a provision addressing some aspects of access to emergency services, but the provisions are by no means uniform from one State to the other.

This is also true with respect to the independent right of appeal.

In essence, Mr. Chairman, it is fair for the Congress to look to the States as laboratories of change. States experiment and do provide very good data with respect to what works and doesn't work.

They inform Congress of what works and they frequently help Congress adopt ideas for the entire Nation based on what has worked at the State level.

We believe in that laboratory system. We also believe, however, that consumers need predictability. They need systems that are easily understandable and they need basic rights that should not vary based on place of residence or payer of care.

The best way to reconcile these interests is by establishing nationwide standards, a floor, that cannot be violated, and States that exceed those standards should be allowed to do so.

We urge you to establish nationwide standards and allow the States to exceed them.

Thank you.

[The prepared statement of Ronald F. Pollack follows:]

PREPARED STATEMENT OF RONALD F. POLLACK, EXECUTIVE DIRECTOR, FAMILIES USA

Thank you for the opportunity to testify at this hearing on consumer protections. Families USA, the national organization for health care consumers, supports nationally enforceable consumer protections. These protections must be designed to ensure that health plan enrollees receive the care they were promised by their health plans. They must include basic protections covering a wide range of consumer concerns, and they must apply to all health plans. We support H. R. 526, the "Bipartisan Patient Protection Act of 2001."

The public needs federal legislation because the protections that do exist today constitute a veritable patchwork quilt that is indecipherable and has many holes. Enormous differences exist today in the protections that are afforded to people

based on the accidental happenstance of a consumer's state of residence and the payer and form of that consumer's health plan. Enormous differences exist in the protections provided by one state versus another. Enormous differences also exist among people *within the same state,* especially between those who get their coverage from an employer who is fully insured *compared* to those who get coverage from employers that self-insure and *compared even further* to those who buy their insurance coverage independently.

Consumers need greater clarity and predictability about the basic protections that are guaranteed to them. Such clarity and predictability can only be created, without stifling state-by-state innovation, by establishing national minimum standards applicable to everyone. As with other fundamental principles that Americans believe should apply to everyone in the nation—such as civil rights laws and environmental laws—consumer protections should apply to everyone. National standards should establish a basic foundation that nobody can fall through.

One of the reasons we support H. R. 526 is that it creates such a basic foundation that everyone will be able to rely on. Everyone—irrespective of the state in which they live, and irrespective of what type of plan they are in—will be able to count on the fundamental protections that consumers need. They will not have to become experts about the complex ERISA statute and other arcana to determine whether they are subject to patient protections.

ANALYSIS OF STATE LAWS

Families USA has issued a number of reports on consumer protections that had been enacted by the states. We named our last report *Hit and Miss* because, as you can easily see from the attached updated chart (see Appendix A to this testimony), the protections vary widely from state to state. There are three types of variations. *First,* as the chart in Appendix A demonstrates, there is wide disparity in the areas covered by state consumer protections. Of the 10 areas of consumer protections analyzed in the report, only one state—Illinois—has adopted protections in at least 9 of those areas. Two states have adopted only one protection. The most common number of protections enacted is 6 out of the 10 we reviewed. Ohio adopted the "prudent layperson" standard for emergency care and provides access to drugs prescribed by physicians that are not on a health plan's formulary; Florida does neither of these things. Conversely, Florida enables patients with disabling or life-threatening illnesses to continue receiving transition care from physicians dropped from a health plan; Ohio does not.

Second, even in states that have adopted specific patient protections, those laws are not applicable to many of those states' residents. With respect to the substantive protections established by some of the states—such as the "prudent layperson" standard for emergency care and the right to receive prescribed drugs not on a health plan's formulary—these rules do not apply to people in self-insured plans. About 43 percent of all employees who get their health care coverage through their employer are not covered by any of these protections, irrespective of what the state has enacted. Approximately 56 million people are in this situation. To make matters worse, it appears that state laws relating to remedial processes—ranging from the right to sue to the right to independent external appeals—*may* be inapplicable to the vast majority of people, approximately 124 million Americans, who get their coverage from a self-insured *or fully insured* ERISA plan.

Third, even in the states that have established specific consumer protections, the details of these protections vary significantly from state to state. The laws that provide access to emergency rooms are an excellent case in point. A majority of states have enacted a provision addressing some aspect of access to emergency services, but the provisions are by no means uniform from state to state. In fact, the very definition of what constitutes an emergency differs depending on what state you are in. Some states, for example, do not specify whether severe pain may indicate the presence of an emergency situation. In some states, plans are prohibited from requiring prior authorizations for emergency services but have not adopted a "prudent layperson" standard as a basis for securing health plan payment for emergency room services. Other states have adopted the "prudent layperson" standard.

States deal with emergency post-stabilization care differently. States often require plans to pay for emergency services necessary to stabilize a patient but require doctors to contact the plan directly to gain authorization for post-stabilization care. States may even require health plans to provide 24-hour access to plan personnel who can authorize continued care following stabilization of the patient. But in some of those states, requests for post-stabilization treatment approval that receive no response within a specified time period are automatically approved. Other states, however, impose no time restraints on how long a plan can take to respond to a request

for post-stabilization care and do not automatically approve care despite the plan's failure to respond.

Another area demonstrating the variability of state consumer protection laws is the one relating to *external or independent reviews of health service denials.*

A majority of states have passed independent review legislation. But the breadth and scope of these provisions vary from state to state, providing consumers absolutely no consistent protection. Some states reserve independent external review for determinations of medical necessity. Other states allow independent external reviews to settle any consumer grievance not resolved internally by the plan.

The make-up of the independent review entity can again vary depending on the state. In some states reviews are performed by physicians or providers who are experts in the treatment of the enrollee's conditions. Other state laws preclude members of independent review boards from having been involved in the initial denial of care or from having a direct financial interest in the outcome of the review. Some states require the Director of Insurance to compile a list of independent review entities. Others require that a member of the health plan sit on the review board.

Another factor that varies from state to state is whether or not the reviewer's decision is binding for the plan or the consumer, binding for both, or not binding at all. Most states specify that decisions made by external reviewers are binding on the health plan. A few states make the decision binding for both the plan and the consumer. In New Jersey the decisions are not binding at all.

Some states require that requests for independent external reviews be made within a certain time period after the initial adverse decision. These time periods range from a low of 15 days after a consumer exhausts the plan's internal grievance system, to a high of two years. Several states impose no time limits on consumers to file a request for an independent external review.

In addition, there is significant variability on the length of time reviewers can take to rule on appeals. Some, but not all, states require external review entities to establish a mechanism so consumers can obtain an expedited review in emergency or urgent cases—and, even in those instances, there is variability concerning time limits related to such expedited reviews.

The net result is that—even in the states that address specific areas of consumer protection (let alone the states that totally fail to address such specific areas)—there is enormous variability from state to state concerning *how* the states treat such areas. Hence, one cannot assume uniformity—and, hence clarity and predictability—if a state happens to address a specific area of consumer protection. This enormous variability cries out for a federal floor so that *all consumers throughout the country* have clear, basic rights that do not change due to the happenstance of where they live.

The creation of a federal floor is not a new idea. There are many examples of laws that create a federal standard and allow the state standard to stay in effect if it is the same or more protective. Some examples include parts of the Clean Water Act, the Endangered Species Act, the Americans with Disabilities Act and the Medical and Family Leave Act. A federal floor to protect all consumers is a crucial and necessary element of H. R. 526.

Before I close my testimony I want to discuss a provision that should be added to H. R. 526—the creation of consumer assistance, or ombudsman programs—that is crucial to making the external appeals process work. The creation of consumer assistance programs is a bill that will be introduced next week by Senators Jeffords and Reed entitled "Health Information for Consumers Act of 2001." These programs are designed to assist consumers in understanding their health care choices and rights, and to *provide assistance to consumers in non-litigative appeals processes.*

Two very diverse states—Vermont and Virginia—established such consumer assistance programs. These programs are crucial to making internal as well as independent external review processes work. Simply stated, consumers need help to make meaningful use of internal and external appeals processes. At the time consumers wish to appeal a plan's denial of important health services, those consumers are likely to be sick or frail—and they have limited capacities to pursue their appeals alone. It is for this reason that they need someone to help navigate the system in order to make the promise of the appeals system more effective.

A Henry J. Kaiser Family Foundation report, entitled *External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare,* indicates how important consumer assistance programs are in making external appeals systems work. In states where external appeals processes have been in existence, the number of people who availed themselves of these processes is very low—less than a few hundred cases per year in the largest states and fewer in the smaller states. The report cites studies indicating that these numbers are low because consumers often are unaware of their rights to an external review and, when they

are sick, they are unable to pursue their appeals rights. Consumer assistance programs are needed to make the system work properly.

No matter whether one supports or opposes the right of consumers to sue HMOs in court and receive a meaningful remedy, there should be universal agreement that we want to solve consumer-health plan problems early—thereby reducing the impulse to litigate. That's why the creation of consumer assistance programs, so that help can be provided on a timely basis for internal and external appeals, is crucial. It is a way to provide non-litigative, non-lawyer remedies on a timely basis before significant damage is done.

Consumer assistance programs help to resolve problems at earlier, less formal stages and obviate the need for more contentious proceedings, such as litigation. Consumers need to have someone to go to for help when they think they are not getting the care they need. A knowledgeable person who can explain the obligations of the patient and the plan may be able to run interference and solve a consumer's problem before a formal grievance is necessary. Additionally, providing assistance throughout the appeals process could make the system work more efficiently and thereby lessen the need for further proceedings, such as litigation.

As a result, any legislative proposal that seeks to deal with problems early and uses external review mechanisms to achieve that objective should include a provision for the creation of consumer assistance programs. We have ample, high-quality precedents in the states for these programs, and we should implement them as part of a patients' rights system.

CONCLUSION

Congress often looks to the states as the laboratories of change. States experiment with various laws. They inform Congress about what works, and frequently Congress adopts these ideas for the entire nation. We believe in the benefits of such a laboratory system. We also believe that consumers need predictability; they need systems that are easily understandable; and they need basic rights that should not vary due to place of residence or payer of care. The best way to reconcile these interests is by establishing nationwide standards—a floor—that can't be violated. We urge you to establish nationwide standards and allow states to exceed these standards.

STATE MANAGED CARE PATIENT PROTECTIONS

MARCH 2001

Families USA has issued two reports on state managed care consumer protections. In July 1996, we released *HMO Consumers At Risk: States to the Rescue* and in July 1998, we released *Hit and Miss: State Managed Care Laws.* On the back is an update of the Families USA *Hit and Miss* chart showing 10 consumer protections that have been passed in various states. The protections, listed by state, apply to those who are covered by state regulated health plans. They do not apply to the one-third of American workers who are covered by employer-sponsored plans and are therefore subject to federal law only. The 10 selected protections are:

1. **Emergency room services**—which states have passed laws setting the "prudent layperson" standard. Some states that only prohibit prior authorization are not included.
2. **Standing referrals**—requiring plans to allow standing referrals to specialists for people with chronic or life-threatening illnesses
3. **Ob-Gyn**—requiring plans to give women direct access to obstetricians and gynecologists, or to allow ob-gyns to serve as primary care providers. States that require direct access for only one annual visit are not included.
4. **Continuity of care**—which states have passed laws requiring plans to allow certain patients to continue to see their physician when the provider's contract with the plan is terminated. Some states require plans to provide transitional care for primary care *only* and not for specialty care; those states are not included in this list.
5. **Ability to obtain drugs**—which states have passed laws requiring the plan to have a process by which members can obtain non-formulary prescription drugs. States that require plans to *disclose* the procedure for obtaining non-formulary drugs (if the plan uses a formulary)—but that do not require that plans *have* such a procedure—are not included.
6. **External Appeals**—which states have passed laws that require a meaningful process for external review of appeals decisions. Some states have set up independent external review processes for limited circumstances—only for experimental and investigational procedures or services, for example; these are not in-

cluded. States that allow the plan to pick any provider—including employees of the managed care plan—to be on the review panels are not included.

7. **Gag laws**—which states have passed laws prohibiting plans from preventing the disclosure of treatment options.
8. **Financial Incentives**—which states have passed laws prohibiting plans from offering incentives to physicians for denying or reducing care.
9. **Clinical trials**—which states have passed laws that require payment of certain routine costs when a patient participates in certain clinical trials.
10. **Liability**—which states have passed laws that allow consumers to sue health plans for not exercising ordinary care when making benefit decisions.

State Managed Care Patient Protections

State	ER	Standing Referrals	Ob-Gyn Direct	Contin. of care	Ability to Obtain Rx	External Review	Gag	Financial Incentive	Clinical Trials	Liability
Alabama		•	•			•				
Alaska				•		•	•	•		
Arizona		•		•		•	•	•	•	•
Arkansas	•		•	•	•		•			
California		•	•	•	•	•	•	•		•
Colorado	•	•	•	•		•	•			
Connecticut	•		•		•	•	•			
Delaware	•		•	•		•	•	•		
District of Columbia	•	•	•	•		•	•			
Florida		•	•	•		•	•	•		
Georgia	•		•		•	•	•	•	•	•
Hawaii	•	•				•	•			
Idaho	•		•				•	•		
Illinois	•	•	•	•	•	•	•	•	•	
Indiana	•		•	•	•	•	•			
Iowa	•			•		•	•			
Kansas	•	•		•		•	•	•		
Kentucky	•	•	•	•		•	•			
Louisiana	•		•		•	•	•	•	•	
Maine	•	•		•	•	•	•	•		•
Maryland	•	•			•	•	•	•	•	
Massachusetts	•	•	•	•		•	•	•		
Michigan	•			•	•	•	•	•		
Minnesota	•	•	•	•		•	•	•		
Mississippi			•							
Missouri	•	•		•	•	•	•	•		
Montana			•			•	•	•		
Nebraska	•		•				•	•		
Nevada	•		•				•	•		
New Hampshire			•		•	•	•	•	•	
New Jersey			•	•		•	•	•		
New Mexico	•	•	•			•	•	•		
New York	•	•	•	•		•	•			
North Carolina	•	•	•		•		•			
North Dakota	•						•	•		
Ohio	•	•	•		•	•	•	•		
Oklahoma	•	•		•	•	•	•			•
Oregon	•		•		•		•			
Pennsylvania	•	•	•	•		•	•	•		
Rhode Island	•			•		•	•	•	•	
South Carolina	•	•	•	•		•	•			
South Dakota	•			•	•		•	•		
Tennessee		•	•	•		•	•			
Texas	•		•	•	•	•	•	•		•
Utah	•	•					•			
Vermont	•	•	•	•	•	•	•	•		
Virginia	•	•	•	•	•	•	•		•	
Washington	•	•	•	•	•	•	•			•
West Virginia	•		•				•	•		
Wisconsin	•	•	•	•	•	•	•			
Wyoming							•			

Note: Data comes from Health Policy Tracking Service.

Mr. BILIRAKIS. Thank you very much, Mr. Pollack.

We do have a couple of votes on the floor. So we are going to break til approximately maybe quarter to 12, 10 minutes to 12, something of that nature. Then we will go into our inquiries.

Thank you.

[Brief recess.]

Mr. BILIRAKIS. The hearing will come to order. I will start questioning. Let's see. We don't have Senator Monson yet.

Mr. POLLACK. I have Senator Monson's proxy.

Mr. BILIRAKIS. I understand she has to catch an airplane.

Mr. POLLACK. She had to catch a plane back for Oklahoma.

Mr. BILIRAKIS. She did not give you her proxy, though.

Commissioner Larsen, why don't we get this thing started. The White House has argued, and Chairman Tauzin touched on this, for a broad set of patient protection through a system that provides deference to State patient protection laws and to the, again, quoting, the traditional authority of States to regulate health insurance.

So I think it is important that we understand the current system and what is the traditional authority of the States and why such deference is important.

I wonder. I was going to ask you and the Senator, but why don't you just go ahead and take the time on this.

Mr. LARSEN. Thank you. Historically, of course, the regulation of insurance generally is with the States under the McCarran-Ferguson Act, and ERISA establishes broad preemption for State regulation, but then saves all insurance laws from regulation.

So we have historically regulated insurers and HMOs and we think that is a very important function and we have an infrastructure in place and literally hundreds and hundreds of employees across the country that assist in handling consumer inquiries and consumer complaints.

There is, as I mentioned, and many of you may be familiar, there are some cases out there that are even calling into question our ability to regulate certain insured ERISA plans, which is a huge problem, but the market essentially is bifurcated between the self-insured plans, which we clearly don't have jurisdiction over, and the insured plans, which historically we have, but there are some questions being raised about whether we can do that or not.

Mr. BILIRAKIS. Can you emphasize really why the deference is important? Mr. Pollack, of course, I'm going to have you go into this, too. But why don't you emphasize it.

Mr. LARSEN. One of the reasons why there has been a historic assignment to the States of the regulation of insurance is that insurance markets vary greatly both by region and by State, and the health insurance market is no exception to that.

The managed care penetration varies tremendously by State. Some States have very little penetration. Some States, like Maryland and others, that have, I think, a fuller set of patient protections, have very extensive managed care penetration.

So the general principles that gave rise to having the States continue regulation insurance, I think, dictate for some level of def-

erence, simply because there are significant differences and different problems that arise in different health insurance markets.

Some are characterized by a large Blue Cross plan. Some have a more competitive marketplace that may serve to have the plans compete more on service.

So there are a wide variety of differences among States and I think the State legislatures have responded to those differences, where they perceive the need to do so, as have the State regulators.

Mr. POLLACK. Mr. Chairman, may I just add one aspect of complexity to this? I agree with what the Commissioner has stated.

There is one facet of complexity that I think needs to be noted, and that is in the area of remedies. And I don't merely mean here on the litigation question, but even on things like external and internal hearings.

There is a question as to whether the ERISA statute preempts the States from regulating any ERISA plan. Here I mean not just those that self-insure, but those that fully insure, as well.

I refer you to actually litigation that arose when the State of Texas adopted its legislation. When Texas adopted its legislation, creating not just the right to use, but also creating an external appeals mechanism, Aetna Insurance sued the State to invalidate the State statute.

The Federal district court in Houston invalidated Texas' external review system, saying that inasmuch as the ERISA statute creates a remedial regimen, the States are preempted from establishing their own.

So one of the questions that ultimately will have to be decided by the Supreme Court is whether not just ERISA sort of carves out self-insured plans, but in those areas of remedies, whether it also carves it out for all employer-provided health coverage.

That is a question that remains open and that undoubtedly is going to go to the Supreme Court.

Mr. BILIRAKIS. What is your position on that?

Mr. LARSEN. My view on that, as well as the substantive rights that the Commissioner spoke about, is fairly similar to what the Commissioner is stating; namely, that where the state——

Mr. BILIRAKIS. You did talk very much about the patchwork and that sort of thing.

Mr. LARSEN. Yes, and it is very hard to decipher, not just for consumers, but for the health plans themselves.

I remember the American Association of Health Plans had this elaborate chart of all the different ways in which they are regulated and I thought it was the most profound argument for why we need a Patients' Bill of Rights.

If you have a Patients' Bill of Rights, you have a floor under which no one could fall through and it would finally put to rest the question as to whether an internal and external appeals requirement established by the States is valid or not.

Mr. BILIRAKIS. Mr. Brown.

Mr. BROWN. Thank you. Mr. Pollack, I will also start with you. Opponents of this legislation, of any of the Federal patient protection bills over the years, have argued that these laws result in huge premium increases, that employers either saddle themselves with these costs and can't do other things that employers need to

do, hire more people or whatever, or perhaps, more likely, those employers drop health care coverage for their employees.

You have done studies about this. Tell us about that. What really will happen, in your mind?

Mr. POLLACK. I appreciate that question, Mr. Brown, because we care deeply about making sure that as many people have insurance and retain insurance.

And there is no evidence that indicates that in those States that have established patients' rights legislation, that there has been a reduction in coverage resulting from that.

Indeed, what you see is that in some States that passed comprehensive legislation, they have actually had no deterioration. Some States that have passed no patients' rights legislation have experienced a deterioration.

So there are a lot of factors that are causing health costs to rise. I could go through a whole list of them, but patients' rights legislation is not one of them.

Mr. BROWN. Well, talk about that, because opponents to this bill say that we are saddling them with more costs with patient protections and they can show cases where obviously premiums have gone up dramatically in the last couple, 3 years, including in those States, in some cases, where they have done some sort of patient protections.

What are the reasons then?

Mr. POLLACK. Well, there are a lot of reasons why costs are rising, having nothing to do with patients' rights legislation.

There is an interesting study, which actually I would advise the committee to circulate to all its members, from the Center for the Study of Health Systems Change, and they catalogued what is changing new rises in costs.

They include a variety of things. I will give you a few examples. One is we are seeing consolidation in the hospital industry, which means that the hospital industry has greater leveraging power in terms of negotiating with health plans.

There are a variety of other factors relating to proliferation of technology, prescription drug cost increases, things that this committee is fully familiar with.

But patients' rights legislation, as adopted by the States, is not a significant factor at all in terms of increasing costs.

You take Vermont, for example. Vermont has a fairly substantial regimen of health protections for patients' rights and, in fact, we are seeing more people covered in Vermont and costs have not risen there differently than in other States.

Mr. BROWN. Mr. Larsen, you said that States want to maintain flexibility regarding patient protection laws. The H.R. 526, we think, does that by establishing a Federal floor to ensure the provision of basic patient protection laws.

Nationally, it allows the States to exceed that, if they choose.

When you look at our legislation, first of all, do the insurance commissioners want to see that, that the legislation works that way, and does our legislation do that?

Mr. LARSEN. Well, the position of the NAIC, the National Commissioners, is that we haven't taken a position on the Federal floor, and it is a body that perhaps is not unlike Congress.

I don't know if anything could be more complex than Congress, but we have elected officials, appointed officials, democrats, republicans.

So the issue of Federal floor hasn't, I guess, gelled for the commissioners.

I can speak to you as the Maryland Commissioner, not that I'm two-faced, but put a different hat on, and simply say that as a practical matter, I think that it is important that everyone have a basic level of protection.

But I do want to add that there are States, and I think if you look at Mr. Pollack's chart, which is a great chart, there certainly is a patchwork and in some cases, there is a reason.

Alaska and other States don't have any managed care to speak of and the question would be, well, do you want to require health plans to set up systems that really may not have particular relevance.

So I think there is legitimacy to that point, but I also recognize that you do want, in other States maybe where something hasn't happened, to make sure that there is a basic level of protection.

Mr. BROWN. Does our substantially equivalent language fill that bill to give the States a flexibility, yet have a national standard and allow stronger State laws?

Mr. LARSEN. I think the substantially equivalent approach is about the best approach we've seen, because it does provide flexibility rather than trying to match up exactly.

It is very hard to look at one law and then look at another law and say does this prevent the application of this law.

I know there's kind of a whole bunch of different standards out there, but we found with HIPAA that even with relatively straightforward requirements, that was a very difficult and laborious process.

And when you're looking at complex provisions like access to OB/GYN and other provisions, it is hard to make that match-up. So the substantially equivalent approach, we think, is a much more workable approach and, yes, it does provide, I think, a fair level of deference.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Who should be the ultimate judge on whether a state's laws meets the substantially equivalent definition?

Mr. LARSEN. Of course, I have to answer that the States should make that final determination.

Mr. BILIRAKIS. The State meaning the Governor, the legislature, the Governor.

Mr. LARSEN. I think there should be initial review. The initial review should be done by the States. I think they are most conversant with their own laws and how they interpret their own laws.

Mr. BILIRAKIS. But who within the state? Should it be the Commissioners, should it be the legislature, should it be the Governor, should it be all three?

Mr. LARSEN. I think as a practical matter, it would come from the Governor. I think that's the appropriate way, especially as someone who is appointed by the Governor of our State. I think it should be by the Governor.

Mr. BILIRAKIS. Dr. Ganske, to inquire.

Mr. GANSKE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Did Chairman Tauzin wish to inquire?

Chairman TAUZIN. I will, but I will be glad to yield, Mr. Chairman.

Mr. BILIRAKIS. All right.

Mr. GANSKE. Mr. Larsen, I am glad that you are here today. I had a very interesting conversation with a former State insurance commissioner, who is now a member of the U.S. Senate, on this and he told, me he was very forceful in his feelings, that it was inappropriate 25 years ago for Congress to take away from State insurance commissioners the liability issue and that from his perspective, that we needed to remove the ERISA preemption as it related to medical judgment type decisions, because I think all of us want to allow national corporations that are working in many States to be able to design a uniform benefits package.

That was the reason for the pension reform in the first place under ERISA.

Would you comment on that for a moment?

Mr. LARSEN. Well, I must say that with respect to any of the liability provisions, particularly, the national association does not have a position on that.

Notwithstanding our distinguished former colleague's views, who I have great respect for, and I think the fact that he is a U.S. Senator reflects the views that other people hold of him.

Mr. GANSKE. It shows how high you can rise.

Mr. LARSEN. That's right. You know, I think many commissioners view the liability issues as really kind of outside the regulatory realm in which we deal.

It really gets into what I think is tort issues and what has been described here. If a corporation is actually found to do harm to someone, should they be held accountable for that?

That really, I think, we view, is not an insurance regulatory issue, as we think about it.

Mr. GANSKE. I was very gratified to hear you affirm the substantially equivalent standard that we have, which would basically be the mechanism, as I see it, for consultation between the State insurance commissioners, their Governor, and then an application to the Secretary of Health and Human Services, who, by the way, is a former Governor and I'm sure would give a considerable deference to States on that standard.

It is just that my understanding of your statement was that there could be a benefit from a uniform floor, but that our bill would allow States that have gone beyond that to basically implement their own clause.

Mr. LARSEN. The most important piece, if I may, just briefly, is to preserve the ability of States to go beyond the Federal standard, particularly if their markets, I think, dictate additional protections.

Mr. GANSKE. Mr. Pollack, would you care to comment on that, also?

Mr. POLLACK. Yes, Mr. Ganske. There's a really interesting issue about the ERISA statute and I just want to go back in history about what happened when the ERISA statute was enacted.

Those of us who think ERISA should be modified are not critical of what was enacted when Congress considered it in the 1970's.

In the 1970's, Congress actually was trying to make a patient whole when they had a dispute with an insurance company. The context of what Congress was dealing with in the 1970's was a system of fee for service care and the way disputes arose between insurance companies and consumers was you went to your physician, the physician provided you with care, and then you applied to your insurance company to receive payment for that, and the dispute arose when the insurance company said we are not going to pay for that claim.

And so when the ERISA statute said we are going to pay just for the service that was originally denied, in fact, the ERISA statute, in that context, was making the person whole.

The context has changed today. Today, somebody goes to a managed care plan and the managed care plan says, no, we are not going to provide you with this service because it is not medically necessary, and then you go to a hospital or a physician to get the care and they won't provide it because they haven't gotten authorization from the managed care plan.

So it is not inconsistent to say when ERISA was enacted in the 1970's, it made sense. It makes no sense today in a totally different context.

Mr. GANSKE. I appreciate that. Mr. Larsen, have you had a chance to look at our bill? We basically tried to codify the Supreme Court's P. Pegram v. Herdrich decision, which was contractual benefits continue to stay under ERISA's authority while medical judgment type decisions would go to the States, where they have always been in States.

Have you had a chance to look at the language on our bill?

Mr. BILIRAKIS. A brief response to that, Mr. Larsen.

Mr. LARSEN. The NAIC has not taken a position on the language and hasn't met. We are meeting in 2 weeks to go over these issues and I would be happy to respond in writing to your request.

Mr. GANSKE. Thank you.

Mr. BILIRAKIS. Mr. Pallone, to inquire.

Mr. PALLONE. Thank you, Mr. Chairman. In my opening statement, I expressed my concern that this new bill or potential bill by Senators Frist and Breaux would be moving us in the wrong direction and basically whittling down patient protections and slowing down the process perhaps of getting Mr. Dingell and Ganske's bill passed.

The two concerns that have been raised, and I guess I am really quoting Congress Daily and other reports, because there is no bill at this point, is with regard to scope, not so much the floor, but the opt-out for States with low HMO enrollment or adverse impact on premiums.

I think we are told that if the costs went up by 2 percent, the States could opt out, or if there was low HMO enrollment.

Again, I haven't heard from the Senators specifically, but that is what we are hearing.

Then the other thing, of course, is this requirement to go to Federal court.

I just wanted to hear some comments on that. Maybe Mr. Pollack could comment on the Federal court requirement. I used to be a clerk in the Federal court in my law school days and I know they

were tremendously backlogged. They didn't necessarily have expertise in this area, because so much of this involved State law, and my fear would be that it just makes it that much more difficult for somebody to be heard.

But I would like your comment on that.

Mr. POLLACK. I am actually surprised about the debate on this issue. I happened to be in St. Louis during the third Presidential debate and the very first question asked of the President was what would you do with respect to the Patients' Bill of Rights.

What President Bush stated in response to that first question was that we have passed patients' rights legislation in Texas and I am going to try to see that we get for the United States what we achieved in Texas.

Now, what does Texas have? Texas allows you to sue in State court.

Now, the issue, I think, really is largely a question of how much time it takes to litigate. Anybody who litigates in the Federal court system, and I used to be the dean of a law school, knows that the Federal court system, there is a great deal of backlog. It takes considerably more time to get cases adjudicated.

So as a result, the relief that somebody is seeking, whatever this body thinks is appropriate in terms of relief, comes much later when you go through the Federal court system.

Mr. PALLONE. Even in terms of the expertise, usually these personal injury cases are handled in State court and they have more of an expertise.

Mr. POLLACK. Absolutely. This is not something that the Federal courts generally have jurisdiction over. That is right.

Mr. PALLONE. Now, what about the scope aspect? I guess I can ask both of you that. Again, I don't know for sure what the Senators have in mind, because we don't have a bill, but we are hearing that they might have these opt-outs for States with low HMO enrollment or with costs that go up by, say, 2 percent.

It seems to me you can argue over the floor, but these two options are just not acceptable, because that would mean that there would be no protection in certain States.

I just wanted to know your opinion on that.

Mr. POLLACK. I don't even understand how you would implement such a provision. Congressional Budget Office has given estimates of last year's Norwood-Dingell bill and what they said was over the course of 10 years, it would exceed 2 percent, but over each year, it was really a fraction of that.

I don't know how a Governor or a State legislature or the Secretary of Health and Human Services could administer that. It would purely be an allegation that could not be substantiated until you have actually seen the regimen actually properly implemented.

I think we can tell from the States, however, that have adopted these patients' rights protections that the costs don't come close to 2 percent.

My fear is that offering that kind of an out could offer a potential smokescreen for those who do not want to have that protection, even though there would be no scientific validation that the costs would exceed 2 percent.

Mr. PALLONE. Thank you.

Mr. LARSEN. Briefly, in Maryland, for example, we review and approve all health insurance rates and HMO rates. So we have a fair amount of experience in looking at rate filings.

It is sometimes very difficult to attribute rate increases to any particular factor. So I don't know exactly what the process is, because we haven't seen it either, but I know that trying to correlate a particular rate increase to a particular law or set of laws can be difficult.

With respect to the low HMO penetration, obviously, I don't know what low is and whether there would be a standard for that, and how low is low and where does that leave—if there even is some managed care penetration, where are those consumers.

So conceptually, the opt-out for low penetration seems to at least make sense, but, again, I don't know how that would be implemented.

Mr. PALLONE. Thank you.

Mr. BILIRAKIS. Chairman Tauzin, to inquire. The Chair thanks the gentleman.

Chairman TAUZIN. Thank you, Mr. Chairman. Let me first, Mr. Larsen, talk about the substantial equivalence concept. I have read the Frist proposal yesterday and in his proposal, he provides for exactly that concept, but he provide that upon the certification by the Governor of a State, that the State program is in substantial equivalence to the Federal standards, that there would be an advisory board judgment on that issue, recommendation to the Secretary of HHS, who would then make a final determination as to whether it was or was not.

If it was not, in his opinion, it would be a consultation whereby any disagreements over the substantially equivalence would be worked out.

Is that or is that not a workable plan, in your view?

Mr. LARSEN. Again, the NAIC hasn't opined on the specifics of it. I will say, generally, that whatever the process is, it has to be a relatively simple and timely process.

Again, our experience with doing these types of things under HIPAA and HCFA was fine, but it was just a laborious process for a much smaller set of issues.

So that there needs to be timeframes and not too many steps involved so that it can be resolved quickly and then give State legislatures time to respond if, for example, it is agreed that there is not substantial equivalence.

Chairman TAUZIN. Let me take issue a little bit with the notion that the President endorsed a Federal plan that would provide for all State lawsuits on these issues.

I think as I heard his statements, and I have had private meetings with him on this subject matter, we look at the principles derived from the White House, he certainly expects the national plan to give due deference to State plans like Texas, but I don't think he ever endorsed the notion that all of these issues should be tried in State court.

I don't think he said that in the debates and I don't think he meant that, if you thought he meant that, but that is debatable.

Let me ask you a little bit about why I think we are in this fight or this discussion, because you said you were surprised by it, Mr. Pollack.

In discussion of the Frist bill last night, I asked some questions that I didn't get some great answers to yet and maybe you can help me with.

You are exactly right about the universe the way it existed at one time. We went to get our medicine and our medical service and then we applied to the insurance company and found out whether we got paid or not. Very often the doctor found out whether he got paid or not. If he didn't get paid by the insurance company, sometimes he didn't get paid. That was sort of the way the world worked.

Nowadays, we live in a different kind of context, with managed care making a decision about whether or not our plan covers the type of medicine or services we are looking for.

But suppose I live in an area where—in a condition where I am rich enough I can afford it, that when my HMO tells me we don't cover the kind of medicine you want or the kind of service you want, I say, well, fine, I will see you in litigation, I will see you somewhere; in the meantime, I am going to get it. I go to my doctor and I say I want this, do it for me.

What I have then is a fight over a contract, essentially, on whether or not I am going to get paid, reimbursed for what I already paid for in medical services.

Let's say I live in a State where I am indigent, but my State has a charity hospital system, like Louisiana had, and I am not doing well at all and my HMO won't cover my services and I have to have it.

Do I have an affirmative duty to go over to the charity hospital and say I have to have this, this is life-threatening, do it for me, or under the State plans, as you have seen them, do I simply not get my services and can I sit back an sue my HMO?

Mr. POLLACK. Well, I don't think any of us who have helped work on patients' rights legislation, I served on the President's Commission that developed the Patients' Bill of Rights. I was on the subcommittee that drafted the first Patients' Bill of Rights.

None of us thought that when we were establishing internal and external appeals rights and so on, that what we were doing was saying that this was a pretext for changing the coverage in a plan.

Obviously, there is a question of fact as to whether the plan does or doesn't cover it.

Chairman TAUZIN. Whether you are covered or not.

Mr. POLLACK. I fully appreciate that. I appreciate what Mr. Shadegg said about employers. Clearly, these are questions of facts.

But a true remedial process is not intended to change the scope of the coverage that is provided.

Chairman TAUZIN. My time is going to run out. What I am asking essentially is do you agree that the plaintiff in any of these cases, the patient plaintiff, whether it is in a review process or a lawsuit, has an affirmative duty to minimize his damages? That is, to take advantage of whatever health care services he can get if his HMO won't give them to him.

Mr. POLLACK. I think the common sense response to your question, Mr. Chairman, is yes. But it is not because you want to avoid litigation. It is because I want to get good health care.

Chairman TAUZIN. You want to get good health care, that is right, but it has an effect on the litigation.

Here is the final point I want to make, Mr. Chairman, and I know my time is up.

It seems to me we are in this debate about where a suit is tried, because we have migrated from a situation where denial of coverage is now considered potential malpractice, potential tort.

What was formerly a contract situation, purely a contract situation, are you going to pay me, are you going t pay the doctor, are you going to reimburse me for the services, has become a question of whether I get the services at all, is it really covered or not.

Traditionally, we have handled the Federal issues of coverage as a contract matter under Federal law. The issues of malpractice is a tort matter under State law, and that now we have a confusion of the two, because under the new delivery of health care plans, the initial decision to provide coverage or not in some cases means you either get it or you don't.

That can, in some cases, mean that you have got a potential tort problem on your hands, as well as a contract problem. Is that right?

Mr. POLLACK. Mr. Chairman, I don't want to complicate things further, but if you look at the Texas statute and then follow the litigation that arose in terms of Aetna's challenge of the statute, it does raise some of the questions that you suggested.

In fact, the Court of Appeals for the Fifth Circuit said that—it actually divided this concept into two parts. It said if you provide services and you provide them poorly, so you have got a situation of the nature of malpractice, then you can litigate.

On the other hand, the Fifth Circuit Court of Appeals said if you are denied care because of a medical necessity decision, it said if that is what we interpreted this Texas statute to cover, we would have invalidated it for violating the ERISA statute.

Now, my concern about this is that these decisions about medical necessity really require medical judgments and yet we are treating them as if they are administration of a health plan rather than medical judgments, and I think that is a mistake and I think the most common grievance that an individual has that has you all focusing on a Patients' Bill of Rights is when people get denied care and they think that denial was improper because a decision was made it is not medically necessary.

We have got to stop this—we are really dancing on the head of a pin here in terms of trying to create distinctions between what is appropriate for the courts to review and what is pure administration of a plan.

Most of the decisions that people want to contest that have been determined so far by the Federal courts to be decisions relating to administration of plans are really medical necessity decisions.

Chairman TAUZIN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mrs. Capps.

Mrs. CAPPS. Thank you. I want to hear from you more on that last bit, but I want to just acknowledge that to me, this hearing

today, which I believe is the first one we have had on this particular topic, is further testimony of the fact that we have momentum now, both from the President's statements, no matter how they are interpreted, and also that we passed legislation in the last session, good legislation on this topic, which enjoyed bipartisan support.

In fact, to have this expert testimony from both of you now, and the Honorable Monson, as well, it gives us a chance to make sure that this time when we do this again, that we do it in the best way.

It is huge and since the bill is based on Texas statute and it has been challenged, I would hope that we could use your expertise and others to make sure that the bill does the things that it should do.

Now, I am mindful that your last statement, Mr. Pollack, sort of put it back square to where it should be, I would like to know from each of you what we should hone on to make it really work this time and so that it will avoid some of the contests that have happened in the past.

Mr. POLLACK. Let me raise a point in response to your question that we have not dealt with in the course of this hearing.

I think there is a consensus in this panel that we would prefer to see disputes resolved at the earliest moment in the least contentious manner.

There may be significant differences about the litigation provision, and I appreciate them and they are strongly felt points of view about how to create that litigation right, but I think everybody agrees that if we can avoid litigation, if we can get things resolved early before there is harm caused, we are doing the patient the best thing that we can do for them.

One of my concerns, I had it in my written testimony, I did not talk about it in my oral testimony, is how do we buildup this internal and external review mechanism so that no matter where you come out on the litigation provision, there is less litigation that results.

One of the things that I would suggest that hopefully is part of a compromise that will ultimately get worked out here is that in strengthening the internal and external appeals system, we have got to make sure that consumers get some help in that system.

I don't mean in litigation. I mean in terms of the internal and external appeals mechanisms.

What happens typically in an internal or external appeals system is that the health plan comes in with their medical director and/or their attorney, coming on the side of the patient who is filing the appeal is the patient, who is bewildered about this internal and external appeals mechanism.

And to make matters worse, that person tends to be sick at the time they are making this appeal, because that is why they are appealing.

We need some kind of assistance for the consumer so that they can handle this internal and external appeals system in a way that produces a satisfactory result, so that nobody resorts to litigation in the end, and I hope that this is part of the compromise that you all work out that you would not find as either a Democratic or a Republican proposal, but something that just makes a great deal of common sense.

Mrs. CAPPS. Thank you. I have a further question, maybe for Mr. Larsen, but I believe my colleague would like to continue.

Mr. GANSKE. If the gentlelady would yield.

Mrs. CAPPS. Yes, I will yield.

Mr. GANSKE. I would like to hear from Mr. Larsen on exactly Mr. Pollack's point—that state insurance commissioners have had ombudsmen and they are a good option for patients. You know what we are talking about in this type of situation.

I have gone in and advocated for patients in their internal review and it is a pretty intimidating situation when the patient is sitting there on a chair in front of a panel of about eight people, including attorneys.

Do you have any suggestions on this?

Mr. LARSEN. I concur on that point completely. I think that the more assistance that can be provided to the consumer, the better.

In Maryland, we have an advocacy unit that assists at the internal level and then Maryland is somewhat unique, because our external review is done through our department. We retain the IROs. It is not the health plan, the independent reviewers.

So we have complaint investigators that interact with the consumer and the consumer, I think, has the comfort of knowing there is a State agency involved, and that is why I think ours is tremendously effective, because as you probably know and as was mentioned, people going through this process are often ill, upset, either because they are ill or their children are ill or their parents are ill, and it can be intimidating.

So it is quite important that there be some vehicle for assistance to people that go through the process.

Mr. GANSKE. Thank you. Mr. Chairman, I would ask unanimous consent that the gentlelady be given an additional minute.

Mr. BILIRAKIS. Well, without objection, but——

Mrs. CAPPS. I can see my Chairperson sighing, so if you would like to move on. Maybe I will just pose it, and if it comes out in another way.

It kind of picks up, Mr. Larsen, on what you just said. We have talked about the patchwork of States and the Federal floor that we perhaps agree could be there.

But how about States, and maybe Maryland is one, that go further than that?

Mr. LARSEN. Well, we do, and that is why I think it is so critical that—and I guess it gets back to your original question.

The most important thing, from our perspective, and I know liability is a hugely important issue to many of you, is the clarity of the role and the clarity of what is preempted and what is not preempted.

There is so much ERISA litigation because it is such a complicated convoluted statute, and if you do nothing else to clarify with language exactly who does what and when.

For example, if something is found not to be substantially equivalent, if a State law is not, who fills that void? Does that mean the State is enforcing Federal law? Many States can't enforce Federal law. Does that mean the resources are there?

It takes a lot of focus to kind of play through every possible scenario and have the statute be very clear, because if it is not clear,

health plans will use that to litigate, well, this is not clear, this is preempted, this isn't preempted.

It is so important and it is often overlooked in some of the conceptual issues about right to sue and other issues, who is going to be doing it.

Mrs. CAPPS. That is good advice. Thank you.

Mr. BURR [presiding]. Thank you, Mr. Larsen. Mr. Shadegg, to inquire.

Mr. SHADEGG. Thank you, Mr. Chairman. Let me first begin, Mr. Pollack, by associating myself with your remarks that you just made a moment ago. I couldn't agree with you more, that I think we are close to a consensus on some key issues.

And I heard you use the word compromise and as you know, I have used that word here repeatedly. I think it is very important, as I made clear in my opening statement, that we abandon the extremes in this debate.

I held these charts up before, I am going to take time to do it one more time.

This chart illustrates the point you just made, which is we need to assist people in going through internal and external review, and the best assistance they can get is by their own doctor, who is saying to the HMO "my patient needs this treatment."

And the virtue of requiring cases to go through external review, in my view, 100 percent of the cases, will change the dynamic that currently exists, and that dynamic right now is because the plan can tell the doctor how to practice medicine, we are getting plans, usually bureaucrats or non-practicing doctors telling doctors how to practice medicine, and that makes the doctors angry.

And you know what? If I were one, I would be angry by being told by a bureaucrat how to practice.

I think the point you made that we all want to avoid litigation is a critical one. Litigation is not the answer here in the vast majority of cases.

It is the answer, and I am a strong proponent of holding HMO's liable when they actually injure somebody or kill somebody. I simply prefer that that lawsuit be filed after a panel—I prefer a panel of doctors or at least a doctor has reviewed the case and told the plan whether they were right or wrong.

One of the concerns I have is that the other structure proposed for this legislation avoids that, and the other structure is a structure which says you go through internal review and then if you've got your lawyer, you don't go through external review. You go straight to court, and that is this loop down here.

It is in the bills that have been discussed this morning, and it is a loop that simply says if you want to go straight to court and if you want to avoid the administrative review process where you go through external review and a doctor tells the HMO whether they ought to be treating you, you avoid that loop.

The bad part about that is that now you no longer have doctors telling HMOs what the standard of care is in America. You instead of have patients being diverted into courtrooms, and I couldn't agree more with what you said about the importance of avoiding litigation.

Mr. Larsen, I want to turn to your comments. You said that you think States have very strong internal and external review processes that are working and you urged us very passionately not to abandon those State internal and external review processes.

I agree with you. This is a chart that you are probably familiar with. In health care in America today, roughly 70 percent is governed by ERISA. That is, it is an employer-purchased plan.

Those are divided, as Mr. Pollack explained earlier, into the self-insured plans and the insured plans.

The remaining 30 percent of health care in America today is non-ERISA plans. We are talking about the plan that your State of Maryland offers you, that is not governed by ERISA. You are talking about a plan that I might go buy as an individual purchase myself.

Right now, as an insurance commissioner, you have jurisdiction over a part of ERISA when it is an insured product and you have jurisdiction over this totally non-ERISA provision.

My question of you is, in some of the bills that have been proposed right now, they propose to extend all the Federal patient protections and to preempt your internal and external review process to 100 percent of all these.

They want to say, okay, because the Federal Government is going to enter the field and it is going to prescribe an internal and external review process, which all of these bills are almost identical on, and I think it is a good process and I agree with Mr. Pollack it has to be a good process, they want to say that the Federal process should extend not just to ERISA, which the Federal Government currently has jurisdiction over, but they want to say that that internal review process dictated by the Federal Government must extend to all State governed insurance plans that have no ERISA jurisdiction right now, and they do the same with the patient protections.

Do you know of abuses occurring on the State side, where there is a need to extend the Federal patient protections, and, on top of that, the Federal procedures, the internal and external review, over onto the State side essentially preempting the internal and external review process that you favor?

Mr. LARSEN. No, I am not aware of abuses. I mean, we handle those cases currently.

I guess the way I would answer that is to say that in accordance with, I think, the prior testimony, is that we would strongly oppose any effort to preempt what we think is working, to varying degrees and depending on markets.

I recognize that they are not all consistent across the States, but to set up a flat across-the-board preemption and not allow us to continue on the 30 percent of the individual and non-ERISA group plans, as well as the insured group plans, we can't support that.

Mr. POLLACK. Mr. Shadegg, would you permit me to comment on your question?

Mr. SHADEGG. Sure.

Mr. POLLACK. One of the things that I am concerned that gets raised from your question is that the States actually have substantial variety in the way that they implement these internal and external reviews.

For example, there is a huge variance in terms of the time limits for resolving any of these hearings. Some of them are done in a very timely manner, some of them are done in a way that I don't think you would consider timely.

There are different questions about who resolves, who makes these decisions, and what the standards are as to who should make those decisions.

There are different questions as to the binding nature of these internal and external appeals.

So the only point I want to make in response to your question is that this wide variance, even for the States that have adopted internal and external appeals systems, does call for some kind of floor here so that people don't have to wait for decisions to be rendered in a way that becomes meaningless and that it gets done in such a way that they are binding and that the people making those decisions are truly objective.

Mr. SHADEGG. My time has expired, but let me just comment on this point.

I think that the point, from my perspective, is, first of all, when we start discussing what should be federally governed, how far should we extend the patient protections and should substantial equivalence, for example, be decided by the State or by the Federal Government, how far should we extend the FEDERAL internal and external review procedure, I think it is absolutely legitimate to say that to the extent the Federal Government already governs 70 percent of health care, the Federal Government has every right to set the standards and to prevail in that area.

But I have to tell you, I don't understand why the Federal Government should preempt States in the regulation of health insurance plans that are solely state-based right now.

But more importantly, you argue for uniformity. I guess my response to that is, first, you made the point earlier that you thought the experimentation or the fact that the States could be different laboratories, you made that point earlier.

If we preempt everything and set a single Federal standard, there will be no laboratory. But more important even than that is the point that not a single complaint do I get, either in Arizona, where we have passed a Patients' Bill of Rights that protects these people in this category or anywhere else, do I ever get any complaints about what is happening at the State level.

Where I get complaints is what is happening under ERISA, where people get harmed and can't be made whole.

Mr. BURR. The gentleman's time has expired. Mr. Pollack, briefly.

Mr. POLLACK. The only comment I would make to this, Mr. Shadegg, is really there are two purposes for establishing this on a national basis.

One is the confusion that exists is very profound for consumers in terms of what their rights are and if you continue to have many different kinds of systems, it actually perpetuates that confusion.

Second, I would suggest to you that there are some things that even in the diversity of this panel, you would probably feel are basic kinds of rights that people should have in this appellate system.

There should be certain rights about the objectivity of the hearing officer. There should be certain rights about the timeliness of this process.

I don't think that that is an onerous burden and it certainly would make it far easier for consumers to get complaints resolved in a timely manner.

Mr. SHADEGG. Mr. Larsen, I challenge you to bring me a single complaint by a state-based individual from Maryland or any other State where we have passed a Patients' Bill of Rights, in those States that have done it, where they say, well, we are confused by this process and we don't understand how we enforce our rights.

The reality is——

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

Mr. SHADEGG. The reality is that at the state-based level——

Mr. BURR. I am sure that he has put the challenge.

Mr. SHADEGG. [continuing] they are not being abused. It is ERISA that is causing this problem, and I think Mr. Ganske will agree with me on that.

Mr. BURR. The gentleman's time has expired. The Chair would recognize the gentleman from New York, Mr. Engel, for purposes of questioning.

Mr. ENGEL. Thank you, Mr. Chairman. I am of the view, as many of our colleagues have expressed, that we need a Federal floor for all consumers to ensure basic minimum of protections and to ensure that patients have access to new technology.

We had a hearing last week on Medicare beneficiaries who are having difficulty getting access to new technology, and, uniformly, members were concerned that Americans should have the benefit of access to new devices and other technology quickly.

We are told, and I would like you to comment on that, in the private health insurance market, and Tennessee is one State, for example, Tennessee has enacted an external appeals process that does not let consumers appeal when they have been denied a treatment that a health plan has called investigational or experimental.

This is one of the ways, we are told, that health plans deny patients access to newer technologies, by calling them experimental, even if they are FDA-approved.

It seems to me that if we don't have a Federal floor, we run the risk of a situation where some consumers wouldn't be protected for these types of cases and might be denied access to the latest technology through health plan chicanery.

I would like to ask Mr. Pollack, firstly, and then ask Mr. Larsen to comment. Would you agree that if we don't set a strong minimum Federal floor, we run the risk of having a situation of patients being denied access to new technology, because some States won't include such basic protections in their appeals process?

Mr. POLLACK. The answer is yes, and I think it makes sense, as I said earlier in my testimony, to have this floor. I don't think that Commissioner Larsen and I disagree about enabling the States to experiment and to impose provisions that are more protective for people.

But I think we need to have a floor and I think you are giving one illustration as to why it would be useful to have that floor.

Mr. ENGEL. Mr. Larsen.

Mr. LARSEN. In answer to your particular question, without a Federal floor, of course, everyone won't end up with the same rights and possibly the same access to treatment. So I don't disagree with that.

I guess the view of the NAIC is that in an ideal world, States are given full flexibility to do what they want, but as a practical matter, I think we all understand that under that scenario, you end up with the somewhat inconsistent laws that we have today and some provide greater protection to consumers than others.

So as a consequence, I guess what I am trying to communicate is if you go with the Federal floor, and we understand why you would do that, the most important thing is to make sure that the floor is not a ceiling and that we can go even beyond for the States that exceed even what Congress determines is the minimum level, because under the laboratory theory, some States think that there is more to be done.

Mr. ENGEL. I couldn't agree with you more. Uniformly, everyone felt that these new technologies were not getting into people's hands, even if they were approved, and that is one of the major concerns that I have.

If things are approved and they can help people, we don't need layers of bureaucracy preventing people from getting them or a denial of newer technologies by health plans.

Mr. POLLACK. And this is a very common dispute that occurs between plans and patients. So what you are describing as an illustration is actually something that we know occurs a great deal among patients and their plans.

Mr. ENGEL. And I think we also don't need people going from State to State, where if there is no floor, you could have an increase in people going from State to State to try to find a State that would provide the technologies.

I think if we have the floor, obviously, there will be less of that, because there will be a minimum amount that people can know that they have, regardless of what State they are in.

Mr. POLLACK. We are a very mobile society and to change such basic rights based on the happenstance that you just happen to cross State borders makes no sense.

Mr. ENGEL. Thank you. Thank you both for your testimony. I yield back the balance of my time, Mr. Chairman.

Mr. BURR. The gentleman's time has expired. The Chair will take the balance of time and recognize himself for purposes of questions.

Mr. WYNN. Mr. Chairman.

Mr. BURR. Let me recognize the gentleman from Maryland. If the gentleman is ready, I'm really not ready.

Mr. WYNN. I don't know that I'm ready.

Mr. BURR. I would find it very educational. I will recognize the gentleman from Maryland.

Mr. WYNN. Why don't we just move to the next panel?

Thank you for your graciousness. I will proceed quickly.

On the question of increased cost to business, an argument, of course, to be made that the right to sue would drive up cost of plans, eliminate certain coverages.

What is the element or elements that result in this alleged increase in cost? Is it the frivolous suits? Is it the more extensive treatment, or is it compensation awards?

To the extent that there is an increase in cost directly linked to the right to sue, what does it flow from?

Mr. POLLACK. I would suggest to you that in the past, when we have had this debate about litigation, it is usually occurred in the context of malpractice, and there what most people say, the analysts that have looked at this is that in terms of the actual money judgments, those really do not constitute a very significant cost.

Where people have been worried about costs is the practice of defensive medicine and there you get very different kinds of estimates as to what the cost of defensive medicine is.

In the context of managed care, that problem minimizes itself. It is far different than it is in fee for service care, because, remember, in fee for service, there is every incentive to provide as many services as possible to begin with, because that's how a provider makes their money.

In the managed care context, all of the economics incentives are in the opposite direction.

So I would suggest that the fears that people have raised in the context of malpractice litigation do not exist here in the context of trying to deal with abuses by managed care companies, all of whom really have strong incentives to keep costs down and to reduce the number of services that are provided.

Mr. WYNN. Thank you. I just want to make sure I'm correct in my understanding. With external abuses, they only deal with the medical necessity question and not the compensation question, is that correct?

Mr. POLLACK. In a fee for service system, you still could have some kind of external review system to challenge a denial by an insurance company to pay for a service that's already been rendered.

But typically, you're right. Typically, the issue is dealing with a medical necessity decision.

Mr. WYNN. So in order to get to questions of compensation for injury or denial, to get us out of the field of malpractice, you would still have to resort to the courts, is that correct?

Mr. POLLACK. No. If the internal and external appeals system is working properly, then hopefully you can get this denial of care resolved at an early stage and have the health plan be told, if they have improperly denied care, to provide that care so that there is never any resort to litigation.

I think the resort to litigation is a very, very infrequent situation, especially if a managed care plan has failed to abide by the decision at an external hearing.

Mr. WYNN. I would agree. I would just be concerned that there are situations in which the denial of care initially or timely care results in injury and what recourse the patient has except for the court.

Mr. POLLACK. If the injury has occurred, that the denial or delay resulted in injury already, then probably they will need to have to resort to the court system.

Mr. WYNN. And I guess the third question I have is, I have speculated that there was some deterrent value from having either an external review or, to my way of thinking, a greater deterrent value from having the availability of litigation, which is to say that the prospect that there would be costs associated with denial of care or improper diagnosis would have a deterrent effect on creating a more careful environment or a better environment.

Mr. POLLACK. Absolutely. I think the strongest argument for having a right to litigation with a meaningful remedy is precisely what you just said, and that is its deterrent value.

I don't think most of us think there is a great value in big money judgments that go to very few people. But what is useful is for a health plan to understand that if they cavalierly deny care improperly, at the end of that road, they may have greater liability than had they provided the service as originally they should have.

And today, under Federal law, there is no such deterrent, because the only thing under Federal law you can sue for when you go to Federal court is the monetary value of the service that was originally denied, and that means you have a remedy that comes too little and too late and it really provides an incentive to a health plan to continue denying, because they'll never have greater liability than if they provided the service on a timely basis.

So this litigation issue we are talking about really needs to be looked at as a deterrent issue.

Mr. WYNN. Thank you, Mr. Chairman. I relinquish my time, and thank you, again.

Mr. BURR. The gentleman fulfilled my wishes that I was educated by his line of questions. Thank you.

The Chair would recognize himself for questions. Mr. Pollack, are people denied care in the Medicare system today?

Mr. POLLACK. Sure.

Mr. BURR. And for what reason?

Mr. POLLACK. A variety of different reasons.

Mr. BURR. What is the primary reason?

Mr. POLLACK. I'm not sure I can pick one, but it might be that in some instances, a physician may say you don't need the specific care. It might be, if they are in the Medicare Plus Choice plan, that their HMO will say we think it is medically unnecessary that you get the service.

Mr. BURR. Aren't there a host of things——

Mr. POLLACK. Yes, there are.

Mr. BURR. [continuing] that Medicare does not reimburse for?

Mr. POLLACK. Yes. For example, it doesn't reimburse for outpatient prescription drugs.

Mr. BURR. There is a host of procedures that are FDA-approved that Medicare for years it will take them to make a decision as to whether they cover that procedure.

Mr. POLLACK. And if a beneficiary of that program feels aggrieved by that process——

Mr. BURR. There is an appeals process.

Mr. POLLACK. [continuing] there is an appeals process.

Mr. BURR. The question that I wanted to ask you was given that we are in agreement that the appeals process was important, should we extend liability to HCFA for the 37 million seniors that

are under Medicare because it is not just enough to be able to appeal it, but the question is could they have been harmed based upon HCFA's actions not to adequately provide an array of services for them?

Mr. POLLACK. There is no question, if a service is improperly denied, there ultimately should be a right to litigate.

Mr. BURR. What if it was just in the scope of the defined coverage? It just didn't cover that. It may have covered the area, but there was a new procedure that was added. That new procedure didn't have a reimbursement code. So whoever provided the service, the physician, the hospital, wherever, couldn't provide that technology for that patient, and the patient was damaged?

Mr. POLLACK. That probably is a question of fact which can be adjudicated.

Mr. BURR. So do we need a formal liability extension to the Health Care Financing Administration for Medicare if we talk about the extension of this?

Mr. POLLACK. Mr. Burr, it is not typically HCFA that makes those determinations. No, it does not. These determinations are generally delegated to insurance companies which act on behalf of HCFA that make these decisions.

Mr. BURR. And do you, for a minute, believe that if we made those insurance companies liable for those decisions, the courts wouldn't interpret that, but that's an extension fo HCFA. They are a contract company.

Exactly the argument that so many managed care companies have made and so many self-insured companies have made about leaving it to the courts to determine the extent of liability.

I don't think that there is a huge gap, contrary to some of the debate that you've heard, about where members of this panel are.

I think where the question is is where we have inserted the court for interpretation of what we mean, the court to interpret, on somebody's behalf, whether an employer made a coverage determination; if they did, are they now liable.

And I've seen eight different versions of language. I am convinced that there are people out there trying to make sure that we cap the liability in some way, shape or form so that employers are not undressed with this legislation.

But the reality is that none of us know, if challenged in court, exactly what the determination will be about the extent of liability.

If we are going to do it the private sector, then we ought to expose government just as heavily, because they make the same coverage determinations that private sector companies do about the scope of their coverage, and, in many cases, I would tell you that the private sector does them a heck of a lot better and a heck of a lot faster than the Health Care Financing Administration currently does today.

Mr. POLLACK. The dispute that took place earlier this morning between members of the panel, I think there clearly was a common goal. The common goal was that where employers are not involved in decisionmaking concerning the regimen of care, that they should be exempted from any liability.

On the other hand, I also think there is a consensus that if it is the employer who is making these decisions that redound to the harm of the consumer, then the employer should be liable.

Now, there is a fine question as to how do you implement that common goal, but I do believe that if an employer is making a decision that results in a person improperly being denied care, then in that instance, and I don't think there are many such instances, but in that instance, then certainly the employer should be held liable.

Mr. BURR. Certainly the courts would welcome the opportunity to define improperly based upon case by case by case. I thought it odd that this bill does exclude those of us covered FEHBP. There are a number of bills, but I think it does.

I want to thank both of you—Mr. Pitts does not want to be recognized. I want to thank you for your testimony. I want to thank you for the contribution.

I am sure that we have still got a lot to learn as we prepare for markup of legislation, not only in the subcommittee, but in the full committee. But we thank you for everything.

Mr. LARSEN. Thank you.

Mr. POLLACK. Thank you.

Mr. BURR. I will adjourn this panel. At this time, I would call up the second panel.

Mr. GANSKE. Would the chairman——

Mr. BURR. The chairman will as soon as he introduces the second panel, please.

The second panel consists of Mr. Stephen—and I am going to make an attempt at this, Steve—deMontmollin.

Mr. DEMONTMOLLIN. Yes, sir.

Mr. BURR. Great. I am not going to say it again, though. Vice President and General Counsel, AvMed Health Plan; Mr. Donald Palmisano, a member of the AMA Board of Trustees; Ms. Jane Greenman, Deputy General Counsel, Human Resources, Labor and Benefits, Honeywell Corporation; Ms. Sara Rosenbaum, Director, Center for Health Service Research and Policy.

Welcome to all four of our witnesses for panel two. At this time, the Chair would recognize Steve for his opening statement.

STATEMENTS OF STEPHEN J. deMONTMOLLIN, VICE PRESIDENT AND GENERAL COUNSEL, AVMED HEALTH PLAN; JANE F. GREENMAN, DEPUTY GENERAL COUNSEL, HUMAN RESOURCES, LABOR AND BENEFITS, HONEYWELL; DONALD J. PALMISANO, MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; AND SARA ROSENBAUM, DIRECTOR, CENTER FOR HEALTH SERVICES RESEARCH AND POLICY

Mr. DEMONTMOLLIN. Thank you. Mr. Chairman and members of the subcommittee, my name is Steve deMontmollin. I am Vice President and General Counsel of AvMed Health Plan, Florida's oldest and largest not-for-profit HMO, serving some 300,000 members, including approximately 30,000 Medicare members, Federal employees under FEHBP, and Medicaid members throughout the State.

Today I am testifying on behalf of the American Association of Health Plans, which represents approximately a thousand HMOs,

PPOs, and similar network plans providing coverage to 140 million Americans.

My comments will focus on the significant negative impact health plan liability expansion will have on quality of care, health care costs, and the number of uninsured, as well as AAHP support of meaningful and timely dispute resolution through independent medical review by physicians, rather than medical decisionmaking by trial lawyers, judges and juries.

But before I speak on these issues, I would like to share the results of a national survey just released by AAHP yesterday on physicians' attitudes about the current malpractice system and their attitudes about the most effective ways to resolve coverage disputes.

The survey found that doctors think the current medical liability system is unfair, raises costs, leads to defense medicine, hurts patient relationships, reduces reporting of medical errors, and does not improve the quality of care.

Doctors prefer an independent medical review panel over extended health plan liability to resolve disputes over coverage. Doctors would rather have a patients' bill of rights without expanded health plan liability than no bill at all.

Now, these findings are consistent with the position of the American Medical Group Association, which, in a letter dated March 2 to Senator McCain, said that they represent 300 medical practice groups, employing over 60,000 physicians in 41 States.

Their members are physician providers for over 30 million patients, and they include the Mayo Foundation, the Leahy Clinic, Henry Ford Health System, the Cleveland Clinic, and Permanente Federation.

The letter announces that AMGRA opposes, however, waiving ERISA preemption to permit participants in employer-provided health plans a right to sue health plans.

Making litigation the first concern of health plans and the first concern of a patient upon entering a physician's office erodes years of trust and works against successful health outcomes for the patient.

AMGRA favors a strong appeals process and believes a strong appeals process is a practical alternative to expanding liability. Expedited review of medical decisions is the responsible approach to ensuring that patients receive the care they need, while holding the health plan and physician accountable for ensuring that the proper level of high quality care is administered.

The results of this survey and of the AMGRA findings reinforce once and for all the very significant problems with the current malpractice system and the very significant dangers associated with expanding such a system to health plans.

First, with respect to quality proponents of expanding health plan liability, claimant liability expansion is necessary to improve quality of care.

In fact, we need only to look to the current medical malpractice liability system as proof that an expansion of such a system will do nothing to improve quality.

The current malpractice liability system discourages the identification and reporting of mistakes, allowing quality problems to

perpetuate. Numerous interested parties, some of which have called for expanded health plan liability, have recognized this.

Last year, the AMA testified that "The very fear of existing legal liability or its misapplication are the greatest hurdles to pioneering patient safety efforts. If the fear of litigation continues to pervade efforts to improve patient safety and quality, our transformation into a culture of safety on behalf of our patients may never be fully realized."

Members of the subcommittee, there is a poster that is on the right side of the dais and it is the third quote on that particular poster, and I might say that also up there is a quote from President Clinton's Advisory Commission on Consumer Protection in which it was stated, "Perhaps the most significant deterrent to the identification and reduction of errors, that is, treatment related injuries, is the threat of costly adversarial malpractice litigation." Expanding health plan liability will also lead to reduced quality of care by promoting defense utilization. And with respect to Mr. Wynn's comments earlier, that is a major problem with the current system.

Just as the current system encourages physicians to practice defensive medicine, a system that expands health plan liability will force plans to provide coverage for unnecessary services that do not benefit patients in order to avoid costly litigation.

With respect to the impact on costs and the uninsured, proponents of expanding health plan liability claim that such an expansion will result in a minimal cost increase, but the reality is that expanding health plan liability will significantly increase cost and in doing so will cause millions of Americans to join the ranks of the uninsured.

In an analysis prepared by the Barents Group, it was estimated that an expansion of health plan liability would result in cost increases of between 2.7 percent and 8.6 percent nationally, and, most recently, we are seeing health care premiums in Arizona rising between four and 6 percent because of a new HMO law that exposes health plans to expanded liability.

Despite the increase in cost of the health care system due to the medical liability system, the scope and breadth of attack from trial lawyers continue to expand.

The current class action onslaught by trial lawyers is a good example of lawsuits that are a means to squeeze additional funds out of the health care system, which ultimately means from the pockets of workers and their families who pay premiums and employers who subsidize their employees' coverage.

As an alternative to expanding a flawed liability system, AAHP supports a Federal independent medical review process to ensure that coverage disputes are resolved up front and consumers get the care they need and when they need it.

With independent medical review, coverage disputes regarding medical necessity are resolve by independent doctors with appropriate clinical experience, not trial lawyers appealing to juries who may or may not compensate them for their alleged injuries months or even years later.

A vast majority of States have chosen to adopt independent medical review over liability expansion, as well, and the second poster

that has been placed before you shows that of those States that have considered both liability and independent medical review legislation, 32 out of the 39 have chosen to adopt independent medical review instead of expanded liability.

Mr. BURR. Mr. deMontmollin, I am going to ask you to summarize as quickly as you can.

Mr. DEMONTMOLLIN. In conclusion, the well-documented flaws, many of which have been identified by physicians of the current liability system, should be sufficient evidence that expanding health plan liability is an ill conceived policy.

Such an expansion will only serve to reduce health care quality and lead to more uninsured individuals.

Thank you for your time.

[The prepared statement of Stephen J. deMontmollin follows:]

PREPARED STATEMENT OF STEPHEN DEMONTMOLLIN, VICE PRESIDENT AND GENERAL COUNSEL, AVMED HEALTH PLAN ON BEHALF OF THE AMERICAN ASSOCIATION OF HEALTH PLANS

Mr. Chairman and members of the Committee, my name is Steve deMontmollin, and I am Vice President and General Counsel of AvMed Health Plan. Based in Gainesville, Florida, AvMed is Florida's oldest and largest not-for-profit HMO, serving some 300,000 members, including approximately 30,000 Medicare members, throughout the state. AvMed contracts with close to 7,000 physicians and 126 hospitals, is federally qualified under the terms of the federal HMO Act, and is privately accredited by the National Committee for Quality Assurance (NCQA) and the Joint Commission on Accreditation of Healthcare Organizations.

Today I am testifying on behalf of the American Association of Health Plans (AAHP), which represents approximately 1,000 HMOs, PPOs, and similar network plans providing coverage to over 140 million Americans. AAHP member plans are dedicated to a philosophy of care that puts patients first by promoting coordinated, comprehensive health care.

I appreciate the opportunity to participate in today's hearing and to express the views of AAHP on the issue of expanding health plan liability and its potential impact on the quality and cost of health insurance in the United States.

My comments today will focus on three general areas:

I. The significant negative impact health plan liability expansion will have on quality of care;
II. The significant increases in costs and the number of uninsured that will result from any expansion of health plan liability; and
III. AAHP's support of meaningful dispute resolution through independent medical review by physicians rather than medical decisionmaking by trial lawyers, judges and juries.

Additionally, I'd like to share the results of a national survey just released by AAHP yesterday on physicians' attitudes about the current malpractice system and their attitudes about the most effective ways to resolve disputes with health plans over coverage issues. I believe the results of this survey reinforce once and for all the very significant problems with the current malpractice system and the very significant dangers associated with expanding such a system to health plans.

I. IMPACT ON QUALITY

Proponents of expanding health plan liability claim that liability expansion is necessary to improve quality of care. In fact, we need only look to the current medical malpractice liability system as proof that an expansion of such a system will do nothing to improve quality.

For instance, the alarming incidence of preventable medical errors continues to be a significant problem, due in large part to the punitive environment associated with the current medical malpractice liability system. In its landmark report, the Institute of Medicine (IOM) estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors.[1] Yet, unfortunately, the current malpractice liability system discourages health care professionals from identifying and reporting their mistakes, allowing quality problems to perpetuate. In fact, the IOM

[1] IOM Committee on Quality of Health Care in America, *To Err is Human,* 1999

itself stated in its report that the "fear of legal discoverability or involvement in the legal process is believed to contribute to underreporting of errors."

In addition, numerous interested parties—some of which have called for expanded health plan liability—have recognized the flaws with the current malpractice liability system.

- **Clinton Commission Report.** In its final report, President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry said of the current malpractice system that "perhaps the most significant deterrent to the identification and reduction of errors [i.e., treatment-related injuries] is the threat of costly, adversarial malpractice litigation." (President's Commission, *Final Report,* March 1998)
- **AMA Statement.** In 1997, then AMA President-Elect Nancy Dickey said of the current system, "The problem is that the climate of blame in this country, fueled by the litigation process where we have to identify someone at fault who will then pay exorbitantly, makes it difficult to walk out and finger yourself [when you make a medical mistake]." (*New York Times,* Dec. 9, 1997)

Expanding health plan liability will also lead to reduced quality of care by promoting "defensive utilization management." Just as the current system encourages physicians to practice "defensive medicine," (i.e., to provide care that is not necessary in order to protect themselves from malpractice suits) a system that expands health plan liability will force plans to perform "defensive utilization management." In other words, plans will be forced to provide coverage for unnecessary services that do not benefit patients in order to avoid costly litigation. In its cost estimate of the liability provision in U.S. Senate Bill 6, the Democrat's "Patients' Bill of Rights" legislation, the Congressional Budget Office (CBO) recognized this implication, stating, "[expanding health plan liability] would mean not only that more plans would be successfully sued but, more importantly from a cost perspective, every judicial decision awarding damages to a plaintiff for a plan's coverage decision would increase the risk of suit for all other plans with similar coverage policies."[2] Thus, instead of making coverage decisions based on the best available evidence, plans will be influenced to make such decisions based on the latest jury verdict or court decision.

Therefore, it is hard to believe that expanding this flawed system would benefit any patients. To support this statement, let me share with you some of the results of the AAHP survey of physicians I mentioned earlier.

- The overwhelming majority of doctors (78%) say that the threat of malpractice lawsuits does *not* make them deliver better quality care.
- Over nine out of ten doctors (92%) think the threat of a liability suit has increased defensive medicine.
- Over half of the physicians surveyed (57%) say that the current medical liability system makes physicians *less* willing to report medical errors.

II. IMPACT ON COST & AFFORDABILITY

While I believe that the argument against expanding liability can be made solely from the quality standpoint, let's talk briefly about the impact on cost and the number of uninsured Americans.

Proponents of expanding health plan liability claim that such an expansion will result in a minimal cost increase. But the reality is that expanding health plan liability will significantly increase costs and, in doing so, will cause millions of Americans to join the ranks of the uninsured. In an analysis prepared for AAHP, the Barents Group estimated that an expansion of health plan liability would result in cost increases of between 2.7 percent and 8.6 percent nationally.[3] State analyses also reflect similar estimates. For example, according to the fiscal note submitted by the Minnesota's Department of Employee Relations in response to liability legislation, health plan liability requirements would increase premiums by 5%.[4] Similarly, a recent AP news article indicated that health care premiums in Arizona will rise between 4 and 6 percent because of a new HMO law that exposes health plans to expanded liability.[5]

The AMA has long recognized the large cost impact of the current medical malpractice system.

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[2] CBO, June 16, 1999

[3] Barents Group, "Impacts of Four Legislative Provisions on Managed Care Consumers, 1999-2003," April 22, 1998.

[4] Minnesota Department of Employee Relations, "Revised Fiscal Note for S.B. 953," April 1999.

[5] "Premiums Expected to Rise Further Because of New Law" *The Associated Press State and Local Wire,* January 27, 2001.

- **AMA Testimony.** In testimony before the U.S. House Ways and Means Subcommittee on Health, the AMA stated, "Although patients, physicians, and health care providers are most directly harmed by the present liability system, society as a whole is also harmed. *The spiraling costs generated by our nation's dysfunctional liability system are borne by everyone* [emphasis added]." (AMA testimony, May 20, 1993)
- **AMA/Reform Coalition Statements.** Pronouncements from the National Medical Liability Reform Coalition, which includes the signature of the AMA, include the following:
  "[W]e believe that in resolving medical and product liability claims, the civil justice system currently:
  —costs too much and works much too slowly;
  —adds billions of dollars annually to the national health care bill in medical liability premium costs and by encouraging doctors and other health care providers to practice "defensive medicine" as a hedge against potential lawsuits; and
  —adds unnecessarily to the cost of pharmaceuticals and medical devices."[6]
- And, in the AAHP survey findings released just yesterday, nearly *every* doctor surveyed (95%) believes that the current medical liability system has raised costs. Of these, 73% say that the system substantially raises costs.

Despite the increase in costs to the health care system due to the medical liability system, the scope and breadth of attacks from trial lawyers continue to expand. To paraphrase remarks made by Pennsylvania Medical Society president-elect, Howard A. Richter, MD, just last month in testimony before the Pennsylvania House Insurance Committee—abuse of the medical liability system is a cancer that is deteriorating life and is creating serious problems with the care patients receive.

I believe there is perhaps no better example that is indicative of this abuse of the liability system than the current class action onslaught by trial lawyers. Presently there are more than 30 class action lawsuits pending against a number of health plans in a federal district court in Florida that seek nothing less than the total dismantling of this nation's employer-based system of health care coverage. These cases have been brought by various groups of well-known trial lawyers, some of whom were involved in the tobacco litigation settled by the States. The enormous fees they were able to obtain in tobacco litigation are now being used to bring these class actions against health plans.

What the trial lawyers in the class actions pending in Florida have brought are lawsuits only in the descriptive sense. Rather they are a means to squeeze additional funds out of the health care system—which ultimately means from the pockets of workers and their families who pay premiums and employers who subsidize their employees' coverage—through the threat of protracted litigation. The suits question the well-grounded policy and purchasing decisions of federal and state officials, who have enacted laws governing managed care plans and contracted with managed care plans to cover tens of millions Americans. Such decisions include those made by (1) federal policymakers to create the Medicare +Choice program, Medicaid managed care, and the managed care options in the Federal Employees Health Benefit Program, (2) state policymakers to create a comprehensive regulatory scheme for managed care plans and the state insurance and health commissioners who enforce that scheme and (3) state purchasers to select managed care plans for tens of millions of state employees and Medicaid beneficiaries. Any changes in the law that would lend support for these types of efforts will accomplish only one thing—the sapping of resources available for health care for the benefit of trial lawyers.

III. INDEPENDENT MEDICAL REVIEW—A BETTER WAY TO RESOLVE COVERAGE ISSUES

AAHP believes that expanding the current flawed liability system that is designed to assess damages *after* consumers allegedly have been harmed, does not give consumers what they truly need—a resolution for coverage disputes that is expeditious, and based on medical facts.

Instead, AAHP supports a federal independent medical review process, to ensure that coverage disputes are resolved upfront and consumers get the care they need when they need it. With an independent medical review, coverage disputes regarding medical necessity and appropriateness are resolved by independent doctors with appropriate clinical experience—not trial lawyers appealing to juries who may or may not compensate them for their alleged injuries, months or even years later. I

[6] National Medical Liability Reform Coalition, Medical Liability: Principles for Reform, Feb. 1993

cannot over-emphasize the difference. Independent medical review—conducted on an expedited basis when necessary—gets patients coverage when it is warranted. Lawsuits do not. With independent medical review in place, there is no basis for expanded liability.

The vast majority of States have chosen to adopt independent medical review over liability expansion as well. Of the states that have considered both liability and independent medical review legislation, 32 out of 39 have chosen to adopt independent medical review instead of expanded liability.

In my own state of Florida, a bill to expand health plan liability was ultimately vetoed by then-Governor Lawton Chiles. In his words, "The key to any dispute resolution system for health care claims is that it be fast, fair, and efficient. The tort system is often none of those." Governor Chiles wisely believed that Floridians were much better served by independent medical review rather than an expansion of liability.

Similarly, the results of AAHP's national survey of physicians show that:

- Three out of four doctors (75%) prefer an independent appeals process over new lawsuits as the way to resolve disputes with health plans over coverage; and
- The overwhelming majority of physicians (73%) would rather Congress enact a Patients' Bill of Rights with an independent appeals process but no new lawsuits than not pass any bill at all.

A federal system of independent medical review that provides consumers with consistency and certainty no matter where they live should be allowed to work. Expanding liability and bypassing the independent medical review process add nothing to consumer protection. To the contrary, they would shift the focus from a system that resolves disputes in a reasonable and timely manner to one that is premised on high stakes litigation.

In conclusion, the well-documented flaws, many of which have been identified by physicians, of the current malpractice liability system, should be sufficient evidence that expanding health plan liability is an ill-conceived policy. Such an expansion will serve only to reduce health care quality and lead to more uninsured individuals. Independent review by physicians is a much more effective and expeditious way to achieve the goals of providing quality, affordable care and preventing harm to patients.

I hope that at the end of this hearing you will ask yourself—who is it that truly benefits from expanding liability? Let me leave you with one final result from AAHP's national survey of physicians:

- Almost three-fourths of physicians (72%) think that trial lawyers would benefit the most if health plans were made subject to new lawsuits.

Thank you for the opportunity to share our views on this important issue.

Mr. BURR. Thank you. Ms. Greenman, we would recognize you for your opening statement.

STATEMENT OF JANE F. GREENMAN

Ms. GREENMAN. Mr. Chairman, members of the committee, I am Jane Greenman, Deputy General Counsel of Honeywell International.

I am appearing here today on behalf of the ERISA Industry Committee, also known as ERIC, and I am a member of the Board of Directors of ERIC.

Mr. Chairman, employers voluntarily offer health plan benefits to 80 percent of private sector employees to assure a healthy and productive workforce and to compete for, successfully compete for and retain valued employees.

Employer-sponsored programs leverage the purchasing power of large companies and coalitions of smaller companies and the expertise of benefits specialists employed by these companies to maximize efficiencies, reduce costs and help employees navigate through the complex health insurance system.

The position of liability on insurers who offer coverage creates practical and economic burdens that will be unacceptable for a benefit that is not part of a company's core business purpose.

The fundamental objective of patient protection reform as it applies to employer-sponsored plans should be to ensure timely processing of health claims and fair review of denied claims to facilitate the delivery of patient care when it is needed.

ERISA claims procedures have already been adapted by the Department of Labor to provide timely and responsive review processes that are appropriate to both pre-service and post-service benefit determinations.

Legislation is required and desirable to enable the department to incorporate reasonable external review procedures into these claims rules.

I might add that these claims rules have not yet had a chance to really go in to be implemented and to prove their efficacy at this point in time.

New causes of action and tort damages are neither necessary nor desirable to ensure that plan participants have access to timely and fair review procedures.

Indeed, increased litigation is likely to result in reduced benefit coverage.

Under ERISA, plan fiduciaries must ensure full and fair review of denied claims. The Department of Labor revised ERISA claims procedures clarify full and fair in a managed care environment.

These procedures will facilitate timely access to care. Tort liability will do nothing to enable patients to obtain care, particularly emergency or urgent care.

Bills that permit a patient to obtain such care while their case is being reviewed will be far more effective than tort liability if patient protection is really our true goal.

None of the flaws in the current system will be fixed by attaching the burden of new tort liabilities.

In the face of even the threat of increased liability, employer health plans are likely to downsize and avoid liability by adopting strict schedules of covered treatment, designating reimbursement amounts, avoiding direct participation as an intermediary between plan participants and service providers, and abandoning their current role and direct claims processing on behalf of participants, as well as direct oversight of that process.

None of these options are desirable to employees or employers.

Mr. Chairman, a number if bills recognize and seek to address the serious problem of imposing health care tort liability on employers. Regrettably, each of them fails. They would insulate employers from liability only if they avoid direct participation or are not the designated decisionmaker.

Determination of an employer's role, however, will be a question of fact requiring significant litigation.

Moreover, if the legislation fails to adequate address what the burden of proof would be that would have to be met, and an employer may be forced to prove a negative proposition, the absence of direct participation or involvement.

Additionally, plaintiffs may be able to bypass this test all together by suing an employer in its roles both as plan sponsor and as a plan fiduciary.

Since employers often represent deep pockets, they would be swept along in this tide of litigation. Under all scenarios, additional

tort litigation will not fix the medical system and it will increase medical health costs.

Mr. Chairman, in today's fiercely competitive global markets and in a volatile economy, employers will not accept the financial risks of a tort system.

Many employers are already investigating a means of exiting the system or severely curtailing their participation in the system.

The fact is ERISA does not, has not, nor is it likely to preempt malpractice liability. No participant is prevented from seeking judicial relief from medical malfeasance under State malpractice law, nor do we believe that they should be.

ERISA is neither intended nor should it regulate the clinical quality of medical care of medical malpractice.

The Supreme Court has held, in the Pegram case, that ERISA does not regulate medical treatment and does not preempt State law malpractice actions.

Mr. Chairman, members of the committee, the debate over patient protection has been conducted as if tort liability is the only available means of protecting plan participants.

The fact is increased liability will not achieve a better medical system. It will increase costs, drive employers out of the system, drive consumers into inefficient systems, and deny health care to those who need it most.

Thank you for your attention, and I will be pleased to respond to any questions.

[The prepared statement of Jane F. Greenman follows:]

PREPARED STATEMENT OF JANE F. GREENMAN, DEPUTY GENERAL COUNSEL, HONEYWELL, ON BEHALF OF THE ERISA INDUSTRY COMMITTEE

Mr. Chairman and members of the Subcommittee: My name is Jane Greenman. I am Deputy General Counsel, Honeywell. I submit this statement on behalf of The ERISA Industry Committee ("ERIC").

THE ERISA INDUSTRY COMMITTEE

The ERISA Industry Committee ("ERIC") is an association representing the Nation's largest employer-sponsored benefit plans. As the sponsors of health, pension, savings, disability, life insurance, and other benefit plans covering tens of millions of participants and beneficiaries, ERIC's members share Congress's strong interest in the success and expansion of the employee benefit system in the private sector.

VOLUNTARY EMPLOYEE BENEFIT PLANS

Employers voluntarily offer health plans to their employees. These employer-sponsored plans should be supported, subject to ERISA protections for participants, not penalized.

Major employers provide valuable and important benefits to their employees through their voluntary employee benefit plans. Although employers are not required to provide benefits to their employees, voluntary employee benefit plans have been extraordinarily successful in delivering needed health, retirement, and other benefits to tens of millions of employees and their families. Today, over 80 percent of employees in the private sector receive some form of employee benefit plan coverage.

Employers have a strong interest in providing voluntary employment-based health care coverage to employees and their families. Employers seek to foster a healthy and productive workforce, to respond to workers' concerns about economic security and affordable basic health care, and to offer health care coverage as part of a competitive compensation and benefit package that attracts and retains valued workers. Employers' health care coverage arrangements represent an investment in quality and productivity. Each arrangement is tailored to the specific needs of the employer and its workforce.

Employer-sponsored benefit plans can offer advantages that employees could not obtain if they tried to purchase the same benefits on their own. Employers contribute their expertise in plan design and the organization of delivery systems to obtain high-quality benefits that are delivered timely, efficiently, and cost-effectively relative to individually available coverage. Moreover, employer-sponsored plans representing groups of employees are in a stronger position than individual consumers to bargain to obtain high quality benefits at a reasonable price. Plans sponsored by large employers have been very successful in exercising bargaining power on behalf of their participants and beneficiaries, and an increasing number of small employers are able, through voluntary coalitions, to achieve the same kind of leverage to the advantage of their employees.

THE BEST PATIENT PROTECTION IS GOOD PROCESS, NOT LITIGATION

ERIC believes the fundamental objective of patient protection reform, as applicable to employer-sponsored plans, should be to ensure timely processing of health claims and fair review of denied claims to facilitate delivery of patient care when needed. ERISA's original claims procedure regulation was promulgated with pension plans and indemnity-type health plans in mind. However, ERISA claims procedure can readily be adopted to provide timely and responsive claims review processes appropriate to today's managed care environment, which involves both pre-service and post-service benefit determinations.

Thus, ERIC has repeatedly urged the U.S. Department of Labor to issue a revised ERISA claims procedure. The revised claims procedure regulation issued by the Department of Labor in November 2000 can fill this need, with modifications to correct some of its flaws. The Department appears to lack authority to address external review procedures in its regulation, however. To incorporate external review into its claims procedure regulation, an ERISA amendment authorizing the Department to do so would be needed.

PARTICIPANTS CAN BE PRETESTED WITHOUT RESORTING TO LITIGATION

It is not necessary to amend ERISA to add new causes of action and tort damages in order to ensure that plan participants have access to timely and fair claims review procedures. ERISA requires plan fiduciaries to ensure that participants receive a full and fair review of denied claims. Now that the Department of Labor's revised claims procedure regulation has clarified what "full and fair" review means in a managed care world, plan practice will improve significantly, and complaints should decrease accordingly. If a plan fails to meet the regulation's new standard, ERISA gives participants the right to seek injunctive relief. Fiduciaries who consistently fail to meet the new standard can be barred from continuing to acting in a fiduciary capacity.

Tort liability is also not necessary to enforce external review decisions. For example, some patient protection bills have included provisions that make external review decisions "self-executing"—that is, the external review decision itself would authorize the participant to obtain care without further action by the plan.

The argument that tort liability is necessary to prevent "undue delay" in claims decisions is also unpersuasive. In addition to expedited review procedures, all of the leading patient protection bills include provisions authorizing emergency care without preauthorization if certain standards are met. Plan participants who believe they are in imminent danger while their review is pending can avail themselves of this patient protection.

Admittedly, legislative action may be needed to bridge the gap between the Department of Labor's revised claims procedure regulation and the need for external review and liberalized emergency care procedures. ERIC believes that, working together, we can find reasonable ways to bridge any gaps left by current claims procedure rules. Giving participants the right to sue for tort damages instead of filling those gaps is simply not a reasonable approach to assuring procedural fairness for participants.

TORT LIABILITY IS MORE COSTLY AND LESS EFFECTIVE THAN AVAILABLE ALTERNATIVES

There is broad consensus that our medical tort liability system is broken. A few victims of medical malpractice may receive large monetary awards after they are injured, but such awards do nothing to improve the timeliness or quality of health care even for such victims who are awarded significant damages. Health care providers respond to this dysfunctional liability system by engaging in "defensive medicine"—treating patients for the purpose of lowering their liability risk rather than improving the quality of care.

Amending ERISA to include tort liability effectively expands our dysfunctional medical liability system to include employers and the health plans they sponsor. But expanding tort liability does nothing to fix the underlying problems in the liability system itself. Health plans can be expected to take steps to minimize or avoid liability, such as adopting schedules of covered treatments or medical procedures and designated reimbursement amounts, to avoid any "direct participation" or exercise of discretion. The ultimate losers in such a system will be the plan participants. It is irresponsible to subject group health plans to a broken and dysfunctional tort system when simpler, faster, fairer, and less costly alternatives are available.

Moreover, in the face of potential tort liability, virtually all employers will abandon any direct role in claims processing or determination. Employees would be the ones hurt by employers abdication of the role they play as employee advocates with insurers or managed care entities.

To further discourage employer-sponsored plans, a number of patient protection bills authorize causes of action and tort damages under both federal and state laws, without assuring consistency between them or precluding simultaneous suits under both federal and state laws. This is a serious problem for any employer, but particularly for multi-state employers like most ERIC members.

Although a number of patient protection bills purport to limit employers' exposure to lawsuits, under the bills' new cause of action provisions, the bills, in fact, fail to protect employers from litigation. A number of bills protect employers only if they avoid "direct participation," or are not the designated "decision-maker" in plan decisions. However, before a suit against an employer can be dismissed, a court will have to find that the employer did not "directly participate" in the plan's decision. Since this will require the court to make a factual determination, litigating the issue will be time-consuming and costly—even if the employer ultimately prevails. The patient protection bills do not expressly address the burden of proof. If the burden is on the employer to demonstrate that it did not engage in "direct participation," the employer's burden could be extremely difficult to meet, since the employer will be required to prove a negative: that it did not engage in "direct participation."

Since an employer can wear "two hats" under ERISA—both as the plan sponsor and as a plan fiduciary—the protection that the "direct participation" provisions appear to offer might be completely illusory. Plaintiffs could circumvent the limitations imposed by a "direct participation" provision by suing an employer in its capacity as a plan fiduciary and not in its capacity as employer or plan sponsor. The pending patient protection bills do not expressly foreclose such suits.

Regardless of who is sued under these new provisions, employers and employees will ultimately bear the cost of litigation. Employers and employees pay the cost of administering health plans. If the firms that administer health plans incur additional litigation costs, the added costs will inevitably be passed through to employers and employees through higher premium costs, reduced health coverage or benefits, or both.

DON'T UNDERESTIMATE EMPLOYERS' AVERSION TO TORT LIABILITY

Policy makers should not mislead themselves into thinking that employers will not alter their behavior when confronted with health plan tort liability for the first time. Some will eliminate coverage under their plans for medical procedures that cause frequent disputes. Others will move away from managed care plans that feature low deductibles and copayments in favor of indemnity-type plans with high deductibles and copayments. Still others will reduce the overall scope of coverage offered to offset the cost of expected tort litigation. Finally, and most seriously, recent surveys show more than half the employers sponsoring health plans will consider terminating coverage entirely.

TORT LIABILITY HURTS MORE CONSUMERS AND PROVIDERS THAN IT HELPS

Inevitably, the burden of employers' retreat from sponsoring employment-based health plans in the face of new tort liability will be borne by employees and their dependents, especially low-wage employees who can not afford high deductibles and copayments, in the form of reduced coverage, significantly increased cost-sharing, and higher out-of-pocket costs. Health care providers are likely to feel the impact as well, in the form of lower patient volume and increased uncompensated care.

ERISA DOES NOT PREEMPT MEDICAL MALPRACTICE LIABILITY

If a participant in an ERISA-governed health plan is the victim of medical malpractice, ERISA does not prevent the participant from obtaining relief under State malpractice law. ERISA regulates the administration of employee benefit plans; it does not regulate the practice of medicine.

In our view, and the view of the courts more recently addressing the issue, medical malpractice lawsuits against persons or entities responsible for performing medical procedures are not preempted by ERISA. The practice of medicine has traditionally been governed by State law, including State medical malpractice standards. There is no evidence that, when Congress enacted ERISA, it intended to regulate the clinical quality of medical care and medical malpractice.

Recent decisions of the U.S. Supreme Court support our view. For example, in 2000, in the Pegram case, the Supreme Court held that ERISA does not regulate medical treatment decisions and pointedly observed that ERISA does not preempt State-law malpractice actions against HMOs.[1]

Recent federal appeals court decisions have followed the same approach. For example, in *Dukes v. U.S. Healthcare, Inc.,* the Third Circuit Court of Appeals held that claims for injuries arising from medical malpractice were not completely preempted by ERISA and therefore did not permit removal of the case from a state to a federal court: "There is no allegation here that the HMOs denied anyone any benefits that they were due under the plan. Instead, the plaintiffs here are attempting to hold the HMOs liable for their role as the arrangers of their decedents' medical treatment."[2] Other circuits have come to a similar conclusion.[3] The decisions distinguish benefits claim cases (which seek to recover benefits and are therefore governed by ERISA) from quality of care cases (which challenge the quality of care and are governed by State medical malpractice standards). Although there are some conflicting lower-court decisions, most of them are older cases, decided before the Supreme Court's recent decisions.[4]

IN CONCLUSION

In conclusion, the debate over expended ERISA liability is often conducted as though tort liability is the only available means to achieve the objective of protecting plan participants. It is not the only available means, and it is clearly the least desirable.

Mr. BURR. Ms. Greenman, I thank you for your testimony.

At this time, the Chair would recognize Dr. Palmisano for an opening statement.

STATEMENT OF DONALD J. PALMISANO

Mr. PALMISANO. Thank you, Mr. Chairman. Good afternoon. My name is Donald Palmisano. I am a board member of the American Medical Association and a practicing vascular and general surgeon in New Orleans, Louisiana.

Thank you for inviting me to speak with you today.

Managed care organizations, like physicians and all other health care professionals, must be held accountable for their decisions. Accountability is the issue.

So if a managed care organization makes a negligent medical decision that harms or kills a patient, that organization must take responsibility.

This is a critical point to understand. It is about the patient. Is it fair to grant a shield of immunity to managed care organizations, a shield which is not given to any other business entity, except under very limited circumstances?

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[1] *Pegram v. Herdrich,* 530 U.S. 211 (2000); *see also De Buono v. NYSA-ILA Medical & Clinical Service Fund,* 520 U.S. 806 (1997); *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Inc. Co.,* 514 U.S. 645 (1995).

[2] 57 F.3d 350, 361 (3d Cir. 1995).

[3] See, e.g., *Pacificare of Oklahoma, Inc. v. Burrage,* 59 F.3d 151, 155 (10th Cir. 1995) ("The present claim does not involve the administration of benefits or the level or quality of benefits promised by the plan; the claim alleges negligent care by the doctor and an agency relationship between the doctor and the HMO...Just as ERISA does not preempt the malpractice claim against the doctor, it should not preempt the vicarious liability claim against the HMO if the HMO has held out the doctor as its agent.").

[4] See, e.g., *Rodriguez v. Pacificare of Texas, Inc.,* 980 F.2d 1014 (5th Cir. 1993); *Ricci v. Gooberman,* 840 F. Supp. 316 (D.N.J. 1993).

We think not, and the vast majority of Americans agree. But why is this even a question? ERISA was never intended to apply to managed care. There is no sound policy reason why this law, this book should leave injured patients with no real remedy when they have been injured by a negligent health plan.

The judiciary agrees with this point. Numerous Federal judges have called on Congress to amend ERISA. In one instance, a Federal judge had to throw out a case and he complained that "The tragic events set forth in this woman's complaint cry out for relief. Nevertheless, this court has no choice but to slam the courthouse doors in her face and leave her without any remedy." This is truly an issue of fundamental fairness and I think many of us here already would agree that health plans need to be held accountable.

So what is the best solution for this problem? As we explain in our written statement, the best solution must reflect the relative strengths of the different courts and levels of government.

Under the principle of federalism, the States retain powers not delegated to the Federal Government. Historically, the States have retained jurisdiction to govern the practice of medicine and the delivery of health care.

We are proposing, therefore, a split cause of action. So if a patient is injured by a negligent health plan, the patient must have a legal remedy in either the State or Federal court, but not both, because States retain jurisdiction to govern the practice of medicine. If a case involves a medical judgment, the case should go to State court.

Federal courts, on the other hand, should hear cases they have traditionally decided under ERISA. Eligibility of benefits claims.

So an acceptable patient protection bill should, in a limited fashion, remove ERISA preemption. This would allow State laws to govern the delivery of health care.

The bill also should provide an adequate Federal remedy for patients injured when a plan makes a negligent non-medical decision.

Our proposal is no way arbitrary. The Judicial Conference of the United States has expressed support for this view. The Judicial Conference, headed by Chief Justice Rehnquist, stated in a letter to a conference committee just last year, "The State courts have significant experience with personal injury claims and would be an appropriate forum to consider personal injury actions pertaining to health care treatment." The letter also urged Congress "to provide that in any managed care legislation agreed upon, the State courts be the primary forum for the resolution of personal injury claims arising from the denial if health care benefits." This solution also would protect the rights of States and their citizens. Every State legislature has passed laws governing the delivery of health care services.

In addition to existing common law rights, eight States have passed laws granting their citizens a cause of action against negligent health plans.

We urge Congress, therefore, not to pass a Federal only cause of action and destroy State law.

The insurance industry claims to continue that making health plans accountable in this targeted way will open Pandora's box of

evils. Those arguments have already been made in many State capitols and have been rejected.

The doom and gloom predictions by the insurance industry have not come about.

President Bush has stated repeatedly that the patient protection laws in Texas are working well. Despite the insurance industry's claims, health care costs in those States have not skyrocketed. Employers have no suddenly dropped health care benefits, and the courts have not been overrun by plan participants trying to file frivolous suits.

In closing, the patient protections we support, including accountability, closely reflect President Bush's principles.

We agree, a Federal Patients' Bill of Rights must ensure that every patient enrolled in a health plan enjoys strong patient protections, and because many States have passed patient protection laws that are appropriate for their States, deference should be given to those State laws.

The AMA believes that these principles are incorporated in the framework of the Ganske-Dingell patient protection bill, which is why we support that bill.

Mr. Chairman, the entire committee, Mr. Tauzin, thank you again for inviting me to speak today.

[The prepared statement of Donald J. Palmisano follows:]

PREPARED STATEMENT OF DONALD J. PALMISANO, MEMBER, AMA BOARD OF TRUSTEES ON BEHALF OF THE AMERICAN MEDICAL ASSOCIATION

Mr. Chairman and members of the Committee, my name is Donald J. Palmisano, MD, JD. I am a member of the Board of Trustees of the American Medical Association (AMA), a Board of Directors member of the National Patient Safety Foundation (NPSF) and the Chair of the Development Committee for the same foundation. I also practice vascular and general surgery in New Orleans, Louisiana. On behalf of the three hundred thousand physician and medical student members of the AMA, I appreciate the opportunity to comment on the issue of state and federal roles in health plan accountability.

Identifying the Issue

The Employee Retirement Income Security Act of 1974 (ERISA) established an elaborate regulatory system intended to ensure that employees receive the pension benefits which their employers have promised them. The statute was enacted in response to widespread allegations of pension funds mismanagement and fraud. In addition to preventing these abuses, the statute sought to create uniform regulatory requirements that would govern the administration of pension and benefit plans, thereby encouraging employers to offer employees these benefits. The intention of the bill's sponsors therefore was to ensure that employers doing business in more than one state could design financial benefits plans that could operate nationwide and would not face conflicting state requirements. To override then current state laws that sought to regulate pension plans, Congress incorporated broad preemption language into ERISA.

Most of the remedies included in ERISA were also geared toward protecting plan assets. ERISA's appeals procedures and civil enforcement mechanisms were all directed at ensuring that plan fiduciaries handled plan *funds* properly and prudently for the plan participants' benefit. **The drafters of ERISA never anticipated or intended the bill to protect plan participants who sought to access services, such as medical care, as part of a health care benefits package.**

The drafters of ERISA also could not have anticipated the eventual effects of ERISA and its preemption provision because of the dramatic changes the health care market itself has undergone. In 1974, the health care delivery system was entirely different from today's market. Over the last several decades, we have seen a transformation in employer-sponsored health care plans from traditionally insured or "fee-for-service" to managed care. This transformation

has given rise to new types of arrangements and relationships for financing and delivering health care that were not foreseen by the framers of ERISA in 1974.

A Matter of Fundamental Fairness

In the era of managed care, health plans increasingly make decisions that directly affect the care that patients receive. Illustrations of these practices include: inappropriately limiting access to physicians through restricted networks (blocking patient access to specialists); refusing to cover or delaying needed medical services (transplants, transfusions, therapies); drawing treatment protocols too narrowly (patients discharged from a hospital prematurely); offering payment incentives or creating deterrents to care (disciplining physicians who refer patients for necessary medical care); and discouraging physicians from fully discussing health plan treatment options (gag rules and gag practices).

These non-financial functions were never intended to be covered or regulated by ERISA. Instead, **the states typically regulated the practice of medicine and, more generally, the delivery of health care.** Even the federal courts have repeatedly noted that the regulation of quality of care has traditionally been a matter of state law, and that quality of care standards should be enforced in state courts.

Nevertheless, under many circumstances, ERISA currently preempts state-based causes of action, thereby preventing injured patients from recovering against health plans that have acted wrongfully. As a result, ERISA's federal preemption of state liability actions leads to harsh consequences for many patients harmed by their health plans.

The federal judiciary has also observed the incongruity and inherent unfairness resulting from ERISA preemption, with several federal judges calling on Congress to amend ERISA. One case involved a 41-year-old father of four who went on a drinking binge and committed suicide. After his death, his widow said that the health plan had refused to approve a detoxification program after an earlier suicide attempt. Unable even to look at the merits of the case, the U.S. District Judge threw it out of court, saying that ERISA gave the health plan a "shield of immunity." The judge went on to say that "the tragic events set forth in Diane Andrews-Clarke's complaint cry out for relief . . . Nevertheless, this court has no choice but to . . . *slam* the courthouse doors in her face and leave her without any remedy."[1] According to Judge Young, "the shield of near absolute immunity now provided by ERISA simply cannot be justified . . . Even more disturbing to this Court—[he said]—is the failure of Congress to amend a statute that, due to the changing realities of the modern health care system, has gone conspicuously awry from its original intent."[2]

Allowing plans to continue to escape liability for negligent decision-making through this statutory loophole leaves patients in serious jeopardy. If ERISA plans know they can avoid liability due to ERISA preemption of state law, they have no incentive to act responsibly and provide needed and contracted for medical care.

Consider, for example, some evidence presented in a lawsuit against one of the nation's largest insurance companies last year. The case involved a deputy district attorney, Mr. Goodrich, who died of stomach cancer after trying for 2½ years to get his insurance company to approve the cancer treatment that the insurance company's own physicians had recommended. During the trial, a training video of the insurance company was admitted into evidence. The training film showed one of the company's attorneys instructing claims handlers, and telling them "[a]s a practical matter, you really may have to do more on a non-ERISA plan to protect against some of the legal exposure we're talking about."

The bottom line is that patients who receive health benefits through ERISA plans are currently denied the same rights and remedies as patients in non-ERISA plan. This is a simple question of fairness. It is also a matter of the public's will and desire. A vast majority of Americans believe that health plans should be legally accountable for negligent decisions that injure or kill patients.[3] We strongly agree.

While some federal courts continue to view ERISA as preempting all state-based causes of action against health plans, many federal courts have allowed injured patients' complaints against health plans to survive ERISA preemption scrutiny. In

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[1] *Andrews-Clarke v. Travelers Insurance Co.,* 984 F. Supp. 49, 64-5 (D. Mass. 1997).

[2] *Id.*

[3] Fifty-three percent (53%) of Americans favor legislation making it easier to sue managed care plans that make negligent decisions which cause injury or harm to patients. Harris Poll #56, September 29, 1999. Henry J. Kaiser Family Foundation, Harvard School of Public Health survey conducted on January 25, 2001, found that 75% of Americans support patient protection legislation, including the right to sue health plans.

fact, most ERISA experts acknowledge a definite trend in federal courts whereby the courts are deciding that causes of action against health plans based on medical decisions or "mixed" medical-eligibility decisions are not preempted by ERISA. In other words, injured patients or the estates of deceased patients may increasingly pursue legal remedies in state courts under state law. Legislative ERISA reform, however, is necessary to *ensure* that *all* patients are protected.

A Developing Trend

Because of the existing "preemption" provision of ERISA, patients enrolled in ERISA plans lack the remedies currently available to patients participating in non-ERISA plans. Many courts have recognized this problem. In *Corcoran v. United Healthcare*,[4] for instance, a patient who had a high-risk pregnancy was advised by her physician to be hospitalized as she approached her due date. The plan, however, denied the request and instead authorized nursing home care. When the patient was at the nursing home and the nurse was off-duty, the fetus went into distress and died. The woman sued the plan alleging that the plan was negligent in not hospitalizing her. The federal court, however, decided that because the woman's claim involved a decision about the availability of hospitalization it was actually a "benefits" decision, and consequently preempted by ERISA. As a result, the woman could only proceed under ERISA, which provides as the woman's *sole* remedy the benefits sought—in this case pre-delivery hospitalization. The woman therefore could obtain no real legal remedy under either ERISA or state law.

Several other federal courts, however, have taken the position that ERISA was never intended to preempt injured patients from suing managed care plans for negligence simply because the plans contract with private employers or unions. These courts have looked to the preemption doctrine as articulated in the *Pilot Life Insurance Co. v. Dedeaux*[5] and *Metropolitan Life Insurance Co. v. Taylor*[6] cases, and then focused on the *Dukes v. U.S. Healthcare, Inc.*[7] case. In *Dukes,* the Third U.S. Circuit Court of Appeals acknowledged a previously identified distinction between "quality of care" decisions and "quantity of benefits" claims, and found that state law claims addressing the quality of care that the enrollees received were outside the scope of ERISA remedies and were not preempted.

After the *Dukes* case, a federal court in Connecticut found in *Moscovitch v. Danbury Hospital*[8] that a claim against an ERISA plan in which the enrollee challenged the medical and psychiatric decisions of the plan administrator was *not* preempted by ERISA, despite the plan's allegations to the contrary. The enrollee had on two occasions attempted suicide and was hospitalized both times. Determined to be suicidal on a third occasion, the patient was again hospitalized. Deciding that hospitalization was no longer medically necessary, the plan administrator on this occasion transferred the enrollee from the hospital to a treatment center, where he committed suicide.

Similarly, federal courts in Pennsylvania, Missouri, and Illinois, in the *Tiemann v. U.S. Healthcare, Inc.*[9], *Harris v. Deaconess Health Services Corp.*[10], and *Crum v. Health Alliance-Midwest, Inc.*[11], respectively, all found that plan participants and beneficiaries could bring their negligence claims against the health plans in state court—ERISA did not preempt them. In *Harris,* a plan participant had sought authorization for hospitalization, for what he thought was appendicitis. The plan denied him admission and his appendix ruptured. The participant suffered permanent physical injury as a result. In *Crum,* a plan participant believed that he may be suffering a heart attack and sought admission to an emergency room. The plan's advisory nurses twice denied him permission for emergency room services, and he died of a heart attack.

As we have stated, however, this federal trend remains in its nascent stage and without clear leadership from Congress, the court rulings will remain inconsistent and unpredictable. Many patients will continue to have no legal remedies when their health plans act negligently and cause them injury or death.

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[4] 965 F.2d 1321 (5th Cir. 1992).
[5] 481 U.S. 41 (1987).
[6] 481 U.S. 58 (1987).
[7] 57 F.3d 350 (3d Cir. 1995), *rev'g Visconti v. U.S. Healthcare,* 857 F. Supp. 1097 (E.D. Pa. 1994), and *Dukes v. United States Healthcare Sys. of Pennsylvania, Inc.,* 848 F. Supp. 39 (E.D. Pa. 1994), *cert. denied,* 116 S. Ct. 564 (1995).
[8] 25 F. Supp. 2d 74 (D. Conn. 1998).
[9] 93 F. Supp. 2d 585 (E.D. Pa. 2000).
[10] 61 F. Supp. 2d 889 (E.D. Mo. 1999).
[11] 47 F. Supp. 2d 1013 (C.D. Ill. 1999).

A Complementary Solution

Under the principle of federalism, the federal and state governments maintain a complementary relationship; the states retain all powers not delegated to the federal government. The Tenth Amendment of our U.S. Constitution reiterates this principle by assuring that "the powers not delegated to the United States" nor prohibited to the states "are reserved to the states respectively, or to the people."

The political theory underlying this judicial philosophy was that the local or state governments were best equipped to address the needs of their citizens. The Founders were also generally concerned about an excessively powerful, excessively centralized national government. As a result, many of the Founders sought to ensure that the national government would be empowered to legislate only in those areas in which the separate states were incompetent.

Historically, the states have retained jurisdiction to govern the practice of medicine and, more generally, the delivery of health care for their citizens. The states, for instance, retain virtually sole authority to license and regulate health care professionals and institutions, as well as to provide remedies to citizens who are harmed by the negligent acts of those practicing medicine. When health plans, insurance companies, or even employers, make medical treatment decisions—and in essence, practice medicine—they should therefore be held accountable under state law, in state courts.

Recent statements by the Judicial Conference of the United States, which is headed by Chief Justice Rehnquist, prove instructive on this issue. In a March 2000 letter to the Chairman of the conference committee on managed care legislation passed in the 106th Congress, the Judicial Conference stated that: **"Personal injury claims arising from the provision or denial of medical treatment have historically been governed by state tort law, and suits on such claims have traditionally and satisfactorily been resolved primarily in the state court system . . . The** *state courts* **have significant experience with personal injury claims and** *would be an appropriate forum to consider personal injury actions pertaining to health care treatment***."** (Emphasis added).

The Judicial Conference urged Congress "to provide that, in any managed care legislation agreed upon, **the state courts be the primary forum for the resolution of personal injury claims arising from the denial of health care benefits.**" (Emphasis added).

Recent federal case law reflects the Judicial Conference's policy favoring state court jurisdiction over cases regarding medical judgments. The Supreme Court in last year's *Pegram v. Herdrich*[12] case stated that health plan coverage decisions often involve medical and administrative components which are "inextricably mixed," and the "eligibility decisions cannot be untangled from physicians' judgements about reasonable medical treatment." The Court expressly declined to find a "fiduciary malpractice claim" under ERISA, and noted that permitting such a cause of action would create the unattractive possibility of ERISA preemption of state medical malpractice laws. **The Supreme Court's reasoning therefore supports the contention that state courts remain the appropriate forum for holding health plans accountable.** Many lower federal courts have made similar statements, acknowledging that states retain "their traditional police powers in regulating the quality of health care."[13]

Not only does the federal judicial branch—including the U.S. Supreme Court—recognize the importance of states retaining jurisdiction over the practice of medicine, the states also are trying to exercise their authority over the regulation of medical care. *Every state legislature* has passed laws governing the delivery of health care services to its citizens, whether pertaining to external appeal rights, utilization review, access to emergency services, or some other patient protection. Eight states have passed laws expressly authorizing statutory causes of action against health plans, in addition to the state "common law" actions already recognized by their courts.

Texas, for instance, in 1997 passed a statute that creates a new state cause of action against health insurance carriers, HMOs, and other managed care entities who breach their duty to exercise ordinary care when making health care treatment decisions, and the breach causes harm to the patient. An additional seven (7) states—Arizona, California, Georgia, Louisiana, Maine, Oklahoma, and Washington—have passed similar health plan accountability statutes.

We strongly urge Congress therefore to recognize the legitimate authority of states and incorporate a bifurcated cause of action into a bipartisan

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[12] 530 U.S. 211.

[13] (*Corporate Health Insurance Inc. v. Texas Department of Insurance,* 5th Cir., June 20, 2000, No. 98-20940, 215 F.3d 526; 2000 U.S. App. LEXIS 14215).

patient protection bill. The bill would need to remove in a targeted fashion ERISA preemption, permitting states to pass or retain their own legislation which would protect the legitimate interests of their citizens. Additionally, removing ERISA preemption in this manner would preserve prior federal court decisions that have recognized state common law causes of action.

The "split" between the federal and state causes of action must be made according to whether the plan exercised medical judgment when making its decision. The judiciary has repeatedly relied on that criteria, and so should Congress. When a health plan intervenes in the medical decision-making process, and imposes its medical judgment on the patient, the plan is engaging in the practice of medicine and should be held accountable under state law. If the plan has not made a medical judgment and has made simply an eligibility decision, the claim should be brought in federal court.

Because of the gross inadequacy of ERISA remedies, an acceptable patients' bill of rights must modify ERISA to also permit a meaningful federal cause of action when an enrollee has been injured by a health plan's decision that did not involve medical judgment. As we mentioned above, ERISA was enacted to protect pension plan and other employee benefit financial assets. ERISA needs to be updated to reflect the current managed care market and protect plan participants and beneficiaries when their group health plans act negligently and cause them harm.

Some advocates of plan accountability have suggested that patient protection legislation should provide only a federal cause of action. **A federal cause of action alone however would wipe out those state statutes as well as state common law rights which have provided citizens with state law remedies against health plans for negligent medical decision-making.** Additionally it would *prevent* forty-two (42) other state legislatures from passing similar patient protection legislation in the future. The AMA firmly believes that Congress should not override the will of the states by passing a federal-only cause of action.

Creating solely a federal remedy for health plan and employer misconduct would also violate the most basic principles of federalism. Chief Justice Rehnquist has warned that **"Congress should commit itself to conserving the federal courts as a distinctive judicial forum of limited jurisdiction in our system of federalism . . .** *[M]atters that can be adequately handled by states should be left to them . . .*"[14] (Emphasis added).

To provide all patients with adequate remedies, Congress must enact federal legislation permitting patients to seek legal recourse against managed care plans under state law when the plans' negligent medical decisions result in death or injury.

Controlling Litigation

A bifurcated cause of action would grant all Americans who receive employer-based health benefits an extremely important patient protection, which they both need and desire. This protection could, and should, be coupled with other critical patient rights that would directly benefit patients while both directly and indirectly benefiting health plans.

As we have noted, many federal courts have begun to allow injured patients to bring causes of action against health plans in state courts. The pleadings and legal theories for these cases will increasingly mimic the pleadings and theories of those cases that have successfully withstood ERISA preemption scrutiny. As a result, managed care organizations will most likely become increasingly subject to liability—despite ERISA—for improper claims decisions that result in patient injury or death.

When patients have been successful in bringing legal actions against ERISA plans, current law provides few protections for the plans. In many jurisdictions, patients would be able to proceed directly to court without appealing internally or externally, recover potentially unlimited punitive damages, and theoretically, could proceed against their employers, as well. **Critical to any acceptable patient protection bill, therefore, are provisions granting employers protection against unwarranted liability, independent external appeals provisions that would eliminate unnecessary litigation, and limitations on punitive damages.** With these provisions, health plans and employers would also certainly benefit from the bill.

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[14] Remarks of Chief Justice William H. Rehnquist at the American Law Institute Annual Meeting, May 11, 1998.

Restricting Negligence Actions

Crucial to an acceptable patients' bill of rights are a grievance system and an internal and independent external appeals provision. Without a grievance system, disgruntled patients with legitimate, though perhaps minor, complaints against their health plans would be required to go to court to resolve their disputes. And patients who are seeking medical care and have serious coverage disputes with their health plans, need and want timely coverage determinations and medical treatment, not lengthy and expensive litigation.

We therefore consider it essential that a patient protection bill provide patients with access to a grievance system and an internal and independent external appeals process, which would effectively eliminate any need for litigation.

An acceptable bill, for instance, could require patients first to appeal coverage denials directly to reviewers selected by their plans. The plans could control whether an internal review would be conducted, but their decision would have to be timely and account for the medical exigencies of the specific case. If the plan chose not to waive this requirement, the patient would be obligated to complete the internal review before proceeding to an external appeal.

External appeals should be independent, binding on the plan, timely and conducted by qualified physicians (MDs/DOs) of the appropriate specialty. To ensure that their decisions are truly independent, plan definitions of "medically necessary" and "investigational and experimental treatment" must not be binding on the external reviewers. An effective independent appeals process would resolve virtually all of the egregious cases—like *Corcoran*—without the need for litigation. **We firmly believe that with access to efficient, effective, and truly independent external appeals entities, patients will rarely need to go to court.**

Employer Liability

The insurance industry and some other opponents of patient protection legislation have alleged that a patient protection bill would place employers in jeopardy. They claim that by holding *health plans* accountable for their own negligence, the legislation would somehow expand employers' liability. These concerns, though understandable, can easily be addressed and remedied in a bipartisan patients' bill of rights.

A patient protection bill can offer real and meaningful protection to employers and other plan sponsors. The bill for example could expressly state that it does *not* authorize a cause of action against an employer or other plan sponsor, and only an employer or plan sponsor that *directly participates in making an incorrect medical determination for an individual claim decision* could be held accountable. Consequently, only if an employer or plan sponsor *directly participated* in *making an incorrect medical decision for an individual claim decision* under its group health plan, and that decision resulted in injury or wrongful death, could it be exposed to a state law claim. Even then, to recover, the injured patient would have to prove: (1) that the employer directly participated in making an incorrect medical determination on that particular claim for benefits, (2) that individual decision caused the patient's injury or death, and then (3) that the employer's conduct also met *all* elements of an applicable state law cause of action.

Some opponents of patient protection legislation have spuriously alleged that employers will be held liable for simply selecting the plans, under this scenario. We therefore believe that the bill should explicitly state that employers and other plan sponsors cannot be held liable for fulfilling their traditional roles as employers and plan sponsors. The bill should provide **"safe harbors,"** for instance, for the following activities: *(I) any participation by the employer or other plan sponsor in the selection of the group health plan or health insurance coverage involved or the third party administrator or other agent; (II) any engagement by the employer or other plan sponsor in any cost-benefit analysis undertaken in connection with the selection of, or continued maintenance of, the plan or coverage involved; (III) any participation by the employer or other plan sponsor in the process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary; and (IV) any participation by the employer or other plan sponsor in the design of any benefit under the plan.*

Additionally, because many employers and other plan sponsors seek to advocate for their employees during the review and appeals processes, **an acceptable patient protection bill should explicitly protect employers and plan sponsors functioning as patient advocates as well.**

Some advocates of patient protection legislation have suggested that a federal bill should mirror the Texas "accountability" statute. In fact, the provisions we have

identified would provide employers the same if not greater protection than what is offered in the Texas law. Both our principles and the Texas statute protect employers, and neither specifically excludes from liability employers who "play doctor" and improperly intervene in medical decisions. We note, though, that our proposed principles also expressly protect employers functioning as employers.

We anticipate that some employer advocacy groups will continue to allege nevertheless that employers would, despite these employer protections, still be exposed to liability under such a bill. Interestingly, in our many discussions with many of these organizations, we and the sponsors of several patients' rights bills have explicitly requested alternative language that the employer groups believe would adequately address their concerns. In every instance, these organizations have failed even to propose such language. After our repeated and diligent efforts to arrive at an agreement, we have begun to think that some of the organizations are not genuinely interested in solving what they claim is a potential problem.

We acknowledge that if an employer "plays doctor" and directly participates in making an incorrect medical determination on a particular claim for benefits, the employer could potentially be held liable in state court. In such an extraordinarily rare situation of an employer directly interfering in a specific medical treatment decision and injuring a patient, should it not be exposed to liability? **President Bush apparently thinks so, since he stated in his Principles for a Bipartisan Patients' Bill of Rights that he would hold those employers accountable "who retain responsibility for and make final medical decisions."**

Exhaustion of Remedies

In order to ensure that the external appeals process can effectively reduce litigation while encouraging timely coverage decisions, patients must be required to utilize the appeals process. **Patients therefore should have to exhaust all administrative remedies before going to court.**

The purpose of the appeals process is to ensure that coverage disputes may be resolved in a timely fashion, so that patients may obtain the medical treatment to which they are entitled before they unnecessarily suffer harm. If, because of the health plan's conduct, they suffer serious and irreparable harm or die, they or their estates should not be required to exhaust all administrative appeals. At that point, the patient is no longer seeking the medical treatment, but instead desires and needs court protection. Consequently, the patient or the patient's estate should not be required to spend additional time and money unnecessarily in an appeals process. To complete the external appeals process under those circumstances would be futile. The patient should at that time be allowed access to the court system.

Texas law includes a very similar exception in its appeals process. Under Texas law, a person is permitted to bypass the independent review if harm has already occurred.

Limiting Punitives

As we have shown, several federal appellate courts have found that patients' claims against their health plans can at times be brought as negligence actions and therefore are not preempted by ERISA. Managed care organizations consequently are increasingly becoming subject to new liability—despite ERISA—for improper claim denials that injure or kill patients. For those cases, federal courts are permitting state statutory and common law to govern the resolution of these claims, many of which also seek punitive damages.

In the past, for non-ERISA cases, juries have been awarding progressively larger punitive damage awards against health plans. In 1993, a southern California jury awarded $89 million to the estate of Nelene Fox, finding that her insurer, HealthNet, improperly denied her autologous bone marrow transplant treatment with high-dose chemotherapy for her breast cancer. Of the $89 million, 90 percent of the award ($77 million) was attributed to punitive damages. More recently, a jury rendered a $120 million verdict against Aetna U.S. Healthcare for improperly delaying treatment for 41-year-old David Goodrich, who had been diagnosed with leiomyosarcoma of the stomach. Of the $120 million award, $116 million represented punitive damages.

Presuming that some courts will be favorably disposed—as others have been—to new legal theories that plaintiffs' attorneys are presenting, this trend can only be arrested through federal legislation. An acceptable patient protection bill should, therefore, include meaningful and reasonable limits on punitive damage awards.

Cost

In the past, many opponents of health plan accountability have alleged that federal patient protection legislation would cause health care premiums to skyrocket.

Although no cost reports are presently available for pending federal patients″ rights legislation, the fact remains that if plans were forced to accept responsibility for their decisions, costs would not be significantly affected.

We are aware for instance that in Texas, the first state to adopt managed care accountability legislation, this issue was hotly debated. Milliman and Robertson completed an actuarial determination of the cost of the Texas liability legislation to a Texas-based HMO and set the cost at only 34 cents per member per month. A study prepared by William M. Mercer, Inc. and the AMA demonstrates that managed care accountability legislation would only increase premiums between .5% and 1.8%.

In fact, the American Association of Health Plans (AAHP) and the Health Insurance Association of America (HIAA) surveyed their HMO members in Texas and "could not find one example" where the Texas patient protection law forced Texas HMOs to raise their premiums or provide unneeded and expensive medical services.[15]

Other representatives of the insurance industry have also publicly admitted that holding plans accountable will not significantly drive up health care premiums. Jeff Emerson, the former CEO of NYLCare, stated in a July 11, 1999, *Washington Post* article that he is "...not going to make the argument that it's going to be a lot of money." Aetna/USHealthcare spokesman, Walter Cherniak, stated in the same *Washington Post* article that "we would charge the same premium to a customer with the ability to sue as we do those who do not have the ability to sue." Why? "Those judgments to date have been a very small component of overall health care costs," according to Cherniak.

In fact, the four-year-old Texas law that allows HMOs to be sued for their negligent medical decisions has prompted little litigation—approximately ten lawsuits out of the 4 million Texans in HMOs. Texas State Senator David Sibley, a Republican, stated two years after this bill was enacted, that "those horror stories" raised by the HMO industry "just did not transpire." President George W. Bush, who was then the Texas Governor, has repeatedly affirmed that he thinks this law has worked well in Texas.

Some opponents of HMO accountability have alleged that employers would drop their health benefits if ERISA preemption is removed. In many industries, however, companies provide additional incentives to attract and keep quality employees or else lose them to competitors, and one of the basic corporate benefits is full or partial health care coverage. It is therefore very unlikely that companies will eliminate health benefits simply because health plans are held accountable for the coverage and medical decisions they make.

Tort Reform

The issue of liability caps has been raised frequently in recent discussions of health plan accountability in patient protection legislation. Within the context of medical malpractice, the AMA has long supported tort reforms, including reasonable caps on damages. In recent years, we sought the passage of tort reform legislation, which passed the House of Representatives but has consistently failed in the Senate. A number of Senators from both parties have opposed reasonable limits on non-economic damages.

When discussing caps in a patients' bill of rights, several issues must be addressed. What would be considered "reasonable" caps for damages? What type of damages would be capped? Would a federal bill permit state tort reform laws to remain intact? Would the caps apply only to federal causes of action? Would a disparity between state and federal caps create undesirable and unnecessary forum-shopping? Would caps applicable to health plans also apply to all other health care providers?

The AMA fully recognizes the complexity of these and various other issues associated with tort reform, and we believe that tort reform must be addressed. With that said, we question whether adequate support exists in the Senate to pass meaningful tort reform in the context of patient protection legislation. If sufficient votes are not present, we would urge Congress to pass an acceptable patient protection bill at this time and then continue to push for meaningful tort reform. **The AMA remains fully committed to both issues, but recognizes that coupling them together, could kill both.**

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[15] September 28, 1999, *Washington Post.*

Conclusion

We appreciate the Committee's interest in addressing the issue of health plan accountability and the respective state and federal roles. As we have indicated, the AMA strongly believes that ERISA must be reformed to permit injured patients or their estates to recover against negligent health plans. The most sensible solution to this problem parallels the traditional roles of the state and federal governments, allowing states and their courts to continue to govern the practice of medicine while the federal courts adjudicate strictly benefits decisions under ERISA. Without this type of ERISA reform, any patient protection or health care quality legislation would not fully ensure fairness for all patients.

The AMA understands that several patient protection bills will be or are being considered, and we are committed to working with both Congress and the President to reach agreement on a bipartisan patient protection bill that can be enacted into law this year. We thank the Chairman and this entire Committee for the opportunity to discuss this critical issue.

Mr. BURR. Thank you, Doctor.

The Chair would recognized Ms. Rosenbaum for a opening statement.

STATEMENT OF SARA ROSENBAUM

Ms. ROSENBAUM. Thank you very much, Mr. Chairman. My testimony addresses two basic issues. The first is an overview of the current legal baseline that governs managed care liability, and the second is how Congress should approach the question of managed care liability in the context of a Patients' Bill of Rights.

With respect to the first question, outside of a shield that I believe was unwittingly given to private employers by Congress 25 years ago when it created ERISA, there is no area of law, with the limited exception of the kind of sovereign immunity situation that Mr. Burr asked about, in which a defendant is not held accountable for the death or injury of another person.

It is a basic proposition of American law and one that has its roots in a thousand years of common law that people should have to answer under the law for the injuries they cause.

Beginning in the 1700's, in England, health professionals were recognized as accountable under common liability principles.

In the 1960's, in the United States, the notion of liability for medical injury was first extended to corporations, to hospitals. Hospitals predicted when the first cases came down, the Darling case and other cases that followed in its wake, that we would stop having hospitals because of medical liability.

That didn't happen, to put it mildly.

The notion, furthermore, that Congress is considering for the first time extending medical liability to HMOs is simply incorrect. For at least 20 years and probably longer, HMOs have been recognized as liable for the medical harm they cause.

Since the landmark case of Dukes v. U.S. Health Care, furthermore, it has been recognized that HMOs can be liable for the medical injuries they cause to members of ERISA plans.

The major contribution of the Supreme Court's unanimous decision in Pegram v. Herdrich was, in fact, to reframe the liability issue for the lower courts, to make clear to the lower courts that when a case involving a beneficiary or a participant of an ERISA plan comes to the courts, there are some claims that are Federal ERISA claims that fall within the limited jurisdiction of Federal courts, and those are known as fiduciary claims.

There are other claims that fall outside the scope of ERISA, and those are medical claims. The court simply dismissed any notion that in the modern health system, we can distinguish any longer between something called a coverage claim and something called a care claim.

What we have is medical decisions. So given this baseline and given the instructions that a unanimous court has now given to the lower courts, what should Congress do?

Since State law is the source of all law related to medical liability for injuries, whether individual or corporate, the remedy for persons who are injured belongs with the States, and this is true whether the person is injured by an HMO administering a benefit plan under ERISA or an HMO administering a Medicare Plus Choice plan.

To create a Federal remedy for medical coverage injuries, and I put that in quotes, effectively undoes what a unanimous court did last year attempts to resurrect an ERISA shield for managed care organizations, while leaving physicians and hospitals totally exposed in State court.

Furthermore, it would relegate families to a continued bifurcated obligation where medical injuries are concerned, and would cause needless disruption in their ability, in the very, very rare instances where medical injury happens, to pursue their legal remedies.

In my view, and this has been said a number of times this morning, the external appeals process that you are likely to establish under managed care reform will, in fact, take even the limited number of medical injury cases we see today and reduce the number even further.

We can probably expect that employers will begin to simply certify cases over to the external appeals process rather than spending a lot of time on internal appeals. That is an option under the Ganske-Dingell bill and one that I presume many employers would be happy to take.

Some of my best friends are ERISA fiduciaries and have to make these decisions on a monthly or relatively frequent basis and it is very difficult.

So if there is a good, fair external appeals process, I assume that, in fact, a lot of the burden that falls to employers today will evaporate or at least be significantly reduced.

Given the very limited role of liability and medical liability, I would say that it is a very unwise idea to overturn Pegram at this point.

[The prepared statement of Sara Rosenbaum follows:]

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

Mr. Chairman and Members of this Subcommittee: Thank you for extending me this opportunity to testify before you today on one of the most important aspects of the managed care patient protection legislation now under Congressional consideration—access by families enrolled in ERISA plans to legal remedies for medical injuries. I commend Congress for its ongoing effort to find a resolution to this problem. The task is obviously a difficult one and cannot be resolved without addressing ERISA preemption, one of the most complicated areas of social welfare law.

My testimony is based on my work as a health law professor and draws extensively on my collaboration with Professors Rand Rosenblatt and David Frankford of

Rutgers University Law School in Camden, New Jersey. Our textbook, *Law and the American Health Care System,*[1] was the first health law textbook to extensively present health law in an ERISA context and was cited in the Supreme Court's opinion in *Pegram v Herdrich*[2] as a leading textual authority regarding the legality of managed care design under ERISA.

In this testimony I explore two issues. The first is the emerging "legal baseline" regarding the liability of managed care organizations for medical injury. The second is the question of whether in fashioning this legislation, Congress should adhere to this emerging baseline in fashioning remedies for members of ERISA plans who suffer medical injuries.

1. THE LEGAL BASELINE

For many years it has been settled law that an HMO or other managed care company can be held liable for injuries flowing from substandard medical care. Managed care organizations are "hybrid" entities that provide the medical care they furnish; thus, in the eyes of the law they undertake medical treatment and thus are accountable for medical acts that injure or kill. Liability can be predicated on theories of vicarious or direct negligence.[3]

Since the 1995 landmark decision in *Dukes v U.S. Healthcare,*[4] federal courts, in deciding questions of removal jurisdiction under 28 U.S.C. § 1441, have consistently held that where an ERISA participant or beneficiary brings a lawsuit that alleges medical injury, the claim arises under *state* law and thus is not a federal claim under ERISA.[5] Until this past Supreme Court term, the *Dukes* "quantity/quality" distinction supplied the analytical framework for distinguishing between ERISA health benefit cases that involved state, as opposed to federal law.

In *Pegram v Herdrich* a unanimous Supreme Court altered this analytic framework by introducing the concept of "mixed" and "pure" eligibility decisions. *Pegram* is best known for its holding that fundamental aspects of managed care design (*Pegram* concerned the use of financial incentives in employer-sponsored health benefit plans) do not constitute a breach of fiduciary duty under ERISA. However, the Court's opinion did not end here. The Court went on to discuss at length the concept of fiduciary decision-making under ERISA.

ERISA's remedies apply to "fiduciary" decisions and activities. Claims challenging the legality of ERISA fiduciary decisions thus are governed by ERISA remedies.[6] But legal claims that do not constitute a challenge to an "ERISA fiduciary" decision fall outside the limits of ERISA and are not subject to ERISA preemption.

In *Pegram* the Court distinguished between medical decisions and fiduciary decisions. Writing for the Court, Justice Souter fundamentally restructured the analytic framework for deciding when a medical injury case is governed by state law. In the view of the Court, state law should govern in any case in which medical injury is alleged to have flowed from flawed medical judgement, regardless of the context in which that judgement is exercised:

> [P]ure "eligibility decisions" turn on the plan's coverage of a particular condition or medical procedure for its treatment. ″Treatment decisions,″ by contrast, are choices about how to go about diagnosing and treating a patent's condition: given a patient's constellation of symptoms, what is the appropriate medical response? These decisions are often practically inextricable from one another * * * * This is so not merely because, under a scheme like Carle's, treatment and eligibility decisions are made by the same person, the treating physician. It is so because a great many and possibly most coverage questions are not simple yesorno questions, like whether appendicitis is a covered condition (when there is no dispute that a patient has appendicitis), or whether acupuncture is a covered procedure for pain relief (when the claim of pain is unchallenged). The more common coverage question is a whenandhow question. * * *
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> The kinds of decisions * * * * claimed to be fiduciary in character are just such mixed eligibility and treatment decisions * * * *.

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[1] Foundation Press, NY, NY (1997; 2001-2002 Supplement [forthcoming, Summer, 2001])

[2] 120 S. Ct. 2143, 2149 (2000).

[3] See. e.g., *Boyd v Albert Einstein Medical Center* 547 A. 2d 1229 (Pa. Super., 1998); *Chase v Independent Practice Asso.,* 583 N.E. 2d 251 (Mass. App. 1991); *Petrovitch v Share Health Plan of Ill.* 719 N.E. 2d 756 (Ill., 1999); *Shannon v McNulty* 718 A. 2d 828 (Pa. Super., 1998); *Jones v Chicago HMO* 730 N.E. 2d 1199 (Ill, 2000).

[4] 57 F. 3d 350 (3d Cir., 1995); cert. den. 116 S. Ct. 564 (1995).

[5] See, e.g., *In re U.S. Healthcare* 193 F. 3d 151; cert. den. 120 S. Ct. 2687; *Lazorko v Pennsylvania Hospital* 2000 WL 1886619; *Corporate Health v Texas Department of Insurance* 215 F. 3d 526 (5th Cir., 2000); and additional cases cited in *Law and the American Health Care System,* Ch. 3(E)

[6] ERISA § 502; 29 U.S.C. § 1132.

> [W]e think Congress did not intend * * * * any other HMO to be treated as a fiduciary to the extent that it makes mixed eligibility decisions acting through its physicians. * * * * Our doubt * * * * hardens into conviction when we consider the consequences that would follow * * * *. What would be the value to the plan participant of having this kind of ERISA fiduciary action? It would simply apply the law already available in state courts * * * *. ERISA was not enacted * * * to federalize malpractice litigation in the name of fiduciary duty for any other reason. * * * *.
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> The mischief of Herdrich's position would, indeed, go further than mere replication of state malpractice actions with HMO defendants. * * * * The physician who made the mixed administrative decision would be exercising authority in the way described by ERISA and would therefore be deemed to be a fiduciary. * * * * Hence the physician, too, would be subject to suit in federal court * * * *. This * * * * in turn would raise a puzzling issue of preemption. On its face, federal fiduciary law applying a malpractice standard would seem to be a prescription for preemption of state malpractice law, since the new ERISA cause of action would cover the subject of a statelaw malpractice claim.[7]

The Court thus restructured the logic of the *Dukes* case, moving from a world of quality versus quantity into a world of mixed eligibility versus pure ERISA coverage decisions unrelated to medical coverage. This reframing of the analytic structure that federal courts should use in deciding injury claims brought by ERISA plan litigants is consistent with the Court's 1995 decision in *New York State Conference of Blue Cross and Blue Shield Plans versus Travelers Insurance Co.*[8] which held that "in the field of health care, a subject of traditional state regulation, there is no ERISA preemption without clear manifestation of Congressional purpose."[9]

Two important cases at the federal appellate level have considered *Pegram* in the nearly one year since it was handed down—certainly not enough time to claim a hard trend. But given the subtleties of *Pegram,* these cases provide at least some insight into where the courts may go.

The first case, *Corporate Health v Texas Dept. of Insurance,*[10] considered the legality under ERISA of a multi-part Texas law which: (a) established a new medical liability cause of action for substandard care furnished by managed care organizations; established anti-retaliation and anti-indemnification protections for physicians; and (c) established independent external review procedures of managed care coverage decisions. The court found that the liability and anti-indemnification provisions were not-preempted by ERISA; the court further held that even if the external review statute was saved as a law that regulates insurance, it could not apply to ERISA plan decisions because it directly conflicted with the substantive terms of ERISA. Following the *Pegram* decision, this third prong was re-argued and the Court reaffirmed its earlier holding.[11] Little can be gleaned from the decision in a *Pegram* context, because at its heart the *Corporate Health* case concerned a direct conflict between state and federal law on the issue of access to external review, not the type of preemption at issue in the liability cases. Furthermore, the Texas law itself distinguished between medical torts and review of insurance coverage cases; in following the old "quality/quantity" distinction first drawn in the *Dukes* case, the statute was not-easily re-filtered through a post-*Pegram* analysis.

The far more important case in this context is *Lazorko v Pennsylvania Hospital*[12] decided by the Court of Appeals for the Third Circuit, the appellate court that first identified clearly the "quality/quantity" distinction in the *Dukes* case. *Lazorko* was a medical injury case brought against a physician and a health plan following the death of a plan member from severe and untreated mental illness. The plaintiff in the case alleged that the physician's decision to cut off her treatment led to the woman's death and that the company's practice guidelines were a proximate cause of the physician's decision to stop permitting treatment. In holding that neither the claims against the physician nor those against the plan were preempted, the court specifically considered the impact of *Pegram:*

> U.S. Healthcare counters with two basic arguments, neither of which we find persuasive. First, it argues that Dr. Nicklin's refusal to hospitalize Patricia Norlie-Lazorko amounts to a denial of benefits because hospitalization is a benefit under Jonathan Lazorko's HMO plan. We reject this characterization of the claim. Lazorko is not arguing that his plan is supposed to permit hospitaliza-

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[7] *Pegram v Herdrich,* 120 S. Ct. 2154-2158.
[8] 514 U.S. 645 (1995)
[9] *Pegram,* 120 S. Ct. at 2158.
[10] 215 F. 3d 526 (5th Cir., 2000); reh. 2000 WL 1035524.
[11] Id.
[12] 2000 WL 1886619 (3d Cir.)

> tions for mental illness and that U.S. Healthcare refused his wife's request for guaranteed service. Instead, he is arguing that, when confronted with his wife's requests for additional treatment, Dr. Nicklin, influenced by U.S. Healthcare's financial incentives that penalized a decision to grant additional hospitalizations, made the medical decision not to readmit her to the hospital. Because Lazorko's claim is one concerning the propriety of care rather than the administration of that care, the claim is not completely preempted. In other words, the claim here is that the denial of Norlie- Lazorko's request for hospitalization occurred in the course of a treatment decision, not in the administration of the Lazorkos' plan. * * * *
>
> U.S. Healthcare's second contention is that, in light of the recent Supreme Court decision in [*Pegram*] subjecting an HMO to liability is improper because Pegram recognized the centrality of financial incentives to the operation of an HMO. Pegram, however, does not alter our analysis. In evaluating the question of the circumstances under which an HMO owes a fiduciary duty to the members of an ERISA plan, the Pegram court held that mixed eligibility decisions by an HMO (i.e., decisions involving not only the coverage of a particular treatment by the plan but the reasonable medical necessity for the treatment) are not fiduciary decisions under ERISA.[13]

The bottom line in all of this is that cases involving a challenge to the quality of decisions regarding the propriety of a course of treatment belong in state court and that pure coverage decisions—i.e., where there are no medical facts in dispute and medical judgement is not called for—fall within the ambit of ERISA fiduciary decisions and remain subject to ERISA's exclusive federal remedies.

2. CONGRESS' CHOICES

Given this legal baseline, I believe that Congress has three choices in the area of remedies for medical injuries to persons who receive their health care through ERISA plans. First, it can elect to do nothing and allow the issue to further develop in the lower courts. Second, it can elect to depart from the Supreme Court's framework and instead create a federal remedy for medical coverage injuries. Third, it can amend ERISA to codify the Supreme Court's interpretation of ERISA and allow the application of state remedies for injuries involving the faulty exercise of medical judgement.

For four reasons, the sensible approach is the final one. First, this approach parallels the guidance to the lower courts provided by the *Pegram* decision. To now try to fashion new statutory remedy rules for the courts to apply will throw the entire matter into chaos. The Court drew this line because of states' historic primacy in the regulation of medical care; remedies for medical injuries tied either to the exercise of substandard professional judgement or the substandard operation of medical care corporations are a direct extension of this state power. In recasting the issue of remedies in this manner, the Court essentially recognized the role that states always have played in the oversight of medical care. Its review of the history and purpose of ERISA in both the *Pegram* and *Travelers Insurance* decisions underscores the vital but limited purpose of the law. ERISA is intended to allow covered entities the ability to administer employee benefit plans free of variable state law; it was not intended to create a federal tort for medical malpractice.

Second, the Court's reasoning flows from the very fabric of managed care. In a managed care environment, any attempt to resurrect some notion of a "medical coverage" decision that can be spliced from the medical care itself is simply futile. In the concept of health care quality, managed care is an attempt to allocate medical resources in the treatment of patients in accordance with sound principles of medical care. When this effort goes wrong—either because the deciding physician makes a bad call or because the treatment guidelines under which the physician is practicing are themselves medically defective—the case should be viewed as a medical care case. Only those decisions that involve neither medical facts nor the exercise of medical judgement belong in federal court and covered by ERISA remedies.

Third, to force the creation of a new federal remedy for something called a "medical coverage injury" will inevitably as the Supreme Court predicted, federalize control over the quality of medical care by federalizing remedies for poor medical performance. Were a federal remedy to be created, all medical injury cases would get dragged into federal court and extensive time would be invested in deciding whether each particular claim is a federal one that relates to "coverage" or a state claim that relates to "treatment." *Pegram* actually provides relatively clear guidance to lower

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[13] Id. pp. 6-7.

courts: medical injury cases are state law cases, while cases with no allegation of substandard medical judgement or standards remain federal.

Resurrecting the concept of "medical coverage" for federal tort purposes would be worse than simply leaving matters alone. Writing federal remedies is extremely difficult, particularly when they get grafted onto an already complex jurisprudential picture. In creating a new federal remedy, Congress inevitably will introduce new terms, concepts, and nuances that will cause the courts to not merely to depart from *Pegram* but even to reconsider whether the new Congressional remedy follows the earlier *Dukes* approach. This task of learning new "case sorting rules" will be added to an already overburdened federal system that is supposed to be a system of limited jurisdiction to hear uniquely federal claims, not state medical liability claims except in diversity situations. Furthermore, by introducing medical quality accountability as an express matter of federal law, Congress would begin to tip the entire matter of oversight over medical care quality into the federal domain.

Fourth, to federalize medical judgement torts would be anything but supportive of families. The best research into the area of medical liability claims suggests that these cases are quite rare.[14] States themselves maintain strict controls over medical liability claims, frequently requiring exhaustion of preliminary review procedures, limiting the types of remedies that can be made available for medical injuries, and generally imposing procedural requirements that are designed to weed out frivolous litigation. Furthermore, S. 283, recently introduced by Senator McCain, contains adequate protections to shield employers from claims of liability under state law.

State courts are not the Wild West when it comes to medical liability cases. To put medical injury cases in federal courts works an extreme hardship on the few families whose need for judicial access is the result of death or injury from substandard treatment decisions. Federal courts are typically far away geographically, federal practice is a specialized area of law practice, and federal courts are actually far less experienced in the management of medical injury claims.

If Congress completes work on a federal patient protection act, the final law surely will contain an external appeals system to permit access to prospective help before the injury happens. I remain confident that a strong external review process will aid considerably in heading off medical injury before it occurs and thus reduce liability litigation generally in the long run and further, that retaining state law authority over medical claims is the correct thing to do.

Mr. BURR. I thank you for your statement, Ms. Rosenbaum.

At this time, the Chair would recognize the chairman of the full committee, Mr. Tauzin, for the purposes of questioning.

Chairman TAUZIN. Thank you, Mr. Chairman. Dr. Palmisano, in your statement, you draw a clear bright line between decisions of the health plan that impose a medical judgment on the patient and decisions that simply make an eligibility decision.

Ms. Rosenbaum talks about the Pegram case and how it gets into the subtleties of that issue.

You drew a nice bright line. When is eligibility of coverage not a medical decision, in your view?

Mr. PALMISANO. Yes, sir. One example would be when there is a dispute as to whether the contract would cover some service.

Whether or not a stepson who comes to live with a family is covered under that policy, when it is not clear at the beginning that those were the people enrolled in the plan, issues like that.

The State court issue that we talk about, the medical decision-making would be where the doctor decides whether or not a patient has appendicitis and needs an operation.

An example that I had that I have testified to Congress before about, where someone is telling me that a patient who has a piece of clot in the carotid artery that breaks off and goes to the brain and the patient has a transient stroke, and I witness this, because the patient cleared up in a matter of minutes, they tell me it is not

[14] Harvard Medical Practice Study Group, *Patients, Doctors and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York* (1990).

an emergency and, therefore, the patient will have to be worked up as an outpatient. Those are medical decisions.

Chairman TAUZIN. I think I understand clearly when something looks like a medical decision, but what really eludes me, and I think Pegram talks about these mixed eligibility and treatment decisions, is how you draw a bright line between them.

I am trying to find a common sense way of doing that. You try to say, clearly, when it is a medical decision, this ought to be something treated under State law. When it is an eligibility decision, you treat it under the Federal ERISA preemption statute.

But when I think about real instances, and I asked you to give me a couple of them, I can envision a decision on eligibility resulting in denial and a patient not getting the medical treatment he needed, being severely harmed and asking for a remedy somewhere.

Why is that less of a medical malpractice case or a treatment decision than about whether or not this is an emergency?

Mr. PALMISANO. Hopefully, those types of issues will be resolved with greater information so that the customer of the insurance of the employee would understand better what is actually covered under the policy in the plain light of day before the emergency comes up, before the need for medical services comes up.

Chairman TAUZIN. But you do concede that as the Pegram case pointed out, that you get into an awful lot of gray areas, where you don't know whether it is an eligibility decision or whether it is a medical treatment decision or whether it is both.

Mr. PALMISANO. My esteemed colleague here is reminding me that one example would be that if there is treatment for a condition and the policy clearly states in the policy that we don't give certain types of chemotherapy, it is not covered in here, and, again, it goes back to what the contract says.

My view is that if you are informed, like when I operate on a patient, I hope my truly informed and gives an informed consent, because we spend time explaining what the diagnose and treatment options are.

Chairman TAUZIN. But you see, the problem is, as I understand it, the difficulty arises not where there is a clear statement about whether something is not covered. It is in the ambiguities. It is whether this is medically necessary or whether this is an emergency or whether the language covers this particular circumstance.

It is not very clear whether it does or not. On the one hand, I can look at it and say that is an eligibility decision. On the other hand, someone else may look at it say, no, no, no, no, if the person doesn't get this treatment, there are serious medical consequences, this is a malpractice case if he doesn't get the treatment.

Mr. PALMISANO. I think if the policy was clearly written in plain English, and some policies are not, as we can all attest to, where you have to get several lawyers to understand what the words mean, and then we are still not sure, because there are different opinions, what we really need to do is understand what is covered and what is not covered.

Chairman TAUZIN. Let me ask further. It looks like, in the Pegram case, that Justice Souter did acknowledge that there were mixed decisions.

Mr. PALMISANO. Yes.

Chairman TAUZIN. Where would you treat those mixed decisions under your scheme?

Ms. ROSENBAUM. You are certainly right, Mr. Chairman, to note that this is very complicated. The kind of dichotomy that the courts are laboring under today or before Pegram were laboring under, the quantity versus the quality distinctions, raised similar problems.

In any legal system that is a system driven by federalism, whether it is Federal law that applies to some classes of action and State law that applies to other classes of action, whatever court gets the case at the first blush is always going to have to make a threshold decision about where the case belongs.

So I would say it is probably not likely that Congress, no matter how hard it works, can draw the kind of bright that line that would forever eliminate the need for somebody to make a judgment call for a court right at the outset about what belongs where.

The nice thing about Pegram and the reason why it is so much better a framing of the issue than the Dukes quality/quantity distinction is that the court actually sets up a pretty simple test.

What the court is asking lower courts to look to in Pegram is whether, in order to resolve the patient's case, somebody had to exercise some medical judgment.

In an example where I want acupuncture to relieve my backache, and my plan, no matter how much I might need or benefit from acupuncture, simply doesn't cover acupuncture, I happen to be a law professor, I could read the contract for a managed care company and tell somebody that acupuncture is not a covered benefit. There is no medical judgment.

If, however, the decision is whether a child's cleft palate is cosmetic or a medical condition, any court can look at that kind of case quickly and know that there was no way that the case could have been resolved without somebody with professional qualifications deciding the case.

Now, this will all become a lot easier under a new bill because it will be the very cases that went to external review, and that is how you will know that there is either State jurisdiction or Federal jurisdiction.

Chairman TAUZIN. My time is out, but I want to put a question before all the panelists, and you don't have to answer it now. I would love for you to do it in writing.

The court, in Pegram, did specifically note that ERISA makes separate provisions for suits to receive particular benefits and that the court would not "discuss the interaction of such claim with State law causes of action." That's a footnote that you don't refer to, Ms. Rosenbaum, in either your memorandum last year or in your testimony today.

The question is, isn't the legislation we are discussing today dealing with specific benefits and how can you claim to provide an objective legal analysis when you don't address that language in your analysis, language of the Pegram court.

Don't answer it now. I don't have time, I am out. Just give me a legal—if you will, an answer in writing. If you will all respond, I would appreciate it.

Mr. BURR. The gentleman's time has expired. The Chair would recognize Mr. Brown for questions.

Mr. BROWN. Thank you, Mr. Chairman. Charts seem to be the order of the day, so if Courtney would put up just three charts that I want you to look at. These are simple, with big print, easy to read, even for us.

The first one is under current law, this is current law, doctor orders treatment, HMO denies the medical treatment, patient appeals to the HMO, HMO is the judge and jury of the case, treatment is denied, the patient is injured or dies, the patient or the family go to Federal court under ERISA, and it is tough luck, ERISA says HMOs are exempt.

Patients can only recover the value of the benefit itself denied.

The next chart is the Ganske-Dingell bill. Doctor orders treatment, HMO denies medical treatment, patient appeals to independent external review, and patients gets treatment, or doctor orders treatment, HMO denied medical treatment, the patient is injured or dies before the appeal is completed, patient goes to State court, the court awards appropriate damages, according to State tort limits, if warranted.

We have seen today and heard certainly since really before the Presidential race, but certainly during the race, of the law in Texas. We have seen a very similar law to the Ganske-Dingell proposal, and we have seen that there have been very small number of lawsuits, although the discussions, the other side often are a high litigious society as in how this will bring on a cascading of lawsuits.

Mr. Wynn and Mr. Pollack today established, I thought, pointed out the possibility of lawsuits certainly makes managed care plans behave differently if there were not the possibility of a lawsuit hanging over them, so that patients are much more likely to get appropriate care, what the physician and the patient have decided is the best care from that HMO.

The President now, though, says he wants to keep us out of State court and his proposal and some opponents to this bill say the same thing.

Would you, Ms. Rosenbaum, point out to those of us up here that are non-lawyers the differences, explore the differences for us between what State and Federal court means here in terms of access to the courts, the waiting period, the waiting time, the expense to the plaintiff and, for that matter, the expense to the defense, all of that, so we better understand the difference between State and Federal court and what all this means.

Ms. ROSENBAUM. Certainly. The first thing to recognized, which I know that Congress is well aware of because if your authority over the Federal courts, is that Federal courts are set up as courts of very limited jurisdiction. They are only supposed to hear certain kinds of cases.

They are not actually the broad backbone judicial system of the country. The broad backbone judicial system is the State court system. It is the State court system that reflects the common law, that decides most of the legal disputes that happen in the United States, and certainly when it comes to personal injury actions, the kinds of actions that we can trace all the way back to a thousand

years ago, when courts first got going, those are the bread and butter of the State court system.

Certainly, anybody who has been in the State court knows that State courts are hardly perfect, there can be backlogs in State courts, but there are many more of them. There are many more State courts and State court judges.

In addition, States supplement their State courts with various kinds of preliminary steps they could take to resolve disputes.

State courts are close to home. Most lawyers who practice today are familiar with the legal procedures and the rules of their State courts.

Just as Federal courts are courts of limited jurisdiction, lawyers who spend their time doing Federal litigation tend to be a much rarer breed. They are more specialized, they may be less accessible, particularly if you look in a small town or a rural area.

If you look at the travel time that it takes to get to Federal court, it can be quite considerable, where a court sits only in one part of a State.

I used to live in Maryland and now live in Virginia. If you are in the Cumberland area of Maryland and you have to travel to Baltimore, except when the court is riding circuit, it is a real burden.

Federal courts are supposed to hear specified claims. So under ERISA, they have a major role to play with those claims, when they arise, that are ERISA claims.

What Pegram makes clear is that there is a big difference between an ERISA claim and a claim brought by an ERISA participant.

You can be an ERISA plan participant and have a lawsuit that has nothing to do with ERISA, and the whole message from the Supreme Court back to its lower courts was you shouldn't be involved in medical injury cases.

We have a perfectly good thousand year old, to put it most simply, legal system which has evolved in this country into our State court system, supplemented by State legislatures, and that is where these cases belong.

Mr. GREENWOOD [presiding]. Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Chairman. I appreciate the testimony of this panel. I did get a chance to read your testimony in advance.

Dr. Palmisano, I want to begin with you. As you might guess, I agree with probably the vast majority of your testimony. I certainly agree that health care plans should be held accountable and that ERISA, as interpreted today, saying that they are absolutely immune for consequential damages from negligent decisions that incense bad public policy, as I said earlier.

I want to focus on a couple of issues. I think, quite frankly, there are perhaps three issues that divide the two sides, or three big issues that are dividing the two sides, precluding us from reaching a compromise.

One of those is the State court versus Federal court issue. A second issue, also, is the question of employer liability. The third is the question of exhaustion of external review.

And I think everybody here has said external review is very important to incenting care, and I am glad there is agreement on that point.

I would like to start with page 15 of your written testimony. Your testimony, quite frankly, is very, very well written and it clearly is, I think, conformed to the language of the Kennedy-Dingell-Edwards legislation.

But I think it is, in part, mistaken and I want to discuss that issue with you.

On this question of employer liability, I think you probably would agree with me that passing legislation that will, in fact, allow employers to be sued under circumstances when all they did was procure an insurance plan is going to be impossible. I don't think we can do that, and I desperately want to pass legislation.

At the bottom of page 15 of your testimony, after having said that you think employers should be not able to be sued, you say, and this is the last full sentence, "Consequently, only if an employer or plan sponsor directly participated in making an incorrect medical decision or an individual claim decision under its group health plan and that decision resulted in injury or wrongful death, only in that circumstance could it be," and then turning over to the next page, "exposed to a State law claim."

Now, that statement is technically incorrect, is it not, Doctor? And the reality is you are exposed to the claim, that is, you may be sued by the mere allegation that you directly participated, right?

Mr. PALMISANO. Well, what we want to do is set a standard in America. Of course, anybody can sue you if they have got enough money. In fact, if they don't have the money, they can just go get somebody.

Mr. SHADEGG. Precisely the point. But under other language, for example, the designated decisionmaker language, you would not have that fact question in front of the jury.

You would designate a health care decisionmaker who was responsible for making that decision and could respond in damages and in that circumstance, you would not be able to sue the employer and raise that fact question and hold the employer in all the way into the lawsuit.

I guess I am wondering why you would not support or if indeed you would consider supporting the designated decisionmaker language that I have actually spent hours discussing with your colleagues at the American Medical Association.

I am trying to find out, is this an in-stone position or are you willing to look at language that further protects employers when they don't make the medical decision?

Mr. PALMISANO. I think, Mr. Shadegg, we all are on record saying that if the employer does not make the medical decision, the employer should not be liable. So we agree on that.

Mr. SHADEGG. And you make the statement they shouldn't be exposed to a claim. That is what it says.

Mr. PALMISANO. They shouldn't be exposed to liability, but wait a minute. We are all exposed to claim. Somebody can sue you tomorrow, sue me tomorrow.

Mr. SHADEGG. No, that is not true. That is absolutely not true. The reality is HMOs are not exposed to a claim for consequential damages today. That is why we are here.

Mr. PALMISANO. Well, that is why we are here, right.

Mr. SHADEGG. That is my whole point.

Mr. PALMISANO. And that is why there is a great injustice in the system, and that is why we are trying to fix it.

Mr. SHADEGG. I agree. But I guess my point is there is language called the designated decisionmaker language which precludes this possibility and does not allow employers to be sued.

You see the exception there that says an employer may be sued.

Mr. PALMISANO. May I say one more thing? Another possibility is that someone could be designated and that could be some sort of sham corporation with no assets.

Mr. SHADEGG. Well, the law actually requires that they be responsible for the medical decision and that they be able to respond in damages, and indeed in the language that I discussed with Mr. Norwood's staff last year, you would say that if it is an insured plan, as opposed to a self-insured plan, the insurance company is automatically designated.

So for my little restaurant, Joe Jordan's, Joe Jordan doesn't self-insure. He goes out and buys a plan from Aetna. Aetna would be automatically on the hook for damages.

I would like to ask the other two witnesses if they don't agree that this language does expose the so-called direct participation language.

Does it not, in fact, expose employers to being sued and to be held in the case all the way to the end because it is a fact question?

Ms. GREENMAN. In my view, there is absolutely no question that the language of direct participation would expose employers to expensive and ongoing litigation.

The one issue or question that I would raise, even with the designated decisionmaker concept, is that employers, if you look at—this really comes up more in self-insured plans as opposed to fully insured plans.

Within self-insured plans, which tend to be maintained by larger employers, since they have the wherewithal to do that, the claims that—the role that employers typically will play is to intercede or to get involved in reviewing a claim after it has been denied by the plan administrator, the contract plan administrator.

So that if the claim has already been denied and denied again, if it is appealed back to the administrator, the employer may be the sort of court of last resort from an internal review perspective.

I was both in private practice and now represent in-house with Honeywell. I have never seen an employer step in to overturn a grant of a benefit. I have seen employers step in on behalf of employees to try and get them the coverage or to make a decision overturning the contract administrator.

It is that benefit, even with a designated decisionmaker concept, because employers, you are absolutely correct, employers will refuse to play the role of designated decisionmaker and exit the decisionmaking process all together.

Mr. SHADEGG. Under designated decisionmaker language, an employer could step in and say we think you ought to grant the ben-

efit and that would not change that there is still somebody who is liable. That is, the designated decisionmaker, whether they accept that advice or don't.

Mr. deMontmollin. I don't know now to pronounce your last name.

Mr. DEMONTMOLLIN. It is deMontmollin. We believe that the bill clearly does bring the employer closer to that litigation.

Mr. Whitfield made the comment that there are no bounds on the innovation or the originality of trial lawyers in this area.

Clearly, already under COBRA and under HIPAA, COBRA for the extension of benefits and HIPAA on discrimination, the employer is making those decisions, for the most part, and is getting closer to this issue.

So we feel very strongly that as happened in California, where a suit was brought under the criminal torture statute against the HMO for not extending physical therapy benefits beyond the amount that was contained in the contract and an effort to made to bring the employer in at the same time, we believe an expansion of health plan liability would get us closer, a slippery slope closer to that point where employers would be included.

Mr. SHADEGG. Could I ask all the witnesses to respond in writing to the designated decisionmaker language that is out there and has been discussed?

Thank you.

Mr. PALMISANO. We will be happy to do that.

Mr. GREENWOOD. Without objection. The gentleman's time has expired. I apologize to the panel for missing the first 3½ hours of his hearing, but the last 12 minutes has been fascinating.

A question that I would like to pose to Mr. deMontmollin. We have heard a lot of discussion over the course of the debate on this issue about whether or not the Texas statute would give us some inclination as to what to expect in terms of the frequency of claims and those who argue for State jurisdiction argue that Texas demonstrates to us that, see, there weren't a lot of suits, there was no flurry of legal activity.

My understanding is that it is not quite that simple, but, in fact, the law was held in abeyance for some time by the courts.

Could you comment on that, please?

Mr. DEMONTMOLLIN. I believe that the Fifth District Court of Appeal has made it clear and has limited the Aetna decision in such a way so that it applies only to a medical malpractice action in the State and then vicarious liability for the particular health plan.

So clearly there is no comparison between what is being debated by this subcommittee and what happened in the Texas scenario.

However, with respect to Texas, we believe that there is clearly a strategy on the part of the trial bar to select only those cases that they think are most likely to lead to substantial damages and then hopefully to use those particular cases for that purpose of setting a precedent and then I think that the potential for floodgates opening is very realistic.

A second issue I think that is very important is one that was brought up by the Physician Insurance Association of America, PIAA, and their studies reflect that it takes about 54 months really for a case to get to the court ultimately.

Of course, the Texas law has only been in effect since 1997.

We think that the biggest problem here is the misimpression that the Texas law in some way provides aid and comfort to those who would expand health plan liability at the Federal level, and we would suggest that the clear opinion of the Circuit Court of Appeal was that it is a run of the mill medical malpractice type of case that, in the opinion of that court, the HMO could be held vicariously liable for, which is similar to the quality/quantity dichotomy that we have seen in other circuits.

Mr. GREENWOOD. Did you want to comment?

Ms. GREENMAN. Yes, if I may, to add to my colleague's comments. I would suggest that the Texas statute cannot be looked at as comparable to the proposed legislation, because that statute was enacted in the—ERISA protections and ERISA preemptions still exist.

So that there has not been any change to ERISA preemption. To the extent that an action is brought that is pure medical malpractice, an employer cannot be brought in because of ERISA protections and ERISA preemption, and if it is purely a payment determination, I think even under the Texas provisions, there would be no cause of action.

So I don't think that you can necessarily analogize, even if the course of litigation had run, between the Texas statute and proposals now before Congress.

Mr. GREENWOOD. Thank you for that.

Mr. PALMISANO. Mr. Greenwood, we would take the position, also, that Pegram is not a change in the current law, but that rather it is a preservation of what the existing law is.

Mr. GREENWOOD. Speaking of pure medical malpractice, let me just question Dr. Palmisano.

Some of us who are advocates of medical malpractice for your profession, and I have introduced legislation of my own in the past Congress and I will in this one, have been a bit dismayed that your association has not supported the notion that we ought to marry medical malpractice provision to patients' protection legislation.

I would appreciate it if you could comment on why that is. I think it was in your testimony that you felt that such legislation would bring down both pieces.

Particularly, I think you have expressed concern about the Senate. Have you actually done the vote counting there? Are sure of whereof you speak?

Mr. PALMISANO. I guess the only people that can be of things in the future are a higher level than myself.

Mr. GREENWOOD. Oh, no, we can do that.

Mr. PALMISANO. But we have looked at the votes and we don't have the votes and we think the whole thing would go down. But you are absolutely right. The American Medical Association is on record as being for tort reform, and we think that ought to be a separate bill all by itself.

And we think a meaningful Patients' Bill of Rights is essential, because right as we talk today, people are being hurt around the country right now and we think something needs to be done.

So someone talked about being on the head of a pin, some reference to that. I think whatever we need to do, we need to reason

together, look at everyone's ideas, and come up with something that will get help for the people out there now, and we will support a meaningful tort reform bill and we are on record.

The bill that we support is essentially the California bill, which is the MICRA legislation in California, with the cap on——

Mr. GREENWOOD. But would it be fair to say, and then I will yield, that if, in fact, the calculus changed or the calculus were determined to be that adding tort reform for medical malpractice, in fact, gained us votes for this legislation, would the American Medical Association then support the marriage?

Mr. PALMISANO. The American Medical Association is not going to go against two of its policies, but what we would do is make a careful analysis and talk to everyone as best we could in the House and Senate to see whether or not it would destroy, so that we end up with nothing.

In other words, what we would like to do is get tort reform done separately.

Mr. GREENWOOD. None of us wants that. Thank you. The gentleman from Texas, Mr. Green, is recognized.

Mr. GREEN. Thank you, Mr. Chairman. I have a number of questions, but let me follow up on that line of questioning first.

Most medical malpractice lawsuits are filed in State courts, from my understanding. The State of Texas has addressed medical malpractice.

Do we really have a national problem, a Federal problem with medical malpractice lawsuits, Doctor?

Mr. PALMISANO. Well, the problem with medical malpractice lawsuits or suits that are filed against health care professionals is a serious problem, it has been a problem in the United States, and some States have taken dramatic action that has stopped the increase in premiums and allowed patients to have access to physicians.

California is one example, Indiana is another example, and our own State of Louisiana is another example.

Mr. GREEN. I only have 5 minutes, but let me say that that is a State option now and I am sure my Republican colleagues, you really wouldn't want to take away that States' rights effort.

Mr. PALMISANO. We certainly would not want any Federal law to supersede a better State law. So it would basically a floor that you all have talked about before. In medical mal, it would be a floor.

We would never want it to preempt a better State law. We think Louisiana is head and shoulders above some of the other places.

Mr. GREEN. Instead of adding to making a bill better, I would look at adding that maybe more like a poison pill. Would you look at that?

Mr. PALMISANO. Some people have used that term. We have deliberately not used that term. What we are saying is that we think that everyone wants to do what is in the best interest of the American public, both the people that have the opportunity to vote, as you all do, and those of us who participate in this discussion.

So what we are trying to do is just reason together and we have—according to our count of the votes, this would destroy a meaningful Patients' Bill of Rights by doing that.

Mr. GREEN. I appreciate that. Mr. deMontmollin, in fact, my question was to talk about the Texas experience, and I am sorry if you have to repeat, but we have another committee going on in Telecom also.

You said that it takes 54 months for a lawsuit to come to fruition, to be filed?

Mr. DEMONTMOLLIN. That is a study by the Physicians Insurance Association of America.

Mr. GREEN. Again, since you are testifying on Texas law, and I wasn't there and I came to Congress in 1993, but served 20 years in the legislature, Texas still has a 2-year statute of limitations, if I am correct.

Mr. DEMONTMOLLIN. Correct.

Mr. GREEN. From the date of discovery or 2 year statute. So where do you get 54 months? Because if I discover some problem, I have 24 months to file that lawsuit. So there should be lawsuits on file right now, shouldn't there be, in the State of Texas?

Mr. DEMONTMOLLIN. I don't believe that would necessarily be the case. For instance in Florida, there is a period——

Mr. GREEN. I want you talk about Texas, because I am familiar with it and that is the law we are looking at, that we are comparing the Dingell-Ganske bill with Florida. Does Florida have a 2-year statute of limitations?

Mr. DEMONTMOLLIN. Yes.

Mr. GREEN. But if I discover some injury by a doctor or by denial of coverage, I guess it bothers me that 54 months seems pretty long, because do you know how many lawsuits have been filed in Texas since 1997 based on the Patient Protection Act that was passed in Texas? How many lawsuits?

Mr. DEMONTMOLLIN. It may just be one, and the reason for that has already been expressed by me in my opinion in my strategy.

Mr. GREEN. I want you to say it again so I can ask you questions about that.

Mr. DEMONTMOLLIN. I believe that it is the strategy of the trial bar in Texas to allow—to make sure that that process in Texas does not impact on the deliberations of both Congress, as well as some other States. But clearly those States——

Mr. GREEN. Let me say I think you give the trial bar in Texas much more organization efforts, because I think the biggest complaint mostly is our plaintiff's lawyers are really out there doing their own thing instead of that.

But you are saying that the law has been effective since 1997 in Texas and there is only one lawsuit filed. I heard there were five.

Mr. DEMONTMOLLIN. I don't know how many there are, but even if there were only one, I believe that it is consistent.

Mr. GREEN. But if there was a date of discovery of an injury, someone is not filing that lawsuit then in Texas for the last 4 years.

Mr. DEMONTMOLLIN. And potentially the agreement by Aetna and the other carriers in Texas voluntarily to have external review would suggest that the external review process is working in Texas, or it suggests that most HMOs are providing 100 percent of all of the necessary and appropriate care and simply trying to im-

pact that one-third of all health care that is inappropriate and unnecessary.

Mr. GREEN. Again, I think what you said is that the review process, external review process has been very successful, and that is part of the Ganske-Dingell bill, but it is also—I know the statistics I looked at a year ago is that just over half of decisions by those external review boards were in favor of the patient.

Is that your statistics?

Mr. DEMONTMOLLIN. It is not in Florida, but I will accept yours in Texas.

Mr. GREEN. Which causes me some concern because if we don't have an external review process, then half the time, the people who make that complaint are not receiving adequate medical are. Does that seem reasonable?

Mr. DEMONTMOLLIN. No, to this extent. We certainly support external review systems and independent review by physicians of requests for care under a concurrent review system, which explains the difference between the actions of a physician who, once he delivers the care and an injury occurs, clearly, the only thing that is left is recompense in a medical malpractice action.

On the other hand, if an HMO makes a coverage decision, one Mr. Tauzin and others have described today, then clearly there is an opportunity in most States to go to an internal and then external review system.

Mr. GREEN. But that is not a medical decision. That is a coverage decision.

Mr. DEMONTMOLLIN. It is a mixed coverage——

Mr. GREEN. I think we could probably draft it to take care of that. Mr. Chairman, since I am the only one on my side, do I get any more time to follow up?

Mr. GREENWOOD. We will think about that. For the moment, the gentleman's time has expired. The Chair recognizes the gentleman from Iowa, Mr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman. Mr. deMontmollin and Ms. Greenman, maybe you don't think that anything should be changed on liability and ERISA, but do you think that one should have to complete a course of the internal and external review before that would happen?

Ms. GREENMAN. I think we need to give external review and the new DOL claims regulations a chance to see whether they are, in fact, effective. I don't think tort liability is the answer when you are talking about employers, in particular.

If you look at the mixed——

Mr. GANSKE. I am not talking about employers. I am just talking about the health plans.

Ms. ROSENBAUM. I think it might be helpful to define what a plan is.

Mr. GANSKE. No. I only have so much time. I just want to know. Do you think that before you can go to court, in whatever bill comes out of Congress, that the appeals process should be exhausted, yes or no?

Ms. ROSENBAUM. Yes.

Mr. DEMONTMOLLIN. Yes.

Mr. GANSKE. Okay. I want to talk about one of the anecdotes that the HMO industry always says doesn't exist or that we shouldn't legislate on.

Here is a little boy. He's tugging at his sister's shirt. Sometime later, his parents found out he had a temperature of 105. His mother phoned their HMO. This is all documented in a book called Health Versus Wealth.

They phoned the HMO, and were told they could only get authorized treatment from one hospital, about 75 miles away, even though the kid was really sick, according to the mother.

So that HMO reviewer didn't say take this baby to the nearest hospital, if you want it to be paid for by us, you only can take it to one hospital. In route, the kid suffers a cardiac arrest, after they have passed three emergency rooms.

They are lucky, because the nurses and the doctors, when they finally get there, are able to revive the kid. They are lucky.

But he ends up with gangrene in both hands and both feet and all have to be amputated.

Now, that was a medical judgment decision on the part of that reviewer when they phoned in and it resulted in irreparable harm.

Now, under ERISA, the only remedy allowable to this little boy is the cost of care denied.

Mr. deMontmollin, is that fair?

Mr. DEMONTMOLLIN. I would be happy, Mr. Ganske, if you would provide me——

Mr. GANSKE. Yes or no, is that fair?

Mr. DEMONTMOLLIN. It may very well be fair, depending upon the circumstances of that particular case. Let me explain what I am talking about.

Mr. GANSKE. The judge reviewed the case.

Mr. DEMONTMOLLIN. In Florida, as an example, and, certainly, I don't know what year that occurred in, but in Florida and in most of the States, first of all, it was obviously an emergency condition and the person could have gone immediately to the closest emergency room.

Mr. GANSKE. This wasn't a——

Mr. DEMONTMOLLIN. We have a system called——

Mr. GANSKE. These parents——

Mr. DEMONTMOLLIN. [continuing] admit one to one with nurses——

Mr. GANSKE. Excuse me, Mr. deMontmollin.

Mr. DEMONTMOLLIN. I'm sorry. Excuse me.

Mr. GANSKE. These parents were not health care professionals.

Mr. DEMONTMOLLIN. I wouldn't expect them to be.

Mr. GANSKE. You wouldn't expect them to. But they talked to somebody at the HMO who made that medical judgment and it resulted in this little boy never again being able to hold in his hand a basketball, or touch the face of the woman he marries with his finger.

And I will tell you what. If he had a finger and you pricked it, it would bleed. And if you are going to tell me that that HMO should only be liable for the cost of his amputations and that that is justice, let me tell you, this was reviewed by a judge and he thought it was atrocious.

Now, I am going to get to the point on this. Okay. You tell me how we can devise language that will provide justice for this without having a segment that says you have to complete external review unless you have suffered irreparable harm or injury or death.

Provide me with the language, because this is a matter of fundamental justice.

Ms. GREENMAN. If I may, Mr. Ganske. I believe that if HMOs are required, in the situation of urgent care or emergency are, which this was, that parents took the child to the nearest emergency room, subsequently went through external review, you don't have time in that kind of emergency situation to go through external review, but getting recompense in court is little comfort to that little boy.

Mr. GANSKE. Under our bill, when it passes, these parents, because of the emergency, the layperson's definition of emergency, would have been able to take him and drop him off at the first hospital.

Ms. GREENMAN. They would be able to go to the nearest hospital and it would be able to go through external review.

Mr. GANSKE. It would have prevented that.

Ms. GREENMAN. In order to be reimbursed, if it is determined that it was, in fact, an emergency.

Mr. GANSKE. Under external review?

Ms. GREENMAN. He would get care first is what I am saying.

Mr. GANSKE. Well, we certainly hope that under our bill, that we can prevent cases like this. But let me give you another example.

The patient sustains injuries to his neck and spine from a motorcycle accident. He is taken to a hospital. The hospital's physicians recommend treatment.

He is refused that treatment by the HMO. By the time the HMO finally gets around to getting an authorization, he is paralyzed.

Ms. GREENMAN. Well, let me ask. What confused me about that——

Mr. GANSKE. I want to just ask something, okay? Under ERISA today, that employer plan is liable for nothing other than the cost of his treatment denied, isn't that right?

Mr. DEMONTMOLLIN. No.

Ms. GREENMAN. No.

Mr. GANSKE. Well, you are liable for—yes, you may have ongoing medical expenses because he is now quadriplegic or paraplegic.

Ms. GREENMAN. Let me ask a fundamental question. If this person came in with a broken neck and spine, why did the hospital refuse to deliver care while they were waiting for prior authorization of payment?

Payment, this is about payment and not the delivery—there is a distinction between the payment and the provision of urgent care.

Mr. GANSKE. But the fact of the matter is that for most people, payment makes the determination; i.e., Mr. Plosicka, in Texas, whose HMO, NowCare, told him we are not going to pay for your hospitalization anymore, even though your physician says that you are suicidal and if you go home, and if the patient goes home, he may commit suicide.

NowCare said, hey, you can stay in the hospital if you want to, but we are not going to pay for it, and for most people that means they can't.

So they took him home and he drank half a gallon of antifreeze and he died.

And you know what? Under Texas law, that company is liable, and it should be. They are liable. And this is why we need the enforcement, because under Texas law——

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

Mr. GANSKE. Under Texas law, they were supposed to get an expedited review before they sent him home, and they just ignored it.

Mr. GREENWOOD. The gentleman from Arizona, Mr. Shadegg, is recognized for 5 minutes.

Mr. SHADEGG. Thank you, Mr. Chairman. I think the last discussion by my colleague, Mr. Ganske, whose passion on this issue I admire and respect, illustrates how sad the situation currently is.

The reality is we are allowing the debate over liability to create a situation that just happened, that he just showed you.

I have discussed with a number of people the prospect of passing separately the patient protection provisions of this bill and putting aside the liability issues.

The reality is, as Mr. Ganske knows, the patient protections provisions of his bill and of the last bill I dropped are virtually identical. They have been signed off by the patient advocacy groups and they would have prevented that incident.

They would not have given that family a lawsuit, but they would have prevented them from even needing a lawsuit, because under those patient protection provisions, the law would have said you may go to the first emergency room that is closest to you and you may get the care, and that is not an issue, you do not have to drive 75 miles.

And I guess one question I would put to Mr. Ganske and my colleagues on the other side of the aisle is if, at the end of this session of Congress, or, for that matter, tomorrow, we cannot resolve these liability issues, would they be willing to join me in passing the patient protection provisions, because those are critical.

I don't expect an answer here today.

Let me turn to the issue of exhaustion of administrative remedies and, again, put out some language.

Dr. Palmisano, again, I want to focus on this issue, because I think it is one of the critical ones. The question of exhaustion of administrative remedies really doesn't apply in the case that we just heard about, because there were, of course, no administrative remedies that could have been utilized under that circumstance.

But under either bill, any bill that is being considered here right now, save and except perhaps for the Senate bill from last year, this problem would have been solved, because the law would have said you get emergency are immediately.

But your testimony, which, again, I said I agreed with most of it, at page 18, says twice, "Patients must be required to utilize the appeals process," and then it goes beyond that and says "Patients, therefore, should have to exhaust all," and you use the word all, "administrative remedies before going to court."

I couldn't agree more with that language and that statement. I think it is critical. I think it is critical because of what we talked about before, and that is if you require all cases to go through administrative appeals, then you get a decision by a panel of doctors telling the plan what is the right care, what should be given under this circumstance.

By the way, in that circumstance that we just heard about, if you went through an external appeal after the incident—actually, under the law, there wouldn't have been any injury in that case if we had either bill now, but the panel of doctors could have said, yes, the care should have been delivered at the closest hospital.

On the other hand, that panel of doctors could have said, you know what, these injuries would have been sustained no matter what, they would have been sustained before you got even to the first hospital.

But I guess my question is in the language of the Kennedy-Edwards bill, there are two very large exceptions. One is called late manifestation of injury. That is to say, you wait until after the time that appeal, external appeal had to be filed, and then you file your lawsuit.

Now, that is a loophole that allows a trial lawyer to take 100 percent of all cases and say I am not going through an external appeal, I might lose an external appeal, I am just going to wait until the deadline passes and I am going to file my lawsuit.

So that exception consumes 100 percent of the rule.

The second exception is called immediate and irreparable harm, and you talk about this in your testimony.

At the middle of page 18, you say "If they suffer serious and irreparable harm or die, they should not be required to exhaust administrative appeals."

Of course, if they suffer it, but the exception here is all they have to do is—all the lawyer has to do is allege it. You see the word there and you have the language before you that says if the lawyer doesn't want to go through external appeal, if he wants to get straight into court and exact a settlement, he simply alleges immediate and irreparable harm.

My question of you is why, if you understand the importance of external appeal, allowing doctors to tell plans how to practice medicine and what care Americans ought to get, which doctors ought to do, they went to school to do that, why do you favor these two exceptions that will create complete loopholes to the administrative appeal process?

Mr. PALMISANO. The two exceptions, death and irreparable harm——

Mr. SHADEGG. It is not death and irreparable harm. It is irreparable——

Mr. PALMISANO. Death is one exception.

Mr. SHADEGG. That is one of them.

Mr. PALMISANO. Irreparable harm is the second exception.

Mr. SHADEGG. But the second one I asked you about is this one which simply says late manifestation of injury, which says, look, I don't want to go through external appeal because my lawyer told me not to, because I might lose, I am just going to wait until after the deadline is passed and go ahead and file my lawsuit.

That exception consumes 100 percent of the cases.

Mr. PALMISANO. Certainly the plan has the right under the bill, the plan has the right to institute the external appeal.

Mr. SHADEGG. Actually, that language has been taken out of this latest version.

Mr. PALMISANO. In the latest version, it has been taken out. Well, again, what we are saying, any refinements that need to be done, in regard to your other question, we are happy to look at any language you have, to work with you, but what we want to do is we do not want people—if someone dies, we don't want the family to have to say, well, we are going to wait until external review, we are going to go forward, and they can bring their experts and so on.

So in other words, would you deny someone, if, after external review, would you deny them the right to go to court?

Mr. SHADEGG. Actually, under the legislation I wrote, I would not. I would let them go to court even after external review, but I would give the external review panel a presumption, a rebuttable presumption in the court, because, quite frankly, I think we ought to let these decisions be driven by medical doctors' advice.

That is where I come down on this issue.

What I wouldn't do is what this legislation does, which creates two loopholes through which an aggressive trial lawyer, and I know good ones and I know bad ones, and the good ones would never pursue those loopholes, because they really care about the people they are representing and they would say go through external review, get the care.

But there are, sadly, in that profession, like there are probably in every profession, some people that work at the fringes and they will take those two loopholes that are in the current Edwards-Kennedy bill and they will file a lawsuit in 100 percent of the cases and their goal won't be care and their goal won't be a jury verdict, because they know they can't ever prove these points.

Their goal will be to extort money and they extort that money and drive up the cost of health care for reasons that have nothing to do with caring for patients.

Mr. GREENWOOD. The gentleman's time has expired. The Chair, sensing the eagerness of the gentleman to inquire again, erred and recognized him prematurely and to make up for that, I will recognize the gentleman from Texas for a second round, and then Mr. Buyer.

Mr. BUYER. I have not had a first round.

Mr. GREENWOOD. Mr. Buyer, would you be willing to let Mr. Green go, and then you will close?

Mr. BUYER. Fine.

Mr. GREENWOOD. Thank you.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. SHADEGG. Point of order. Mr. Chairman, is there going to be a chance for a third round after Mr. Buyer?

Mr. GREENWOOD. Perhaps informally, Mr. Shadegg. We will consult with the Democrats and see if that is a possibility.

Mr. GREEN. Thank you, Mr. Chairman, and I won't take any more than my 5 minutes.

I, again, appreciate my colleague from Arizona's line of questioning about certain trial lawyers would file lawsuits. That goes against the testimony you heard that it is organized in Texas and organizing trial lawyers anywhere is like herding cats, I think. None of them fit in there.

So I think you read a lot into the Texas trial bar that I haven't seen in my 25 years.

But let me ask a question of Ms. Rosenbaum. Ms. Rosenbaum, health plans and even employers today and we have heard it argued that they aren't making medical decisions, they are making coverage decisions, and they argue that they are not acting like doctors, but they are administering the plan.

It seems to me that that may be an artificial distinction that plans are using to try to shield themselves from liability.

In your testimony, you discussed how the traditional concept of coverage can no longer be separated from decisions about care itself in a managed care environment.

How can managed care blur the line between coverage and treatment or care?

Ms. ROSENBAUM. When an employer decides to offer a managed care product, and I use that phrase broadly, there are a lot of different kinds of managed care products, but what distinguishes a managed care product from a traditional or conventional insurance product is that if you look at the contract, which the center which I direct studies, we have studied the contracts for about a decade now, the distinguishing feature is that it is the sale of health care and, in fact, in the leading case, the leading managed care liability case, which was sort of the fundamental building block on which most managed care law is built today, a case called Boyd v. Albert Einstein, the court made it very clear this was not an ERISA case and it was a straight liability case.

And the court made very clear that the reason that an HMO, unlike a conventional insurer, can be liable for lapses in medical judgment is because it sells health care.

Now, it is very true that there are—and this is exactly what the Supreme Court was trying to drive at in Pegram.

There are certainly some cases that would still fall on what the court calls pure coverage side of the line. There is no medical judgment involved at all in deciding the issue.

But as a unanimous court pointed out, a lot of what an HMO does or managed care organization does, because it is a hybrid creature, because it is simply a modern version of a health care provider, from the law's point of view, it makes treatment decision and it allocates health care resources to its members based on those decisions.

If you look at the writings of people like Dr. David Eddy, who are leading writers on managed care, they understand that what an HMO does is it allocates the resources it has to make the best possible care choices it can for its patients.

Now, I know that the industry would very much like for footnote seven, I believe it is, to swallow up the entire main holding in the Pegram case.

There was a footnote, an aside by the court, saying, look, we are not passing on whether there are certain kinds of pure cases left

that fall outside of the reach of ERISA. We know there are cases that are still ERISA cases.

But it is simply contrary to the case to continue to deny that what the court did was to say that the old way we have of thinking about medical care is gone in managed care, because we are buying and selling medical care now and we are ensuring what we buy and sell.

And so that changes the whole way we approach these liability questions and that is why the court said there is simply no coverage issue left in these medical judgment cases. They are professional liability cases.

The court could have said, and it didn't, that our holding today only applies to the personal treating physician of the patient.

It didn't. It simply said that when physicians who work for HMOs make medical decisions, what they are doing is making decisions about treatment.

It is inevitably going to take a while for that kind of change and thinking to filter down.

But you saw the first real sign of this, actually, not in the Corporate Health Case, but in the LaZorko case, which came out of the third circuit a few months ago, in which a physician said to a woman, it was very much like the Texas case, "You can't have any more mental health treatment. I am not allowing you to have any more treatment," and she committed suicide, and the court said, citing Pegram, this is a medical judgment case. It doesn't belong in Federal court.

And that is why I think the only answer here is to send the cases back to State court and State law.

Mr. GREENWOOD. The gentleman's time has expired. The Chair thanks the gentleman from Indiana for his forbearance, and recognizes him for 5 minutes.

Mr. BUYER. Thank you. I read the testimony last night and I want to associate myself with the comment by the counsel from Honeywell, that the best protection for plan participants is a strong claims review process, not litigation and tort damages.

There are a lot of employers who self-insure and the last thing we want to do is grow a population in the uninsured.

There are many corporations in Indiana who self-insure, I am very concerned about them.

And I would like to yield the balance of my time to Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Buyer. Mr. deMontmollin, let me start. Have you had a chance to read the language of the Kennedy-Edwards bill?

Mr. DEMONTMOLLIN. Yes, I have.

Mr. SHADEGG. Would you agree that the exceptions that I have pointed out to exhaustion consume the rule?

Mr. DEMONTMOLLIN. There is no question about it.

Mr. SHADEGG. Would you agree with me that they consume it 200 percent of the time?

Mr. DEMONTMOLLIN. Yes. To that end, because I am the general counsel of a health plan and because I have done for—after I was an assistant U.S. Attorney, medical malpractice defense work for a long period of time, the problem with this kind of language is there is no question but that the thin liability case that heretofore would

not be filed will be filed in this scenario and there won't be an effort to get to the right decision from a medical standpoint, but rather it will go directly into court.

Mr. SHADEGG. Ms. Greenman, have you read the language of the Kennedy bill?

Ms. GREENMAN. Yes, I have.

Mr. SHADEGG. And would you agree that the exceptions consume the rule?

Ms. GREENMAN. I would. I would also suggest that, to Mr. Buyer's comment, that the likely result of employers exiting their role in self-insured plans would, because of these exceptions, swallow up the rule or the intended exclusion, would be to have—to revert to the kind of cookbook lists that we had 25 years ago, where there is a list of covered procedures, there is a list of fees that are reasonable and customary in a given location, and you eliminate the exercise of medical judgment or discretion in making coverage determinations.

Yes, there are gray areas. Yes, there are knotty problems that have to be worked through. But I think a formulaic approach, which will avoid liability and is the most likely result, is not the right answer for consumers or patients.

Mr. SHADEGG. Ms. Rosenbaum, I would like to ask you kind of a final question that I haven't addressed, which is the question of the state-Federal court split.

In his testimony, Dr. Palmisano says, "When a health plan intervenes in the medical decisionmaking process and imposes its medical judgment on the patient, the plan is engaging in the practice of medicine and should be held accountable under State law."

I absolutely agree with that in concept. I think when plans decide to become doctors, they ought to be held liable.

I don't necessarily agree with your reading of Pegram. There is a split going on here.

On the one hand, you had the Corporate Health Insurance case, which, in your testimony, you say really doesn't analyze this issue properly, and that might be a valid point.

Then you have the LaZorko case, which clearly has decided this issue in the third circuit and says, yes, these are state-based claims.

I want to ask you a question that is going to require you to stop and reflect for a moment.

The trial lawyers that I have talked to have said with regard to this emerging exception for so-called medical malpractice, which has been growing, but in LaZorko, dramatically following Pegram, one reading of Pegram.

Trial lawyers that I talked to, I went to and said, look, doesn't this solve the problem; can't we now bring these HMOs to the bar and get at them when they make medical decisions and harm people.

They have come back to me and said no. All of you make the point that this is the trend in the law and that we are going there, which raises the question whether we need a bill. But the trial lawyers I talk to say, "Look, Congressman, to prove a medical malpractice case, you have to bring in multiple expert witnesses. You have to establish that the plan engaged in the practice of medicine.

You have to establish that there is a standard of care. You have to establish that they breached that standard of care, and you have to establish that as a proximate result of that breach, there has been damage."

And they say, "Congressman, that is an incredibly complicated and very expensive lawsuit to bring."

And what they say is "I want a simple lawsuit for breach of the duty to provide the care, denial of a benefit. I want the same bad faith lawsuit. You promised to insure me. You didn't deliver the benefit. I am suing you for bad faith, hey." And they want that simple, straightforward breach of contract lawsuit, not this complicated medical malpractice lawsuit.

And the concern I have is if we allow this to sort itself out, at least until the Supreme Court says the fifth circuit is right or the third circuit is right, if we allow to sort this out and all cases have to be med mal cases, aren't we going to drive doctors—one of the problems in these med mal cases is that the insurance company, as soon as it has been sued, or the HMO, as soon as it has been sued for malpractice, it names as the defendant the doctor himself.

And my trial lawyers say now we have the doctor as a defendant in the case when we wanted the doctor as the patient's witness, the patient's expert in the case.

My question to you is have you thought that through and do you have the same concern I have of converting all these simple breach of contract cases into med mal cases, where only the very expenses ones will get compensated and the little ones won't?

Ms. ROSENBAUM. If I understand the question, you are asking whether in order to aid consumers at this point, it would not be better actual to hold on to the Federal tort potentially to the concept of a bad faith breach of contract or wrongful denial of contractual benefits.

Actually, I would say, from my reading of the bad faith breach of contract cases, that they are very difficult to prove, because you have to demonstrate that either the defendant acted with flagrant disregard for the terms of the contract or with actual knowledge of an intentional withholding of a covered benefit.

Mr. SHADEGG. To that point, all of the bills that we have been writing use the mere negligence standard. So you really don't have to establish bad faith.

Ms. ROSENBAUM. Even if you use a mere negligence standard, you are actually, I think, not that far removed from a medical tort. That is, you are going to have to demonstrate that somebody failed to use due care.

If you look at the leading case in the field, really, which is the Wickline case and you look at the standard that the court set for negligent utilization review, or the Bedrick case, which is one of the leading cases on medical necessity denials of coverage, you look at the proof that a lawyer had to mount to win the case for Ethan Bedrick and it was very similar.

Once you are into medical judgment you have got to demonstrate a standard, a duty, a breach, and with a—and, therefore, I don't know that framing the issue as a contractual issue, if the contract is for medical care, gets you out of the box you are in.

So the issue then is whether Congress, in the middle of this haziness, wants to try it is hand at a contractual medical care standard cause of action, and run the risk of yet sending the court's off in another direction as opposed to staying with where the Supreme Court set us off now a year ago, seeing where this plays out.

Mr. GREENWOOD. The gentleman's time has expired. The Chair recognizes the gentleman from Kentucky, Mr. Whitfield, for 5 minutes.

Mr. WHITFIELD. Thank you, Mr. Chairman. I'm sorry that I was late, and I was particularly interested in the liability issue, and because I don't know what questions have been asked, I am just going to ask a few simple questions and hope that you all bear with me.

Dr. Palmisano, I just want to make sure that I understand what the position is of the AMA at this point.

It is my understanding that if it is determined to be a medical decision under your proposal, the lawsuit would be in the State court.

If it is determined to be a non-medical decision or a fiduciary decision, then it would be in Federal court. And that you have listed three or four safe harbors that you feel like would provide protection for employers.

Is that basically correct?

Mr. PALMISANO. That is correct, sir.

Mr. WHITFIELD. Where are you all on putting a cap on punitive damages, non-economic damages, some of those issues?

Mr. PALMISANO. On page 19 of the testimony that we handed in, we are saying that an acceptable patient protection bill should, therefore, include meaningful and reasonable limits on punitive damage awards.

Mr. WHITFIELD. So you all are not supporting, at this point, any cap on non-economic damages.

Mr. PALMISANO. No, we are not. We are not. But you see, the reason I hesitate, if this becomes a State action, then it goes to the law of the State.

In Louisiana, for instance, there is a cap. In Louisiana, there are no punitive damages, except for a death caused by drunk driving or a toxic tort. In California, there is a cap of $250,000 on non-economic.

But it would go to the State, whatever the State law is on a limitation of damages.

Mr. WHITFIELD. But on the Federal claim, would you support a cap on punitive and non-economic?

Mr. PALMISANO. The American Medical Association supports a cap on punitive damages and we are open to discussions on any other damages. But we think it is absolutely critical that the insurance companies, the managed care companies also be in the same position as everyone else in the United States.

It has to be under the laws and subject to suits. And some of the discussion that you did miss about some of the problems that some of your colleagues, one of your colleagues has with this particular bill that is up on the podium right there, remember that the courts have the responsibility under Federal law and the Rule 11 and the States have similar laws.

If something doesn't have merit, it is a frivolous suit, then they can award punishment damages for that. Also, you have to have a reason to stay in court. So if somebody brings a completely frivolous case to court, you have to have an expert to sustain. Otherwise, you are going to be sent out on a summary judgment that you don't have an expert to support your view.

Mr. WHITFIELD. And who is it that is from George Washington University? I'm not sure I remember the name of the case, but the most recent Supreme Court decision, that began with a P.

Ms. ROSENBAUM. Pegram.

Mr. WHITFIELD. Pegram. Your understanding of the ruling of that case is what?

Ms. ROSENBAUM. My understanding of the Pegram case is that it is a clarification of what—Pegram does two things. One is make clear that managed care is a perfectly legal form of employee benefit to give, and the other is that it makes clear what is and is not an ERISA fiduciary decision.

It is the ERISA fiduciary decisions that fall within the remedies that ERISA gives. Those are the Federal cases. And what the court said basically is that when HMOs, through their physicians, make mixed decisions, those are not fiduciary decisions. Those are simple medical judgment decisions and they belong under State law.

Mr. WHITFIELD. Under that case, would it be possible for employers to make mixed decisions?

Ms. ROSENBAUM. Would it be impossible?

Mr. WHITFIELD. No. Would it be possible. Well, my understanding of the way most employer benefit plans work is that an employer generally doesn't hire its own physicians. There may be a few employers who literally run the equivalent of their own HMO. They literally have physicians on staff or under contract and they administer their own plans to a literal degree.

Most employers actually are in a position of, as Mr. Greenman pointed out, of reviewing the treatment decisions that were made by the HMO who either administers their plan or who gives them an insured plan.

Mr. WHITFIELD. Well, I spent a number of years with CSX Corporation, which is a railroad holding company, and it was not my responsibility to deal with managed are plans that were available, but I do know that the department responsible was on the phone a lot with the company that they had contracted to provide the coverage and there were decisions going back and forth and discussions and everything else.

So I am assuming that you would agree that if you wanted to protect employers as much as possible, not just because they are employers, but because you do not want to do anything that would encourage them to drop plans or to change plans and create more uninsured.

Ms. ROSENBAUM. Absolutely not.

Mr. WHITFIELD. You do agree that this area of trying to define specifically what is a medical decision and what is not is a difficult issue, I am assuming.

Ms. ROSENBAUM. Yes, although it is in this regard that I found Mr. Shadegg's proposal most interesting, because actually the effect of directed decisionmaking would be to draw quite a bright line be-

tween what is the ERISA fiduciary and what is, in fact, a medical decision that does not fall within the ambit or ERISA.

I think that that is a very important point that bears further analysis because it might, in fact, add the very thing that you would need to be able to recognize very quickly when a decision is a medical decision and when the decision is simply the decision that goes to the administration of the non-medical part of the employee benefit plan.

Mr. WHITFIELD. But you feel like that his proposal, which I didn't hear, is certainly worth exploring.

Ms. ROSENBAUM. Certainly worth exploring.

Mr. WHITFIELD. May I just ask one other question? Then I will close out.

On the safe harbor conditions that you all proposed at the AMA, were they significantly the same as what was in the Ganske-Dingell bill, as far as you know? The safe harbor.

Mr. PALMISANO. The answer is yes.

Mr. WHITFIELD. Thank you.

Mr. GREENWOOD. The gentleman's time has expired, as has this round of questioning. The committee thanks the witnesses for their testimony.

The Chair asks unanimous consent that members may insert additional remarks and extraneous materials into the record of the hearing.

The Chair intends to hold the record open for written questions to the witnesses and their responses for 30 days.

The hearing is adjourned.

[Whereupon, at 2:31 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

THE GEORGE WASHINGTON UNIVERSITY
MEDICAL CENTER
march 22, 2001

The Honorable JOHN B. SHADEGG
United States House of Representatives
432 Cannon House Office Building
Washington, D.C. 20515-0304

DEAR REPRESENTATIVE SHADEGG;

It was, as always, a pleasure to appear before you at last week's hearing. You asked me to respond to you in writing regarding your proposal to allow employers and other entities that maintain ERISA group benefit plans to enter into agreements with "directed decision-makers" for purposes of liability for injuries under health benefit plans.

Obviously it is difficult to answer you without more information, and I would need to study a written proposal closely in order to be able to give you a solid response. However, my immediate reaction is that I find the idea intriguing and worth pursuing. There may indeed be valid reasons where injuries arising from ERISA health benefit plans are concerned to permit the use of designated decision-makers.

I look forward to learning more about your proposal.

Sincerely,

SARA ROSENBAUM, J.D.
Harold and Jane Hirsh Professor of Health Law and Policy

cc: The Hon. John D. Dingell; The Hon. Mike Bilirakis, Chair, Subcommittee on Health; The Hon. Sherrod Brown; The Hon. Joe Barton; The Hon. Fred Upton; The Hon. James C. Greenwood; The Hon. Nathan Deal; The Hon. Richard Burr; The Hon. Ed Whitfield; The Hon. Greg Ganske; The Hon. Charlie Norwood; The Hon. Barbara Cubin; The Hon. Heather Wilson; The Hon. John Shadegg; The Hon. Charles W. Pickering; The Hon. Ed. Bryant; The Hon. Robert Ehrlich, Jr.; The Hon. Steve Buyer; The Hon. Joseph Pitts; The Hon. Henry A. Waxman; The Hon. Ted Strickland; The Hon. Tom Barrett; The Hon. Lois Capps; The Hon. Ralph Hall; The

Hon. Edolphus Towns; The Hon. Frank Pallone, Jr.; The Hon. Peter Deutsch; The Hon. Anna G. Eshoo; The Hon. Bart Stupak; The Hon. Eliot Engel; The Hon. Albert R. Wynn; The Hon. Gene Green

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THE GEORGE WASHINGTON UNIVERSITY
MEDICAL CENTER
March 22, 2001

The Honorable W. J. "BILLY" TAUZIN
Chairman
Committee on Energy and Commerce
United States House of Representatives
2183 Rayburn House Office Building
Washington, D.C. 20515-1803

DEAR MR. CHAIRMAN;

It was an honor to have been invited to testify before your Committee last week. This letter provides the analysis you requested regarding Footnote 9 in *Pegram v Herdrich,* 120 S. Ct. 2143, 2154.

Ever since *Pegram* was decided, the managed care industry has invested a great deal of energy touting Footnote 9 as an important limit on *Pegram's* reach. There are indeed rare instances in which a footnote in a Supreme Court decision rises to a level of importance that literally transcends the decision itself. Perhaps the most famous example of this is the Court's "discrete and insular minorities" footnote in *U.S. v Carolene Products Inc.* 304 U.S. 144, 154 (fn. 4) (1938). This footnote, which was remembered long after the decision, presaged much of the Court's later work in the area of civil rights law.

The *Pegram* footnote in question is hardly the type of note that students decades from now will be studying. Indeed, the very wording and placement of Footnote 9 in *Pegram* underscores the Court's view regarding the necessity under ERISA of separating claims that arise from the exercise of medical judgement by managed care physicians (not fiduciary acts) from those that arise from non-medical acts of plan administration (fiduciary acts).

In my written testimony before the Subcommittee, I presented a lengthy excerpt from the main text of *Pegram* itself. In the opinion itself, Footnote 9 essentially falls within this excerpt. The excerpt concerns the Court's separation of ERISA-governed fiduciary decisions from medical decisions that lie beyond the limits of ERISA. As the excerpted language underscores, the decision draws a distinction between "pure eligibility" decisions that fall into the area of non-medical plan administration from those decisions that are medical and relate to the medical operation of managed care. Only the former decisions, according to the Court, are subject to ERISA's exclusive remedies. There are other "mixed eligibility" decisions made by plan physicians during the course of treatment, that relate to the standard of care that a patient will receive from the managed care company. The Court was concerned that these medical decisions not be confused with "pure" decisions and classified as decisions subject to the reach of ERISA.

In attempting to illustrate which types of decisions fall where, the Court readily acknowledged (as I likewise did my testimony) that there certainly are limits to what can be classified as a "mixed eligibility" decision. This is all that Footnote 9 says and this is why the footnote is placed where it is, i.e., as a general caveat to the Court's concept of where ERISA's reach ends.

No one disputes that at some point a decision becomes "pure." The Court even supplies us with an example of a "pure" decision. *Pegram,* 120 S.Ct. at 2154 (whether in a case of appendicitis, where no medical facts or judgement is in play, a certain procedure is covered under the terms of the contract.) Furthermore, the placement of footnote 9 (squarely in the middle of the Court's discussion as to why the *Pegram* case in fact represents just such an example of a mixed decision) serves to make the "mixed eligibility" analysis stand out even more clearly.

I did indeed consider Footnote 9 carefully when I originally read the case and concluded as I have indicated that it simply states the obvious. In its wording and its placement, Footnote 9 seems to me to constitute no more than a restatement of the fact that when medical judgement, medical fact, and medical treatment are not on the line, ERISA remedies should apply.

I thank you for this opportunity to follow up. Please do not hesitate to contact me if I can be of further assistance.

Sincerely,

SARA ROSENBAUM, J.D.
Harold and Jane Hirsh Professor of Health Law and Policy

cc: The Hon. John D. Dingell; The Hon. Mike Bilirakis, Chair, SubCommittee on Health; The Hon. Sherrod Brown; The Hon. Joe Barton; The Hon. Fred Upton; The Hon. James C. Greenwood; The Hon. Nathan Deal; The Hon. Richard Burr; The Hon. Ed Whitfield; The Hon. Greg Ganske; The Hon. Charlie Norwood; The Hon. Barbara Cubin; The Hon. Heather Wilson; The Hon. John Shadegg; The Hon. Charles W. Pickering; The Hon. Ed. Bryant; The Hon. Robert Ehrlich, Jr.; The Hon. Steve Buyer; The Hon. Joseph Pitts; The Hon. Henry A. Waxman; The Hon. Ted Strickland; The Hon. Tom Barrett; The Hon. Lois Capps; The Hon. Ralph Hall; The Hon. Edolphus Towns; The Hon. Frank Pallone, Jr.; The Hon. Peter Deutsch; The Hon. Anna G. Eshoo; The Hon.Bart Stupak; The Hon. Eliot Engel; The Hon. Albert R. Wynn; The Hon. Gene Green

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AVMED HEALTH PLAN
GAINESVILLE, FLORIDA
April 9, 2001

The Honorable MICHAEL BILIRAKIS
Chairman, Subcommittee on Health
United States House of Representatives
2269 Rayburn House Office Building
Washington, DC 20515

DEAR CHAIRMAN BILIRAKIS: Thank you for the opportunity to testify before the Subcommittee on Health hearing on March 15, 2001 entitled, "A Smarter Health Care Partnership for American Families: Making Federal and State Roles in Managed Care Regulation and Liability Work for Accountable and Affordable Health Care Coverage." Per your request, I have attached the written responses to your follow-up questions from the hearing.

Again, thank you for the invitation to testify before the Subcommittee on Health and please do not hesitate to contact me should you need further information on these issues or any other health issue that may come before Congress.

Sincerely,

STEPHEN J. DEMONTMOLLIN
Vice President and General Counsel, AvMed Health Plan

Attachment

RESPONSES FOR THE RECORD

Question (1) All of the managed care bills involve more Federal government regulation. They may raise the cost of health care and will allow for more litigation. Many of the patient protections appear to be common-sense and the external appeals process, at least, seems to have good consensus as an alternative to litigation and consumer frustration. A weakening economy increases concerns over new government programs and increased costs. What could be the result if we do not have carefully-crafted legislation that minimizes these potential problems?

Legislation that increases costs and expands employer and health plan liability will produce serious and adverse consequences for working families. Cost increases generated by legislation will add to the number of uninsured workers. Based on well-documented historical patterns, it is evident that this loss of coverage will be concentrated among low income workers. (See R. Kronick and T. Gilmer, "Explaining the Decline in Health Insurance Coverage, 1979-1995," *Health Affairs,* March/April 1999)

In some instances, employers will be forced to stop offering coverage altogether, due to cost increases and/or the risk of multimillion dollar verdicts against them in connection with their activities administering the health benefits plans that they voluntarily offer. In other instances, employers will pass the cost increases through to employees in the form of higher premiums and cost-sharing or reduced benefits. Already, approximately 10 million Americans are offered employer-sponsored health coverage but decline it and are left uninsured. These are predominantly lower wage workers who find it difficult to pay their share of premiums; with expanded liability forcing employers to increase employees' share of premiums, many more workers and their family members will decline coverage offered to them and be left uninsured. (P. Cooper and B. S. Schone, "More Offers, Fewer Takers For Employment-Based Health Insurance: 1987 and 1996," *Health Affairs,* Nov/Dec 1997)

Notably, there would be no offsetting benefits to adopting policies that increase costs and expand liability. There is no evidence that expanded liability would in any way improve the quality of or access to care; to the contrary, physicians report that the current liability systems produces lower quality care and reduces access to care.

Question (2) There has been a lot of talk about how some of the current bills would really just codify existing court interpretations, such as that in the recent Supreme Court decision in *Pegram,* or existing state laws, such as those in Texas. Can you address how similar or dissimilar these proposals are to these existing laws?

Liability under current proposals—such as the Ganske-Dingell bill—is very different and much more expansive than liability under either the Texas law and the *Pegram* decision.

Texas liability does not apply to health plan coverage denials and only pertains to medical malpractice—where a physician was negligent in delivering medical services and the health plan is vicariously liable for this negligence. According to the 5th Circuit Court decision,

> [w]hen the liability provisions are read together, they impose liability for a limited universe of events. *The provisions do not encompass claims based on a managed care entity's denial of coverage for a medical service recommended by the treating physician: that dispute is one over coverage, specifically excluded by the Act. (emphasis added)* Rather, the Act would allow suit for claims that a treating physician was negligent in delivering medical services, and it imposes vicarious liability on managed care entities for that negligence.

Liability under *Pegram* pertains only to treating physicians and medical malpractice. Specifically, *Pegram* applies to situations where a treating physician makes a treatment decision that was both negligent and had implications for "eligibility."

Unlike liability under the Texas law and *Pegram,* the proposed expansion of liability under the Ganske-Dingell bill would allow state and federal law claims for a much broader scope of issues, including health plan coverage denials and virtually all administrative duties under the plan.

For further discussion on liability under *Pegram*, see *Pegram's Significance for Managed Health Care* by Louis Saccoccio, General Counsel for AAHP at Appendix I.

Question (3) Can you provide some of the most common reasons why health plan coverage decisions sometimes take longer than some of us think they should?

Nearly all coverage decisions are made quite rapidly. It is important to recognize that health plans are required to make decisions within timeframes specified by federal and state law.

One reason why some coverage decisions may take longer than expected is that plans are not always provided with all the information necessary from providers to make coverage decisions. A significant problem with the way the Ganske-Dingell bill is structured is it holds plans liable for delays that commonly are due to physicians not getting plans the information they need. There should be an affirmative obligation on physicians to give a plan the information necessary for the plan to make a coverage decision. This will protect patients by ensuring that plans have the information needed to make decisions as quickly as possible.

This is an issue that is not particular to commercial plans. The U.S. Department of Health and Human Services' Office of the Inspector General recently found that improper Medicare payments cost the government $13.5 billion in 1999. One of the top reasons for improper payment was due to providers submitting insufficient documentation or no documentation to support the services for which they were billing Medicare.

A second reason why coverage decisions may take longer than expected is that sometimes physicians and patients believe the patients' medical conditions warrant expedited decisions, yet the physicians do not request that decisions be made in accelerated timeframes. Virtually all of the state laws relating to appeals provide for accelerated timeframes in urgent circumstances, yet physicians do not always request that such decisions be made under the accelerated timeframes. There should be an obligation on the physicians to let the plans know when they believe coverage decisions should be made under the expedited timeframes. That will eliminate any potential for delay in coverage decisions.

Question (4) What do you believe the impact of expanded liability will have on quality of care?

Based on the experience with the current liability system that applies to physicians, it is clear that expanded health plan liability will diminish the quality of medical care. Physicians recognize that the current malpractice system does not improve quality of care. In a recent national survey of physicians, 78% of doctors say the threat of malpractice lawsuits does *not* make them deliver better quality care. (Ayres, McHenry & Associates, Inc., *National Survey of Physicians Regarding Liability Issues,* prepared for AAHP, Feb. 2001)

Additionally, it is widely agreed that malpractice liability inhibits error identification and improvements in patient safety and quality. Over half of physicians say that the current medical liability system makes physicians less willing to report

medical errors, according to the same national survey. In 1998, the AMA House of Delegates directed the AMA to oppose a reporting system which would have required notifying the Joint Commission on Accreditation of Health Care Organizations (JCAHO) of all unexpected occurrences that resulted, or could have resulted in a patient's death or serious injury. According to a headline in the AMA publication, American Medical News, on this issue, "[l]iability concerns override patient safety in house [of delegates] debate on new Joint Commission reporting requirements." Moreover, President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, referring to the current malpractice system, has said that "perhaps the most significant deterrent to the identification and reduction of errors [i.e., treatment-related injuries] is the threat of costly, adversarial malpractice litigation." It is also widely agreed that malpractice liability causes physicians to practice defensive medicine.

These negative influences on quality and patient safety would only be compounded by expanded liability for health plans. For instance, just as the current system encourages physicians to practice "defensive medicine," a system that expands health plan liability will force plans to conduct "defensive utilization management" and provide coverage for unnecessary services that do not benefit patients in order to avoid costly litigation.

Question (5) What do you think the impact will be of expanded liability on the cost of health insurance?

Again, looking to the experience with the current medical malpractice system, it is clear that expanded health plan liability will substantially add to health care costs. Nearly all doctors—95%—believe that the current medical liability system has raised costs, according to the national survey of physicians. Of these doctors, 73% said that the system substantially raises costs.

Additionally, analyses have found that the expansion of health plan liability will have a significant cost impact. The Barents Group has estimated that expanded liability will result in cost increases of between 2.7 and 8.6% nationally. State analyses reflect similar estimates. The state of Minnesota estimated that health plan liability would increase premiums by 5%. Most recently, in Arizona, health plan premiums are increasing 4-6% in response to a new law that expands health plan liability.

The Congressional Budget Office (CBO) estimated the cost of expanded health plan liability as part of S. 6, the Patients' Bill of Rights Act of 1999, legislation introduced and considered in the 106th Congress. However, CBO's cost estimate appears to consider only a narrow portion of the liability expansion—coverage denials—contemplated by the Ganske-Dingell bill. This bill creates liability in situations that extend far beyond coverage denials. For example, the bill creates a basis for liability caused by an alleged delay in approving coverage, even when the plan decision is made within specified deadlines. The Ganske-Dingell proposal also creates liability for failure to perform any other duty under the plan, which encompasses any alleged violation of the bill's scores of new provisions and alleged violations of previously enacted statutes, such as COBRA and HIPAA.

Question (6) According to a recently issued report by HCFA (March 12, 2001), the US spent more than $1.2 trillion dollars on health care in 1999, 5.6% more than in 1998. In this environment, we need to carefully evaluate enacting legislation that will further add to this burden and drive up costs. What concerns do you have with respect to additional liability provisions and health care costs?

See answers to questions 1 and 5 above.

Question (7) Today, when consumers have problems with their health plans, they may call either their state or the Federal Department of Labor. Various legislative proposals in Congress have attempted to craft changes to this structure which would subject certain health plans to dual federal and state regulation. This arrangement would not only seem to add to the cost of coverage, but create confusion for patients about who to call for help when necessary. Is this a fair assumption?

Dual regulation will cause confusion for consumers, health plans and regulators. Some legislative proposals would simultaneously apply differing federal and state standards to health plans. Given the extraordinary breadth, complexity and detail of the federal proposals and the layering of these proposals on top of a large body of state statutes and regulation, it often will be difficult to tell which standard applies to a given set of circumstances. This confusion will apply to consumers seeking help, regulators implementing standards and health plans working to adhere to those standards. Moreover, health plans required to adhere to differing standards covering the same subject matter will be forced to increase resources devoted to administrative costs and will find it difficult to adopt consistent policies. For instance, some proposals now being considered appear to permit both federal and state exter-

nal reviews of the same claim. Plans receiving differing decisions from each review will find it impossible to adopt consistent coverage policies.

Question (8) Have lawsuits been a successful tool in achieving health care quality for consumers?

No. As noted in the answer to question #4, lawsuits have not been a successful tool in achieving health care quality for consumers in the medical malpractice context. In addition to recognizing that the current malpractice system does not improve quality of care, numerous interested parties—including physicians—have noted that the current malpractice liability system discourages the identification and reporting of mistakes, allowing quality problems to perpetuate. For example, last year, the AMA testified that "the very fear of existing legal liability or its misapplication are the greatest hurdles to pioneering patient safety efforts . . . If the fear of litigation continues to pervade efforts to improve patient safety and quality, our transformation into a culture of safety on behalf of our patients may never be fully realized."

As noted before, according to a recent national study, 92% of physicians think the threat of a liability suit has increased defensive medicine. Expanding health plan liability will only lead to reduced quality of care by promoting "defensive utilization management" by health plans in an effort to avoid lawsuits.

Question (9) What other mechanisms are available that serves to measure health plan quality?

Currently, there are numerous mechanisms which serve to measure health plan quality, including state and federal quality assurance requirements, accreditation, and quality measure reporting, such as HEDIS reporting.

State laws: States generally require an HMO to file a description of its internal quality assurance (QA) program and activities before obtaining a state license. Regulators review the description and, during site reviews, interview staff and check records to assure that the description is accurate. Some states, such as Pennsylvania, Iowa, and Kansas, even require HMOs to obtain periodic accreditation by an independent external accrediting body.

Under the NAIC HMO Model Act, which has served as the basis for many state laws, HMOs are required to establish procedures to assure that services meet reasonable standards of quality of care consistent with prevailing professionally recognized standards of medical practice. These procedures must include an internal program to monitor and evaluate the quality of care provided. At a minimum, this program must include a written statement of goals and objectives, a written quality assurance plan specifying who within the HMO is responsible for implementing the plan, systems for ongoing and focused evaluations, a system for credentialing and peer review of providers, and processes to initiate corrective action when deficiencies are identified. In addition, HMOs are required to record formal QA activities, develop an adequate patient record system, make clinical records available to determine compliance with QA standards, and report QA program activities to the HMO's board, providers, and staff periodically.

Reflecting growing state interest in quality-related issues, the NAIC also has adopted three new model acts dealing in greater specificity with standards for quality assurance, utilization review, and credentialing activities for all types of health plans.

Federal HMO Act: "Federally qualified" HMOs are required to have an ongoing QA program that: stresses health outcomes to the extent consistent with the state of the art; provides review by physicians and other health professionals of the process followed in the provision of services; uses systematic data collection to evaluate performance and patient outcomes, provides interpretations of these data to participating providers, and institutes needed changes; and includes written procedures for taking corrective action whenever the QA program determines that care has not been provided when it should have been or that care that is unnecessary or does not meet quality standards has been provided.

Other Standards: Plans that participate in Medicare, Medicaid, and FEHBP must also comply with additional standards relating to quality assurance.

Accreditation and HEDIS reporting: Accreditation is an evaluative process in which a healthcare organization undergoes an examination of its operating procedures to determine whether the procedures meet designated criteria as defined by the accrediting body, and to ensure that the organization meets a specified level of quality. Given that employers and other purchasers are using this data to determine whether plans meet certain standards of care quality, health plans are increasingly being accredited by bodies such as the National Committee for Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations and the American Accreditation HealthCare Commission/URAC.

Similarly, plans are increasingly participating in the Health Plan Employer Data and Information Set (HEDIS)—a performance-measurement tool designed to help healthcare purchasers and consumers compare the quality offered by different managed care organizations—since many public and private healthcare purchasers now require HEDIS reporting. Beginning in 1999, HEDIS reporting was also integrated into the accreditation process by NCQA.

To better comprehend how health plans promote health care quality through accreditation and/or compliance with applicable laws, see the chart attached at Appendix II, "Summary of Health Plan Quality Oversight Reporting Requirements."

Question (10) The standards of conduct for processing claims for coverage for employee benefits plans are under Federal law. There are Federal remedies for breaches of such conduct. There are federal processes for appeals and we are talking about expanding the federal requirements. All of ERISA case law for the past 25 years is in federal court. All of the regulations are set out by the Department of Labor. Why should we now have 50 state courts create new and inconsistent standards of conduct for the processing of claims for benefits? What experience do state courts have in interpreting ERISA and do we want 50 different interpretations of what are now federal standards of conduct?

State courts have very little experience in interpreting ERISA. Virtually all ERISA actions are required to be brought in Federal court. The sole exception is an action under 502(a)(1)(B) to recover benefits or enforce rights under the terms of the plan. There is concurrent Federal and state jurisdiction for this type of action. Nevertheless, a state court must always apply Federal ERISA law when deciding this type of case. Additionally, only ERISA remedies are available. As a result, even in the rare circumstance where an action is brought in state court, the Federal law is applied.

Under the Ganske-Dingell bill, benefit decisions involving medical necessity are carved out of federal law and allowed to be the subject of lawsuits in state court *under state law*. Therefore, this is a significant departure from current ERISA practice. For the first time, state law and state causes of action with state remedies would be applicable to ERISA benefit decisions. Therefore, what may be a basis for liability in one state may not be a basis for liability in a second state. ERISA plans would be subject to having to comply with 50 different state concepts of what is or is not an acceptable benefit determination, including what remedies may apply.

Additionally, utilization management often involves the use of guidelines or criteria developed through national panels, national societies, the Agency for Health Care Research and Quality, etc. These guidelines are evidence-based and promote an alignment between evidence and practice as recommended in a recent Institute of Medicine (IoM) report. (IoM, *Crossing the Quality Chasm,* March 2001) Having 50 different state standards would interfere with meeting the challenge recently posed by the IoM and closing the gap between scientific evidence and how medicine is actually practiced.

Question (11) Under the bifurcated Federal-State liability approach in H.R. 526, what is there to prevent a plaintiff from suing simultaneously in state and federal court on the same denial—alleging failures in both the medical and non-medical areas? Why would a plaintiff's attorney ever not sue in both venues simultaneously?

The Ganske-Dingell bill creates a bifurcated process, which includes no barrier to allowing patients to file suits in both state and federal court based on the same set of facts and circumstances. For example:

- An individual could file a claim in state court for a claims denial based on medical necessity. He/she could also bring suit in federal court for the same harm based on a plan's alleged failure to disclose its utilization review procedures.
- An individual could file a claim in federal court based on a decision concerning a contract exclusion for cosmetic procedures. He/she could also bring suit in state court for the same harm for a claims denial based on the allegation that the decision required an evaluation of medical facts and thus is a medically reviewable decision eligible for state court.
- An individual could file a claim in state court for a claims denial alleging failure to cover a medically necessary prescription drug. He/she could also file a claim in federal court for the same harm alleging (1) improper application of cost-sharing under a tiered formulary or (2) failure to perform a duty under the terms of the plan when making a formulary exception decision under Section 118 of the Ganske-Dingell bill.

As a result, it is entirely possible that plaintiffs' attorneys will file suits in both venues. In many cases, trial lawyers would more actively pursue the forum which allows them to circumvent lower limits on damages by having a case tried in the court with higher limits (forum shopping). For example, trial lawyers could pursue the suit in state court, rather than federal court, because the $5 million punitive

damages (civil assessment) cap contained in the Ganske proposal would only apply in federal suits. Alternatively, trial lawyers could pursue whatever forum had a more favorable judge or had more favorable demographics for selecting potential jurors. In the alternative, trial lawyers could pursue the suit in federal court, rather than state court, if a state has enacted strong tort reform.

Question (12) Since employers voluntarily provide health care benefits, do you agree that if we increase the uncertainty from the threat of litigation or the cost of providing coverage that some employers will stop providing coverage?

Yes. According to a recent poll conducted by Harris Interactive, if the cost of health insurance increased by an average of about four percent, seventy-six percent of employers say their companies would "pass most of the costs through to their employees with either reduced benefits or increased premiums." Under this same scenario, the poll reported that a "sizable number of employers say they would reduce the number of retirees covered (45%), the number of dependents covered (17%) and the number of employed covered (17%)." (Harris Interactive, "Unintended Consequences: How the "Patients Bill of Rights' Could Greatly Increase the 44 Million Without Health Insurance," February 16, 2000)

Moreover, the Lewin Group LLC has estimated that every 1% real increase in premiums would result in an additional 300,000 uninsured Americans. This relationship disproportionately affects low-income workers. A recent study found that low-income workers are disproportionately affected by increases in health care spending. (Kronick and Gilmer, "Explaining the Decline in Health Insurance Coverage, 1979-1995," *Health Affairs,* Vol. 18, March/April 1999)

Question (13) The White House principles state that after an independent review decision is rendered, patients should be allowed to hold their health plans liable in federal court if they have been wrongly denied needed medical care.

I want to ask questions about what it means to be denied medical care, because it seems to me all a plan can do is deny coverage. I want to know what is broken and what is not broken in terms of remedies for wrongful denial of claims for coverage.

First, if coverage is agreed to but a doctor provides poor quality care or is alleged to have committed malpractice that is addressed by state common law. In other words, the ERISA preemption applies to the denial of coverage not to malfeasance in the performance of a medical service. Do you agree on this point?

Yes. Under the bill, ERISA preemption does not affect physician medical malpractice. Physician medical malpractice would continue to be addressed by state law in state court.

Question (14) Second, if the patient does get the care but the issue is later reimbursement of the cost of care, current Federal law has a full remedy for that under ERISA. If the patient got the care there is no harm to the patient due to a coverage decision—only the need to get reimbursed. Is this correct?

This is correct—retrospective denials do not implicate patient care, and thus, there would be no harm to the patient due to a coverage decision. In such situations, there is a remedy under ERISA available in which the patient can recover the benefits due under the plan. The Ganske-Dingell bill, however, would expose health plans to expanded liability even for retrospective denials where the patient has already received the care and the only dispute is over payment.

Question (15) Third, if a plan follows the rules on expedited appeals and fully complies with whatever decision the external appeals board has made—they have done everything right in terms of the independent entity—why should they be subject to further action for damages in court?

External review is an alternative to expanded liability; there is no rationale for adding expanded liability to external review. Unfortunately, the Ganske-Dingell bill permits health plans to be sued for uncapped damages when they follow the bill's rules relating to appeals and comply with the external review decision. In fact, the Ganske-Dingell bill permits health plans to be sued even if the plan decision is *upheld* by independent medical review. Additionally, it permits lawsuits in federal court against plans even if a plan approved rather than denied coverage and acted within the bill's timeframes for making coverage decisions, if the plaintiff alleges the decision should have been made more rapidly. Thus, under this bill, health plans can be sued even if they follow the rules and make correct coverage decisions. It is difficult to fathom what purposes such lawsuits serve.

Question (16) If the plan makes a final decision denying a claim and follows all the time lines in the law and the new law requires an expedited external appeals process where there is an emergency, why should the plan be liable for what may or may not be an erroneously denied claim?

Nearly all states have emergency care rules which prohibit prior authorizations in emergency situations. As a result, the alleged claims denials referred to in the

question will only arise in non-emergency situations. For such non-emergency situations, an expedited external appeals process is available and can get consumers coverage on an expedited basis when warranted.

As stated in the previous answer, there is no basis for adding expanded liability when an external appeals process—which can be conducted on an expedited basis when necessary—is available. This appeals process ensures that coverage disputes are resolved upfront and consumers get the care they need when they need it. With an independent review, coverage disputes regarding medical necessity and appropriateness are resolved by independent doctors with appropriate clinical experience. Plans should have the opportunity to address coverage disputes through external appeals before harm occurs, rather than having to pay for damages that could easily have been avoided through such appeals.

Question (17) Please address this fact pattern. A plan makes an initial denial of claim because the patient or the doctor has not provided enough information for coverage to be granted. Later during the appeals process the patient or doctor does provide the information and coverage is awarded. As a result, there was a week delay in the doctor performing a treatment. Should the plan be held liable where the right information was not provided to them by the patient or doctor?

No. As noted in the answer to question #3, a significant problem with the way the Ganske-Dingell bill is structured is that it holds plans liable for delays that are due to providers and patients not providing plans with the information they need to make coverage decisions. An affirmative obligation on the part of physicians to give the plan the information necessary for the plan to make a coverage decision will protect patients by ensuring that plans have the information needed to make decisions as quickly as possible.

Question (18) A plan makes an initial denial of coverage on an item. The patient does not pursue any appeals but later it is clear that the item should have been covered and would have helped the patient. Should the plan be liable where the patient did not even seek an appeal?

First, plans have an obligation to notify their members when they have the right to file an appeal and how to file an appeal. Plans should not be held liable when the patient has not appealed a coverage decision. The patient, in consultation with his or her physician—not the health plan—is in the best position to know if there is a need to file an appeal. Effective appeals systems—both internal and external—are an opportunity to avoid harm. Plan can not be held liable for harm alleged to result from a coverage denial where no appeal was filed.

Similarly, as noted in the answer to question #3, a health plan should not be held liable for delays when physicians and patients believe their medical conditions warrants and expedited decision, yet there is no request that a decision be made in an accelerated timeframe.

AVMED HEALTH PLAN
GAINESVILLE, FLORIDA
April 9, 2001

The Honorable W.J. TAUZIN
Chairman, Energy and Commerce Committee
United States House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

DEAR CHAIRMAN TAUZIN: Thank you for the opportunity to testify before the Subcommittee on Health hearing on March 15, 2001 entitled, "A Smarter Health Care Partnership for American Families: Making Federal and State Roles in Managed Care Regulation and Liability Work for Accountable and Affordable Health Care Coverage." Per your request, enclosed is a written response to your question posed at the hearing.

To paraphrase your question: The court in *Pegram* specifically noted, in footnote 9, that ERISA makes separate provisions for suits to receive particular benefits and that the court would not discuss the interaction of such claim with state law causes of action. How does liability under *Pegram* relate to liability under the Ganske-Dingell proposal? Doesn't the Ganske-Dingell bill deal with specific benefits? Can you address the language in this footnote?

Answer: Liability under current proposals—such as the Ganske-Dingell bill—is very different and much more expansive than liability under the *Pegram* decision. Liability under *Pegram* pertains only to treating physicians and medical malpractice. Unlike liability under *Pegram,* the proposed expansion of liability under the Ganske-Dingell bill would allow state and federal law claims for a much broader

scope of issues, including health plan coverage denials and virtually all administrative duties under the plan.

Footnote 9 in the *Pegram* opinion further emphasizes the point that the Court's decision is not directed at coverage decisions made by health plans, even if the decision involves an evaluation of medical necessity (like the emergency care example addressed by the footnote). Instead, *Pegram* deals with the treatment decisions of treating physicians that have implications for eligibility. In *Pegram,* the physician's failure to correctly diagnosis an urgent care situation (appendicitis) meant that the plan would not cover urgent care. A correct diagnosis by the physician would have resulted in coverage for urgent care. The Court decided that these treatment decisions made by a patient's doctor should not be turned into ERISA fiduciary decisions. In contrast, coverage decisions made by the plan fall within the purview of ERISA plan administration.

To further supplement my answer, I have enclosed a paper prepared at the request of the *Yale Journal on Health Policy, Law and Ethics,* by Louis Saccoccio, General Counsel at the American Association of Health Plans, entitled: "*Pegram's* Significance for Managed Health Care."

Again, thank you for the invitation to testify before the Subcommittee on Health and please do not hesitate to contact me should you need further information on this issue or any other health issue that may come before Congress.

Sincerely,

STEPHEN J. DEMONTMOLLIN
Vice President and General Counsel, AvMed Health Plan

Attachment

PEGRAM'S SIGNIFICANCE FOR MANAGED HEALTH CARE

By Louis Saccoccio

On June 12, 2000, in an unanimous opinion written by Justice Souter, the U.S. Supreme Court, reversing a decision of the U.S. Court of Appeals for the Seventh Circuit, held in *Pegram v. Herdrich*[1] that "mixed eligibility" decisions made by HMO physicians are not fiduciary decisions under the ("ERISA")[2]. In so ruling, the Court upheld the concept that the reasonable sharing of financial risk with HMO[3] network physicians for providing health care to a given patient population does not run afoul of ERISA's fiduciary requirements. This result is a significant victory for managed health care plans, their network physicians, and their members.

Although the decision's impact on the viability of physician risk sharing is clearly positive, the decision's impact on the question of HMO liability under ERISA remains less clear. Some, including the U.S. Department of Labor, argue that this case represents a shift in ERISA preemption law. They argue that *Pegram* would now preclude ERISA preemption of state law causes of action aimed at HMO coverage determinations that involve questions of medical necessity or experimental or investigational treatments. A more reasonable reading of the case consistent with its facts, however, leads to the conclusion that *Pegram* represents nothing more than a common sense answer to a simple question. What law should apply when a treating physician makes a treatment decision that may arguably raise issues of eligibility for coverage? *Pegram's* answer does not represent a shift in the law regarding ERISA preemption of HMO coverage decisions.

The importance of *Pegram* does not end, however, with its resolution of the question of the scope of ERISA's fiduciary requirements in the realm of a physician's practice of medicine. The greater impact of the *Pegram* decision may lie in its language addressing the proper role of the courts in addressing the social and policy questions that arise from managed health care. In this regard, the Court in *Pegram* unambiguously stated that the debate about managed care belongs not in the courts, but in the legislature. This clear message already is having an impact in class action litigation filed against health plans where broad allegations under ERISA and the Racketeer Influenced and Corrupt Organizations Act (RICO)[4] seek to challenge (some would say destroy) managed health care practices.

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[1] 530 U.S. 211, 120 S.Ct. 2143 (2000).

[2] 29 U.S.C. § 1001 *et seq.* (1994).

[3] Although the form of managed health care plan in *Pegram* was a health maintenance organization, or HMO, the analysis in this paper equally applies to other managed health care plans to the extent they share the financial risk for the delivery of health care services with their network providers.

[4] The Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961-1968 (1994).

Pegram Background

Mrs. Herdrich originally brought medical negligence claims against Dr. Pegram, and state law fraud claims against Carle, and the HMO owned by Carle in Illinois state court.[5] The medical negligence counts went to trial in state court resulting in a $35,000 verdict for Herdrich. Additionally, the defendants removed the state fraud claims to federal court alleging they were preempted by ERISA. The federal district court dismissed the state fraud claims, but allowed Herdrich to amend her claims to state a claim under ERISA. Herdrich then amended her claim alleging a breach of ERISA fiduciary duty on the part of the defendants. The claim was premised on the fact that the physician/owners of the HMO potentially were entitled to year-end bonuses based on the difference between the cost of providing medical care and HMO revenues. Herdrich argued that this created an improper incentive to limit treatment. The federal district court subsequently granted defendants' motion to dismiss the amended ERISA claim for a failure to state a proper claim, and Herdrich appealed.

The U.S. Court of Appeals for the Seventh Circuit reversed the decision, finding that Herdrich had alleged sufficient facts to make out a claim for breach of fiduciary duty under ERISA.[6]

Pegram, Medical Malpractice, and ERISA Preemption

The issue before the Court in *Pegram* was the application of ERISA's fiduciary duty principles to HMO treating physicians who make "mixed eligibility decisions".[7] The Court had no occasion to address the issue of whether HMO coverage decisions involving medical necessity issues fall outside the scope of ERISA's preemption of state law. Nevertheless, the issues are closely enough related to pose the question of whether *Pegram* has brought a shift in the law that narrows the application of ERISA preemption with respect to HMO coverage decisions involving medical necessity.

Any application of the *Pegram* decision to the question of ERISA preemption of state law for liability arising from HMO coverage determinations must be made in light of the facts before the Court. The heart of the case before the Supreme Court was simply a treating physician's misdiagnosis of appendicitis. As a result, Herdrich was able to convince an Illinois state court jury that Dr. Pegram failed to properly and timely diagnose her condition, and was awarded $35,000 in damages for her injuries. However, because it was alleged that Dr. Pegram's year-end compensation in part was based on the financial health of the HMO, Herdrich argued that Dr. Pegram's misdiagnosis, coupled with her ostensible interest in the financial health of the HMO, raised the issue of breach of fiduciary duty under ERISA.

The Court rejected Herdrich's claim that the HMO, acting through its physician owners, breached its duty to act solely in the interest of beneficiaries by making decisions affecting medical treatment while allegedly being influenced by the terms of the HMO physician compensation structure. In doing so, the Court expressed doubt that Congress intended physicians to be treated as ERISA fiduciaries to the extent that they make mixed eligibility decisions during the course of treating their patients.[8]

The Court correctly recognized that when examining the question of whether a treating physician acted for good medical cause as opposed to his or her own financial interest, the answer to that question "would require reference to standards of reasonable and customary medical practice in like circumstances."[9] But, the Court pointed out, this is the very standard used in medical malpractice cases: "[F]or all practical purposes, every claim of fiduciary breach by an HMO physician making a mixed decision would boil down to a malpractice claim, and the fiduciary standard would be nothing but the malpractice standard traditionally applied to physicians."[10] As a result, the Court saw no reason to turn traditional medical malpractice cases into ERISA fiduciary cases simply because the treating physician assumed some of the financial risk for the treatment of the patient.

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[5] For a summary of the procedural background of *Pegram* in the lower courts, see *Herdrich v. Pegram,* 154 F.3d 362, 365-367 (7th Cir. 1998).

[6] *Herdrich v. Pegram,* 154 F.3d 362 (7th Cir. 1998).

[7] The term "mixed eligibility decision" is one created by the Court. It arises from the Court's view that Dr. Pegram's treatment decision that Herdrich's condition did not warrant immediate attention resulted in the HMO's not covering immediate care, while it would have done so had Dr. Pegram made the proper diagnosis and judgment to treat. 120 S.Ct. at 2154. The Court's use of the term "eligibility" appears to be interchangeable with the concept of coverage.

[8] 120 S.CT at 2158.

[9] 120 S.Ct at 2157.

[10] *Id.*

Thus, *Pegram* is a case about treating physicians, medical malpractice, and the ERISA fiduciary implications of malpractice in light of physician risk sharing. The Court rightly recognized that it would be folly to convert run of the mill malpractice actions involving treating physicians that take place within the HMO context into ERISA fiduciary actions. However, this conclusion is a far cry from the position taken by some in the trial bar and by the Department of Labor (see below) that *Pegram* stands for the proposition that HMO coverage decisions involving questions of medical necessity are now subject to state tort actions.

The Department of Labor Interprets Pegram

In September, 2000, the Department of Labor ("DoL") filed an *amicus curiae* brief before the Supreme Court of Pennsylvania in *Pappas v. Asbel.*[11] This case is again before the Pennsylvania Supreme Court after the United States Supreme Court, on June 19, 2000, vacated the Pennsylvania court's earlier decision and remanded the case for reconsideration in light of *Pegram.*[12] The DoL's brief in *Pappas* sets out its interpretation of how it believes *Pegram* narrows ERISA preemption of state tort claims for negligence. As discussed below, the DoL interpretation ranges far beyond the holding in *Pegram.*

The issue before the Pennsylvania Supreme Court in its initial decision in *Pappas* was whether state law negligence claims against an HMO, U.S. Healthcare, were preempted by ERISA.[13] The claim arose from an alleged delay in the HMO's authorization to transfer the plaintiff to a hospital capable of treating his condition. The Pennsylvania Supreme Court held in this initial decision that negligence claims against an HMO do not "relate to" an ERISA plan, and are therefore not preempted.[14]

Interestingly, DoL previously had filed an *amicus curiae* brief with the U.S. Supreme Court supporting U.S. Healthcare's petition for *certiorari* in *Pappas.*[15] In that earlier brief, DoL argued that the Supreme Court of Pennsylvania's decision was overbroad and incorrect. DoL stated that ERISA's fiduciary standards preempt state law because an HMO's coverage decision is considered an act of plan administration even when medical judgment about how to treat a patient is involved.[16]

In the brief filed before the Supreme Court of Pennsylvania in *Pappas* on remand from the U.S. Supreme Court, DoL now argues that the case should be remanded to the Court of Common Pleas to decide whether U.S. Healthcare made a "mixed eligibility decision".[17] DoL claims that "*Pegram* holds that treatment decisions and mixed treatment and eligibility decisions by physician employees of an HMO are governed by state malpractice standards and not by ERISA fiduciary standards."[18] According to DoL, if the Court of Common Pleas finds that U.S. Healthcare made a "mixed eligibility decision", as the U.S. Supreme Court in *Pegram* used that term, then there is no preemption and the state law claims may proceed against U.S. Healthcare.[19]

DoL's interpretation of *Pegram* as set out in its recent *amicus* brief attempts to expand the holding of the case far beyond what the plain language of the decision supports. It extends the concept of mixed eligibility decisions beyond the HMO treating physician addressed in *Pegram* to the HMO itself with no support or basis.

The foundation for the *Pegram* decision was a clear reluctance by the Court to expand the concept of ERISA fiduciary principles to physicians treating patients with its resulting interference with traditional state medical malpractice law. In contrast, HMO coverage decisions within the context of ERISA employee benefit plans, even when involving medical necessity, have traditionally been recognized as

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[11] The *amicus curiae* brief was filed in the Supreme Court of Pennsylvania No. 00098 E.D. Appeal Docket 1996, *Pappas v. Asbel.* Copies of DoL briefs are available on DoL's website at www.dol.gov.

[12] *United States Healthcare Systems of PA, Inc. v. Pennsylvania Hospital Insurance Co.,* 120 S.Ct. 2686 (2000).

[13] *Pappas v. Asbel,* 555 Pa. 342, 344; 724 A.2d 889, 890 (1998).

[14] 555 Pa. At 351-52; 724 A.2d at 893-94.

[15] The DoL brief in the U.S. Supreme Court was filed in December 1999 in docket No. 98-1836, *United States Healthcare Systems of PA, Inc. v. Pennsylvania Hospital Insurance Co.*

[16] DoL *amicus curiae* brief before the U.S. Supreme Court at 6-10, docket No. 98-1836, *United States Healthcare Systems of PA, Inc. v. Pennsylvania Hospital Insurance Co.*

[17] DoL *amicus curiae* brief before the Supreme Court of Pennsylvania at 17, No. 00098 E.D. Appeal Docket 1996, *Pappas v. Asbel.*

[18] *Id.* at 10-11.

[19] *Id.* at 11-12.

benefit determinations within the purview of ERISA preemption.[20] Contrary to the position taken by the DoL, *Pegram,* dealing as it does with the decisions of treating physicians, does little to change the landscape of ERISA preemption for HMO coverage decisions.

Pegram and the Role of the Federal Courts in Health Care Policy

Maybe more significant than the holding of *Pegram* is Justice Souter's discussion of managed care and the respective roles of the federal judiciary and Congress when it comes to addressing the debate over managed care. After all, the holding that mixed eligibility decisions made by HMO treating physicians should be left to state medical malpractice law does little more than confirm what is probably already common practice. As a direct example, Herdrich proceeded with and won a judgment in a state malpractice action in her case. However, with the filing in the last eighteen months of multiple class action lawsuits against several large health plans alleging general violations of ERISA and RICO,[21] *Pegram* gives the lower federal courts clear direction as to how they should go about dealing with these cases and their attempts to set health care policy through litigation.

The Court recognized that for over 27 years, Congress has promoted the formation of HMO practices, and stated that "[i]f Congress wishes to restrict its approval of HMO practice to certain preferred forms, is may choose to do so. But the Federal Judiciary would be acting contrary to the congressional policy of allowing HMO if it were to entertain an ERISA fiduciary claim portending wholesale attacks on existing HMOs solely because of their structure, untethered to claims of concrete harm."[22]

Maio—Pegram's Message on Class Actions

The impact of this message already has been felt in a recent decision that should directly influence the outcome in the numerous class action lawsuits mentioned above. The case, *Maio v. Aetna,* was decided by the U.S. Court of Appeals for the Third Circuit on August 11, 2000.[23] It affirmed the dismissal of a class action lawsuit filed against Aetna and its regional subsidiaries that was based on alleged violations of RICO. Significantly, the Third Circuit relied in part upon the Supreme Court's analysis in *Pegram* when finding that plaintiffs failed to state a claim under RICO.

In its opinion, the Third Circuit examined the plaintiffs' damage theory in light of *Pegram.* The court indicated that absent specific allegations by plaintiffs that the quality or quantity of their benefits under the health plans had been diminished, the "only theoretical basis for appellants' claim that they received an 'inferior health care product' is their subjective belief that Aetna's policies and practices are so unfavorable to enrollees that their very existence . . . demonstrates that they overpaid for the coverage."[24]

Looking to *Pegram,* the Third Circuit rejected this theoretical basis for recovery. The court stressed that under this theory the plaintiffs would be asking the court to pass judgment on Aetna's policies and practices leading to a "myriad of practical problems which undoubtedly arise in a situation in which the federal courts are asked to determine the social utility of one particular HMO structure as compared to another."[25] The court refused to accept plaintiffs' notion implied by their complaint that it should evaluate the social utility of Aetna's health plans. To stress this point, the court indicated that this theory would require the trier of fact to "inappropriately act as a state regulatory commission and determine the value of Aetna's product."[26]

The Third Circuit's refusal to go down the road of passing judgment on a health plan's otherwise legal policies and practices with its "myriad of practical problems" gives a clear signal that *Pegram's* most significant impact may come from its clear message of restraint to the federal judiciary in the debate over managed care.

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[20] *See, e.g., Cannon v. Group Health Service of Oklahoma, Inc.,* 77 F.3d 1270 (10th Cir. 1996); *Kuhl v. Lincoln National Health Plan of Kansas City, Inc.,* 999 F.2d 298 (8th Cir. 1993); *Corcoran v. United Healthcare, Inc.,* 965 F.2d 1321 (5th Cir.), *cert. denied* 506 U.S. 1033 (1992).

[21] MDL-1334, MDL-1364, MDL-1366, and MDL-1367 pending before the U.S. District Court for the Southern District of Florida.

[22] 120 S.Ct. at 2157.

[23] 221 F.3d 472 (3rd Cir. 2000).

[24] *Id.* at 496.

[25] *Id.* at 499.

[26] *Id.*

Conclusion

The Court's decision in *Pegram* has given the federal courts direction when addressing physician compensation arrangements and risk sharing in the context of ERISA. It has validated the concept that the treatment decisions of physicians, even if mixed with ERISA eligibility questions, are to be left to the purview of state medical malpractice law. Moreover, the Court's resolution of these issues does not mean a shift in how the federal courts should analyze ERISA preemption questions relating to HMO medical necessity decisions. Contrary to the views of the DoL, *Pegram* did not hold that HMO coverage decisions involving medical necessity issues are subject to state medical malpractice law.

Pegram's most significant impact, however, may be in its call for judicial restraint when federal courts are faced with broad challenges to managed health care practices. The Court's clear message was that the courts were not the appropriate venue for the making of health care policy. That responsibility remains with Congress.

THE ERISA INDUSTRY COMMITTEE
WASHINGTON, DC
April 23, 2001

The Honorable W.J. BILLY TAUZIN
Chairman, House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable MICHAEL BILIRAKIS
Chairman, Subcommittee on Health Committee
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

DEAR CHAIRMAN TAUZIN:
DEAR CHAIRMAN BILIRAKIS:

I am writing to respond to your request for our view on whether the Supreme Court's decision in *Pegram v Herdrich,* 530 U.S. 211 (2000), changed the law governing ERISA preemption and, specifically, on the relevance of footnote 9 of the Court's opinion to this question.

In our view, footnote 9 makes it clear that *Pegram* does not change the law governing ERISA preemption.

In *Pegram,* the Supreme Court addressed the question of whether an HMO's mixed eligibility and treatment decisions are fiduciary acts within the meaning of ERISA. A plan beneficiary had claimed in *Pegram* that an HMO, acting through its physician-owners, violated its ERISA fiduciary duty to act solely in the interest of beneficiaries by making medical treatment decisions while influenced by an arrangement under which the physician-owners profited by minimizing medical services. The Court held that ERISA does not treat HMOs as fiduciaries when they make mixed eligibility and treatment decisions and that therefore the beneficiary did not have an ERISA cause of action against the HMO for breach of fiduciary duty.

In footnote 9, the Court observed:

> "ERISA makes separate provision for suits to receive particular benefits. See 29 U.S.C. § 1132(a)(1)(B).[1] We have no occasion to discuss the standards governing such a claim by a patient who, as in the example in text[2], was denied reimbursement for emergency care. Nor have we reason to discuss the interaction of such a claim with state-law causes of action, see *infra,* at 235-37."

At pages 235-37, the Court observed that if the plaintiff's position in *Pegram* had prevailed, the question whether ERISA preempts state malpractice law would have been raised since, under the plaintiff's theory, the treating physician (as well as the HMO) could be held liable under ERISA for breach of fiduciary duty:

> "This result, in turn, would raise a puzzling issue of preemption. On its face, federal fiduciary law applying a malpractice standard would seem to be a prescription for preemption of state malpractice law, since the new ERISA cause

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[1] By contrast, ERISA § 502(a)(2), 29 U.S.C. § 1132(a)(2), authorizes suits for appropriate relief under ERISA § 409, 29 U.S.C. § 1109(a), which makes a fiduciary personally liable for any losses incurred by the plan (or for any profits made by the fiduciary) as a result of its breach of fiduciary responsibility.

[2] In the text, the Court referred to an example in the Government's *amicus* brief involving an HMO that refused to pay for emergency care on the ground that there had not been an emergency.

of action would cover the subject of a state-law malpractice claim. See 29 U.S.C. § 1144 (preempting state laws that "relate to [an] employee benefit plan"). To be sure, *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 654-655 (1995), throws some cold water on the preemption theory; there, we held that, in the field of health care, a subject of traditional state regulation, there is no ERISA preemption without clear manifestation of congressional purpose. But in that case the convergence of state and federal law was not so clear as in the situation we are positing; the state-law standard had not been subsumed by the standard to be applied under ERISA. We could struggle with this problem, but first it is well to ask, again, what would be gained by opening the federal courthouse doors for a fiduciary malpractice claim, save for possibly random fortuities such as more favorable scheduling, or the ancillary opportunity to seek attorney's fees. And again, we know that Congress had no such haphazard boons in prospect when it defined the ERISA fiduciary, nor such a risk to the efficiency of federal courts as a new fiduciary-malpractice jurisdiction would pose in welcoming such unheard-of fiduciary litigation."

The Court thus decided nothing at all about ERISA preemption. To the contrary, footnote 9 emphasized that the Court was *not* deciding the standards governing benefit claims, such as claims for reimbursement of health care expenses, or the interaction between benefit claims and state-law causes of action. There was no reason for the Court to decide these issues. The only issue in the case was whether mixed eligibility and treatment decisions by HMO physicians were fiduciary decisions under ERISA.

Both footnote 9 and the Court's comments on pages 235-37 emphasize that the Court deliberately chose not to "struggle" with the "puzzling issue of preemption." The Court's comments on preemption were dictum in any event, since the Court was able to resolve the issue before it—which involved the application of ERISA's fiduciary standards, not state law—without deciding the preemption issue.

It is perilous to seize on dictum to predict how the Court will decide a future case. For example, on the same day *Pegram* was decided, the Court refused to follow dictum in its 1993 *Mertens* decision. See *Harris Trust & Savings Bank v. Salomon Smith Barney Inc.,* 530 U.S. 238, 249 (2000) ("Salomon invokes *Mertens* as articulating an alternative, more restrictive reading of [ERISA] § 502(*l*) that does not support the inference we have drawn . . . But the *Mertens* dictum does not discuss—understandably, since we were merely flagging the issue, see 508 U.S. at 255, 260-61—that ERISA defines the term 'person' without regard to status as a cofiduciary . . ."). The *Harris Trust* decision thus demonstrates that dictum in an opinion is not a reliable indicator of how the Court will decide an issue when the issue is actually presented to the Court for decision in the future.

We hope our comments will be helpful to you. If we can be of further assistance, please let me know.

Sincerely,

MARK J. UGORETZ
President

cc: The Honorable John Shadegg
U.S. House of Representatives
432 Cannon House Office Building
Washington, D.C. 20515

Nandan Kenkeremath
Counsel, House Committee on Energy & Commerce
H316 Ford House Office Building
Washington, D.C. 20515

Doug Stoss
Legislative Assistant to Representative John Shadegg
432 Cannon House Office Building
Washington, D.C. 20515

NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS
April 19, 2001

The Honorable MICHAEL BILIRAKIS
Chairman
Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

DEAR REPRESENTATIVE BILIRAKIS: Attached please find our responses to the questions raised by you in connection with the testimony of the National Association of Insurance Commissioners (NAIC), at the March 15, 2001 hearing regarding federal and state roles in managed care.

On behalf of the members of the NAIC, I would like to thank you for the opportunity to testify before your Subcommittee.

Sincerely,

STEVEN B. LARSEN
Chair, Health Insurance & Managed Care (B) Committee
Commissioner, Maryland Insurance Administration

Attachment

RESPONSES FOR THE RECORD OF COMMISSIONER STEVEN LARSEN

Question 1. The White House, in its statement of principles, has provided for a broad set of patient protections through a system that provides "deference" to State patient protection laws and to "the traditional authority of states to regulate health insurance." Can you explain the current system, what is the traditional authority of the States, and why such deference is important?

The enactment of the Employee Retirement Income Security Act of 1974 (ERISA) created a dual federal-state regulatory structure in this country for health insurance and health benefits. Under ERISA, generally, federal law governs employer-sponsored group health plans. However, state laws that regulate the business of insurance are saved from preemption by virtue of the saving clause (Section 514 of ERISA). As a consequence of the saving clause, states regulate fully insured employer-sponsored plans by regulating the health insurers and HMOs that cover the services and benefits under the plan. The saving clause was enacted to preserve the states' traditional role of regulating insurance, including the regulation of insurance policies purchased by ERISA plans (fully insured plans).

The states have taken this role seriously. They have enacted patient protections for consumers in individual and group plans under their authority to regulate the business of insurance, and they have an established infrastructure to enforce these rights. State regulators are presently enforcing many of the patient protection provisions that are being considered by the Congress and that are included in the President's "Principles for a Bipartisan Patients' Bill of Rights".

Deference is important because states have adopted protections tailored to their state markets based on size, population, structure and need. One size regulation does not fit all. To require all states to adopt the same blanket regulation for all situations could result in over-regulation of and unneeded expense to the marketplace. State legislatures are sensitive to their marketplaces and consumer concerns, and when needed, they have been proactive in establishing consumer protections that are tailored to the needs of their individual states' health care markets. In addition, states have expertise in their laws and their markets, and they have an effective infrastructure in place that can quickly and efficiently respond to consumers. Consumers are not forced to call Washington, DC with a local issue. Congress should recognize the states' efforts and expertise in developing these protections and give the states the greatest amount of flexibility in preserving and enforcing these protections.

Question 2. Your testimony uses the term "taken as a whole". What are your views on the use of "substantially equivalent" and the modifier "taken as a whole"? How important is it that the standard be flexible?

It is critical that the standard be flexible for states. Although some of the legislative proposals generally attempt to save state laws that are equal to or more protective than the proposed federal standards using the HIPAA "prevents the application" standard, the President's Principles seek to preserve state authority beyond the federal floor. The concepts of "state certification" and "substantial equivalence" will give greater deference to the states and preserve more of their laws.

Using these concepts, the states would certify that their statutory and regulatory patient protections taken as a whole are "substantially equivalent" or are comparable to the federal standards and that the state laws should remain in force. This approach would prevent the debate from getting bogged down in whether the state language is exactly the same as the federal bill, especially if the intent and the outcome are similar. This flexible approach would allow as many state laws as possible to remain in place, and it would allow states room to apply the protections in a manner appropriate for their health insurance markets.

While "substantially equivalent" and "taken as a whole" were the prevalent approaches that had been introduced at the time of the hearing, other approaches are being developed that also would preserve and give deference to state laws. Approaches such as "consistent with the intent of the legislation" and "comparable to the federal legislation" are being discussed. We welcome any approach that allows states to continue to enact reforms based on their state markets and gives states maximum flexibility in how they meet the federal requirements, while ensuring that all individuals have a basic level of protection.

Question 3. If a State passed a law which found that a set of State patient protections meets the relevant federal standards for acceptability, should we recognize that finding as final? In other words, the national objectives are the full patient protections but the State makes a finding and not Federal bureaucrats. Would you support that concept?

Yes, to both parts of the question. States already will be analyzing their laws to see if they comply with the federal law and will identify any areas of state law that need to be amended. States know the full scope of their laws and where the protections are located within the statutes and regulations. State laws are already operational, and states are enforcing these laws. States will be in the best position to evaluate whether the state laws measure up to the federal law not only as the laws are written but also as they function and operate in a real world situation.

Question 4. Should Congress look at some of the existing patient protection laws in the states and simply grandfather them in. In other words, should Congress make findings that certain state provisions are good patient protections and there is no need for further disruption or uncertainty?

While our membership has not discussed this approach, we do welcome approaches that would preserve state laws through a grandfathering process. Issues that would need to be considered under this approach would be how the determination is made regarding which state laws to grandfather, and whether states would have the flexibility to amend these protections in the future in response to changes in the market. States are more able to respond quickly to the needs of industry and consumers, and we would not like to see a static approach implemented that would lock the states into outdated or antiquated laws.

Question 5. Do you agree that two laws on the same issue should not apply at the same time? If they both applied would it not just create unnecessary conflict and confusion?

Yes, it is important that two laws not apply at the same time. These questions highlight why it is so important that deference be given to state laws and states be given maximum flexibility to preserve as many state laws as possible. If the state law remains in place, there is no need for both state and federal laws to apply at the same time to the same entity. The state laws would apply to individual and group fully insured plans as they do now and the federal law would apply to self-funded plans. This would avoid unnecessary conflict and confusion.

Question 6. If a State chooses not to meet the Federal standard but simply continue with its own laws wouldn't that mean that there would be dual regulations, which could be inconsistent and which there might be conflicts in enforcement?

This would result in dual regulation, with the state enforcing state law over insurance coverage and the federal government enforcing the federal protections for all group plans, either insured or self-insured. Consumers could be confused by these distinctions.

In terms of enforcement, the states have an effective infrastructure in place to enforce these laws (see Question #14), but there is still the question of how the new federal standards will be enforced. There is no federal infrastructure in place such as there is in the states to enforce patient protections, and none of the current proposals appropriate money to the federal agencies to develop an infrastructure. As such, we suggest that Congress give the Department of Labor (DOL) the authority to contract with those states that want to enforce the federal patient protection standards for all group plans, including self-funded ERISA plans. This contract arrangement would be voluntary on the part of those states that want this enforcement authority and would be done on a state-by-state basis. The DOL-state contract

structure would function like other federal arrangements that give federal grants to the states to implement and enforce federal programs.

Question 7. What should we do about a State that has very little managed care penetration? Should States with little managed care in the state be subject to the same approach as states with significant managed care?

Our members believe all consumers deserve a basic level of patient protections. Having said that, we ask Congress to recognize that states have tailored their patient protections to their markets and to give deference to and preserve those state laws to the greatest extent possible. The states have adopted protections based on size, population, structure and need of their markets. As this question implies, one size regulation does not fit all. To require all states to adopt the same blanket regulation for all situations could result in over-regulation of and unneeded expense to the marketplace. State legislatures are sensitive to their marketplaces and consumer concerns, and when needed, they have been proactive in establishing consumer protections that are tailored to the needs of their individual states' health care markets.

Question 8. If there is a dispute between the State position that its laws are sufficient and a Federal bureaucrat, should it be reviewable in court and who should get any deference on that issue?

Because of the extensive nature and complexity of the patient protections, reasonable people are likely to disagree on whether a state law offers sufficient protections to consumers. The focus should be on whether the intent and the outcome of the laws are similar, not whether every single word of every provision is exactly the same. If we lose sight of the big picture and the protections offered as a whole, every little detail of every law will be litigated. We would prefer not to have these types of disputes settled in courts while consumers wait to have the state patient protection laws enforced.

In these types of disputes, if a state can reasonably assert that the state law offers sufficient protections, we believe the state should be given deference. Unless a state's assertion has no reasonable basis or evidence, there should be a presumption that the states are in the best position to evaluate whether the state laws measure up to the federal law not only as the laws are written but also as they function and operate in a real world situation. The states will also know how and why a state law has been tailored to its particular market and can explain how the tailored state law offers sufficient patient protections.

Question 9. In your testimony you mention the need for an appropriate transition period. How is the State legislature going to know what passes a given standard without some information from whomever decides on the test?

To date, the proposed standards in the various bills seem broad enough to allow the states to make the determination regarding whether their laws meet the overall goals and intent of the legislation; however, this question implies that the states need to wait for federal regulations setting forth criteria and examples of how to meet the standards. Either way, states will need time to review their laws, compare them to the federal law, and determine what changes, if any, need to be made. In addition, states will need time to enact the changes in their legislatures. Not all state legislatures meet every year, and even some that do may consider only non-budgetary or fiscal issues every other year. Several years will need to be afforded for the states to complete the process.

Question 10. Can you describe some of the problems the states had in enacting the Health Insurance Portability and Accountability Act (HIPAA) provisions?

The process of reviewing state laws and making them HIPAA-compliant was very labor-intensive. HIPAA had a much narrower focus regarding insurance laws than the patients' bill of rights provisions. HIPAA essentially addressed three issues: (1) guaranteed issue in the small group market and for a small class of individuals; (2) guaranteed renewability of all health insurance policies; and (3) portability (creditable coverage so people do not have successive preexisting condition exclusions when they change jobs and plans). The patients' bill of rights covers a much greater number of provisions, and these provisions are much more complex. Therefore, it is essential that the states have as much flexibility as possible to not have to rewrite their laws if they accomplish the same objective. That is why a deferential standard of review is appropriate.

Question 11. How have the states and Health Care Finance Administration and the Department of Labor been working together since the enactment of HIPAA?

Generally the relationships have been good. HCFA and DOL staffs attend NAIC meetings regularly, and work with individual states on a case-by-case basis. However, it is not the best model to have more than one regulator for insured plans. We understand the plans' concerns about having to deal with both state and federal regulators on insurance products. It is confusing, time-consuming, and not a logical

allocation of resources. Again, HIPAA's breadth was relatively small compared to the patients' bill of rights, and neither federal agency has the resources or infrastructure to be an effective insurance regulator and ensure that the rights conferred to patients are actually enforced.

Question 12. Do you have any comments on HCFA or DOL enforcing the law? What problems arise when the federal government enforces part of the insurance laws in a state and the state enforces other parts?

These agencies do not have the resources (money or staff) or the infrastructure established to make sure these protections are enforced. The patients' bill of rights does not appropriate any funds to create this infrastructure, which by the way, would duplicate the state infrastructure.

As we stated in Question #11, it is not the best model to have more than one regulator for insured plans. We understand the plans' concerns about having to deal with both state and federal regulators on insurance products. Also, it is not helpful for consumers to have two regulators for insurance laws. They will not know which regulator to call if regulation and enforcement is on a provision-by-provision basis. It is confusing, time-consuming, and not a logical allocation of resources. The states regulate insurance and enforce these laws, and the federal government should let the states continue to do so.

As we stated in Question #6, Congress could give the Department of Labor (DOL) the authority to contract with those states that want to enforce the federal patient protection standards for all group plans, including self-funded ERISA plans. This contractual arrangement would be voluntary on the part of those states that want this enforcement authority and would be done on a state-by-state basis. The DOL-state contract structure would function like other federal arrangements that give federal grants to the states to implement and enforce federal programs.

Question 13. Why is it so important for the states to enforce the patient protections?

While we are sometimes accused of engaging in a "turf war," we believe for several reasons that it is best for the consumers if the states not only keep their state laws, but also enforce the patient protections.

First, state regulators are presently enforcing many of the patient protection provisions that are being considered by the Congress and that are included in the President's Principles. The most important way states enforce these laws, and thus ensure that consumers get the benefits to which they are entitled, is through state internal and external review processes. Internal and external review standards are the heart of the patient protections. Enforcement of the other patient protections, through these review processes, is what makes the other protections real, rather than illusory. Congress should not disrupt these state processes.

We should note here that if Congress preempts internal and external review processes, Congress would be threatening the ability of state insurance departments to handle any type of consumer question, complaint or grievance. Consumers' complaints often initiate these review processes.

Second, as we discuss in Questions #14, infrastructure is critical for enforcing any new patient protections and the states have an extensive infrastructure in place to protect consumers. The federal government does not. State insurance departments have established their regulatory infrastructures based on their markets and have allocated significant resources to assist consumers. Consumers are able to call their state insurance departments and the departments can quickly and efficiently respond. Consumers are not forced to call an agency in Washington, DC and be routed around looking for the right contact person. State systems that are working and that are user-friendly for consumers should not be preempted by Congressional action that cannot guarantee the enforcement of these protections.

Question 14. Explain the infrastructure that the states have in place already to enforce patient protections.

Infrastructure is critical for enforcing any new patient protections. Not only have states established a statutory framework of patient protections, but also states have a regulatory structure in place that is able to handle and quickly respond to consumers' complaints and grievances. This regulatory structure includes: consumer representatives and market conduct reviewers who respond, investigate and enforce the patient protection standards; toll-free consumer telephone lines and Internet access; and on-site representatives to respond to complaints.

Just to quantify the level of state resources (time, money and people-power) that is necessary to regulate the business of insurance and to successfully handle consumer concerns, in 1999 state insurance departments responded to more than 3.3 million consumer inquiries and followed-up on more than 448,000 consumer complaints or grievances. State Departments of Insurance employed 1,045 financial examiners, 345 market conduct examiners, 384 financial analysts, 786 complaint ana-

lysts, and 75 consumer advocates. The examiners conducted 1,562 financial exams, 1,122 market conduct exams, and 554 combined financial and market conduct exams.

State insurance departments have established their regulatory infrastructures based on their markets and have allocated significant resources to respond to consumers. Consumers throughout the country have easy access to a network of assistance. State systems that are working should not be preempted by Congressional action that cannot guarantee the enforcement of these protections.

We are concerned by the potential impact of any federal patient protection legislation on consumers. If the federal legislation preempts state laws and state infrastructure, the federal government does not have the resources (money and staff) or the infrastructure to enforce these new protections. With all due respect, we do not think consumers benefit from the preemption of state law or state infrastructure. As such, we ask Congress to recognize the effective state infrastructure already in place and to preserve it so consumers in insured plans may continue to enjoy the benefits of state oversight.

NATIONAL CONFERENCE OF STATE LEGISLATORS
April 11, 2001

The Honorable MICHAEL BILIRAKIS
Chairman, Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

DEAR CHAIRMAN BILIRAKIS: Thank you for giving me the opportunity to testify before your subcommittee at the hearing on "A Smarter Health Care Partnership for American Families: Making Federal and State Roles in Managed Care Regulation and Liability Work for Accountable and Affordable Health Care Coverage." Attached is my response to the six follow-up questions you posed. I have also attached a copy of NCSL's policy on managed care reform.

On behalf of the National Conference of State Legislatures, I want to express our continued support for the establishment of patient and provider protections for individuals who receive health care services from managed care entities. We look forward to working with you and your colleagues, both in the House and the Senate, to achieve this goal. Please call Joy Johnson Wilson in the NCSL Washington Office or me if we can be of additional assistance to you or your staff as you proceed on this important issue.

Sincerely,

ANGELA MONSON
Oklahoma State Senate, President-Elect, NCSL

Attachment
Enclosure

RESPONSES FOR THE RECORD OF SENATOR ANGELA MONSON

Question 1. If a state passed a law that found that a set of state patient protections meets the relevant federal standards for acceptability, should that finding be recognized as final at the federal level? In other words, the national objective is the full patient protections but the state makes a finding, not the federal government? Would you support that concept?

Yes, we would support this concept. NCSL has long-standing health insurance policy that states, "Where states already have similar legislation in place, a process for declaring 'substantial compliance' should be developed." We believe this could apply to a single state law or a set of state laws that, when viewed in their totality, provide similar protections and as such, meet or exceed the national patient or provider protection objectives.

Question 2. Should Congress look at some of the existing patient protection laws in the states and simply "grandfather" them in? In other words, should Congress make findings that certain state provisions are good patient protections and there is no need for further disruption or uncertainty?

NCSL would support "grandfathering-in" existing state laws. It would be particularly useful for patient or provider protections that have already been enacted by a majority of the states and that are similar across the states. A good example would be a ban on "gag clauses." It would be relatively easy for the federal legisla-

tion to include a "gag clause" protection that would not be imposed in a state that has a "gag clause" ban in effect in state law when the federal law is enacted.

Question 3. Do you agree that two laws on the same issue should not apply at the same time? If they both applied would it create unnecessary conflict and confusion?

I am not sure that I agree. I do not think it is unusual to have more than one law address an issue or different parts of an issue. This situation certainly exists in the health insurance area, where state laws regulating health insurers do not apply to individuals who receive their health care coverage through federally regulated, self-insured entities. This situation causes confusion among consumers and could easily be rectified by amending the Employee Retirement Income Security Act (ERISA) to permit states to regulate self-insured entities. However, there are no active proposals to do so. We would be pleased to work with you on crafting legislation that would accomplish this. The enactment of federal legislation that would provide protections to individuals in federally-regulated plans similar to those already in effect for individuals in state-regulated plans would go a long way towards alleviating confusion and inequities among similarly situated individuals with respect to their health care coverage and related protections.

Question 4. What should we do about a state that has very little managed care penetration? Should states with little managed care be subject to the same approach as states with significant managed care penetration?

Establishing an approach based on managed care penetration assumes that there is a significant relationship between managed care penetration and the existence of state law regulating the managed care industry. I am not certain that a significant relationship exists. Even the states with the lowest rate of managed care penetration have enacted state laws regulating the managed care industry. Some of these states have done substantial work in this area. Alaska, the state with the lowest rate of HMO penetration in the United States, has enacted laws providing for: freedom of choice; a point of service option; direct access to chiropractic care; inpatient care after childbirth; an independent appeals process; a ban on gag clauses; and a ban on financial incentives. Vermont, ranked 48th of the 50 states and the District of Columbia in HMO penetration has enacted state laws providing for: direct access to obstetricians and gynecologists; standing referrals; continuity of care; an emergency care service mandate; the prudent layperson standard; disclosure of restrictive drug formularies and procedures for obtaining coverage of nonformulary drugs; a definition of medical necessity; an independent appeals process, a ban on gag clauses, a ban on financial incentives; prompt payments to providers; independent ombudsman programs; and the licensing of medical directors.

Because a state cannot be compelled to enact federal insurance legislation, a state could, by failing to enact complying state law, "opt out" of all or some of the federal provisions regulating managed care entities and permit the federal government to do so. This would not require any special treatment under the federal law because a federal "fall back" provision would have to be part of any federal insurance legislation. We believe that, if states are given sufficient time to review their laws and to make revisions and adjustments to them, most states will want to maintain regulatory authority in this area regardless of the rate of HMO penetration in the state.

Question 5. If there is a dispute between the state position and a federal representative over whether its laws are sufficient, should it be reviewable in court? Who should get deference on that issue?

Deference should be given to states and their assessment of their laws. NCSL urges the adoption of a process that presumes the state law is sufficient if the state determines that it is. So once a state has certified, by a process established in the federal law, that a particular state law is equally protective, there would be a presumption that the state has made a correct determination. We would urge the first level of review to be at the federal department level, if a party (the appropriate parties to challenge a state determination should be specifically identified in the federal law) challenges the state certification. NCSL would certainly not want to preclude any state from seeking relief through the courts if it feels the federal review process has not treated it fairly.

Question 6. In your testimony, you mention the need for an appropriate transition period. How is the state legislature going to know what passes a given standard without some information from whomever decides on the test?

We believe the effective date of the federal legislation in each state should occur after the state legislature has met in a regular session. After the federal legislation is enacted, states will know whether and how state laws will be preempted. The transition period is needed to permit states to assess the status of their laws, to make any changes that they deem appropriate and to determine any additional steps (e.g., certify state law as equally protective) the state may wish to pursue.

If, for example, more protective state laws are "saved" from preemption, a state may want to revise its existing laws to make them more protective than the federal law to maintain state regulatory authority. If the federal standard saves "equally protective or more protective" state laws, a state will want to review its laws to make a state determination regarding the status of the state laws compared to similar or comparable federal law. Even if the federal law is less clear and suggests that a state law or some group of state laws that are equally or more protective than the federal law would be saved from preemption, the state should have the opportunity to make its assessment and to determine whether it wants to assert state authority with respect to a law or group of laws in the state according to the procedure established in the federal law. For example, a state legislature may direct the state insurance commissioner or governor to save state regulatory authority for a certain law or group of laws by statute, based on their review of those laws. States will need some time to make an assessment of the affected state laws and to determine what the appropriate next step should be.

NATIONAL CONFERENCE OF STATE LEGISLATURES

OFFICIAL POLICY

POLICY: Managed Care Reform
COMMITTEE: Health

NCSL supports both the establishment of needed consumer protections for individuals receiving care through managed care entities. We also support the development of public and private purchasing cooperatives and other innovative ventures that permit individuals and groups to obtain affordable health coverage. We strongly oppose preemption of state insurance laws and efforts to expand the ERISA preemption. The appropriate role of the federal government is to: (1) ensure that individuals in federally-regulated plans enjoy protections similar to those already available in most states; (2) establish a floor of protections that all individuals should enjoy; and (3) to provide adequate resources for monitoring and enforcing federally-regulated provisions. The Senate-passed version of the "Patient Bill of Rights," generally preserves the traditional role of states as insurance regulators, and focuses most of its attention on the federally regulated, self-funded ERISA plans. Individuals who receive their health care through these plans have not benefited from the state laws enacted to provide needed protections for individuals who receive care through managed care entities. It is appropriate and necessary for the Congress to address the needs of these individuals.

States have taken the lead in providing needed regulation of managed care entities. The reforms at the state level have enjoyed bi-partisan support and have been successful. If states had the ability to provide these protections to people who receive their health care benefits from self-funded ERISA plans, we would surely have done so. We have asked for the privilege on many occasions.

Today we see federal legislation that will largely preempt these important state laws and replace them with federal laws that we submit the federal government is ill-prepared to monitor and enforce. None of the would provide additional resources to the U.S. Department of Labor or to the U.S. Department of Health and Human Services to hire and train staff to implement the many complex provisions of these bills.

Preemption of State Laws And State Regulation of Managed Care Entities

It is widely believed that the pending legislation creates a federal floor and would not preempt state laws that are more protective of consumers. We are not certain that is true. Unless state legislatures adopt legislation that mirrors the federal legislation, state insurance commissioners would not be authorized to continue to regulate managed care entities under any preempted state laws. In some cases ironically, state insurance commissioners would be unable to enforce existing state law that would have afforded these same individuals needed protections. As a result, after passage of the federal legislation, the regulation of managed care entities could be largely a federal affair. Again, we believe the current federal infrastructure for the oversight and enforcement of health insurance regulations is inadequate. The federal government will not be able to deliver on the promise and may very well prevent states from delivering on theirs regarding patients rights.

Access to Health Insurance Proposals

NCSL strongly opposes proposals that exempt association health plans (AHPs), Health Marts and certain multiple employer welfare arrangements (MEWAs) from critical state insurance standards. These proposals would permit more small employers to escape state regulation and oversight through an expansion of the ERISA

preemption. States have tailored their health care reforms to fit local health insurance markets and to address the concerns of local consumers.

- *The impact on federal insurance reforms.* The federal government, through the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), made an effort to stabilize and improve consumer protections (through state regulation) of these markets. Enactment of AHP/MEWA provisions in any form would undermine these efforts. We are particularly concerned about: (1) the impact on state small group and individual insurance markets; and (2) the opportunity inadequate regulation provides for fraud and abuse. These concerns are in addition to our larger concerns about the ability of the federal government to adequately regulate an expanded health insurance market.
- *The impact on state insurance markets.* Recent state reforms have guaranteed small employers access to health insurance and have made coverage more affordable for many small businesses by creating large insurance rating pools. These large pools assure that all small firms can obtain coverage at reasonable rates, regardless of the health of their employees. The success of these state small group reforms, however, depends on the creation of a broad base of coverage. By expanding the exemption provided in ERISA, the House-passed bill would shrink the state-regulated insurance market and threaten the viability of the markets and any reforms associated with these markets. These proposals undermine HIPAA by creating incentives for healthy groups to leave the state-regulated small group market, only to return when someone becomes ill. This incentive for adverse selection would be disastrous, compromising state reforms and raising health care costs for many small firms and individuals.
- *Fraud and abuse.* MEWAs have become notorious for their history of fraudulent activities. The House-passed bill would undermine federal legislation that specifically gave states the authority to oversee MEWAs. A policy adopted because federal regulation had proven ineffective in preventing abuses. Under the proposed legislation, many MEWAs could become exempt from state regulation by becoming federally certified as Association Health Plans (AHPs). The proposal does not provide sufficient protections for employees and employers against victimization by unscrupulous plan sponsors.