be asked where is the security for property, for reputation, for life, if the sense of religious obligation *desert* the oaths, which are the instruments of investigation in Courts of Justice? And let us with caution indulge the supposition, that morality can be maintained without religion.—Whatever may be conceded to the influence of refined education on minds of peculiar structure—reason and experience both forbid us to expect, that national morality can prevail in exclusion of religious principle.—

'T is substantially true, that virtue or morality is a necessary spring of popular government.—The rule indeed extends with more or less force to every species of Free Government.—Who that is a sincere friend to it, can look with indifference upon attempts to shake the foundation of the fabric?—

Promote, then, as an object of primary importance, institutions for the general diffusion of knowledge.—In proportion as the structure of a government gives force to public opinion, it is essential that the public opinion should be enlightened.—

* * * * *

Observe good faith and justice towards all Nations. Cultivate peace and harmony with all. Religion and Morality enjoin this conduct; and can it be that good policy does not equally enjoin it?—It will be worthy of a free, enlightened, and, at no distant period, a great nation, to give to mankind the magnanimous and too novel example of a People always guided by an exalted justice and benevolence.—Who can doubt that in the course of time and things, the fruits of such a plan would richly repay any temporary advantages, which might be lost by a steady adherence to it? Can it be, that Providence has not connected the permanent felicity of a Nation with its virtue? The experiment, at least, is recommended by every sentiment which ennobles human nature.—Alas! is it rendered impossible by its vices?

In the execution of such a plan nothing is more essential than that permanent, inveterate antipathies against particular nations and passionate attachment, for others should be excluded; and that in place of them just and amicable feelings towards all should be cultivated.—The Nation, which indulges towards another an habitual hatred or an habitual fondness, is in some degree a slave. It is a slave to its animosity or to its affection, either of which is sufficient to lead it astray from its duty and its interest.—Antipathy in one nation against another disposes each more readily to offer insult and injury, to lay hold of slight causes of umbrage, and to be haughty and intractable, when accidental or trifling occasions of dispute occur.—Hence frequent collisions, obstinate, envenomed and bloody contests.—The Nation prompted by ill-will and resentment sometimes impels to War the Government, contrary to the best calculations of policy.—The Government sometimes participates in the national propensity, and adopts through passion what reason would reject;—at other times, it makes the animosity of the Nation subservient to projects of hostility instigated by pride, ambition, and other sinister and pernicious motives.—The peace often, sometimes perhaps the Liberty, of Nations has been the victim.—

So likewise a passionate attachment of one Nation for another produces a variety of evils.—Sympathy for the favourite nation, facilitating the illusion of an imaginary common interest in cases where no real common interest exists, and infusing into one the enmities of the other, betrays the former into a participation in the quarrels and wars of the latter, without adequate inducement or justification: It leads also to concessions to the favourite Nation of privileges denied to others, which is apt doubly to injure the Nation making the concessions; by unnecessarily parting with what ought to have been retained, and by exciting jealously, ill-will, and a disposition to retaliate, in the parties from whom equal privileges are withheld; and it gives to ambitious, corrupted, or deluded citizens, (who devote themselves to the favourite Nation) facility to betray, or sacrifice the interests of their own country, without odium, sometimes even with popularity:—gilding with the appearances of a virtuous sense of obligation, a commendable deference for public opinion, or a laudable zeal for public good, the base or foolish compliances of ambition, corruption, or infatuation.

As avenues to foreign influence in innumerable ways, such attachments are particularly alarming to the truly enlightened and independent Patriot.—How many opportunities do they afford to tamper with domestic factions, to practise the arts of seduction, to mislead public opinion, to influence or awe the public councils! Such an attachment of a small or weak, towards a great and powerful nation, dooms the former to be the satellite of the latter.

* * * * *

Relying on its kindness in this as in other things, and actuated by that fervent love towards it, which is so natural to a man, who views in it the native soil of himself and his progenitors for several generations;—I anticipate with pleasing expectation that retreat, in which I promise myself to realize, without alloy, the sweet enjoyment of partaking, in the midst of my fellow-citizens, the benign influence of good Laws under a free Government,—the ever favourite object of my heart, and the happy reward, as I trust, of our mutual cares, labours and dangers.

GEO. WASHINGTON.

UNITED STATES,
17th September, 1796.

Mr. LOTT. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. NICKLES. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

PATIENTS' BILL OF RIGHTS ACT OF 1999

AMENDMENT NO. 1237

Mr. NICKLES. Mr. President, for the information of our colleagues, we were in the process of debating the Robb amendment dealing with mandatory length of stays for mastectomies. That is a second-degree amendment to an amendment I offered on behalf of myself, Senator GRAMM, and Senator COLLINS that had a limitation on the cost. The cost of the underlying bill cannot exceed 1 percent, nor could it increase the costs or increase the number of uninsured by over 100,000 or the bill would not be in effect.

Senator ROBB's amendment strikes the amendment that limits the 1-percent cost. It is our intention to finish the debate on the Robb amendment. We will vote on the Robb amendment, and it will be our intention for the Republican side to offer a second-degree amendment. We will debate that amendment and vote on it and work our way through the amendments that have been stacked today.

I ask the Parliamentarian how much time remains on the Robb amendment?

The PRESIDING OFFICER. The majority has 46 minutes remaining and the minority has 28 minutes remaining.

Mr. NICKLES. I yield the floor.

Mr. KENNEDY. I yield 5 minutes to the Senator from Maryland.

The PRESIDING OFFICER. The Senator from Maryland is recognized for 5 minutes.

Ms. MIKULSKI. Mr. President, what does a woman do in a few days before she is scheduled to have a mastectomy? How should she spend her time? What should she be doing? Should she be on the phone calling her HMO, trying to figure out what will happen to her after surgery? Who will take care of her, how long will she be in the hospital? Should she be on the phone, dealing with bureaucracy? Should she be dealing with paperwork? Should she be on the phone, dealing with an insurance gatekeeper?

No, I do not think that is what she should be doing and I think the Senate will agree with me. I think she should be with her family. I think she should be talking with her husband, because he is as scared as she is. He is terrified that she might die. He is wondering how can he support her when she comes home.

She needs to talk to her children so that they understand that even though she is going in for an operation, they know their mother will be there when she comes back home but she might not be quite the same. She needs to be with her family. She needs to be with her clergyman. She needs to be with those who love her and support her.

This is what we are voting on here today. Who should be in charge of this decision? When a woman has a mastectomy she needs to recover where she

can recover best. That should be decided by the doctor and the patient. We hear about these drive through mastectomies, where women are in and out in outpatient therapy. They are dumped back home, often sent home still groggy with anesthesia, sometimes with drainage tubes still in place or even at great risk for infection.

Make no mistake, we cannot practice cookbook medicine and insurance gatekeepers cannot give cookbook answers. An 80-year-old woman who needs a mastectomy needs a different type of care than a 38-year-old woman. And a 70-year-old woman whose spouse himself may be 80 might have different family resources than a 40-year-old woman.

Even the board of directors of the American Association of Health Plans states this: ''. . . the decision about whether outpatient or inpatient care meets the needs of a woman undergoing removal of a breast should be made by the woman's physician after consultation with the patient.''

As I said earlier, we go out there and we Race for the Cure. Now we have to race to support this amendment. Let's look at what we have done with our discoveries. We in America have discovered more medical and scientific breakthroughs than any other country in world history. It is America who knew how to handle infectious diseases. It is America who comes up with lifesaving pharmaceuticals.

We have been working together on a bipartisan basis to double the NIH budget. We have joined together on a bipartisan basis to have mammogram quality standards for women. Now we have to join together on a bipartisan basis and pass this amendment.

We must continue our discovery, we must continue our research, and we must continue to make sure that we have access to the discoveries we have made.

This is what this amendment is all about. It allows a woman and her physician to make this decision.

Some time ago very similar legislation was offered by the former Senator of New York, Mr. D'Amato. People on the other side of the aisle had cosponsored this bill. What we are saying here is, if you cosponsored it under Senator D'Amato, vote for it under the Robb-Mikulski-Boxer-Murray amendment. This should not be about partisan politics.

Let's put patients first. Let's understand what is going to happen to a woman. Let's understand what is going to happen to her family. And let the doctors decide. I told my colleagues a few weeks ago—I recalled a few months ago I had gall bladder surgery. I could stay overnight because it was medically necessary and medically appropriate. Surely if I can stay overnight for gall bladder surgery a woman should be able to stay overnight when she has had a mastectomy.

I yield the floor.

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. KENNEDY. I yield 5 minutes to the Senator from California.

The PRESIDING OFFICER. The Senator from California is recognized for 5 minutes.

Mrs. BOXER. Mr. President, I thank Senator KENNEDY for his work on this, and Senator MIKULSKI for her inspirational talk, and Senator ROBB for offering an amendment that I think is crucial to the women of this country. I am eternally grateful to him for putting this amendment together.

Earlier, Senator SMITH made a very eloquent talk about the need to set aside politics and do what is right for the people. I think we have an extraordinary opportunity to do that on this Patients' Bill of Rights. It is really very simple to do. Whether we are Democrats or Republicans or Independents, we can set all that aside and follow this simple rule, asking every time we vote: What is best for the people of our Nation? That is it, the simple question: What is best for the children? What is best for the women? What is best for the men? What is best for the families, the old or the young, et cetera.

The Robb amendment is good for American women. As a matter of fact, the Robb amendment is crucially needed. It is desperately needed. The Senator from Maryland was eloquent on the point. Think about finding out you have breast cancer and learning you have to have a mastectomy. You do not need to be a genius to understand that you want a doctor making the decision as to how long you stay in the hospital.

It is very simple: Mastectomies are major surgery. Cancer is life-threatening and difficult. It is physical pain. It is mental anguish for you and your family. You don't want an accountant or a chief operating officer in an HMO telling you to leave after a few hours, with tubes running up and down you and being sick as a dog and throwing up and all the rest. I hate to be graphic about it, but we have to come to our senses in this debate. What is the argument against this? It is going to cost more? We know the CBO says it is maybe $2 a month to obtain all the benefits in the Patients' Bill of Rights. I think it is worth $2 a month to know a doctor makes the decision.

I want to talk about the CEOs of these HMOs. They make millions of dollars a year. They are skimming off the top, off of our health care quality, and putting it in their pockets. They make $10 million a year, $20 million a year, $30 million a year—one person. If his wife comes down with cancer and needs a mastectomy, do you think he is going to leave the decision to an accountant in an HMO? You know he is not. He is going to dig into his pocket, into his $30-million-a-year pocket, and pay for her to obtain good care.

What about the average woman? What about our aunts and our uncles and our neighbors? They deserve the same kind of attention and care. That is what the Robb amendment will do.

It will do something else. Again, I am so grateful to the Senator from Virginia on this point. Senator MURRAY had offered the mastectomy amendment in committee, and even Senators who were on the original Feinstein-D'Amato bill, Republican Senators, voted against her amendment in the committee. She is on the floor fighting for this.

Senator SNOWE and I, in a bipartisan way, introduced a bill that would require your OB/GYN, your obstetrician/gynecologist, to be your basic health care provider. Senator ROBB has included that in his amendment.

The reality is that a woman does consider her OB/GYN as her primary care physician. Let's make it a guarantee that her OB/GYN can refer her to a specialist. You do not have to jump through hoops.

Mr. President, 70 percent of the women in this country use their OB/GYN as their only physician from the time they are quite young. So the Robb amendment recognizes the reality.

Let me tell you why we should come together, both parties, on this amendment. Let's look at what happens to women who regularly see an OB/GYN. A woman whose OB/GYN is her regular doctor is more likely to have a complete physical exam, blood pressure readings, cholesterol test, clinical breast exam, mammogram, pelvic exam, and Pap test.

This is why it is so important. These are the threats to women.

The PRESIDING OFFICER. The Senator's 5 minutes have expired.

Mrs. BOXER. I ask unanimous consent for 1 additional minute.

Mr. KENNEDY. I yield 1 minute.

Mrs. BOXER. So you can see that the women who use their OB/GYN on a regular basis get what is necessary for them to stay healthy, to avoid the traumas, to avoid the problem of missing, for example, a breast cancer because they do not have that regular mammogram.

In conclusion, we have Senator ROBB who has long been a champion for women's health, and I can tell you chapter and verse that I have worked with him over these years and he has taken the most important issues to the women of this country and has rolled them into one, plus an additional part that deals with the deductibility of premiums if you are self-employed.

This is a wonderful amendment. This is not an amendment that responds to Democrats, Republicans, or any other party. It is for American women and their families. I urge us to support this fine amendment.

I yield back my time.

Mr. KENNEDY. Mr. President, I take 30 seconds to note that on Tuesday afternoon at 3:30 on the Patients' Bill of Rights, on an issue that is so basic and fundamental and important to American women, we have our Members who are prepared to debate this issue, an issue on which, if my colleagues on the other side have a difference, we ought to be debating. We

cannot even get an engagement of debate on this.

I do not know if that means they are willing to accept it. I would have thought they would have the respect at least for the position of several Members, led by our friend and colleague from Virginia, to speak to this issue.

I yield the Senator from Arkansas 3 minutes.

The PRESIDING OFFICER. The Senator from Arkansas is recognized.

Mrs. LINCOLN. I thank my colleague.

Mr. President, I rise today to make clear my position on such a very important issue. In the forefront of the managed care debate in the early nineties, I diligently supported the concept of trying to manage care, to control the cost of health care in this country in order to provide more health care to more Americans. When we did that, we in Congress never envisioned that medical decisions would be taken away from medical professionals or that an insurance company would circumvent a patient's access to specialists.

Again we are debating this issue of how to provide better health care for more Americans. Today we are talking about the Robb amendment which is absolutely essential to women across this country.

Managed care has been a very necessary and useful tool in our nationwide health care network. It has helped us cut the costs, especially in Medicare. But the issue of making sure women have the opportunity to choose as their primary care giver an OB/GYN is absolutely essential. Most women in this day and age go from a pediatrician to an OB/GYN. To have to go back through a primary care giver in order to see an OB/GYN is absolutely ridiculous.

It is so important to do more to see that women have access to quality care. The Robb amendment takes us in the right direction with three very important provisions. It provides women with direct access to an OB/GYN. They should not have to obtain permission from a gatekeeper. I have had staffers in the past who had awful experiences of having to go to a primary care giver and not even bothering to see their OB/GYN to get the speciality care they needed because it took so much time to go through a primary care giver. That is absolutely inexcusable in this day and age with the kind of speciality care, research, and knowledge we have in our medical professionals.

A great example: A lump is discovered in a woman's breast during a routine checkup. The OB/GYN ought to be able to refer that woman for a mammogram rather than sending her back to the primary care physician. The Robb amendment would designate the OB/GYN as the primary care giver. Most women try to do that already. They already view their OB/GYN as their primary physician.

It is especially important for women in rural areas. They are limited in their access and capability to get to their physicians, and if they cannot see an OB/GYN from a rural area, then they likely are never going to get the speciality care they need and deserve.

Most important, we have to make sure our physicians are able to make those medical decisions. One of the most frustrating comments I ever heard from my husband, who is a physician, is when he spent 1 hour 45 minutes on the telephone with an insurance adjustor after seeing one of his partner's patients who had come through surgery. She was still running a fever, and the nurse called him and said: We have to send this woman home because the insurance company said we had to.

He spent 1 hour 45 minutes on the phone with that insurance adjustor, and at the end of that conversation he finally said: If you can send me your medical diploma and if you will sign an affidavit that you will take complete responsibility for this woman's life, then, and only then, should I be able to discharge her from this hospital, because she is sick.

Yet they were not going to pay for it. He said: We are going to keep her in the hospital, and you are going to be responsible, you are going to pay for that bill, and we are going to ensure the woman is well taken care of.

It is so important for the women across this country to know they will have the primary care they need through their OB/GYN.

I appreciate my colleagues' involvement.

Mr. REID. Mr. President, will the Senator yield?

Mr. KENNEDY. I yield.

Mr. REID. Mr. President, I say to the Senator, the manager of the bill, can he indicate to me why no debate is taking place on the most important amendment we have had to the Patients' Bill of Rights in the 2 days we have been here? What has happened?

Mr. KENNEDY. The Senator raises a good question. We are not going to take advantage of the absence of our Republican colleagues. We are asking where they are. We know they are someplace. I can understand why they do not want to engage in this debate. We have a limited period of time. We are ready to debate. Our cosponsors are here and ready to debate this basic, very important issue. I believe they have made a very strong case.

I guess what they are waiting for is for us to run through the time and perhaps they will come out. Wherever they are, they will come out perhaps at least to try to defend their indefensible position on their legislation.

I note the Senator from Minnesota is here and wants to speak for 5 minutes.

The PRESIDING OFFICER. The Senator from Minnesota is recognized for 5 minutes.

Mr. WELLSTONE. Mr. President, I did not rise to defend the Republican Party position. I am sorry to disappoint my colleagues. I say to the good Senator from Virginia, I am not here to speak against his amendment.

I do find it interesting. I do not think I can repeat with the same eloquence and power what my colleagues have said about what this debate is about in personal terms when we are talking about women. But we could also be talking about a child having to get access to the services he or she needs. This is really a life-or-death issue. It is very important for people to make sure their loved ones, whether it be a wife, a husband, or children, get the care they need and deserve. That is what this debate is all about.

I notice that the insurance industry is spending millions and millions of dollars on all sorts of ads talking about how we are going to have 1.8 million more people lose coverage.

All of a sudden, the insurance industry is concerned about the cost of health care insurance. All of a sudden, the insurance industry in the United States of America is concerned about the uninsured. My colleague from Massachusetts says: Where are our colleagues on the other side of the aisle? Not too long ago, just a couple of hours ago, I heard colleagues come out on the Republican side and talk about how this patient protection was too expensive, families would lose their insurance company, the poor insurance industry—which is making record profits—cannot afford to provide this coverage. Where are they now?

As I look at the figures, 10 leading managed care companies recorded profits of $1.5 billion last year. United Health Care Corporation, $21 million to its CEO; CIGNA Corporation, $12 million to its CEO; and the figures go on and on. Yet we have colleagues coming out to this Chamber—apparently not now—trying to make the argument, even though the Congressional Budget Office says otherwise, even though independent studies say otherwise, that we cannot provide decent patient protection for women because it will be too expensive.

It is not going to be too expensive. What will be too expensive and what will be too costly is when women and children and our family members do not get the care they need and deserve and, as a result of that, maybe lose their lives, as a result of that they are sicker, as a result that there is more illness.

Where do the patients fit in? Where do the women fit in? Where do the children fit in? Where do the families fit in?

I say to Senator KENNEDY, we know where the insurance industry fits in. Here are their ads: Sure, the Kennedy-Dingell bill will change health care; people will lose coverage.

This is outrageous. The insurance industry thinks that by pouring $100 million, or whatever, into TV ads and scaring people, they are going to be able to defeat this effort. They are wrong. The vote on this amendment, and on other amendments, and on this

legislation, will be all about whether Senators belong to the insurance industry or Senators belong to the people who elected us. We should be here advocating for people, not for the insurance industry.

I yield the floor.

Mr. KENNEDY. How much time remains?

The PRESIDING OFFICER. The Senator has 7 minutes 14 seconds.

Mr. KENNEDY. I yield the Senator from Virginia 2 minutes.

The PRESIDING OFFICER. The Senator from Virginia.

Mr. ROBB. Mr. President, I thank you. And I thank our distinguished colleague from Massachusetts for his leadership on this whole bill.

I use this moment to simply commend our colleagues, who happen to be women, who have made the most passionate, persuasive case for this particular amendment that could be made.

Frankly, in listening to my colleague from Maryland about the agony women go through before they have to make a decision about a mastectomy, talking about the difficult choices that women have to make, and adding to it the bureaucracy, where we bounce them back and forth, and talking about money—for this particular amendment, I have heard one estimate that it will be 12 cents a year for the increased cost—we will probably, I suggest, save more money in the lack of administration and bureaucracy than it would cost if we allow women to have as their designated primary care provider their obstetrician or gynecologist. This is the person they go to right now to receive their health care, as pointed out so eloquently by the Senator from California.

As the Senator from Arkansas has noted, this is a very real problem. Her husband happens to practice this particular form of medicine. She gave us a compelling reason as to why we should not subject the women of America to this kind of burden.

I am very grateful to my colleague from Washington, who has long led the fight on this particular issue, and my colleague from Minnesota, and others who have spoken out.

I, frankly, do not understand the argument against this particular proposal. There is no one here to make that argument. I am, frankly, surprised. This makes sense for the women of America.

The PRESIDING OFFICER. The time has expired.

Mr. ROBB. Mr. President, with that, I yield back my time to the Senator from Massachusetts so we might hear again from the Senator from Washington.

Mr. KENNEDY. I yield 3 minutes to the Senator from Washington.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Thank you, Mr. President,

Again, I thank my colleague from Virginia, Senator ROBB, and all of the women and men on the Democratic side who have come out to speak for the Robb-Murray-Mikulski-Boxer amendment, which is so essential to women in this country.

I am astounded that the Republicans have fled the Chamber and have not returned to either agree with us in fighting for women's health or to explain why they are going to vote no.

I was astounded in committee when I offered this amendment and it was defeated on a partisan vote. Where are our colleagues on the Republican side who have come before us so many times and said that they are going to be there at the Race for the Cure? Where are the men of the Senate, when they have been there so many times, saying: You bet we stand for women's health.

This is a women's health issue. Young girls go to a pediatrician until they are 12, 13, or 14. At that time, they change doctors, not a primary care physician but an OB/GYN. Why should they be subjected now to HMO rules that say: We are going to change this, and you are going to have to go to a primary care physician in order to be sent to an OB/GYN? OB/GYNs are our primary care physicians.

As I stated this morning, if you are pregnant and have a serious cold or ear infection, or any other challenging problem that develops when you are pregnant, you will be given a different medication, a different procedure that you need to go through than if you are not pregnant.

Your OB/GYN is your primary care physician from the time you are a teenager until the time you reach menopause, whether you are there because you are pregnant or there because a physician is examining you to determine treatment. But you are there. The OB/GYN is your primary care physician. This amendment will guarantee it.

As Senator MIKULSKI so eloquently stated, a woman who has a mastectomy should not be sent home too soon whether she is 25 years old or 80 years old. In this country, on a daily basis, women are sent home too soon because it is considered, by HMOs, to be cosmetic surgery. This is not cosmetic surgery. A mastectomy is serious surgery. Women should be sent home when their doctor determines they are able to go home. That is what this amendment is about.

We urge our colleagues on the other side to vote with us, to join with us in being for women's health care.

I thank my colleagues who have been here to debate this issue. I especially thank Senator ROBB, who has been a champion for all of us. I look forward, obviously, to the adoption of this amendment since no one has spoken out against it.

The PRESIDING OFFICER. The Senator's side has 2 minutes remaining.

Mr. KENNEDY. Mr. President, we are reaching the final moments for considering this amendment. We, on this side, who have been strong supporters of the Patients' Bill of Rights, think this is one of the most important issues to be raised in the course of this debate. It is an extremely basic, fundamental, and important issue for women in this country.

Our outstanding colleagues have presented an absolutely powerful and indisputable case for our positions. We are troubled that we have had silence from the other side.

We listened yesterday about how beneficial the Republican bill was—when it refuses to provide protections to the millions of Americans our colleagues have talked about.

We are down to the most basic and fundamental purpose of our bill; that doctors and, in this case, women are going to make the decision on their health care needs, not the bureaucrats in the insurance industry.

This is one more example of the need for protections. Our colleagues have demonstrated what this issue is really all about. That is why I hope those Members on the other side that really care about women's health will support this amendment.

Mr. President, we are prepared to move ahead and vote on this amendment.

The PRESIDING OFFICER. Who yields time?

If neither side yields time, time runs equally against both sides.

Mr. KENNEDY. Do I have 1 minute left?

The PRESIDING OFFICER. Seventeen seconds.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. How much time do we have?

The PRESIDING OFFICER. Twenty-five minutes 15 seconds.

Mr. JEFFORDS. Mr. President, I know that my worthy opponents have made note of our absence. We are not ignoring this issue. We have a better answer. There will be a Snowe-Abraham amendment presented, probably tomorrow, that will handle this issue. I think the Members will agree that the approach we take will be preferable to the one being taken right now.

I would like to address my colleagues generally on the situation at this time. The Patients' Bill of Rights Act addresses those areas of health quality on which there is broad consensus. It is solid legislation that will result in a greatly improved health care system for all Americans.

The Committee on Health, Education, Labor, and Pensions, the HELP Committee, has been long dedicated to action in order to improve the quality of health care. Our commitment to developing appropriate managed care standards has been demonstrated by the 17 additional hearings related to health care quality. Senator FRIST's Public Health and Safety Subcommittee held three hearings on the work of the Agency for Health Care

Policy and Research, sometimes referred to as AHCPR. Each of these hearings helped us to develop the separate pieces of legislation that are reflected in S. 326, the Patients' Bill of Rights Act. People need to know what their plan will cover and how they will get their health care.

The Patients' Bill of Rights requires full disclosure by an employer about health plans it offers to employees. Patients also need to know how adverse decisions by a plan can be appealed, both internally—that is, within the HMO—and externally, through an independent medical reviewer. Under our bill, the reviewer's decision will be binding on the health plan. We are talking about an external, outside reviewer, and it is binding. There is no appeal. It is binding. They have to do it. However, the patient will retain his or her current rights to go to court.

Timely utilization decisions and a defined process for appealing such decisions are the keys to restoring trust in the health care system. Our legislation also provides Americans covered by health insurance with new rights to prevent discrimination based on predictive genetic information. This is a crucial provision. It ensures that medical decisions are made by physicians in consultation with their patients and are based on the best scientific evidence. That is the key phrase. We want to remember that one because you won't see it on the other side.

It provides a stronger emphasis on quality improvement in our health care system with a refocused role for AHCPR, taking advantage of all the abilities we have now to understand better what is going on with respect to health care in this country, to sift through the information that comes through AHCPR and make judgments on what the best medicine is.

Some believe that the answer to improving our Nation's health care quality is to allow greater access to the tort system, maybe a better lawsuit. However, you simply cannot sue your way to better health. We believe that patients must get the care they need when they need it. They ought not to have to go to court with a lawsuit. They ought to get it when they need it. It is a question of whether you want good health or you want a good lawsuit.

In the Patients' Bill of Rights, we make sure each patient is afforded every opportunity to have the right treatment decision made by health care professionals. In the event that does not occur, patients have the recourse of pursuing an outside appeal to get medical decisions by medical people to give them good medical treatment. Prevention, not litigation, is the best medicine.

Our bill creates new, enforceable Federal health standards to cover those 48 million people of the 124 million Americans covered by employer-sponsored plans. These are the very same people that the States, through their regulation of private health insurance companies, cannot protect. We will protect them.

What are these standards? They include, first, a prudent layperson standard for emergency care; second, a mandatory point of service option; direct access to OB/GYNs and pediatricians—that has not been recognized by the opposition—continuity of care; a prohibition on gag rules; access to medication; access to specialists; and self-pay for behavioral health.

It would be inappropriate to set Federal health insurance standards that duplicate the responsibility of the 50 State insurance departments.

Mr. KENNEDY. Will the Senator yield on that issue?

Mr. JEFFORDS. I am happy to yield.

Mr. KENNEDY. Can the Senator show us one State that has the patient protections included in our proposal? Is there just one State in this country, one State that provides those types of protections?

Mr. JEFFORDS. I believe Vermont does.

Mr. KENNEDY. All of the protections for the patients? I know the Senator understands his State well, but does the Senator know of any other State that provides these kinds of protections?

Mr. JEFFORDS. We are going to provide them with better protections.

Mr. KENNEDY. The scope of your legislation only includes a third of all the people who have private health coverage.

Mr. JEFFORDS. Well, in some areas we go beyond that, as the Senator well knows.

Mr. KENNEDY. No, I don't know. I don't know, because you talk about self-insured plans, and there are only 48 million Americans in those plans. You don't cover the 110 million Americans who have other health insurance plans.

Does the Senator know a single State that provides specialized care for children if they have a critical need for specialty care—one State in the country? We provide that kind of protection. Does the Senator know a single State that has that kind of protection?

Mr. JEFFORDS. I tell you, we have a better health care bill. That is all I am telling you. It will protect more people at less cost. Your bill is so expensive that you are going to affect a million people, and those people are the ones we want most to protect. Those are the people who are working low-income jobs and who will be torn off and removed from health care protection by your bill. We will not do that. We are going to protect those people who need the protection the most from being denied health insurance.

I take back the remainder of my time.

It would be inappropriate to set Federal health insurance standards that duplicate the responsibility of the 50 State insurance departments. As the National Association of Insurance Commissioners put it:

> We do not want States to be preempted by Congressional or administrative actions. . .Congress should focus attention on those consumers who have no protections in the self-funded ERISA plans.

Senator KENNEDY's approach would set health insurance standards that duplicate the responsibility of the 50 State insurance departments. Worse yet, it would mandate that the Health Care Financing Administration, HCFA, enforce them, if the State decides otherwise. It would be a disaster—HCFA can't even handle the small things they have with HIPAA, the Medicare and Medicaid problems—to get involved in the demands that would be placed upon them by the Democratic bill.

This past recess, Senator LEAHY and I held a meeting in Vermont to let New England home health providers meet with HCFA. It was a packed and angry house, with providers traveling from New Hampshire, Massachusetts, and Connecticut. That is who the Democrats would have enforce their bill. It is in no one's best interests to build a dual system of overlapping State and Federal health insurance regulation.

Increasing health insurance premiums causes significant losses in coverage. The Congressional Budget Office, CBO, pegged the cost of the Democratic bill at six times higher than S. 326. Based on our best estimates, passage of the Democratic bill would result in the loss of coverage for over 1.5 million working Americans and their families.

Now, why do you want to charge forward with that plan? To put this in perspective, this would mean they would have their family's coverage canceled under the Democratic bill—canceled. Let me repeat that. Adoption of the Democratic approach would cancel the insurance policies of almost 1.5 million Americans, CBO estimates. I cannot support legislation that would result in the loss of health insurance coverage for the combined population of the States of Virginia, Delaware, South Dakota, and Wyoming—no coverage.

Mrs. MURRAY. Will the Senator yield for a question?

Mr. JEFFORDS. Fortunately, we can provide the key protections that consumers want, at a minimal cost and without the disruption of coverage, if we apply these protections responsibly and where they are needed.

In sharp contrast to the Democratic alternative, our bill would actually increase coverage. With the additional Tax Code provisions of S. 326, the Patients' Bill of Rights Act, our bill allows for full deduction of health insurance for the self-employed, the full availability of medical savings accounts, and the carryover of unused benefits from flexible spending accounts.

Mrs. MURRAY. Will the Senator from Vermont yield for a question?

Mr. JEFFORDS. With the Patients' Bill of Rights Plus Act, we provide Americans with greater choice of more affordable health insurance.

Mrs. MURRAY. Will the Senator from Vermont yield for a question?

Mr. JEFFORDS. Yes.

Mrs. MURRAY. I thank the Senator.

I was listening to his discussion about the Republican bill. The current pending amendment, the Robb-Murray amendment, allows women access to OB/GYNs as their primary care physicians. Will the bill the Senator is discussing provide direct access for all of those women who are not in self-insured programs in this country?

Mr. JEFFORDS. We will have an amendment which will deal with that problem.

Mrs. MURRAY. All women in this country who are not in self-insured programs will have access under the amendment you are going to be offering?

Mr. JEFFORDS. First of all, we defer to the States in that regard.

Mrs. MURRAY. Then I can assume that the women who are not in self-insured programs will not be covered by the Republican amendment.

Mr. JEFFORDS. Our bill covers, as we intended to cover, those who need the coverage now who have no coverage and get the protection to those who need the protection. We will have an amendment that will take care of the problems that are——

Mrs. MURRAY. Not the self-employed. That is the answer.

Mrs. BOXER. Will the Senator yield for a question?

Mr. JEFFORDS. I think the Senator has her own time.

Mrs. BOXER. I wanted to ask the Senator one question.

Mr. JEFFORDS. Yes.

Mrs. BOXER. Is the Senator aware that when he talks about people losing their insurance, there is a $100 million effort going on by the HMOs to scare people into thinking that if the Democratic Patients' Bill of Rights passes—which is supported by all the health care advocate groups in the country—they will lose their insurance?

Is the Senator aware that his own Congressional Budget Office has clearly stated the maximum cost of the Democratic Patients' Bill of Rights is $2 a month?

And further, is the Senator aware that the President, by executive order, gave the Patients' Bill of Rights to Federal employees, and there has been no increase in the premium?

So what I am asking the Senator is, is he aware of this campaign by the HMOs? Has he seen the commercials? Does he believe the HMOs that who have an interest in this, the CEOs of which are getting $30 million a year, really have the interests of patients in their heart?

Mr. JEFFORDS. I say that the Senator was successful in stealing some time from me. Let me say that we have differences of opinions on these bills. There is no question that your bill is much more expensive, that it is going to cost 6 percent, and that CBO estimates 1.5 million people—all of which you say you care most about, I say to the Senator from California, the low-income people, the people who are just barely able to have plans right now, and small businesses that won't be able—1.5 million people will lose their health insurance if your plan is put in.

Mrs. BOXER. I say to the Senator——

The PRESIDING OFFICER. The Senator from Vermont has the floor.

Mr. JEFFORDS. S. 326, the Patients' Bill of Rights Plus Act, provides necessary consumer protections without adding significant new costs, without increasing litigation, and without micromanaging health plans.

Our goal is to give Americans the protections they want and need in a package they can afford and that we can enact. This is why I hope the Patients' Bill of Rights we are offering today will be enacted and signed into law by the President.

Mr. President, I yield to the Senator from Tennessee.

The PRESIDING OFFICER. The Senator from Tennessee is recognized.

Mr. FRIST. Mr. President, I want to take a few minutes to return to the underlying amendment. It has taken me a while to read through the amendment. The first time I saw the amendment was 30 minutes ago. I have just read through the amendment offered by Senator KENNEDY and others which relates to certain breast cancer treatment and access to appropriate obstetrical and gynecological care.

I apologize for not being able to participate directly on in this issue earlier. At the outset, I will say that about 2 years ago, Senator Bradley from New Jersey and I had the opportunity to participate in writing an amendment that actually eventually became law which addressed the issue of postmaternity stay, postdelivery stay. We wrote that particular piece of legislation because we felt strongly that managed care had gone too far in dictating how long people stayed in the hospital and pushing them out after deliveries, and it was a little controversial, although I think a very good bill for the time, because it sent a message very loudly and clearly to the managed care industry that you need to leave those decisions, as much as possible, at the local level where physicians and patients, in consultation with each other, determine that type of care.

The amendment on the floor is different in that it focuses on another aspect of women's care and that is breast cancer treatment. As to the debate from the other side of the aisle, I agree with 98 percent of what was said in terms of the importance of having a woman be able to access her obstetrician and gynecologist in an appropriate manner, the need for looking at inpatient care, to some extent as it relates to breast disease. Yet I think the approach that Senator KENNEDY and others have put on the floor is a good start but has several problems. Therefore, I urge all of my colleagues to vote against that amendment, with the understanding we can take the good efforts from that amendment, correct the deficiencies, and address the very same issues that have been identified so eloquently by my colleagues across the aisle.

Now, in looking at the Kennedy-Robb amendment, on page 2, they talk about:

> . . . health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in his or her professional judgment. . . .

So far, I agree wholeheartedly. But where I cannot vote in good conscience, or allow my colleagues to, without fully understanding the implications, is where they continue and say:

> . . . consistent with generally accepted medical standards, and the patient, to be medically appropriate following—(A) a mastectomy; (B) a lumpectomy; or (C) a lymph node dissection.

I agree with all of that and inpatient care. The part that bothers me is the ''consistent with generally accepted medical standards.'' This goes into the debate we will go into tomorrow, or the next day, on medical necessity and what medical necessity means.

When we talk about what is medically appropriate and medically necessary, you are going to hear me say again and again that we should not try to put that into law, Federal statute. We should not define ''medical necessity'' as generally accepted medical practices or standards. The reason is, as exemplified in this chart, nobody can define generally accepted medical standards. You will go up to a physician and a physician will say: That is what I do every day.

Well, that is not much of a definition, I don't think. Therefore, I am not sure we should use those terms and put them into a law and pass it as an amendment and make it part of the Patients' Bill of Rights.

This chart is a chart that shows the significant variation of the way medicine is practiced today, and that generally accepted medical standards has such huge variations that the definition means nothing. Therefore, I am not going to put into a Federal statute a definition that means very little because I think, downstream, that can cause some harm because maybe a bunch of bureaucrats will try to give that definition.

Mr. SANTORUM. If the Senator will yield, he is arguing that it doesn't mean anything. It means everything. Really it is sort of the opposite of that. It has such an expansive character to it that it can include inappropriate medicine, which is, I think, the point the Senator is making.

Mr. FRIST. I think that is right. My colleague said it much more clearly than I. The definition itself of ''medically necessary and appropriate'' is so important that we should not lock the definition into something that is so

small, so rigid, that we can't take into consideration the new advances that are coming along. That is why when we say generally accepted medical standards or practices, it leaves out the best evidence, the new types of discoveries that are coming on line. That decision should be made locally and should not be definitions put into a statute. Therefore, I am going to oppose this amendment.

Mr. ROBB. Will the Senator yield?

Mr. FRIST. Let me try to get through my presentation.

Mr. ROBB. Will the Senator yield?

Mr. FRIST. I will not yield.

Let me go through for my colleagues why the variation in medical practice has implications that may be unintended and therefore we cannot let the amendment pass.

Reviewing regional medical variations for breast-sparing surgery—basically for breast cancer today—I don't want to categorize this too much because the indications change a little bit. In a lumpectomy—taking out the lump itself and radiating because it is the least disfiguring—the outcome is equally good as doing a mastectomy and taking off the whole breast.

In my training—not that long ago, 25 years—the only treatment was mastectomy. As we learned more and more and radiation therapy became more powerful, we began to understand there are synergies in doing surgical operations and radiation therapy and chemotherapy. We didn't have to remove or disfigure the whole breast. The new therapy ended up being better for the patient but was not generally accepted medically. That sort of variation is shown in this chart.

In this chart, the very dark areas use lumpectomy versus mastectomy. Comparing the two, the high ratio of around 20 to 50 percent, versus going down to the light colors on the chart where this procedure is not used very much, there is tremendous variation. The different patterns of color on the chart demonstrate that a procedure generally accepted in one part of the country may be very different in another part of the country.

For example, in South Dakota, using this ratio of lumpectomy versus mastectomy, the ratio is only 1.4 percent.

In Paterson, NJ, the generally accepted medical standards in that community go up almost fortyfold to 37.8 percent—the relative use of one procedure, an older procedure, versus a newer procedure.

Which of those are generally accepted medical standards? That shows the definition itself has such huge variation that we have to be very careful when putting it into Federal statute. We will come back to that because it is a fundamentally important issue. Medicine is practiced differently around the country. Therefore, the words ''generally accepted medical standards'' have huge variations. We have to be careful what we write into law.

What I am about to say builds on the work of Senators SNOWE and ABRAHAM.

How much time do I have remaining?

The PRESIDING OFFICER. The Senator has 20 minutes 50 seconds.

Mr. FRIST. Again, Senators SNOWE and ABRAHAM will talk more about this a little bit later.

Instead of using language such as ''generally accepted medical standards,'' it has a built-in inherent danger because it defines what ''medical necessity and appropriate'' are.

We should be looking at words as follows: That provides a group health plan and a health insurance issuer providing health insurance coverage, that provides medical and surgical benefits, shall ensure that inpatient coverage—just like the Kennedy-Robb amendment with respect to the treatment of breast cancer—is provided for a period of time as determined by the attending physician, as the Kennedy-Robb amendment does, in consultation with the patient. I think this is ''in consultation with the patient.''

No, they do not have in their bill ''in consultation with the patient.'' I suggest ''in consultation with the patient'' should be part of their amendment.

We would put in ''in consultation with the patient'' to be ''medically necessary and appropriate,'' instead of using their words ''generally accepted medical standards,'' which has such huge variation.

Why not use the better terminology, ''medically necessary and appropriate''?

Use the same indications. Mastectomy is what we will propose, what they propose. Lumpectomy is what we propose, what they will propose. Lymph node dissection, we will use that language.

But ''generally accepted medical standards'' is dangerous. We ought to use such words as ''medically necessary and appropriate.'' Then we are not locked into the variation where there is a fortyfold difference in mastectomies versus lumpectomy, which shows the importance of being very careful before placing Federal definitions of what is ''medically necessary and appropriate'' in Federal law.

Mr. LEAHY. Mr. President, I was going to make a unanimous consent request.

Mr. FRIST. I yield to the unanimous consent request.

PRIVILEGE OF THE FLOOR

Mr. LEAHY. I ask unanimous consent that Alex Steele of my office be granted privilege of the floor today.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. FRIST. In the Kennedy-Robb amendment is the issue of access.

Again, my colleagues on the other side hit it right on the head: Women today want to have access to their obstetrician. They don't want to go through gatekeepers to have to get to their obstetrician or gynecologist. That relationship is very special and very important when we are talking about women's health and women's diseases.

In the Kennedy-Robb amendment, the language is that the plan or insurer shall permit such an individual who is a female to designate a participating physician who specializes in obstetrics and gynecology as the individual's primary care provider.

It is true that in our underlying bill we don't say the plan has to say that all obstetricians and gynecologists are primary care providers. That is exactly right. The reasons for that are manyfold.

Let me share with Members what one person told me. Dr. Robert Yelverton, chairman of the American College of Obstetricians and Gynecologists' Primary Care Committee, stated:

> The vast majority of OB/GYNs in this country have opted to remain as specialists rather than act as primary care physicians.

He attributes this to the high standards that health plans have for primary care physicians, saying:

> None of us could really qualify as primary care physicians under most of the plans, and most OB/GYNs would have to go back to school for a year or more to do so.

You can argue whether that is good or bad, but it shows that automatically taking specialists and making them primary care physicians and putting it in Federal statute is a little bit like taking BILL FRIST, heart and lung transplant surgeon, and saying: You ought to take care of all of the primary care of anybody who walks into your office.

Mrs. BOXER. Will the Senator yield?

Mr. FRIST. I will finish my one presentation, and we will come back to this.

Mrs. BOXER. Will the Senator yield?

The PRESIDING OFFICER. The Senator does not yield.

Mrs. BOXER. Why do you not yield?

The PRESIDING OFFICER. The Senator did not agree to yield.

Mr. FRIST. I simply want the courtesy of completing my statement. I know people want to jump in and ask questions, but we have listened to the other side for 50 minutes on this very topic. I am trying to use our time in an instructive manner, point by point, if people could just wait a bit and allow me to get through my initial presentation of why I think this amendment must be defeated with a very good alternative.

I want to get into this issue of access to obstetricians and gynecologists. In our bill that has been introduced, we take care of this. I believe strongly we take care of it. We say, in section 723: The plan shall waive the referral requirement in the case of a female participant or beneficiary who seeks coverage for routine obstetrical care or routine gynecological care.

We are talking about routine women's health issues. We waive the referral process. There is not a gatekeeper. A patient goes straight to their obstetrician and gynecologist. That is what women tell me they want in terms of access to that particular specialized, trained individual.

It is written in our bill. Let me read what is in our bill.

The plan shall waive the referring requirement in the case of a female participant or beneficiary who seeks routine obstetrical care or routine gynecological care.

Therefore, I think the access provisions in the Kennedy-Robb amendment are unnecessary and are addressed in our underlying bill. Plus, they go one step further in saying that this specialist is the individual's primary care provider. I am just not sure of the total implications of that, especially after an obstetrician who is the chairman of the American College of Obstetrics and Gynecology very clearly states that merely assuming that a specialist is a good primary care physician is not necessarily correct.

Also, in our bill, beyond the routine care—this is in section 725 of our bill where we address access to specialists—we say:

A group health plan other than a fully insured health plan shall ensure that participants and beneficiaries have access to specialty care when such care is covered under the plan.

So they have access to specialty care when obstetrics care and gynecological care is part of that plan.

So both here and in the earlier provision of section 723, where we talk about routine obstetrical care, there is no gatekeeper; there is no barrier; a woman can go directly to her obstetrician and her gynecologist, which is what they want. Or, if you fall into the specialty category in provision 725, you have access to specialty care when such care is covered under the plan.

As I go through the Kennedy-Robb plan, and this is obviously the amendment that we are debating on the floor, there are a number of very reasonable issues in there. Again, I think the intent of the amendment is very good. I do notice secondary consultations in the amendment. I think, as we address the issue of women's health, obstetrical care, breast cancer treatment, access to appropriate care, which we plan on addressing and we will address, I believe, this is the amendment Senators SNOWE and ABRAHAM have been working on so diligently, the idea of secondary consultations.

About 2 months ago we did a women's health conference. It was wonderful. It was in Memphis, TN. It was on women's health issues. Maybe 200 or 300 people attended, focusing on women's health issues. We talked about the range of issues, whether it was breast cancer, cervical cancer, osteoporosis, diseases of the aging process, but an issue which came up was the issue of secondary consultations. Because it is dealing with something that is very personal to them, women say: Is there any way we can reach out in some way with health plans to lower the barriers for us to get a second opinion?

Why is that important? Part of that is important because of this huge variation. If you go to one doctor and he says do a mastectomy, which is very disfiguring, it is very clearly indicated—there are clear-cut indications for mastectomy or lumpectomy today. If you hear two different versions, you may want to get a secondary opinion or a secondary consultation.

What we are looking at in that regard is language similar to this: to provide coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields.

''Medical fields,'' I think we need to go a little bit further and focus on whether it is pathology or radiology or oncology or surgery to confirm—and I think it should be part of the language—to confirm or to refute the diagnosis itself. That is full coverage by the plan for secondary consultations for cancer as it deals with women's health issues.

I think that will be an important part to include as we address this very specific field. It is totally absent in the Kennedy-Robb amendment. I propose offering an amendment which does much of what they say in terms of inpatient care, changing this terminology from ''generally accepted medical standards,'' which I think is potentially dangerous, and move on to the language which I think should be used, which is ''medically necessary and appropriate.''

The access issue, I believe, we have developed. There are other issues in the bill that I will work with Senators ABRAHAM and SNOWE to address, in a systematically and well-thought-out way, so we can do what is best for women in this treatment of cancer, breast cancer, mastectomy, and access to obstetricians and gynecologists. That is something about which we need to ensure that no managed care plan says: No, you cannot go see your obstetrician; or, no, you cannot go see your gynecologist; or, no, you have to hop through a barrier; or, no, you have to go see a gatekeeper before you can see your obstetrician/gynecologist. We are going to stop that practice, and we are going to stop that in the Republican bill we put forward.

I have introduced the concept today—again, it is very important—of medical necessity and how we define what is medically necessary and appropriate. It is something critical. It is something we are going to come back to. I think with all the issues we are discussing, if we try to put in Federal law, Federal statute, a definition of what is medically necessary and appropriate instead of leaving it up to a physician who is trained in the field, a specialist, we are going in the wrong direction and have the potential for broadly harming people.

I urge defeat of this amendment with the understanding we are going to come back and very specifically address the issues I have talked about today.

I yield the floor.

Mr. LIEBERMAN. Mr. President, I rise today to express my support for the Robb-Murray amendment, which provides our mothers, wives, daughters and sisters with direct access to OB/GYN care and strengthens the ability of a woman and her doctor to make personal medical decisions.

The sponsors of this amendment, along with most women and most Americans, believe that a woman should have the choice and the freedom to select an OB/GYN physician as her primary care provider and to determine, in consultation with her doctor, how long she should stay in the hospital following surgery.

Those critical and deeply personal judgments should not be trumped by the arbitrary guidelines of managed care companies. The women in our lives deserve better than drive-by mastectomies. With the Robb-Murray amendment, we will say so in law, and ensure that women receive the services they need and the respect they are owed.

Studies show that when women have a primary care physician trained in OB/GYN, they receive more comprehensive care and greater personal satisfaction when they are treated by doctors trained in other specialties.

We should consider, too, that breast cancer is the second leading killer of women in this country. New cases of this disease occur more than twice as often as second most common type of cancer, lung cancer. More than 178,000 women in this country were diagnosed with breast cancer in 1998. I have no doubt we will someday find the origin and cure for this terrible malady. Until then, though, we have a duty to make the system charged with treating these women respectful and responsive to their needs.

Sadly, the evidence suggests we have a long way to go. We continue to receive disturbing reports about the insistence of some insurance companies to force women out of the hospital immediately after physically demanding and emotionally traumatic surgeries. We have been shocked by stories of women being sent home with drainage tubes still in their bodies and groggy from general anesthesia. This is distressing to me not just as a policymaker, but as a son, father, and husband.

Now, some critics of the Robb-Murray Amendment want to sidestep this problem, and suggest that we are legislating by body part. To that, I say:

Those who oppose this provision are wasting a valuable opportunity to increase the quality of physical health care for over half the population of the United States.

Those who oppose are ignoring the suffering and inconvenience of women throughout this country trying to receive the basic health care that they have every right to expect.

Those who oppose are failing to right a wrong that we have tolerated for too long.

Mr. President, women are being denied the quality of care they are paying for and to which they have a moral right. And this Senate has a chance today to begin fixing this inequity. I urge my colleagues to look beyond the rhetoric and see the very simple and fair logic that calls for the passage of this amendment, and join us in supporting it.

Several Senators addressed the Chair.

The PRESIDING OFFICER. Who yields time? The Senator from Oklahoma.

Mr. NICKLES. Mr. President, how much time remains on this amendment?

The PRESIDING OFFICER. There are 7 minutes and 26 seconds on the side of the Senator from Oklahoma. The other side has used all its time.

Mr. NICKLES. Mr. President, let me make a couple of comments. I heard my friend and colleague from Massachusetts say: Where is everybody in the debate? We have just received the amendment. I would like to look at it, and I had a chance to look at it while some of the debate was going on. I would like to make a couple of comments on it.

I found in the amendment—

Mr. KENNEDY. On that point, will the Senator yield?

Just on the point of the representation you just made. It is virtually the same amendment that was offered in the committee.

The PRESIDING OFFICER. Does the Senator yield?

Mr. NICKLES. No, I do not.

Mr. KENNEDY. It is not a surprise. It is the same amendment, effectively.

Mr. NICKLES. The Senator from Massachusetts says it is the same amendment offered in committee, but that is not factual. The Senator can correct me if I am wrong, but this amendment deals with Superfund. This amendment deals with transferring money from general revenue into Social Security. That was not offered in committee. There are few tax provisions in here. I asked somebody: What is this extension of taxes on page 17? My staff tells me it is a tax increase of $6.7 billion on Superfund. I don't know what that has to do with breast cancer, but it is a tax increase on Superfund.

I know we need to reauthorize Superfund. I didn't know we were going to do it on this bill. I stated in the past we are not going to pass the Superfund extension until we reauthorize it. We should do the two together. Why are we doing it on this bill?

So there are tax increases in here that nobody has looked at. They did not do that in the Labor Committee or the health committee, I do not think. I asked the Chairman of the committee. I don't think they passed tax increases on Superfund. That does not belong in the HELP Committee.

Certainly transferring money from the general revenue fund, as this bill does, into the Social Security trust fund, was not done in the HELP Committee, I do not think. It should not have been done. My guess is the Finance Committee might have some objections. Senator ROTH is going to be on the floor saying: Wait a minute, what is going on?

So there is a lot of mischief in these amendments. Some of us have not had enough time. One of the crazy things about this agreement is we are going to have amendments coming at us quickly. We have to have a little time to study them. Sometimes we find some things stuck in the amendments which some of us might have some objections with.

I want to make a couple of comments on the amendment. In addition to the big tax increases hidden in the bill, this amendment also strikes the underlying amendment that many of us have proposed on this side that says, whatever we should do we should do no harm. If we are going to increase premiums by over 1 percent; let us not do a bill. Maybe people forgot about that, but that is an amendment we offered earlier. This amendment, the Robb amendment, says, let's strike that provision. We do not care how much the Kennedy bill costs.

Some of us do care how much it costs. We do not want to put millions of people into the ranks of the uninsured. We do not want to do harm. Unfortunately, the amendment proposed by Senator ROBB and others would do that. It would strike that provision. It would eliminate that provision.

On the issue of breast cancer and mastectomy and lumpectomy and so on, Senator FRIST has addressed it a little bit. Senator SNOWE and others will be offering an amendment that is related and, I will tell you, far superior to the amendment we have on the floor.

I do not know if we will get to it tonight. Certainly, we will get to it tomorrow. It is a much better amendment. It is an amendment that has been thought out. It is an amendment that does not have Superfund taxes in it. It is an amendment that includes, as this bill does, transfers from the general revenue fund into the Social Security trust.

I urge my colleagues at the appropriate time to vote ''no'' on the Robb amendment, and then let's adopt the underlying amendment which says we should not increase health care costs by more than 1 percent; let's not do damage to the system; let's not put people into the ranks of uninsured by playing games, maybe trying to score points with one group or another group. Let's not do that. Let's not make those kinds of mistakes.

If people have serious concerns dealing with breast cancer and how that should be treated, again, Senator SNOWE, Senator ABRAHAM, and Senator FRIST have an amendment they have worked on for some time that I believe is much better drafted. It does not have Superfund taxes in it. It does not have a transfer of general revenue funds into the Social Security trust fund. It does not make these kinds of mistakes that we have, unfortunately, with this pending amendment.

Mr. GREGG. Will the Senator yield for a question?

Mr. NICKLES. I ask how much time we have?

The PRESIDING OFFICER. The Senator has 2½ minutes.

Mr. GREGG. As I understand it, by repealing the underlying amendment, which would limit the cost increase to 1 percent and would say, in the alternative, if 100,000 people are knocked off the rolls of insured, the bill will not go forward. If we repeal that and those 100,000 people are knocked off the rolls, they are not going to have any insurance for mastectomies; right?

Mr. NICKLES. The Senator is exactly right.

Mr. GREGG. Basically, the proposal of the Senator from Virginia, supported by Senator KENNEDY, uninsures potentially 100,000 women from any mastectomy coverage as a result of their amendment or any other coverage.

Mr. NICKLES. The Senator makes a good point, but probably not 100,000. Estimates would probably be much closer to 2 million people would be uninsured and have no coverage whatsoever in any insurance proposal if we adopt the underlying Kennedy amendment.

Mr. GREGG. Of those 2 million people, we can assume potentially half would be women. So we have approximately 1 million women who would not have insurance as a result of this amendment being put forward on the other side.

Mr. NICKLES. The Senator is correct.

Mr. SANTORUM. Mr. President, will the Senator from Oklahoma yield for a question? As a matter of fact, we have some information just provided to us that under the Kennedy legislation, S. 6, with 1.9 million people no longer being insured, you would have 188,595 fewer breast examinations. If people had their routine breast examinations, of those 1.9 million, a certain percentage would be women, that would be the number of breast exams that would no longer take place if this legislation passed.

We hear so much talk about ''in human terms,'' and they say this argument does not cut. These people are going to lose insurance. They will lose insurance. They will not get coverage so you do not have to worry about covering them for a mastectomy. They are going to find out, in many cases, unfortunately, far too late for even those kinds of treatments to be helpful. That is what we are trying to prevent in not passing a bill that drives up costs dramatically which drives people out of the insurance area.

Mr. NICKLES. I appreciate my colleague's comment. I yield back the remainder of my time and ask for the yeas and nays on the amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

Mr. KENNEDY. I yield myself 2 minutes on the bill.

The PRESIDING OFFICER. The Senator is recognized.

Mr. KENNEDY. Mr. President, the more we debate, the more confused our good colleagues on the other side, quite frankly, become. The underlying amendment dealing with the OB/GYN is the amendment that was offered in committee and that is no surprise.

The other provision the Senator from Oklahoma talks about is funding the self-insurance tax deduction introduced by the Senator from Oklahoma without paying for it. This would subject the bill to a point of order if it was carried all the way through. He did not pay for it.

It is a red herring. Time and time again we have put in the General Accounting Office document which states that the protections in this bill will enhance the number of people insured, not reduce the number.

Does the Senator from Pennsylvania actually believe we are endangering breast cancer tests for women, reducing Pap tests, reducing examinations for breast cancer and yet the breast cancer coalition supports our proposal? Is he suggesting any logic to his position?

Mr. President, I yield back the remainder of the time and look forward to the vote.

The PRESIDING OFFICER. The Senator from Oklahoma.

Mr. NICKLES. Mr. President, I yield myself 1 minute on the bill.

The Senator from Pennsylvania is right. The whole essence of the second-degree amendment is to kill the underlying amendment because the Senator from Massachusetts does not want to say we will not increase costs by more than 1 percent, because, frankly, he wants to, and expects to, increase costs by 5 or 6 percent. The net result of that will be to uninsure a couple million people, half of which could be women, half of which will not get those exams, half of which will not get those screenings, half of which will not get the care they need. That is the purpose of the amendment.

In the process, he also increases Superfund taxes and also comes up with general transfers of money from the general revenue fund to the Social Security fund. That is a mistake.

I urge my colleagues to vote no and keep in mind that in dealing with breast cancer, Senator SNOWE, Senator FRIST, and Senator ABRAHAM will offer a much better proposal later in this debate. I yield the floor.

The PRESIDING OFFICER. All time having been yielded back, the question is on agreeing to amendment No. 1237. The yeas and nays have been ordered. The clerk will call the roll.

The legislative assistant called the roll.

The result was announced—yeas 48, nays 52, as follows:

[Rollcall Vote No. 198 Leg.]

YEAS—48

Akaka	Edwards	Lieberman
Baucus	Feingold	Lincoln
Bayh	Feinstein	Mikulski
Biden	Graham	Moynihan
Bingaman	Harkin	Murray
Boxer	Hollings	Reed
Breaux	Inouye	Reid
Bryan	Johnson	Robb
Byrd	Kennedy	Rockefeller
Chafee	Kerrey	Sarbanes
Cleland	Kerry	Schumer
Conrad	Kohl	Specter
Daschle	Landrieu	Torricelli
Dodd	Lautenberg	Warner
Dorgan	Leahy	Wellstone
Durbin	Levin	Wyden

NAYS—52

Abraham	Frist	McConnell
Allard	Gorton	Murkowski
Ashcroft	Gramm	Nickles
Bennett	Grams	Roberts
Bond	Grassley	Roth
Brownback	Gregg	Santorum
Bunning	Hagel	Sessions
Burns	Hatch	Shelby
Campbell	Helms	Smith (NH)
Cochran	Hutchinson	Smith (OR)
Collins	Hutchison	Snowe
Coverdell	Inhofe	Stevens
Craig	Jeffords	Thomas
Crapo	Kyl	Thompson
DeWine	Lott	Thurmond
Domenici	Lugar	Voinovich
Enzi	Mack	
Fitzgerald	McCain	

The amendment (No. 1237) was rejected.

Mr. NICKLES. Mr. President, I move to reconsider the vote.

Mr. BOND. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 1238 TO AMENDMENT NO. 1236

(Purpose: To make health care plans accountable for their decisions, enhancing the quality of patients' care in America)

Mr. NICKLES. Mr. President, I send an amendment to the desk on behalf of Senator FRIST, Senator JEFFORDS, and others, and ask for its immediate consideration.

The PRESIDING OFFICER (Mr. HAGEL). The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Oklahoma [Mr. NICKLES], for Mr. FRIST, for himself and Mr. JEFFORDS, proposes an amendment numbered 1238 to amendment No. 1236.

Mr. NICKLES. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The text of the amendment is printed in today's RECORD under ''Amendments Submitted.'')

Mr. NICKLES. Mr. President, for the information of our colleagues, we have now disposed of the Democrats' second-degree amendment to the first-degree amendment proposed by the Republicans, which first-degree amendment would limit the cost of the Kennedy health care bill to 1 percent. Now I have sent a second-degree amendment up under the unanimous consent agreement. Each side could offer a second-degree.

The amendment I sent to the desk on behalf of Senators FRIST, JEFFORDS, and others, is a very important amendment, so I hope all of our colleagues will listen to it. The amendment would strike the medical necessity definition that was in the Kennedy bill and replace it with the grievance/appeals process we have in our bill. In other words, it is a very significant amendment, one that we had significant discussion on last week. Some of our colleagues said they really wanted to vote on it last week. We will get to vote on it, depending on the majority leader's intention. If the time runs on this amendment, all time would be used, and we would probably be ready for a vote at about 6:40. Of course, it would be the majority leader's call whether or not to have a vote.

The amendment deals with medical necessity. It replaces the definition in the Kennedy bill with the grievance and appeals process that we have in the Republican package, which I think is a far superior package as far as improving the quality of care. I compliment Senator JEFFORDS, Senator FRIST, and others for putting this together.

I yield the floor.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. Mr. President, this is an extremely important amendment. I think everyone ought to understand exactly what we are trying to do.

We are entering into a new era with respect to the availability of health care, good health care, excellent health care. We have seen pharmaceuticals being devised which would do miraculous things. We are also having medical procedures designed and devices created. But what we have not seen is their being available everywhere, or a standard that will make them available in areas where they ought to be available.

What we are trying to do today is establish that every American is entitled to the best medical care available, not that which is generally available in your area; not be different from one end of the country to the other but that everyone is entitled to that health care, especially if you are in an HMO. They should be, and must be, aware of what is the best health care that would serve you to make you a well person.

For a couple of days now, we have heard many tragic stories about children who were born with birth defects or who were injured because the private health care system failed them in some manner. I know my colleagues on the other side of the aisle have a bill they believe would address these situations. The Republican health care bill addresses the concerns people have about their health care without causing new problems.

Americans want assurance that they will get the health care they need when they need it. I am going to describe exactly how the Republican bill does just that. I am also going to describe how the Republican bill will create new patient rights and protections which

would have prevented the tragic situations described by my colleagues on the other side of the aisle.

Finally, I want to talk about how the Republican bill achieves these goals in an accountable manner, without increasing health care costs, without a massive new Federal Government bureaucracy, and without taking health care insurance away from children and families. It doesn't cost money to increase your ability to make sure you are aware of what is available. The heart of the Republican Patients' Bill of Rights Plus Act is a fair process for independent external review that addresses consumer concerns about getting access to appropriate and timely medical care in a managed care plan.

The Republican bill establishes gateways that ensure medical disputes get heard by an independent, external reviewer. The plan does not have veto power in these decisions. Denials or disputes about medical necessity and appropriateness are eligible for review, period. If a plan considers a treatment to be experimental or investigational, it is eligible for external review. The reviewer is an independent physician of the same specialty as the treating physician. In addition, the reviewer must have adequate expertise and qualifications, including age-appropriate expertise in the patient's diagnosis.

So, in other words, a pediatrician must review a pediatric case and a cardiologist must review a cardiology case. In the Republican bill, only qualified physicians are permitted to overturn medical decisions by treating physicians. The reviewer then makes an independent medical decision based on the valid, relevant scientific and clinical evidence. This standard ensures that patients get medical care based on the most up-to-date science and technology.

The Kennedy bill describes medical necessity in the statute. It does not define it in a manner that ensures that patients will get the highest quality care and the most up-to-date technology.

The Republican bill ensures that physicians will make independent determinations based on the best available scientific evidence. That is the standard, the best available scientific evidence. It is that simple. Health plans cannot game the system and block access to external review. To ensure this is the case, I have asked the private law firm of Ivins, Phillips & Baker to analyze the Republican external review provision, asking two key questions: First, could a plan block a patient from getting access to external review in a manner that is inconsistent with the intent of our provision?

Second, is there any factor that would prevent the external reviewer from rendering a fair and independent medical decision?

I request that the letter be printed in the RECORD.

There being no objection, the letter was ordered to be printed in the RECORD, as follows:

IVINS, PHILLIPS & BARKER,
Washington, DC, July 12, 1999.

Hon. JAMES M. JEFFORDS,
Chairman, Committee on Health, Education, Labor and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: You have asked us to provide you with our opinion on the outcomes of certain medical claims denials under the bill reported out of your Committee, The Patients' Bill of Rights Act of 1999, S. 326 (the ''Bill'').

In each of these examples, a claim is made for coverage or reimbursements under an employer-provided health plan, and the claim is denied. You have specifically asked us to comment on whether the claims would be eligible for independent external review under the Bill, which provides the right to such review for denials of items that would be covered under the plan but for a determination that the item is not medically necessary and appropriate, or is experimental or investigational.

A. Bill's provisions for independent external review

If a participant or beneficiary in an employer-provided health plan makes a claim for coverage or reimbursement under the plan, and the claim is denied, the Bill amends the Employee Retirement Income Security Act of 1974 (ERISA) to provide that he or she has the right to written notice and internal appeal of the denial within certain time-frames set forth by statute.[1] If the adverse coverage determination is upheld on internal appeal, the Bill provides that the participant or beneficiary in certain cases has the right to independent external review.[2]

The right to independent external review exists for denial of an item or service that (1) would be a covered benefit when medically necessary and appropriate under the terms of the plan, and has been determined not to be medically necessary and appropriate; or (2) would be a covered benefit when not experimental or investigational under the terms of the plan, and has been determined to be experimental or investigational.[3]

A participant or beneficiary who seeks an independent external review must request one in writing, and the plan must select an entity qualified under the Bill to designate an independent external reviewer. Under the Bill's standard of review, the independent external reviewer must make an ''independent determination'' based on ''valid, relevant, scientific and clinical evidence'' to determine the medical necessity and appropriateness, or experimental or investigational nature of the proposed treatment.[5]

B. Fact patterns

You have asked us to review whether the following fact patterns would be eligible for external review under the terms of the Bill. You have also asked for our judgment on whether any factor in these examples would compromise the reviewer's ability to make an independent decision.

Fact Pattern 1: An employer contracts with an HMO. The HMO contract (the plan document) states that the ''HMO will cover everything that is medically necessary'' and that the ''HMO has the sole discretion to determine what is medically necessary.''

Question 1: Would any denial of coverage or treatment based on medical necessity be eligible for external review?

Answer: All claims denials would be eligible for independent external review under the Bill.

The hypothetical employer who drafted this plan may have thought that, by covering all ''medically necessary'' items, the plan incorporates medical necessity as one of the plan's terms. Under this apparent view, any coverage denial by the HMO at its sole discretion, would be a fiduciary act of plan interpretation, rather than a medical judgment. Under this view, then, all claims denials would be contract decisions rather than medical ones, and no denials would be eligible for independent external review.

The terms of the Bill clearly prevent this end-run around its intent. The Bill provides that the right of external review exists for any denial of an item that is covered but for a determination based on medical necessity, etc., ''under the terms of the plan.'' That is, the statutory language provides for external review of any determination of medical necessity, etc., even when that determination is intertwined with an interpretation of the plan's terms.

The report of your Committee clarifies that intent. The report explicitly notes that ''some coverage discussions involve an element of medical judgment or a determination of medical necessity.'' After walking through an example of a coverage decision which involves such a judgment, the report concludes that your Committee intends that such ''coverage denials that involved a determination about medical necessity and appropriateness'' would be eligible for independent external review.[5]

That is, under the Bill any interpretation of the plan's terms triggers independent external review when that interpretation involves an ''element of medical judgment.''

To further remove any ambiguity on this point, the Committee report states that any determination of medical necessity is eligible for independent external review, even if the criteria of medical necessity are partly included as plan terms requiring contract interpretation: ''The committee is interested in ensuring that, in cases where a plan document's coverage policy on experimental or investigational treatment is not explicit or is linked to another policy that requires interpretation, disputes arising out of these kinds of situations will be eligible for external review.''[6]

Thus, even assuming that the HMO's determinations in this example are plan interpretations by a fiduciary, they are not saved from independent external review under your bill. Any coverage determination by the HMO in this example involves ''an element of medical judgment or a determination of medical necessity,'' and is therefore eligible for independent external review under the Bill and Committee report. Moreover, the standard used by the HMO in this example for determining medical necessity is not ''explicit,'' and is therefore eligible for independent external review under the Bill and Committee report.

In short, under the hypothetical plan of this example, all claims would involve determinations of medical necessity, and all denials would be eligible for independent external review.

Question 2: Is there any factor that would prevent the reviewer from rendering an independent decision?

Answer. No. The reviewer's decision must be independent. Under the Bill, the reviewer shall consider the standards and evidence used by the plan, but is intended to use other appropriate standards as well. It is expressly intended that the review not defer to the plan's judgment under the deferential ''arbitrary and capricious'' standard of review.

Under the Bill, the independent external review must make an ''independent determination'' based on ''valid, relevant, scientific and clinical evidence,'' to determine medical necessity, etc. In making his or her determination, the independent external reviewer must ''take into consideration appropriate and available information,'' which includes any ''evidence based decision making

Footnotes at end of letter.

or clinical practice guidelines used by the group health plan,'' as well as timely evidence or information submitted by the plan, the patient or the patient's physician, the patient's medical record, expert consensus, and medical literature.[7]

That is, under the Bill the reviewer is instructed to consider standards and evidence used by the plan, but is intended to include other standards and evidence as well. The Committee report clarifies this by stating that the external review shall ''make an assessment that takes into account the *spectrum* of appropriate and available information.''[8] Fleshing out the above-cited list set forth in the statute, the report further clarifies that such information can include, for example, peer-reviewed scientific studies, literature, medical journals, and the research results of Federal agency studies.[9]

Moreover, the reviewer is not bound by the standard or evidence use by the plan, but must rather ''make an independent determination and not be bound by any one particular element.''[10] The Committee report further states that the independent reviewer should not use an ''arbitrary and capricious'' standard in reviewing the plan's decision.[11] That is, the reviewer is specifically prohibited from using the deferential standard now used by federal courts in reviewing certain coverage determinations by ERISA plan fiduciaries.

In short, the Bill provides that the reviewer shall use not only the standards and evidence considered by the plan, but other appropriate standards as well, in rendering its independent judgment.

Fact Pattern 2: A plan covers medically necessary procedures but specifically excludes cosmetic procedures. An infant born to a participant is born with a severe cleft palate. The infant's physician contends that plastic surgery to correct the cleft palate is necessary so the child can perform normal functions like eating and speaking. The plan denies the request on the grounds that it does not cover cosmetic surgery. The participant appeals the decision, arguing that the procedure is medically necessary. The treating physician provides supporting documentation that the procedure is medically necessary.

Question 1: Is the denial of surgery in this example eligible for external review?

Answer: Yes, the denial of surgery in this example is eligible for independent external review under the Bill.

The plan in this example covers surgery generally, but excludes ''cosmetic'' surgery. As with many plans, the term ''cosmetic'' is not defined. There is therefore no express basis in the plan's terms for inferring that ''cosmetic'' is defined as a procedure that is not ''medically necessary and appropriate.'' Does this mean that the claims denial in this example is merely an act of plan interpretation, without any determination of medical necessity? And if so, does this mean that the denial is not eligible for external review?

No. Under the terms of the Bill, any denial based on medical necessity, etc., is eligible for external review. This is so even if the denial is based on plan terms that do not expressly incorporate a reference to medical necessity, as long as interpretation of those terms involves ''an element of medical judgment.''

This intent is spelled out in the report of your Committee, which, as already noted, states that ''The committee recognizes that *some coverage determinations involve an element of medical judgment or a determination of medical necessity and appropriateness.*''[12] The report goes on to give an example: ''For instance, a plan might cover surgery that is medically necessary and appropriate, but exclude from coverage surgery that is performed solely to enhance physical appearance. In these cases, a plan must make a determination of medical necessity and appropriateness in order to determine whether the procedure is a covered benefit.''

The report concludes that, ''It is the committee's intention that coverage denials that involved a determination about medical necessity and appropriateness, such as the example above, would be eligible for external review.''

In the example discussed here, the plan's denial is based on its determination that the procedure is ''cosmetic'' under the terms of the plan. This interpretation of the plan includes a significant element of medical judgment. This is so despite the fact that plan uses the term ''cosmetic'' without an express reference to medical necessity. The essential element of medical judgment is evidenced in part by the fact that the treating physician provides documentation for his or her judgment that the treatment is necessary for certain basic life functions.

In short, the coverage dispute in this example turns on whether the procedure is cosmetic under the plan's terms. Under the Bill as amplified by the report of your Committee, this determination includes an ''element of medical judgment or determination of medical necessity.'' Therefore, the denial is eligible for independent external review under the Bill.

Question 2: Is there any factor that would prevent the reviewer from rendering an independent decision?

Answer: No, the reviewer's decision is independent, for the reasons set forth in our answer to this question in the above Fact Pattern 1. That is, under the Bill the reviewer shall use not only the standards and evidence considered by the plan, but other appropriate standards as well, in rendering its independent, nondeferential judgment as to whether the requested treatment is medically necessary and appropriate or experimental and investigational.

Fact Pattern 3: The employer contracts with an HMO that has a closed-panel network of providers which includes pediatricians. A baby born to a participant is born with a severe and rare heart defect. The infant's own network pediatrician, who is not a pediatric cardiologist (i.e., a pediatric subspecialist), recommends that the infant be treated by such a specialist. The network does not include a pediatric cardiologist. The plan denies coverage for a non-network pediatric sub-specialist, saying that one of the plan's network pediatricians can provide any medically necessary care for the infant.

Question 1: Is the denial in this case eligible for independent external review?

Answer: Yes, the denial of pediatric subspecialist care in this example is eligible for independent external review under the Bill.

The Bill requires that participants have access to specialty care if covered under the plan.[13] The report of your Committee explains that a health plan must ''ensure that plan enrollees have access to specialty care when such care is needed by an enrollee and covered under the plan and when such access is not otherwise available under the plan.''[14]

The bill defines specialty care with respect to a condition as ''care and treatment provided by a health care practitioner . . . that has adequate expertise (including age appropriate expertise) through appropriate training and experience.''[15]

In short, the Bill defines specialty care in terms of whether the care is ''needed'' by the enrollee, and by reference to whether the care is ''adequate,'' and the expertise ''appropriate.''

Under the terms of the Bill, then, a physician's determination that specialty care is required is by its terms a judgment based on the medical necessity and appropriateness of that care. Therefore, the treating physician's recommendation in this example that the infant be treated by a pediatric subspecialist is a judgment of medical necessity. The plan's denial of such specialty care is a denial of an otherwise covered service, based on a judgment of the medical necessity or appropriateness of that service. The denial is eligible for independent external review under the terms of the Bill.

Question 2: Is there any factor that would prevent the reviewer from rendering an independent decision in this case?

Answer: No, the reviewer's decision is independent, for the reasons set forth in our answer to this questions in the above Fact Patterns 1 and 2. That is, under the Bill the reviewer shall use not only the standards and evidence considered by the plan, but other appropriate standards as well, in rendering its independent judgment as to whether the requested treatment is medically necessary and appropriate or experimental and investigations.

Fact Pattern 4: A participant calls the plan to report that the participant's infant is very sick, and inquiries about emergency services. The plan representative pre-authorizes coverage in a participating emergency facility, which is 20 miles away. Alarmed by the infant's various severe symptoms, the participant instead takes the infant to a nearby emergency facility which is only 5 minutes away. Shortly after arrival, the baby is diagnosed as having spinal meningitis, and goes into respiratory arrest. The baby is immediately treated and stabilized, and tissue damage that might otherwise have resulted is avoided. The participant submits a claim to the plan for reimbursement of the emergency treatment. The claim for reimbursement is denied on the grounds that coverage was preauthorized only if provided in the more distant, in-network, emergency facility specified by the plan representative.

Question 1: Would the denial of reimbursement in this case be eligible for independent external review?

Answer: Yes, under the Bill the denial of reimbursement would be eligible for review by an independent external reviewer.

The Bill requires that if a plan covers emergency services, it must in some cases cover such services without pre-authorization, and without regard to whether the services are provide out-of-network.

Specifically, such coverage must be provided for ''appropriate emergency medical screening examinations'' and for additional medical care to ''stabilize the emergency medical condition,'' to the extent a ''prudent layperson who possesses an average knowledge of health and medicine'' would determine that an examination was needed to determine whether ''emergency medical care'' is needed.[16] ''Emergency medical care'' is defined as care to evaluate or stabilize a medical condition manifesting itself by ''acute symptoms of sufficient severity (including severe pain)'' such that a ''prudent layperson who possesses an average knowledge of health and medicine'' could reasonably expect the absence of medical care to endanger the health of the patient or result in serious impairment of a bodily function or serious dysfunction of any bodily organ or part.[17]

That is, under the Bill, reimbursement for the services in this example must be provided if the services satisfy the ''prudent layperson'' standard of the bill. The prudent layperson standard is met if an individual without specialized medical knowledge could reasonably reach the decision, based on the patient's symptoms, that lack of medical care could possibly result in severely worsened health or injury, and that expert medical observation is therefore necessary.

A determination made by the ''prudent layperson'' is therefore a determination of medical necessity or appropriateness—albeit one made under a nontechnical, nonexpert, standard. Under the Bill, a plan is required to incorporate this lower, non-expert or ''prudent layperson'' standard in evaluating whether to cover non-pre-authorized, out-of-network emergency medical care.

In this example, the participant's judgment, based on the baby's symptoms, that the baby should be observed as quickly as possible by medical experts at the nearer facility, is a judgment of medical necessity and appropriateness, made under this lower, non-expert standard. Likewise, the plan's denial of coverage in this case is based on the plan's determination that the participant's judgment concerning medical necessity was in error even under this lower standard.

In short, the coverage dispute in this case involves a judgment of medical necessity and appropriateness under the ''prudent layperson'' standard mandated by the Bill, and is therefore eligible for independent external review under the Bill.

Question 2: Is there any factor that would prevent the reviewer from rendering an independent decision?

Answer: No, the reviewer's decision is independent, for the reasons set forth in our answer to this question in the above Fact Patterns 1, 2 and 3. That is, under the Bill the reviewer shall use not only the standards and evidence considered by the plan, but other appropriate standards as well, in rendering its independent judgment as to whether the requested treatment is medically necessary and appropriate or experimental and investigational.

I hope this letter has been responsive to your request. Please do not hesitate to have your staff contact me for any questions with respect to the points here discussed.

Very truly yours,

ROSINA B. BARKER.

FOOTNOTES

[1] ERISA §§503(b), (d), as added by S. 326 §121(a).
[2] ERISA §503(e), as added by S. 326 §121(a).
[3] ERISA §503(e)(1)(A), as added by S. 326 §121(a).
[4] ERISA §503(e)(4), as added by S. 326 §121(a).
[5] S. Rep. No. 82, 106th Cong., 1st Sess. 46 (1999).
[6] *Id.* at 47.
[7] ERISA §503(e)(4), as added by S. 326 §121(a).
[8] S. Rep. No. 82, 106th Cong., 1st Sess. 48 (1999) [emphasis supplied].
[9] *Id.* at 49.
[10] *Id.* at 48.
[11] *Id.* at 48.
[12] *Id.* at 46 [emphasis supplied].
[13] ERISA §725(a), as added by S. 326 §101(a).
[14] S. Rep. No. 82, 106th Cong., 1st Sess. 32 (1999).
[15] ERISA §725(d), as added by S. 326 §101(a).
[16] ERISA §721(a), as added by S. 326 §101(a).
[17] ERISA §721(c), as added by S. 326 §101(a).

Mr. JEFFORDS. Let me provide examples of how our external review provisions ensure that patients and children get medical care.

Chart 1 illustrates under the Republican bill that the health plan cannot ''game the system'' by blocking access to external review or using some cleverly worded definition of ''medical necessity.'' The Republican provision ensures that people get the medical care they need.

Here is an example of an HMO that has a planned contract which says the HMO will cover ''medically necessary care'' but the HMO has the sole discretion to determine what is ''medically necessary.''

Of course, this is an extreme example. Let's see if it holds up under our external review provision. In this example, the patient and physician may not know the plan's rationale for denying a claim since it is the HMO's sole discretion to determine medical necessity. This can be frustrating for both the patient and the physician.

Under the Republican bill, a denied claim would be eligible for an outside independent medical review. In fact, all denied medical claims under this example would be eligible for review under our provision. This is confirmed by the outside legal analysis which I have submitted for the RECORD. The legal opinion says:

> The statutory language provides for external review of any determination of medical necessity and appropriateness, even when that determination is intertwined with an interpretation of the plan's terms.

The external reviewer would make an independent medical determination. There is nothing in the HMO contract or in the legislative provision that prevents the reviewer from making the best decision for the patient. If the patient needs the medical care, the reviewer will make this assessment. They will get the care. The independent reviewer's decision is binding on the plan.

Chart 2 is an example of a cleft palate. This chart illustrates that patients, and especially children, will get necessary health care services. Plans will not be able to deem a procedure as ''cosmetic'' and thus block access to external review. Only physicians can make coverage decisions involving medical judgment.

An example we have heard many times from our colleagues on the other side of the aisle is of an infant born with a cleft palate. The infant's physician recommends surgery so the child can perform normal daily functions, such as eating and speaking normally. The treating physician says this surgery is medically necessary and appropriate. In this example, the HMO planned contract states: ''The plan does not cover cosmetic surgery.'' It was denied as a claim, saying the child's surgery is not a covered benefit because it is a cosmetic procedure, despite the recommendations of the treating physician.

What does this mean? Does this mean this is the end of the road for this child's family? No. Under the Republican bill, this denial of coverage would be eligible for appeal because the decision involves an ''element of medical judgment.'' Under the Republican bill, medical decisions are made by physicians with appropriate expertise. In this case, it means an independent reviewer would be required to have pediatric expertise.

Finally, the independent medical reviewer would look at the range of appropriate clinical information and would have the ability to overturn the plan's decision. The child would receive the surgery to correct the cleft palate, and the plan would cover this procedure because the reviewer's decision is binding on the plan.

The next chart is on emergency room coverage. The primary point of this chart is that under the prudent layperson standard, parents can use their judgment and take their sick child to the nearest emergency room without worrying about whether the plan will deny coverage.

Another example we are all familiar with is of little Jimmy whose tragic story has been told by Senator DURBIN. His parents called the HMO when their baby fell ill. The HMO nurse recommended the parents take their sick child to a participating hospital an hour's drive away. During their long drive, the family passed several closer hospitals along the way. The child's symptoms grew worse and the baby went into respiratory arrest. By the time they got to the hospital, the one that the HMO said was covered by a plan, it was too late. The tissue damage resulted in the loss of a limb and little Jimmy had to endure a quadruple amputation. This is a horrible situation.

Let's look at what the Republican bill would do to address this type of tragic and unnecessary situation. First, under our prudent layperson standard, a parent would not have to call the HMO to get permission to go to the nearest emergency room. In this case, the parents could have gone to the closest emergency room and little Jimmy would not have gone into respiratory arrest. This tragedy would have been averted under the Republican provision because our bill ensures that emergency room services must be provided without preauthorization and without regard to whether the services are provided out of network.

Say for the sake of argument that the plan denies reimbursements after the hospital has provided the treatment. Under the Republican bill, little Jimmy's family would not be stuck with the hospital charges. They could appeal this decision to an outside reviewer because the decisions about whether care is medically necessary are eligible for external review.

The law firm of Ivins, Phillips & Baker says that under our provision:

> The coverage dispute in this case involves a judgment of medical necessity and appropriateness under the prudent layperson standard mandated by the bill, and therefore is eligible for independent external review under the bill.

This is a quote from the letter that has been previously printed in the RECORD.

Mr. SCHUMER. Will the Senator yield?

Mr. JEFFORDS. The independent medical reviewer can make an independent decision and overturn the plan denying reimbursement. This decision is binding on the plan and not appealable.

Mr. SCHUMER. Would the Senator from Vermont yield for a question?

Mr. JEFFORDS. Let me finish.

Mr. SCHUMER. I thank the Senator.

Mr. JEFFORDS. As Members can see from the examples on these charts, the

Republican Patients' Bill of Rights ensures patients get the medical care they need, that parents can be assured their children will be cared for by appropriate specialists, and that people can go forward to emergency rooms when they are sick, when the children are sick, and can do so with the assurance that their health plan will cover these services.

Establishing these important rights will help families avoid illness, injury, and improve the quality of health care. I believe this is why we are debating this issue today. You can't sue your way to health care. Congress can't create a definition of ''medical necessity'' that is better than letting physician experts make decisions on the best available science. They must practice the best available science.

However, we can improve access to health care services and ensure that people get timely access to the medical care they need. We can ensure that health care we provide is high quality health care. Most important, we can do all these things without increasing health care costs and causing more Americans to lose their coverage.

We accomplish all these goals with the Republican Patients' Bill of Rights.

I yield the floor.

The PRESIDING OFFICER. Who yields time? The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I yield myself 5 minutes.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, this amendment goes to the heart of the issue. I urge our colleagues to pay attention to the exchange we are going to have on the floor of the Senate.

Let us look, first, at what is in the Democratic bill. In the Democratic bill, ''medical necessity,'' as defined on page 86, is ''medically necessary or appropriate.'' That is the standard definition medicine has used for 200 years. It is the standard recommended by none other than the Health Insurance Association of America itself, on page 269:

> Medical necessity. Term used by insurers to describe medical treatment that is appropriate and rendered in accordance with generally accepted standards of medical practice.

Our legislation does what the Health Insurance Association of America recommended. This is the standard that has been used for 200 years. This is the standard that is supported by the medical profession.

The Republican plan knocks that standard out. It knocks it out. What do they put in as a substitute? As a substitute, on page 148, they say ''medical necessity'' used in making coverage determinations is determined ''by each plan.'' ''By each plan.'' The plan can define medical necessity any way it wants.

In their appeals procedure we find that medical necessity issues can be appealed, but medical necessity is defined by the HMO.

That sounds complicated. What does it mean in real terms? Let me read you a few examples of how HMOs have defined medical necessity. Here is a company—I will not give its name—and their definition. The company:

> . . . will have the sole discretion to determine whether care is medically necessary. The fact that care has been recommended, provided, prescribed or approved by a physician or other provider will not establish the care is medically necessary.

In other words, medical necessity is whatever the HMO says. Whatever the HMO says.

Here is an example of Aetna U.S. Health Care, the provision in their Texas contract:

> The least costly of alternative supplies. . . .

Here is another HMO:

> The shortest, least expensive, or least intensive level. . . .

They throw out the medical necessity standard used for 200 years and say, medical necessity will be whatever the HMO wants it to be. That is the heart of this issue.

What do we find when the HMO uses their own medical necessity definition? Who makes the judgment? It is an insurance company bureaucrat. That is what this amendment is all about.

Finally, when you see the appeals procedures which will be addressed by my other colleagues, all you have to do is look at the Consumers Union and many other consumer groups. The consumer groups believe their appeals procedure does not provide adequate protections.

The American Bar Association believes basic consumer protections are not met. The American Arbitration Association makes the same judgment.

This is a status quo amendment. If you want to do nothing about the pain and injury being experienced by children, women, and family members in our country, go ahead and support this program. It is an industry protection amendment. It will protect the profits of the industry; it puts the profits of the industry ahead of protecting patients.

I yield 5 minutes to the Senator from California.

The PRESIDING OFFICER. The Senator from California.

Mrs. FEINSTEIN. Mr. President, the Senator from Massachusetts is absolutely correct. This amendment essentially puts into the bill the basic premise of the Republican plan, which is to let the HMO define what is medically necessary, decide what the treatment should be, what the length of hospitalization should be for a patient, not based on that patient, not based on medical necessity, but based on standards that individuals who have not even seen the patient determine.

I must tell you I have a very real problem with that. The insurance plan would determine medical necessity, not the physician who sees the patient. It would substitute an independent review process for the knowledge and the skill of the independent physician who is actually seeing the patient, who has done the diagnosis, who knows the patient, the patient's history the patient's problems.

This past week I spent a good deal of time in California talking with physicians and patients up and down the State. I probably talked with more than 50 people, including patients, hospital administrators, county medical societies of many different counties as well as the California Medical Association. What I found was a dispirited, demoralized medical profession because medical decisionmaking was being taken out of their hands. I learned that a physician would prescribe medication, the patient would go to the druggist to have the medication filled and the druggist would make a substitution, often without even the doctor knowing. The patient would say: I cannot take this drug. And the pharmacist would have to say: We cannot furnish what your physician prescribed because it was not on your plan's list. This is what we mean by medical necessity—the most appropriate medical treatment for that particular patient in the judgment of the treating physician.

I contend there is not anyone who has not seen a patient, who doesn't know what patient is all about, who can adequately prescribe for that individual. That, in fact, is what is happening.

Let me read a statement by someone who testified before a congressional House committee a couple of years ago in a hearing. This individual was the reviewer for an HMO. As an HMO reviewer, she countermanded a physician. Let me read her words:

> Since that day I have lived with this act and many others eating into my heart and soul. For me, a physician is the professional charged with the care of healing of his or her fellow human beings. The primary ethical norm is, 'Do no harm.' I did worse. I caused death.
>
> Instead of using a clumsy weapon, I used the simplest, cleanest of tools, my words. This man died because I denied him a necessary operation to save his heart. I felt little pain or remorse at the time. The man's faceless distance soothed my conscience. Like a skilled soldier, I was trained for this moment. When any moral qualms arose I was to remember I am not denying care, I am only denying payment.

That is why this Republican amendment is so fallacious. Let me read the actual language in the bill:

> A review of an appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity and appropriateness, or based on a experimental or investigational treatment, shall be made only by a physician with appropriate expertise including age appropriate expertise, who was not involved in the initial determination.

My father, chief of surgery at the University of California, would turn over in his grave with this kind of language. That is not what someone goes to medical school and does a residency, does a surgical residency, does graduate school work for, to get overturned

by an insurance company reviewer who has not even seen the patient. This amendment, I contend, is in the worst of medical practice because it allows a panel that has never seen the patient to make the determination of whether a patient gets a lifesaving operation, gets a drug that might make them well, gets a treatment from which the physician thinks they might benefit.

The PRESIDING OFFICER. The time of the Senator has expired.

Mrs. FEINSTEIN. I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I would like to answer my good friend from California. I do not believe she was listening to my explanation of what this bill does. In fact, we do throw out 200 years of law practice. That shakes the legal community up a bit because they have to learn what is going on in modern medical situations. They have to become aware of how they find out what the best medicine is, not necessarily what is used in that area. It is the best medicine available.

We set a higher standard, and that is why the legal profession is a little bit upset. They do not want to have to learn all this medical stuff. They want to go back to the good old days when they could just call the local doctor and say: What is the general medical practice? And whatever that doctor does is the general medical practice. That is the present standard. We say that is not good enough now.

We are going to make sure that every person in an HMO has the right to the best medical care available, and that is what we explained with chart 1, chart 2, and chart 3. The decision is made by the external reviewer who says: Look, you can use this treatment now, you can use this pharmacy prescription, and that can be cured. You did not use it, you are not going to use it—that is wrong. Give them that care.

Mrs. FEINSTEIN. Will the Senator yield for a question?

Mr. JEFFORDS. Certainly.

Mrs. FEINSTEIN. Does the Senator from Vermont really believe the best treatment can be provided by a reviewer who has never seen the patient?

Mr. JEFFORDS. There is nothing that says the reviewer never sees the patient. The reviewer is an expert. He is the one who is qualified in that profession to know, who reviews the records. There is nothing that says he cannot also see the patient and interview the patient. This is not going to be a judgment done in some courthouse with a jury determining something. This is going to be done by an expert in the field who is dealing with a patient to make sure that patient gets the best available health care, the best of medicine that is available.

Mrs. FEINSTEIN. Will the Senator yield to me a moment?

I met some of the reviewers this past week. They did not see the patient. They made the decisions based on their insurance companies' definitions of medical necessity, not based on the particular needs of the individual patients.

Mr. JEFFORDS. This is new. This does not exist anywhere. We are creating a new policy to ensure the best health care possible for every American.

Mr. President, I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Massachusetts.

Mr. KENNEDY. I want to ask the Senator from California a question. Where in the earlier response does it say they will use the best practices?

Mrs. FEINSTEIN. It does not.

Mr. KENNEDY. It does not say that. To the contrary, does the Senator not agree that we have example after example where HMOs have used definition based on lowest cost?

Mrs. FEINSTEIN. As a matter of fact, I can read terminology right out of insurance contracts, which I was going to read had my amendment been able to come to the floor. As the Senator knows, the purpose of this amendment is essentially to defeat the amendment I was going to offer, that I did offer to the Agriculture Appropriations bill and that I said last week that I was going to offer to this bill, to allow the physician to give the treatment and prevent the HMO from arbitrarily interfering with or altering the treating physician's decision, whether it be the treatment or the hospital length of stay.

Mr. KENNEDY. I yield 5 minutes to the Senator from New York.

The PRESIDING OFFICER. The Senator from New York.

Mr. SCHUMER. Mr. President, I thank the Senator from Massachusetts.

There are two pernicious parts to this amendment. One is removing the accurate definition of medical necessity, as the Senators from Massachusetts and California have pointed out, and the second is putting in an appeals process that is nothing short of bogus in a whole variety of ways. When you look at the appeals process that is being substituted by the Senator from Vermont, you understand how grudging it is, how imperfect it is, how it will not do the job. Let me give a few examples.

First, there is no timeliness. The HMO can initiate the appeals process whenever it wants. It could wait 3 months or 6 months or 9 months before review. Our amendment, which the Senator from North Carolina and I will offer, requires the review process to start when the patient asks.

Second, there is no requirement that the appeals process, after it is finished, be implemented. The HMO can appeal and appeal and appeal.

The two I want to focus on this afternoon are these: First, it is much more limited in scope. I say to my friends and my fellow Americans who are watching this debate, this is not two competing bills; this is one bill that does the job and one bill that seeks to please the insurance industry and still make it look as if the job is being done.

One of the main issues is scope: 160 million covered versus 48 million covered for emergency room, for medical necessity, and for other things. Thirty-eight million people would be included in the Schumer-Edwards amendment who are excluded by this amendment.

Perhaps the greatest area where this amendment is a false promise, is a hoax, is the independent review. The Senator from Vermont said the review is independent. Not so. In the amendment offered by the Senator from Vermont, the reviewer is appointed by the HMO. The reviewer is not even required to have no financial relationship with the HMO. Theoretically, under this proposal, the HMO could pay an ''independent'' reviewer. If we want an independent external review, why shouldn't that reviewer have no ties to the HMO?

How can we tell people that an independent review is independent when the insurer selects the reviewer? If you have ever heard of the fox guarding the chicken coop, here it is. An independent review, as in the amendment we will be voting on in the next few days, requires that the HMO not pick the reviewer. I know the Senator from Vermont has stressed that a pediatrician would review a child's case. I say to my colleagues, if I were a member of an HMO, I would not want a pediatrician who has a financial relationship with the HMO to review the case.

Mr. JEFFORDS. Will the Senator yield for a question?

Mr. SCHUMER. The Senator did not yield to me. I will wait until his time to answer a question.

What I am saying is this: If you want a real review, and hundreds of thousands of Americans want such a review, then vote against this amendment, wait for the Schumer-Edwards amendment, and you will get a true independent review.

In conclusion, this is not so different from the gun debate we had a month and a half ago, where we had a powerful special interest on one side and the American people on the other side, and there were a series of proposals put forward that the powerful special interests liked but were intended to make the American people believe we were making progress.

I cannot tell you how or where or when, but just as in the gun debate, the American people will not be fooled. They want, they demand, a real Patients' Bill of Rights, one that covers 160 million Americans, not 48 million, one that has a real review process, not a sham review process where the reviewer can be paid by the HMO. Please vote down this amendment.

The PRESIDING OFFICER. The Senator's 5 minutes has expired.

Who yields time to the Senator from Pennsylvania?

Mr. JEFFORDS. I yield the Senator from Pennsylvania 10 minutes.

The PRESIDING OFFICER. The Senator from Pennsylvania.

Mr. SPECTER. I thank the Chair.

Mr. President, it is extraordinarily complex to work your way through the various provisions. Representations are being made on both sides of the aisle which are contradictory.

The Senator from New York has just made a contention that the independent reviewer is not independent at all. My reading of the provisions in S. 326 at page 177 set forth the qualified entities as the reviewers and the designation of independent and external reviewer by the external appeals entity which specifies independence.

I will not take the time now to read it. But that reference, I think, would establish the true independence of the reviewer.

My principal purpose in seeking recognition was to deal with the comparison of the standards for ''medical necessity,'' which is the core of the argument at the present time.

The pending amendment seeks to strike the language of the Kennedy amendment, which defines medical necessity as ''medical necessity or appropriate means with respect to a service or benefit which is consistent with generally accepted principles of professional medical practice.''

The language of the pending amendment, which would be substituted, provides for a standard of review as follows, at pages 179 and 180:

> IN GENERAL.—An independent external reviewer shall—
>
> (I) make an independent determination based on the valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; and
>
> (ii) take into consideration appropriate and available information, including any evidence-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus; and medical literature . . .

The accompanying report amplifies ''expert consensus'' as ''including both what is generally accepted medical practice and recognized best practice'' so that the language of the statute itself is more expansive in defining ''medical necessity.'' The commentary goes on to include generally accepted medical practice and adds to it: the recognized best practice.

There is no doubt that in the articulation of these competing provisions, an effort is being made by one side of the aisle to top the other side of the aisle. It is a little hard, candidly, to follow the intricacies of these provisions because, as is our practice in the Senate, an amendment can be offered at any time, and to work through the sections and subsections is a very challenging undertaking.

Mr. SCHUMER. Would the Senator from Pennsylvania yield?

Mr. SPECTER. No, I will not, but I will yield in a minute. I will not now because I am right in the middle of my train of thought. I will be glad to yield in a moment and respond to whatever question the Senator from New York may have.

I supported the Robb amendment, the last vote, because the Robb amendment had provided a standard for medical necessity, generally accepted medical principles, important operative procedures. At this stage of the record, without that definition of the requirement, as articulated in the Robb amendment, I thought that was improvement.

Now we are fencing. To say that the air is filled with politics in this Chamber today would be a vast understatement. But in at least my effort to try to understand what is going on and to make an informed judgment, I am prepared to make a judgment for the Robb amendment or the Kennedy amendment or the Schumer amendment contrasted with the Nickles amendment or the Jeffords amendment. It requires a lot of analysis.

But as I read these plans, I believe that Senator JEFFORDS, Senator FRIST, and Senator NICKLES are correct, that when you take a look at the language they are substituting, it places a higher standard on the HMO, the managed care operation, than does the provision in the Kennedy amendment which they are striking.

Now I would be glad to yield to the Senator from New York on his time.

Mr. SCHUMER. I thank the Senator for yielding.

Mr. SPECTER. I am yielding for a question.

Mr. SCHUMER. I appreciate the Senator searching to come up with the right solution here. I would ask him—he is an excellent lawyer, far better than I am—on page 179 of the bill, (iv), says:

> receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the independent external review . . .

It seems to me—and I ask the Senator the question—that the plan proposed in the substitute envisions the insurer paying the reviewer. That seems to me not to be an independent review.

Mr. SPECTER. I ask the Senator, where are you reading from?

Mr. SCHUMER. This is S. 326, page 179. That is, as I understand it, the exact language of the amendment offered by the Senator from Vermont.

Mr. SPECTER. Would the Senator restate the question?

Mr. SCHUMER. Yes. My question is, given that the amendment envisions the insurer paying the reviewer, as listed in little number (iv) on page 179, how can we say the review in the Jeffords amendment is independent?

Mr. SPECTER. The fact that the insurer pays the reviewer does not impugn or impinge upon the reviewer's objectivity when there are specific standards for the selection of the reviewer and specific standards that the reviewer has to follow.

If I could use an analogy from a practice that I engaged in for a long time as district attorney of Philadelphia, the State paid the fee for the defendant in first-degree murder cases. But there was no doubt that notwithstanding the fact that the Commonwealth of Pennsylvania paid defense counsel, the defense counsel worked in the interests of the defendant.

When you have a determination as to what the HMO ought to be doing, that is something they ought to pay for. But there ought to be a structure to guarantee objectivity by the decision-maker.

Similarly, if I can amplify, if you have a Federal judge paid by the Federal Government, and the Federal Government is a party to the process, nobody would say that Federal judge is going to be biased toward the Federal Government simply because the Federal Government pays his salary.

Mr. SCHUMER. Would the Senator yield for a question?

Mr. SPECTER. I do.

Mr. SCHUMER. If we could give these reviewers lifetime appointments and salary, I might agree with the analogy of a federal judge. But, of course, these reviewers could be immediately——

Mr. SPECTER. The defense lawyers do not have lifetime appointments.

Mr. SCHUMER. I understand.

The second question: On page 175, this reviewer is selected by the HMO, whereas in our plan there is an independent selection process. Again, I rely on the Senator's much greater knowledge of the law. If the reviewer were not selected by the HMO, they would obviously be more independent. That is on page 175.

Mr. SPECTER. If I may respond, on page 177, the qualified entities are defined, and they are the ones that make the determination of the independent reviewer. And a qualified entity is defined to be:

> (I) an independent external review entity licensed or accredited by a State;
>
> (II) a State agency established for the purpose of conducting independent external reviews;
>
> (III) any entity under contract with the Federal Government to provide independent external review services;
>
> (IV) any entity accredited as an independent external review entity by an accrediting body recognized by the Secretary for such purpose; or
>
> (V) any other entity meeting criteria established by the Secretary for purposes of this subparagraph.

I think that language answers the question of the Senator from New York about independence and expertise.

Mr. SCHUMER. I ask the Senator, wouldn't we be better in guaranteeing independence by having the selection of the review panel be made independently of the HMO, given that the HMO—I understand there are some criteria here, but if we are trying to get a truly independent process, it strikes me that it would be a lot better to have the selection be made truly independently, not by the HMO, which obviously has an interest, albeit, as the Senator certainly recognizes and pointed out, with a bunch of criteria.

Mr. SPECTER. Mr. President, if I may respond, I don't understand the question. The reason I don't understand the question is that the specification of independence here is so comprehensive that it guarantees independence.

Mr. SCHUMER. I thank the Senator.

Mr. KENNEDY. Mr. President, I yield 8 minutes to the Senator from North Carolina.

Mr. EDWARDS. Mr. President, if the Senator from Pennsylvania will respond to a question.

Mr. SPECTER. I am glad to respond to a question at this time.

Mr. EDWARDS. I am looking at page 30 of the actual amendment that has been offered. Looking under subsection (B)(ii), this is the designation of independent external reviewer, which goes to the very heart of whether the review is independent or, in fact, is not independent. In subsection (ii) it says there is a requirement that the reviewer ''not have any material, professional, familial, or financial affiliation with the case under review.''

My question to the Senator is—and I would like to see the language in the actual amendment, if he could point to it—what is it that requires that the reviewer not have an ongoing financial relationship with the health insurance company or with the HMO, which would in fact, as the Senator I am sure would recognize, make them not independent?

Mr. SPECTER. Well, I believe that that is provided by the high level of independence specified in the preceding section (3)(A)(ii) which establishes the independence of the qualified entity which selects the independent reviewer.

Mr. EDWARDS. My question is, Can you point to specific language in the bill that requires that the reviewer, in order to be independent, not have an ongoing financial relationship with the health insurance company?

Mr. SPECTER. Well, there is no suggestion that there would be that kind of a relationship. The language which the Senator from North Carolina cited takes care of one category of potential conflict of interest, that they will not have any material, professional, familial, or financial affiliation with the case under review, the participant or beneficiary involved, the treating health care professional, the institution where the treatment would take place, or the manufacturer of any drug, device, procedure, or other therapy proposed for the participant or beneficiary whose treatment is under review.

If your question is, Would there be a triple firewall if you also specify the HMO? I would be inclined to have all the firewalls I could, as I do when I draft documents, as my distinguished colleague did when he practiced law.

Mr. EDWARDS. I thank the Senator very much, and I reclaim the remainder of my time.

Mr. President, there are two fundamental problems with this amendment that go to the very heart of this debate. First, as my colleague from New York pointed out, this review is not an independent review. It is not an independent review by any definition of independence. The reason is, No. 1, the health insurance company, the HMO, chooses the entity which chooses the reviewer. I want to be precise here. That is exactly what the bill provides. The health insurance company chooses an entity; that entity chooses the reviewer. So the health insurance company has control over who ultimately does the review.

No. 2, the only requirement with respect to financial independence or professional independence is the requirement that I just read to the Senator from Pennsylvania, that the reviewing entity not have a financial or professional relationship with the very specific case under review, which means there is nothing to prohibit a reviewer, the so-called independent reviewing body under their amendment, from being somebody who has a longstanding, ongoing relationship with the health insurance company or with the HMO.

Nobody in America, certainly none of my colleagues in the Senate, would believe that an independent review could be conducted by somebody who has an ongoing contractual relationship and receives money from the health insurance company. There is absolutely nothing in this bill which prohibits that. That is why the Senator from New York and I have proposed an amendment that makes it very clear that there is a truly independent reviewing body. That independence is critical and to the very heart of the review process. It is why we need it.

I notice both the junior and the senior Senators from Pennsylvania are on the floor now. In Pennsylvania, these reviews are conducted by a State regulatory body. They are not conducted by some person chosen by an HMO or a health insurance company. Second, in terms of what can be reviewed under the State law of Pennsylvania, any consumer grievance can be reviewed. It is not, as this bill is, limited to what constitutes medical necessity.

Third, under the law of the State of Pennsylvania, the review is de novo, which is absolutely not what this amendment provides.

Let me go back and summarize where we are. No. 1, we don't have, under this amendment, an independent review. We don't have it for two fundamental reasons: No. 1, the health insurance company, the HMO, is allowed to select the body that picks the reviewer. No. 2, the reviewing body is allowed to have a longstanding professional or financial relationship with the HMO that has denied the claim. There is absolutely nothing to prohibit that under this bill. Our amendment, which will be considered at a later time, would not allow that. So there is no independent review.

The second problem is—and this goes to the amendment offered by my colleague from California—this review process is meaningless so long as the reviewing body is bound by the definition of medical necessity contained and written by the HMO. It is absolutely bound by the language of the HMO.

I will add, in committee—I see my colleagues from Massachusetts and Tennessee are here—Senator KENNEDY asked a question to Senator FRIST. The question was:

> Would the Senator accept language that mentions that the decision would be made independent of the words of the contract?

The question Senator KENNEDY posed was: Would you agree that in the appeals process, the determination could be made without regard to the HMO-written definition of medical necessity?

Senator FRIST's answer was: ''No, sir,'' in the committee. So he would not concur to not be bound by the language in the HMO or health insurance contract.

So there are two fundamental problems, and they work in concert to be devastating and to make this amendment devastating to the whole concept of the Patients' Bill of Rights.

No. 1, there is no independent review. The people are picked by the HMO, and they are allowed to have an ongoing financial relationship with the HMO. No. 2, they are bound by an HMO-written definition of medical necessity. That is the very heart of the amendment of my colleague from California, because what this debate is ultimately about is whether health care decisions are going to be made by medical professionals, doctors, or whether they are going to be made by insurance company bureaucrats.

Mrs. FEINSTEIN. Will the Senator yield?

The PRESIDING OFFICER. The Senator's 8 minutes have expired.

Who yields time?

Mr. KENNEDY. Mr. President, I yield 10 minutes to the Senator from Rhode Island.

Mr. CHAFEE. I thank the Chair.

First of all, it is with deep regret that I find myself on the opposite side of an issue from my good friend, the senior Senator from Vermont.

The question before us this afternoon is medical necessity. I believe this medical necessity provision is one of the most widely misunderstood issues in this entire debate.

I think what we want to make clear is what we are not talking about this afternoon. We are not talking about erasing the gains managed care has made in bringing down costs. We are not talking about forcing plans to cover unnecessary, outmoded, or harmful practices. We are not talking about forcing plans to pay for any service or treatment which is not already a covered benefit. This is absolutely not about giving doctors a blank check. What we are talking about is making sure that patients get what they pay for with their premium dollars. It is

about ensuring that an objective standard of what constitutes prudent medical care is used to guide physicians and insurers in making treatment and coverage decisions.

This provision is about making sure that an infant suffering from chronic ear infections gets drainage tubes to ameliorate his or her condition. It is about making sure that a patient with a broken hip is not relegated to a wheelchair in perpetuity but, rather, given the hip replacement surgery that prudent medical practice dictates.

Although some would have us believe that ''medical necessity'' would undo managed care by giving doctors the power to dictate what treatments and services insurers must cover, this isn't accurate. The real issue is, how will questions of coverage and treatment be decided?

S. 1344—a bipartisan bill that I have had the privilege of introducing earlier this year with Senators GRAHAM, LIEBERMAN, SPECTER, BAUCUS, ROBB, and BAYH—would codify the professional standard of medical necessity.

As defined, medically necessary services are those ''services or benefits which are consistent with generally accepted principles of professional medical practice.'' This means the care that a prudent practitioner would give. The medical necessity standard is a well-settled principle of legal jurisprudence which has been used by the courts to adjudicate health law cases for nearly a century.

Many insurance contracts in force today contain some version of this standard. In fact, remarkably similar language is found in contracts written by Prudential and Blue Cross and Blue Shield, to name a few. The contractual definition of medical necessity from a Blue Cross contract is care which is ''. . . consistent with standards of good medical practice in the U.S.''

One of the reasons managed care plans are so adamantly opposed to putting this standard into the law is that some in the industry are beginning to move in a very troubling direction, away from this standard. Here is how an insurance regulator in the State of Missouri explained this very alarming trend:

> Increasingly, insurance regulators in my State are finding that insurers are writing ''sole discretion'' clauses into their contracts—meaning that it is solely up to the insurer to determine whether treatment is medically necessary. Therefore, without an objective standard of what constitutes medically necessary care, and a requirement that treatment and coverage decisions are supported by credible medical evidence, any external appeals process is meaningless.

If an insurance contract gives the plan sole discretion to determine what constitutes medically necessary care, an external review panel's hands are tied; it will have no choice but to enforce the terms of the contract, even if the coverage decision in question is completely irresponsible. Thus, if we don't codify the professional standard, any external review provision we pass in the Senate could be entirely meaningless.

I have a chart here. This includes the actual medical necessity provision from an insurance contract in force today. I have eliminated the company's name, but this tells the whole story. If a plan has the sole discretion to determine what is medically necessary care, it can ignore the doctor's recommendations, the patient's medical record, and any other evidence it cares to overlook in making its determination. You will see it here. Here is the name of the company. That company will have the sole discretion to determine whether the care is medically necessary. The fact that the care has been recommended, provided, described, or approved by a physician or other provider will not establish that care is medically necessary. In other words, talk about putting the fox in charge of the chicken coop. This is it. Here we have the company deciding whether care is medically necessary, and they have the final decision.

Let me give you a real world example of what can happen when a plan has an imprudent definition of medical necessity. A child named Ethan Bedrick was born with cerebral palsy and needed physical therapy to maintain some degree of mobility. The insurer paid for the physical therapy for a while but one day cut off payment for the services—which, by the way, were covered as an unlimited benefit under the plan's contract. The child's doctor thought the care was medically necessary to prevent further deterioration in Ethan's condition, and physical therapy is routinely provided to patients with cerebral palsy.

When the plan was questioned in court as to why the care had been denied, the response was given that it was not medically necessary because, under the plan's definition, medically necessary care is that which will restore a person to ''full normalcy.'' Well, this child has cerebral palsy and he is not going to be restored to full normalcy.

If we do not include an objective standard of medical necessity in this legislation, insurers will be able to bait and switch when it comes to the delivery of services, just as they tried to do with Ethan Bedrick.

The professional objective standard—and not an insurer's practice guidelines or opinions—should be used to determine if care is medically necessary. Without the objective standard, what measure would an appeals body use to determine whether a treatment or coverage decision was accurate or appropriate? Let me deal with two arguments used by those against this medical necessity provision.

First, they say it will prevent ''best practices'' and will force plans to practice substandard care. I have trouble with that. Since the professional standard of medical necessity has been the standard used by the courts for over a hundred years and it is a feature of many insurance contracts today, why hasn't this already had the effect of preventing ''best practice'' medicine? In other words, I don't get the argument that somehow you are not going to practice the best medicine because you have to use what is medically necessary. The fact is that this standard does not lock in the state of medical practice today. Why do we make these giant strides forward? Because we are not locked in, as has been suggested.

Second, it is suggested that adopting this standard is tantamount to giving doctors a blank check and will force plans to cover a whole array of services which are not covered benefits, such as aromatherapy.

The plain fact is, if a plan excludes aromatherapy, or any other service, that is the end of the story. It excludes it. It is out. There is no fuss after that. If it is written in there, it is out. A patient would have no basis for an external appeal in a case where a denied service was clearly excluded.

In summary, I urge colleagues not to be swayed by the health insurance industry. Both Democrats and Republicans alike acknowledge the need for an external appeals process. But make no mistake about it, without a provision to ensure that plans are held to an objective standard of professional medical practice, legislation giving patients access to the external process will be ineffective.

I thank the Chair and the managers of the legislation.

The PRESIDING OFFICER. Who yields time?

Mr. FRIST. Mr. President, I yield myself 5 minutes, and then I will yield 5 minutes to the Senator from Maine.

My amendment is pending. I will review where we are today. My amendment does two things. No. 1, it strikes certain provisions that we believe will be harmful to the quality of health care, and it goes back to medical necessity and defining medical necessity in Federal statute. We will come back and talk about that. My colleagues will talk further about that shortly. We also strike certain provisions that will increase cost and ultimately reduce access to health insurance coverage. Again, people have heard me again and again going back to the patients. We can simply not do anything. I believe it diminishes quality and at the same time diminishes access to make ourselves feel good.

Now, what we have done, we struck that and we replaced that part of the bill—the accountability provisions, the provisions on internal appeal, on external appeal, the issues we have been talking about in the last 15 or 20 minutes—although there is a lot of misconception that we need to straighten out before we actually vote on this bill, because the internal appeals process and external appeals process, which in many ways are the heart of the Patients' Bill of Rights bill, are important to ensure that patients do get the medical care they need and ensure that

ultimately it is physicians, not trial lawyers, not bureaucrats, who make the coverage decisions regarding medical necessity. That is what this amendment is all about. I want to steer the discussion right there.

To simplify things, so we will know how the process works, if you are a doctor and you are a patient, and you say that a particular procedure should be covered, and your plan for some reason says no, well, you need an appeals process if that is what you really believe is appropriate to get that sort of care. What you do under our bill is go to an internal appeals process and work through. That is something in the managed care network. It might be going to another physician within the network. It is a process that has to be set up by each and every managed care plan. That is what we call an internal appeals process.

The bill on the other side of the aisle also had an internal appeals process. If the doctor and patient and the managed care internally could not come to an agreement after going through a specified process, at that point the doctor and patient can go outside the plan. This is where the accountability is so important: Should my plan cover what is medically necessary and appropriate? Outside the external appeals process is where much of the discussion has taken place.

Our bill has that final decision of whether or not something is covered, whether or not it is medically necessary or appropriate, made by a medical specialist—these are words actually in the bill—independent medical specialist, physician making the final decision, not some bureaucrat, not some health care plan, not some trial lawyer. An independent medical specialist is making the final decision in this external process.

Mr. President, 20 minutes ago we had discussed that the external reviewer has to be independent—it is written into the bill that way—has to be a medical person from the same field, a specialist, if necessary. Are they part of the Health Maintenance Organization? Does the Health Maintenance Organization actually hire that person to make a decision?

We have not talked about what our bill does. Our bill says in this external review process there has to be a designated entity. Nobody has talked about that today. Words such as ''unbiased, external entity'' are in the bill. This unbiased entity is regulated by either the Secretary of Health and Human Services in Washington, DC, by the Federal Government, or by the State government. They regulate that entity, not the plan itself.

What about the independent reviewer? Where do they come from? The impression which I have heard again and again is the independent reviewer has ties to the medical care plan and will give a biased view. No; the independent medical specialist making the binding final decision is appointed by the third party entity—not the plan itself but this third party entity regulated by the Federal Government, State government, or signed off for by the Secretary of Health and Human Services. This independence from plan to entity has to be unbiased. That is No. 1, to assure independence.

No. 2, the entity is regulated by the Federal Government or the State government or the Secretary of Health and Human Services.

No. 3, it is written in the bill that that entity does the appointment of the independent medical specialist who makes the final decision.

What information does that medical specialist use to make the final decision? We don't limit the information. In fact, we encourage them to consider all information. It is very specifically written in the bill that the ''independent medical specialist will make an independent determination based on the valid relevant scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment.'' They will take into consideration ''all appropriate and available information, including any evidence-based decisionmaking or clinical practice guidelines.''

The point is this external review person is independent and separate from the entity and separate from the HMO.

I yield 5 minutes to the Senator from Maine.

Ms. COLLINS. First, I commend the Senator from Tennessee for his very lucid explanation clearing up a lot of the misinformation about what is in the Republican package with regard to the independent, impartial, unbiased external review.

This is a very complicated issue. On the surface, the Kennedy bill appears to have a great deal of appeal. It sounds so simple. It reminds me of that expression by H.L. Mencken when he said that for every complicated problem there is a solution that is simple, easy, and invariably wrong.

That fits the Kennedy bill on medical necessity.

Physicians clearly must play a central role in care decisions. No one disputes or wants to minimize the critical role of treating physicians in the process of determining what is medically appropriate and necessary care. However, the very same patient can go to different physicians, be told different things, and receive markedly different care.

This chart illustrates the problem. The Washington Family Physicians Collaborative Research Network studied how physicians treat bladder infections for adult women. This is the second most common problem seen in a physician's office. Mr. President, 137 treating physicians were asked to describe their treatment recommendations for a 30-year-old woman with a 1-day history of the infection and an uncomplicated urinary tract infection. They responded with 82 different treatment options.

Which of these is the prudent physician? Which of these 82 different treatments is the generally accepted principle of medical practice as provided by the Kennedy bill? The Kennedy bill would require health plans to cover all 82 different treatments without any thought being given to what is the best treatment, what is the most effective treatment, what is the newest treatment based on the latest in medical research.

Even if something is consistent with generally accepted principles and professional practice, it may not necessarily be the medically best treatment for that patient. Dr. Jack Wennberg is Dartmouth's premier expert in studying quality and medical outcomes. He testified before our committee recently that medical necessity in one community is unnecessary care in another.

Let me give an example from my home State of Maine. The Maine Medical Assessment Foundation conducts peer review and studies area variations in practice patterns in an effort to identify cases in which too many procedures being performed, unnecessarily putting patients at risk. They did a study that showed that physicians in one city in Maine were performing a disproportionately high rate of hysterectomies. They counseled the physicians in that city and were able to lower the rate, thus saving women from being exposed to unnecessary risks of surgery.

I ask my friends on the other side of the aisle, wasn't that review appropriate? Wasn't that review necessary? Wasn't that review a good idea to save these women from undergoing unnecessary hysterectomies?

Let me give some other examples. The Centers for Disease Control estimates that physicians performed 349,000 unnecessary C sections in 1991. Again, these women were placed at risk for unnecessary surgery. Isn't it a good idea to question in some of these cases the decision of the physician to order this unnecessary surgery?

Let me give yet another example. Despite solid evidence that women who undergo breast-sparing surgery followed by chemotherapy or radiation and women who undergo total mastectomies have similar survival rates, regional preferences—as opposed to medical necessity—still prevail in determining treatment.

There was a recent article in the New York Times which showed that the rate of mastectomies was 35 times higher for Medicare patients in one region of the country than in another. According to another study at Dartmouth, women in Rapid City, SD, were 33 times less likely to have breast-sparing surgery than women in a similar city in Ohio.

Yet another example involves children. Today, treatment for frequent ear infections includes the implantation of tubes. I have a nephew who had this procedure, and I am sure many of

my colleagues have children who have gone through this as well. In fact, almost 700,000 children in the United States have had this procedure. According to a 1994 study published in the Journal of the American Medical Association, however, this treatment is inappropriate for more than a quarter of these children.

The PRESIDING OFFICER. The Senator has used her time.

Mr. FRIST. Mr. President, I yield an additional 3 minutes.

The PRESIDING OFFICER. The Senator from Maine is recognized for an additional 3 minutes.

Ms. COLLINS. In another 41 percent of the cases reviewed, the clinical indications for having the tubes implanted were inconclusive at best.

A 1997 study showed that only 21 percent of elderly patients were treated with beta blockers after a heart attack, despite evidence that mortality rates are 75 percent higher for those not receiving treatment.

I would note, in contrast, that HMO members in plans that submit data to the National Committee on Quality Assurance are 2½ times more likely than members of fee-for-service plans to receive beta blockers.

I could go on and on and on. Perhaps the President's own commission said it best. It concluded that excessive procedures—procedures that lack scientific justification—could account for as much as 30 percent of our Nation's medical bills.

Not to mention posing unnecessary risks as well as pain an suffering for those who undergo these unnecessary procedures.

As we can see by these examples and countless more, there may well be valid, indeed, very worthwhile. In fact, there may be very good reasons for the health plan, in some cases, to suggest an alternative treatment to the one the treating physician has initially selected. It may be far better for the patient than the initial recommendation of his or her physician. These examples show that, even if something is consistent with generally accepted principles of professional medical practice, it is not necessarily appropriate high quality care. That should be our goal. Our goal should be to put the patient first and to provide the best quality care to that patient.

The Republican bill deals with the issue of medical necessity through a strong, independent, external appeals process. That is the way to deal with disputes about medical coverage. A Federal statutory definition of medical necessity is unwarranted and unwise.

I yield the floor, and I reserve the remainder of our time.

The PRESIDING OFFICER. Who yields time? The Senator from Oklahoma.

Mr. NICKLES. Mr. President, how much time remains on both sides?

The PRESIDING OFFICER. The Senator has 5 minutes 30 seconds; the Senator from Massachusetts has 13 minutes 30 seconds.

Mr. NICKLES. Mr. President, that means there is about 20 minutes remaining. Just for the information of our colleagues, I think they can expect a rollcall vote on this and subsequent amendments to begin at about 6:45. So those offices should notify their Senators to expect rollcall votes beginning about 6:45.

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. Mr. President, I yield 5 minutes to the Senator from California.

The PRESIDING OFFICER. The Senator from California is recognized for 5 minutes.

Mrs. FEINSTEIN. Mr. President, if this definition, the definitions we have been debating on what is medical necessity—if the Republican definitions were supported by medical organizations, I might think they are pretty good. But there is virtually no physician-oriented organization anywhere in the United States that I know of that supports this particular definition of medical necessity. Every single one of them supports the definition in the Daschle bill.

I think the Senator from Rhode Island and the Senator from North Carolina spoke eloquently as to why. Since the Senator from North Carolina remains on the floor, I would like to ask him this question. The Senator from Rhode Island read the definition from a particular insurer. Let me reread it:

> [This company] will have the sole discretion to determine whether care is medically necessary. The fact that care has been recommended, provided, prescribed or approved by a physician or other provider will not establish that the care is medically necessary.

Then, in view of that, if you read on the top of page 180, in the bill, which sets out the guidelines for the standard of review for the independent reviewer, at the top of the page and the bottom of page 179:

> The independent reviewer will take into consideration appropriate and available information including any evidence-based decisionmaking or clinical practice guidelines used by the group health plan or insurance issuer.

How would an independent reviewer make a decision?

Mr. EDWARDS. Under the definition the Senator has just read—and I might point out the appeals process that is contained in this amendment is completely controlled by the HMO or health insurance company's definition of medical necessity. Throughout the process it is totally controlled by it.

Mrs. FEINSTEIN. Then if I understand you correctly, if an insurer had in its plan that they will use the least costly alternative available, the independent reviewer would have to find for the least costly alternative?

Mr. EDWARDS. That is absolutely correct.

Let's suppose we had a young child who needed a particular kind of care and every physician who had treated that child recommended the care for the child. But there was a less costly procedure that could be used, so the care was denied. Throughout the appeals process, the determination of whether it ought to be reversed or not would be based on what is the least costly, because it is totally controlled by the definition written by the HMO.

In the language the Senator from California has just read to me, where it says it shall be within the ''sole discretion,'' what that ultimately means is whatever appealing body is deciding, which is bound by that definition, which they are by this amendment—if they are bound by that definition, every appealing body would be left with no alternative but to affirm the decision because the contract says it is left within the sole discretion of the HMO.

It goes to the very heart of the Senator's amendment. It goes to the very heart of this debate. The whole question is, Are health insurance bureaucrats going to make health care decisions or are health care decisions going to be made by doctors and health care professionals?

Mrs. FEINSTEIN. I just read the language. There is no language in this that says the independent reviewer, even in a case of life or death, would necessarily see the patient.

Mr. EDWARDS. That is absolutely correct. There is nothing that requires the independent reviewer to see the patient. You could have some doctor who is nothing but a bureaucrat, who has not seen the patient, does not know what the patient needs, making the decision.

If I could add one thing, another problem with this so-called independent review process is the HMO, the health insurance company, are the ones that are determining. Remember, they choose this entity that chooses the reviewer. They determine who is biased or unbiased.

Mrs. FEINSTEIN. And the entity pays the reviewer as well.

Mr. EDWARDS. They pay the reviewer. We have said it now five different times, but talk about putting the fox in charge of the chicken coop. What we need to be doing is to have some truly independent body making these determinations. They need to be able to make the determination based upon what the patient, in my example the child, really needs, based on what the doctor says the child needs.

Mr. NICKLES. Will the Senator yield?

Mr. EDWARDS. No, I will not.

It is not based on what some insurance company has written into a HMO or health insurance contract.

Mrs. FEINSTEIN. So, in other words——

Mr. NICKLES. Mr. President, regular order.

Mrs. FEINSTEIN. I believe I have the floor, Mr. President.

Mr. NICKLES. Parliamentary inquiry. Aren't Senators supposed to go through the Chair?

Mr. KENNEDY. Regular order. Senators are permitted to inquire and ask questions. That is the regular order, Mr. President. I insist on the regular order, not the interruption of the Senator from North Carolina. Whose time is this on, Mr. President?

Mr. NICKLES. The Senator from North Carolina——

The PRESIDING OFFICER. The time right now, at this point, is not being charged. The Senator from California had 5 minutes that she was controlling after it was allotted by the Senator from Massachusetts.

Mr. KENNEDY. Parliamentary inquiry. Can the Senator be inquired of by a Member of the Senate and answer a question?

The PRESIDING OFFICER. The questions are most appropriately addressed through the Chair.

Mr. KENNEDY. But the Senator is entitled, the Senator from North Carolina, to inquire of the Senator from California, is he not?

Mrs. FEINSTEIN. Or vice versa.

The PRESIDING OFFICER. If he does so through the Chair.

Mr. KENNEDY. I thank the Chair.

Mrs. FEINSTEIN. I inquire of the Senator from North Carolina, through the Chair, if I were a woman suffering from ovarian cancer and I have this policy that I read from, and my physician said there is a small chance a bone marrow transplant might help you——

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. KENNEDY. I yield an additional 3 minutes.

Mrs. FEINSTEIN. But there is a small chance a bone marrow transplant might help you, I would advise that you have it, and if the health plan with this language turned it down, I would have no opportunity to have that bone marrow transplant?

Mr. EDWARDS. You would have absolutely no opportunity and no opportunity to have the decision reversed. I might add, there is a double whammy in this amendment. The double whammy is that the only thing that can be appealed is the determination of what is medically necessary, and what is medically necessary, under the language of their bill is—and I am reading now from the bill—''when medically necessary and appropriate under the terms and conditions of the plan,'' which is what the HMO and the health insurance company's contract says.

People are getting whammied twice: No. 1, you cannot appeal but one thing, which is: Is it medically necessary? No. 2, that determination is based on what the health insurance company or the HMO wrote into the plan.

Mrs. FEINSTEIN. In other words, if I may, through the Chair, if this amendment were to be adopted, every enrollee of an HMO plan would have to read the fine print very carefully, because all an HMO would have to do is put in a disclaimer, either medical necessity based on least cost or medical necessity based on the fact that the plan would have the ultimate say on how medical necessity is defined.

Mr. EDWARDS. The Senator is correct, and the patient would be stuck with that decision initially by the HMO and would be stuck with it throughout the entire appeals process and would have absolutely—it goes to the very heart of this debate: Do we want health insurance companies deciding what is medically necessary, or do we want health care providers, doctors, and patients making the decisions?

Mrs. FEINSTEIN. Who have seen the patient.

Mr. EDWARDS. Absolutely, doctors who have seen the patients. We believe doctors ought to make the decisions.

Mrs. FEINSTEIN. I thank the Senator very much. This has been a helpful clarification. I yield the floor.

The PRESIDING OFFICER. Who yields time?

Mr. NICKLES. Mr. President, I yield myself 5 minutes on the bill.

The PRESIDING OFFICER. The Senator from Oklahoma is recognized for 5 minutes on the bill.

Mr. NICKLES. Mr. President, I was trying to make sure our colleagues understand the procedure in the Senate. When you have colloquies, you go through the Chair. I have noticed some colloquies on this side have bypassed the Chair. Some colloquies on that side have bypassed the Chair. That is not the rule of the Senate. It is important we have discussions according to the rules of the Senate. That is the way we should do it. That way, we do not freeze out other colleagues who want to participate in colloquies. I was not trying to get under my colleagues' skin. It is important we follow the rules of the Senate.

I want to point out that a couple of the statements made by our colleagues are actually very inaccurate. Actually who pays for the plans and entities are very similar in both bills. Under the Democrat bill, S. 6, on page 66: A plan or insurer shall be conducted under contract between the plan or insurer in one or more qualified external appeals entities.

That is page 66.

Under the Republican bill, it is the same thing, the plan selects the entity. They do not select the person who does the review, they select the entity. The entity is licensed by the State, or it is a State agency established for that purpose, or it is an entity with a contract with the Federal Government and they have the reviewers.

My point is, both the Democrat plan and the Republican plan select the entities. They are the same. For them to say, oh, the Republican plan selects the reviewer is false. The Democrat plan, as well as the Republican plan pay for the entities, they select the entities, and the entities themselves are independent, and the entities select the individual reviewer.

There is a little—I do not want to use the word ''hypocrisy''; it is not a word I often use on the floor. But to be railing against the Republican plan, not stating the facts, and then say, oh, by the way; oh, the Democrat plan, the plan selects the entities as well, I just find it to be very inconsistent.

I urge my colleagues to see that in the Republican plan, the proposal we have before us, we say the plans select the entity, and the entity is a qualified entity if it is an independent external reviewer and credentialed by the State or a State agency established for the purpose of conducting the external review, or it is an entity under contract with the Federal Government, or it is an entity accredited as an independent external review entity by an accrediting body recognized by the Secretary of HHS.

I just mention that. It is important we be consistent and that people understand on both sides, the Democrat proposal selects an entity very similar to that of the Republican proposal.

I yield the floor.

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. I yield 1 minute to the Senator from California and then 1 minute to the Senator from North Carolina.

Mrs. FEINSTEIN. Mr. President, I must respond to the Senator from Oklahoma because he mischaracterizes the Democratic plan. His statement might be correct if it were taken in an isolated sense. But if you take it with the medical necessity definitions on page 85 of the Democratic plan, you will see that ''a group health plan and a health insurer, in connection with a provision of health insurance coverage, may not arbitrarily interfere with or alter the decision of the treating physician regarding the manner or setting in which particular services are delivered if the services are medically necessary or appropriate for treatment.''

Then it goes on to define medical necessity as a service or benefit which is consistent with generally accepted principles of professional medical practice. It does not give the plan the opportunity in its fine print to throw out medical necessity.

The PRESIDING OFFICER. The Senator's time has expired.

Mr. KENNEDY. I yield the Senator 2 minutes.

The PRESIDING OFFICER. The Senator from North Carolina is recognized for 2 minutes.

Mr. EDWARDS. Mr. President, I say respectfully in response to my colleague from Oklahoma that there are two things about which I fundamentally disagree with him. No. 1, under our proposal, the State—totally independent—chooses the reviewing body. If my colleagues are really looking for an independent review, I ask them whether they would agree to allow the State to choose the reviewing body instead of the health insurance company, instead of the HMO choosing the entity that chooses the reviewing body. I cannot imagine how they would disagree

with that if they are looking for a truly independent review.

Secondly, the entire issue revolves around what is medical necessity. I say to my colleagues, would they agree to change the language of this amendment so that the initial decision and every appeals decision of the appeals deciding body is not bound by the definition of ''medical necessity'' contained in the insurance written contract? Because so long as the appeals process is controlled by what the HMO wrote, what the health insurance company wrote at the beginning and all the way through the process, the patient does not have a chance. They will never have a chance. My question is to my colleagues——

Mr. GREGG. Will the Senator yield?

Mr. EDWARDS. I will give the Senator an opportunity to respond. My question is whether they will agree, No. 1, with the State choosing a truly independent reviewing body, and, No. 2, whether they will agree that the reviewing body is not bound by a definition written by the health insurance or HMO company.

I yield for a question.

The PRESIDING OFFICER. The Senator's time has expired.

Who yields time?

Mr. GREGG. We have no time.

Mr. FRIST. We have 5 minutes.

Mr. KENNEDY. I yield 1 minute to the Senator for a question.

Mr. GREGG. I appreciate that.

Mr. KENNEDY. Does the Senator still have time left?

The PRESIDING OFFICER. The majority side controls 5 minutes 20 seconds, the minority side, 5 minutes 4 seconds.

Mr. GREGG. Mr. President, I have a question for the Senator from North Carolina which is in reference to the Kennedy bill, section 133, subsection (1)(ii), on page 67:

If an applicable authority permits—

That will be the State authority—

more than one entity to qualify as a qualified external appeals entity with respect to a group health plan or health insurer issuer, then the plan or issuer may select among such qualified entities the applicable plan.

So basically if the State picks two or three different reviewers, under your plan, then the plan gets to choose; isn't that correct?

Mr. FRIST. Whose time is this on?

The PRESIDING OFFICER. On the majority side.

Mr. FRIST. I yield another 30 seconds.

Mr. GREGG. So there is an option under your proposal where plans would have a choice because that is what the language says?

The PRESIDING OFFICER. Who yields time?

Mr. EDWARDS. Am I allowed to respond?

Mr. KENNEDY. I yield the Senator 1 minute.

The PRESIDING OFFICER. The Senator is recognized for 1 minute.

Mr. EDWARDS. My response is very simple.

The language on the preceding page requires that the independent external review entity be designated by the State. That is, if I am reading the language correctly, contained on the preceding page. That is designated by the State. In fact, we say—this is at page 11, I say to the Senator—that ''No party to the dispute shall be permitted to select the entity conducting the review.''

So there are two things operating, I think, in combination in our bill. No. 1, the State has to designate an independent body, and, No. 2, we specifically require that no party to the dispute be involved in designating the reviewing entity.

I might add to that, I think it is also critically important who determines what is medically necessary and what the appeal decision body is bound by in terms of what is medically necessary because I think all of this becomes meaningless if they are bound by what the HMO or health insurance company wrote.

The PRESIDING OFFICER. The time has expired.

Mr. GREGG. Will the Senator yield me another 30 seconds?

Mr. FRIST. How much time do we have?

The PRESIDING OFFICER. Four minutes 20 seconds. The minority has 4 minutes.

Mr. FRIST. I yield 30 seconds to the Senator.

Mr. GREGG. I, therefore, take it in the Kennedy plan, when it says, ''the plan or issuer may select among such qualified entities,'' that that language is not operative, that that does not exist, that that language is a nonfactor.

Let's get serious. This is what your bill says. It says the plans can be selected from the qualified entities. You can pick two or three plans, that the States have chosen to qualify two or three plans, and the people pick the plans. So you are totally inconsistent with your argument.

Mr. EDWARDS. May I respond?

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. I yield the Senator 30 seconds.

The PRESIDING OFFICER. The Senator from North Carolina is recognized for 30 seconds.

Mr. EDWARDS. There is a very simple, straightforward answer to the question. I understand the Senator is reading the old bill. He is not reading the bill that is presently before the Senate.

The PRESIDING OFFICER. Who yields time?

Mr. FRIST. Mr. President, I yield 4½ minutes—how much time is remaining?

The PRESIDING OFFICER. The majority side controls 4 minutes on the amendment.

Mr. FRIST. Mr. President, I yield the remaining time to the Senator from Wyoming.

Mr. GREGG. Would the Senator yield me 10 seconds? Because a misstatement was made.

Mr. FRIST. I yield another 30 seconds to the Senator from New Hampshire.

Mr. GREGG. I am reading from S. 6. That is the bill that was laid down. That is the bill we are debating.

The PRESIDING OFFICER. Who yields time?

Mr. FRIST. I yield 4½ minutes to the Senator from Wyoming.

The PRESIDING OFFICER. There are only 3 minutes 50 seconds remaining on the majority side. The Senator from Wyoming is recognized for that time.

Mr. ENZI. Mr. President, I rise in strong support of improved, reliable quality care for all Americans. To that end, I am pleased to join my colleagues in debating the dangerous concept of putting into law a definition of medical necessity.

The minority argues that putting a definition of medical necessity into the law would assure health care providers absolute autonomy in making all treatment decisions for their patients. They say that is exactly what they want. It is their prescription for high quality health care.

Well then, when asked what patients and providers would use as a guide for the choice of treatment options and delivery of care, particularly in such a dynamic and constantly innovating field such as health care, the minority relies squarely on ''generally accepted medical practice.''

The Democrat plan is a trial lawyer's dream. ''Generally accepted medical practice'' is lawsuit bait. But I can tell you that with the Democrat plan ''medical necessity'' would be absolutely necessary because it is the only way to bridge the bureaucracy.

This is the bill we are looking at from the Democrats. Who can follow the lines? Each one of those lines represent a lawsuit trap. This is lawsuit bait.

Unfortunately, for patients, ''generally accepted medical practice'' is the strict application of medical opinion versus the combination of your doctor's good judgment or opinion and the prevailing evidence-based practice of medicine. The minority approach turns its back on the scientific foundation of medicine. But what other solid ground is there upon which we could build greater quality into our health care system?

The minority, for the first time in Federal law, wants to carve this variability into law, and that law will be followed by rule and regulation—more lawsuit bait. This is a Federal one-size-fits-all budget-busting bureaucracy with lots of lawsuit bait and difficulty in following the whole process.

Let me share with my colleagues the language from the minority bill. Under the subtitle of ''Promoting Good Medical Practice,''—a good title—lies a provision which, in my estimation, would have the exact opposite effect. The bill reads:

A group health plan, and a health insurance issuer in connection with the provision

of health insurance coverage, may not arbitrarily interfere with or alter the decision of the treating physician regarding the manner or setting in which particular services are delivered if the services are medically necessary or appropriate for treatment or diagnosis to the extent that such treatment or diagnosis is otherwise a covered benefit.

Now, let me loop through the rest of their proposal to demonstrate how they essentially ''ban'' the use of trustworthy science and evidence-based medicine. At the end of the same subtitle, we are offered a definition of medical necessity or appropriateness. It reads, ''medically necessary or appropriate means, with respect to a service or benefit, a service or benefit which is consistent with generally accepted principles of professional medical practice.''

To recap the minority policy proposal, they've suggested that doctors make decisions about their patients based just on opinion, and that health plans would, by law, have to cover any and every treatment opinion prescribed by providers. The minority may argue that their proposal limits what plans must pay for to the terms of the contract. However, their plan requires plans to cover all treatments deemed medically necessary, so this provision would, in fact, encompass the universe of health care, heedless of quality and contract alike.

It's my opinion, and a major thrust of the Republican bill, that we should be doing everything we can to help health care providers in their efforts to provide the highest possible quality of care to patients. The minority tells doctors, who are now busier than ever and doing their best to stay atop the innovations in medicine, that ''it's all on you.''

Mr. President, since there has been an effort to infuse real life examples into this debate, it might be helpful for all of the health care consumers at home if we talk about how medical science versus ''generally accepted practices'' actually translates into real life. In the following examples, you'll begin to understand that ''generally accepted practices'' vary from town to town, and the gap gets wider from state to state. This basically means that the quality of your health care may depend more on where you live than on what the prevailing best medical science is on your illness.

Here's an example where I can use my home state of Wyoming. The average number of days spent in the hospital during the last 6 months of life for people living in Wyoming was between 4.4 days and 8 days. In contrast, the average number of days spent in the hospital for the last 6 months of life for people living in New York was between 12 and 22 days. This means that there is nearly a 250 percent variation among States for hospital length-of-stay at the end of life. Who's responsible for this variation and what does it mean about the quality of care we're receiving?

More importantly, how does this jibe with legislating a definition of medical necessity? Remember, the minority want us, for the first time, to carve this variability into law. The law will be followed by rule and regulation. Does this mean that for health plans that have beneficiaries in Wyoming and in New York that what might be determined a medically appropriate treatment for a New Yorker would be deemed medically inappropriate for a patient in Wyoming?

This variation is comprehensive, going beyond hospital lengths-of-stay, from the use of drug therapies to surgical practices. One of the most disheartening and horrifying statistic is regarding women with breast cancer. Despite the solid evidence that women who undergo breast-sparing surgery followed by chemotherapy or radiation and women who undergo radical mastectomies have similar survival rates, it is regional preferences, that is, the general practices of a region, that still prevail in determining a woman's course of treatment. In 1996, women with breast cancer in Rapid City, SD were 33 times less likely to have breast-sparing surgery than women in Elyria, OH. How can anybody look at these variations and view them as the only answer to good medicine?

These inconsistencies in the medical care Americans receive are something we all need to address; that includes health plans and doctors, and ourselves. Make no mistake about our potential as Congress to derail the efforts at quality improvement in American's health care if we're not very careful and very thoughtful about what it is we're doing here today.

On a positive note, we are seeing signs of improvement when it comes to doctors and health plans working together to improve the consistency and overall quality of health care. For example, according to a 1997 Quality Compass report by the National Committee on Quality Assurance, over 50 percent of elderly heart attack patients in HMOs that submitted data were treated with beta blockers, which can reduce mortality rates by 75 percent in those patients. In the same year, patients in regular fee-for-service plans received beta blocker only 21 percent of the time. This is almost a three-fold difference when you compare a coordinated approach to care with a ''generally accepted practices'' approach.

I am very concerned that we need to pass a proposal that responds to these ''consistent inconsistencies'' in the quality and practice of medicine in this country, while also guarding the doctor-patient relationship. After all, outside of family, many of us view our relationship with our doctor as our most trusted.

The solution lies in building on the doctor-patient relationship and infusing our health care system with evidence-based medicine. Our bill does that. Our bill does not turn a blind eye to either the strengths or the weaknesses of today's health care system. Our bill takes a look at what we need to preserve and what we need to improve upon, and offers a responsible solution to enhancing quality and ensuring access.

Our bill will provide patients and their doctors with a new, iron clad support system that will insure access to medically necessary care. An independent, external appeals process will be available for patients whose plan has initially denied a treatment request that the patient and doctor have decided is necessary. In other words, our bill gets patients the right treatment, right away. And it's based on the independent decision of a medical professional who is expert in the patient's health care needs. In rendering a decision on the medical necessity of the treatment request, the expert review will consider the patient's medical record, evidence offered by the patient's doctor and any other documents introduced during the internal review. This covers the ''generally accepted practice'' standard that the minority offers as a singular solution.

Our bill goes further, capturing the other half of good quality health care, which is the evidence-based medicine rooted in science that I spoke about earlier. We would require the expert reviewer to also consider expert consensus and peer-reviewed literature and evidence-based medical practices. Let me say that again; evidence-based medicine, not the varied, town-by-town, tried but not necessarily true, general practice of medicine.

Because we feel so strongly about preserving the trusted relationship between doctors and patients by providing them with the best evidence-based medicine in making treatment decisions, we've included another lynchpin in our bill. We establish the Agency for Healthcare Research and Quality, whose purpose it is to foster overall improvement in health care quality, firmly bridging the gap between what we know about good medicine and what we actually do in health care today. The Agency is built on the platform of the current Agency for Health Care Policy and Research, but is refocused and enhanced to become the hub and driving force of Federal efforts to improve the quality of health care in all practice environments.

The Agency will assist, not burden physicians, by aggressively supporting state-of-the-art information systems for health care quality. This is in stark contrast to the minority proposal, which would require the Secretary of Health and Human Services to Mandate a new, onerous data collection bureaucracy. The Agency would support research in primary care delivery, priority populations and, critical to my state of Wyoming, access in underserved areas. Most important with regard to this research, is that it would target quality improvement in all types of health care, not just managed care. The Agency would also conduct

statistically and scientifically accurate, sample-based surveys, using existing structures, to provide high quality, reliable data on health outcomes. Last, the Agency would achieve its mission of promoting quality by sharing information with doctors, health plans and the public, not tying it up in the knots of an expanded Federal bureaucracy. We need to assist the providers on the front lines. Their job is to make clinical decisions. We need to give them the tools to make these medical decisions based on the proven medical advances made every day through our investment in medical research. It would be a huge mistake to put the Secretary and a Federal bureaucracy between doctors and patients.

Clearly, medical necessity is a long and complicated issue. It is also where the rubber meets the road on improving the quality of medicine in the purest sense. This is where we all must pony up on the true intent of our proposals regarding medical necessity. This is where we peel away the rhetoric and reveal the true implications of our vastly different standards regarding the quality of care we are willing to demand for Americans. I, for one, am demanding that my constituents get the best care possible, with a solid basis in proven, quality, evidence-based medicine and timely access to the advancements and innovations in health care.

Mr. President, I understand and greatly respect the role of doctors and all health care providers in this country. It is for that very reason that I support the creation of a new, independent appeals mechanism to support their efforts in treating their patients. This, in conjunction with strengthening the health care system through strong Federal support for access to evidence-based medicine.

Mr. President, I reserve the remainder of my time.

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, much of this debate may seem technical, but the definition of medical necessity and a fair and independent appeals process are at the heart of any serious effort to end insurance company abuse. Our plan has it; their program does not. That is why Consumers Union—the outfit that publishes Consumer Reports—calls the Republican program ''woefully inadequate'' and ''far from independent.''

No one supports their program but the insurance companies and the HMOs, the very organizations that profit from the abuses of the status quo. Their program is opposed by the American Cancer Society, and virtually every cancer organization in the country. It is opposed by the American Heart Association. It is opposed by the disability community. It is opposed by the women's community, and the people who represent children. These are the patient groups that have the most to lose from low quality and the most to gain from high quality. And they lose under the Republican program.

This amendment will determine whether Senators stand with the patients or with the HMOs.

We yield back the remainder of our time and are prepared to vote.

Mr. NICKLES addressed the Chair.

Mr. KENNEDY. I reserve my time.

Mr. NICKLES. Just to clarify, I think my colleague from Massachusetts spoke incorrectly. The insurance industry does not support our amendment. I think he said that they do. He happens to be factually wrong. I would like to have the RECORD be clear. We ought to be stating facts and we ought to be stating the truth. What he said was not correct. They do not like our bill, either. They have not supported our bill.

My colleague from Massachusetts earlier said they wrote our bill. He is absolutely wrong. I just want to make sure people have the facts.

Mr. President, I will yield back the remainder of our time.

First, I ask unanimous consent that at the expiration of debate time on the pending amendment, votes occur on the following pending amendments: amendment No. 1238, medical necessity, that is the pending amendment; the next amendment would be amendment No. 1236, which is the cost cap, limiting it to 1 percent; the next amendment would be amendment No. 1235 which deals with emergency rooms, by Senator GRAHAM; the next amendment would be amendment No. 1234, deductibility for the self-employed; and the next amendment would be amendment No. 1233, dealing with the scope.

I further ask unanimous consent that following the first vote, there be 4 minutes equally divided for closing remarks prior to the beginning of each vote.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Reserving the right to object, and I will not object, just in response to the Senator's earlier statement, I wonder why the insurance companies are spending more than $2 million opposing our program.

Mr. NICKLES addressed the Chair.

The PRESIDING OFFICER. Is there objection?

Mr. KENNEDY. Mr. President, I reserve the right to object. Unless I am entitled to speak, I will object, Mr. President.

Mr. CHAFEE addressed the Chair.

Mr. KENNEDY. Mr. President, I withdraw my objection.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. CHAFEE. I wonder if we could have an agreement that on the successive votes the Senator from Oklahoma outlined there be a 10-minute break, or whatever he suggests, in there.

Mr. NICKLES. I think our friend from Rhode Island has made a good suggestion. I suggested possibly doing that. I think we will possibly do that after the first vote.

The PRESIDING OFFICER. Is there an objection to the request? Without objection, it is so ordered.

Mr. NICKLES. For the information of all of our colleagues, we are now getting ready to begin a series of votes, beginning with the first vote dealing with medical necessity. We expect there will be four votes tonight, so I encourage all our colleagues to come to the floor to vote.

I encourage all of our colleagues to stay on the floor because it is our intention to reduce the time allotted to each vote to 10 minutes after the first vote.

Mr. REID. Reserving the right to object——

Mr. NICKLES. I did not make a UC.

Mr. REID. Are we going to allow a minute of explanation? Is that in the unanimous consent request?

Mr. NICKLES. Under the unanimous consent that has already been agreed to, we have 4 minutes equally divided.

Mr. REID. I missed that. I apologize.

The PRESIDING OFFICER. Does the Senator from Massachusetts yield back the remainder of his time?

Mr. KENNEDY. Just 30 seconds of the time to point out, in response to the comments of the Senator from Oklahoma, the insurance industry has just spent $2 million in opposition to our program, which basically includes the provisions so eloquently commented on by the Senators from California and North Carolina. Zero has been spent by the insurance companies in opposition, to my best understanding, to the Republican proposal. If it looks like a duck and quacks like a duck, it is a duck.

This is the insurance company's proposal, the HMO proposal. They are the ones that will gain if this amendment of the Republicans is accepted. There is no question about that. It is the disabled, the cancer groups, and the children who will gain if our proposal prevails.

I yield back the remainder of the time.

Mr. NICKLES. Mr. President, I yield back the remainder of my time.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 1238.

The yeas and nays have not been ordered.

Mr. NICKLES. Mr. President, I ask for the yeas and nays on the amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 1238. The yeas and nays have been ordered. The clerk will call the roll.

The result was announced—yeas 52, nays 48, as follows:

[Rollcall Vote No. 199 Leg.]

YEAS—52

Allard	Gramm	Nickles
Ashcroft	Grams	Roberts
Bennett	Grassley	Roth
Bond	Gregg	Santorum
Brownback	Hagel	Sessions
Bunning	Hatch	Shelby
Burns	Helms	Smith (NH)
Campbell	Hutchinson	Smith (OR)
Cochran	Hutchison	Snowe
Collins	Inhofe	Specter
Coverdell	Jeffords	Stevens
Craig	Kyl	Thomas
Crapo	Lott	Thompson
DeWine	Lugar	Thurmond
Domenici	Mack	Voinovich
Enzi	McCain	Warner
Frist	McConnell	
Gorton	Murkowski	

NAYS—48

Abraham	Durbin	Leahy
Akaka	Edwards	Levin
Baucus	Feingold	Lieberman
Bayh	Feinstein	Lincoln
Biden	Fitzgerald	Mikulski
Bingaman	Graham	Moynihan
Boxer	Harkin	Murray
Breaux	Hollings	Reed
Bryan	Inouye	Reid
Byrd	Johnson	Robb
Chafee	Kennedy	Rockefeller
Cleland	Kerrey	Sarbanes
Conrad	Kerry	Schumer
Daschle	Kohl	Torricelli
Dodd	Landrieu	Wellstone
Dorgan	Lautenberg	Wyden

The amendment (No. 1238) was agreed to.

Mr. LOTT. I move to reconsider the vote.

Mr. NICKLES. I move to lay that motion on the table.

Mr. LOTT. Mr. President, I ask unanimous consent that remaining votes in this series be limited to 10 minutes in length. I urge Senators to stay in the Senate Chamber or not to go any farther than the cloakrooms so we can actually hold these next three votes to 10 minutes. Please do so. Senator DASCHLE and I intend to cut off the vote after about 10 or 11 minutes. Please stay in the Chamber.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDMENT NO. 1236

The PRESIDING OFFICER. There are 4 minutes equally divided.

Mr. NICKLES. Mr. President, I yield the Senator from Texas 1 minute.

Mr. GRAMM. Mr. President, the Kennedy Patients' Bill of Rights drives up health care costs by 6.1 percent. It causes 1.8 million Americans to lose their health insurance. It raises the cost of health care for those who don't lose their health insurance by $72.5 billion. By driving up labor costs, it would destroy 194,041 jobs in the American economy by the year 2003. These are not our numbers. These are numbers based on estimates done by the CBO and private research firms that have used those numbers to project the economic impact.

Our amendment simply says if the Kennedy bill drives up health care costs by more than 1 percent when it is fully implemented, or if it pushes more than 100,000 Americans off the private insurance rolls by driving up cost, then the law will not go into effect; it will be suspended.

The PRESIDING OFFICER. Who yields time?

Mr. REID. The Senator from Rhode Island is yielded 2 minutes.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. Mr. President, once again we hear the same old misestimate of the costs associated with the legislation. The true cost calculated by the Congressional Budget Office is 4.87 percent over 5 years. That is exactly what Senator LOTT said on ''Meet The Press'' on July 11. In his words, ''By the way, the Democratic bill would add 4.8 percent cost. That is less than 1 percent a year.''

Mr. GRAMM. Mr. President, may we have order. I can't hear the Senator.

The PRESIDING OFFICER. The Senate will be in order. Those of you who have conversations, please take them to the Cloakroom. This is important debate.

The Senator from Rhode Island.

Mr. REED. I thank the Chair.

As I indicated, the true cost is 4.8 percent over 5 years. ''That is less than 1 percent a year.'' That is what Senator LOTT said on ''Meet The Press.'' Indeed, if you calculate that down to a monthly cost, it is about $2 extra a month to the average family paying health care premiums. It is not going to cause a huge eruption of costs.

It is also to me somewhat disconcerting to think that the insurance industry is worried about people losing their health care coverage. They raise costs every day. They will raise costs to protect their profits.

What this legislation wants to do is guarantee that there is quality in the American health care system.

Make no mistake, this amendment is calculated and designed to undercut all the protections in the Patients' Bill of Rights. It is calculated within 2 years to undercut and remove all of the protections that are so necessary to the American family, which we are fighting for.

This would be a recipe also to reward those companies that have excessive costs, and it would be virtually impossible to figure out what costs are associated with their need for profits versus what costs are associated with the increase in quality in the system. They would be doing the audits. They would essentially be exempting themselves. We are giving them a key to let them out of the responsibilities to their patients and to their consumers. We can't do that.

This is just another red herring, another ruse, and another device to prevent the American people from achieving what they definitely want—rights in the health care system.

The PRESIDING OFFICER. The Senator's time has expired.

The Senator from Oklahoma.

Mr. NICKLES. Mr. President, just to correct my colleague from Rhode Island, he said the cost of the Kennedy bill is about $2 a month. That is not correct. That is not in CBO's report. CBO says most of the provisions would take full effect within the first 3 years, not 5 years; not 1 percent, but a total of 6.1 percent. That is S. 6. That is what we are debating. That is what we are amending.

We are saying that costs shouldn't increase by more than 1 percent.

The Congressional Budget Office says the total costs would be $8 billion in lost Social Security taxes and total lost wages would be $64 billion. That is not a McDonald's hamburger. That is $64 billion in lost wages, according to the Congressional Budget Office. That is not a Republican insurance study. That was the Congressional Budget Office that said people would lose $64 billion in lost wages.

They also said as a result of the Kennedy amendment that people would drop insurance entirely; would reduce the generosity of health benefit packages; they would increase cost sharing by beneficiaries.

I urge my colleagues to vote for this amendment.

The PRESIDING OFFICER. The Senator's time has expired.

Mr. NICKLES. I ask for the yeas and nays on the amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to Amendment No. 1236, as amended. On this question, the yeas and nays have been ordered, and the clerk will call the roll.

The legislative clerk called the roll.

The PRESIDING OFFICER. Are there any other Senators in the Chamber who desire to vote?

The result was announced—yeas 52, nays 48, as follows:

[Rollcall Vote No. 200 Leg.]

YEAS—52

Abraham	Gorton	Murkowski
Allard	Gramm	Nickles
Ashcroft	Grams	Roberts
Bennett	Grassley	Roth
Bond	Gregg	Santorum
Brownback	Hagel	Sessions
Bunning	Hatch	Shelby
Burns	Helms	Smith (NH)
Campbell	Hutchinson	Smith (OR)
Cochran	Hutchison	Snowe
Collins	Inhofe	Stevens
Coverdell	Jeffords	Thomas
Craig	Kyl	Thompson
Crapo	Lott	Thurmond
DeWine	Lugar	Voinovich
Domenici	Mack	Warner
Enzi	McCain	
Frist	McConnell	

NAYS—48

Akaka	Edwards	Levin
Baucus	Feingold	Lieberman
Bayh	Feinstein	Lincoln
Biden	Fitzgerald	Mikulski
Bingaman	Graham	Moynihan
Boxer	Harkin	Murray
Breaux	Hollings	Reed
Bryan	Inouye	Reid
Byrd	Johnson	Robb
Chafee	Kennedy	Rockefeller
Cleland	Kerrey	Sarbanes
Conrad	Kerry	Schumer
Daschle	Kohl	Specter
Dodd	Landrieu	Torricelli
Dorgan	Lautenberg	Wellstone
Durbin	Leahy	Wyden

The amendment (No. 1236), as amended, was agreed to.

Mr. NICKLES. Mr. President, I move to reconsider the vote.

Mr. CRAIG. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 1235

The PRESIDING OFFICER. The question is on the Graham of Florida amendment. There are 4 minutes equally divided.

The Senator from Florida is recognized.

Mr. GRAHAM. Mr. President, most of us here have already voted in favor of the amendment which is before us. In 1997 we adopted virtually this identical language as it relates to the 70 million Americans who are covered either by Medicare or Medicaid. So the question before us is, Should we adopt a different standard of emergency room care for the rest, for the other 190 million Americans?

There are two principal differences between the current law for Medicare and Medicaid and what the Republican alternative would propose. First, as to access to the nearest available emergency room, the current Medicare/Medicaid law says you have the right to go to the nearest emergency room without any additional charge. That is the same provision that is in this amendment. The Republican provision says that a differential charge can be made so you would have to pay more if it happened that the closest emergency room was not an emergency room affiliated with your health maintenance organization.

The second difference is poststabilization care. What is poststabilization care? I quote the language from the Medicare regulations:

> Poststabilization care means medically necessary nonemergency services needed to assure that the enrollee remains stabilized from the time that the treating hospital requests authorization from the health maintenance organization.

Medicare and Medicaid beneficiaries get the benefit of poststabilization care. Our amendment would make that benefit available to all 190 million non-Medicare/Medicaid Americans. The Republican bill would not. It would not say that you are entitled to medically necessary services to continue you in a stabilized condition after you had contacted your HMO and received authorization to do so.

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. GRAHAM. Mr. President, there is no reason why all Americans should not have the same benefits that we voted less than 3 years ago to make available to the 70 million Medicare and Medicaid beneficiaries.

Mr. NICKLES. Mr. President, may we have order in the Senate.

The PRESIDING OFFICER. The Senate will come to order.

Mr. NICKLES. I yield 2 minutes to the Senator from Arkansas.

The PRESIDING OFFICER. The Senator from Arkansas.

Mr. HUTCHINSON. Mr. President, I say to my colleagues, in the area of emergency group services, both bills eliminate prior authorization, and they should. You should not have to call your insurance company before you go to the emergency room. Both bills establish a process for timely coordination of care, including services to maintain stability of the patient.

I will be offering an amendment that will make it perfectly clear in the Republican bill that there can be no greater costs charged for those going to an out-of-network emergency room as those going to an in-network emergency room. There should not be a differential. I will make very certain in my amendment that there is no such differential.

The Graham amendment is flawed, and it is seriously flawed because it uses language that is confusing for patients, confusing for plans and providers, it is vague and ambiguous, and it does not ensure that poststabilization services are related to the emergency condition. That is a gaping loophole. It is a blank check to say you have to provide services for a condition that is absolutely unrelated to the reason you went to the emergency room.

My amendment I will be offering will fix that vague and ambiguous language to be sure that what is provided in the emergency room for poststabilization services are related to the condition for which the patient went to the emergency room.

This is a very dangerous amendment in that it is vague and ambiguous and leaves a blank check, a gaping loophole that needs to be fixed. I ask my colleagues to reject the Graham amendment.

Mr. NICKLES. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 1235. The yeas and nays have been ordered. The clerk will call the roll.

The legislative clerk called the roll.

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 47, nays 53, as follows:

[Rollcall Vote No. 201 Leg.]

YEAS—47

Akaka	Edwards	Lieberman
Baucus	Feingold	Lincoln
Bayh	Feinstein	Mikulski
Biden	Graham	Moynihan
Bingaman	Harkin	Murray
Boxer	Hollings	Reed
Breaux	Inouye	Reid
Bryan	Johnson	Robb
Byrd	Kennedy	Rockefeller
Chafee	Kerrey	Sarbanes
Cleland	Kerry	Schumer
Conrad	Kohl	Specter
Daschle	Landrieu	Torricelli
Dodd	Lautenberg	Wellstone
Dorgan	Leahy	Wyden
Durbin	Levin	

NAYS—53

Abraham	Frist	McConnell
Allard	Gorton	Murkowski
Ashcroft	Gramm	Nickles
Bennett	Grams	Roberts
Bond	Grassley	Roth
Brownback	Gregg	Santorum
Bunning	Hagel	Sessions
Burns	Hatch	Shelby
Campbell	Helms	Smith (NH)
Cochran	Hutchinson	Smith (OR)
Collins	Hutchison	Snowe
Coverdell	Inhofe	Stevens
Craig	Jeffords	Thomas
Crapo	Kyl	Thompson
DeWine	Lott	Thurmond
Domenici	Lugar	Voinovich
Enzi	Mack	Warner
Fitzgerald	McCain	

The amendment (No. 1235) was rejected.

Mr. NICKLES. I move to reconsider the vote.

Mr. HUTCHINSON. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 1234

The PRESIDING OFFICER. The question is on amendment No. 1234 by Senator NICKLES for Senator SANTORUM. There are 4 minutes equally divided. Who seeks recognition?

Mr. NICKLES. Mr. President, I yield the principal sponsor of the amendment, Senator SANTORUM, 1 minute.

The PRESIDING OFFICER. The Senator from Pennsylvania is recognized.

Mr. SANTORUM. Mr. President, I rise in strong support and encourage all my colleagues to support this amendment. The amendment does basically two things. No. 1, it establishes 100-percent deductibility for the self-employed, something for which I know many Members of both sides of the aisle have been striving. One of the things we have said about our health care proposal is that ours is much more comprehensive than the Democratic plan. It looks at the issue of access.

Mr. NICKLES. Could we have order?

The PRESIDING OFFICER. The Senate will please come to order. Again, this is an important debate.

The Senator from Pennsylvania is recognized.

Mr. SANTORUM. As I said, our bill is much more comprehensive. We looked at the question of access and making health insurance more affordable to cover more people, to bring them into the insurance market. Our bill, with this amendment, does that.

The other thing we do is we emphasize that we do not want the Federal Government, the Health Care Financing Administration, to oversee State-regulated plans. Almost all 50 States have passed a Patients' Bill of Rights. They traditionally regulate health insurance. They are doing a very good job. We do not need to impose HCFA regulations and HCFA control over every State insurance department. It is the wrong approach. It is Washington getting its teeth into the State pie. That is unnecessary.

The PRESIDING OFFICER. The Senator's time has expired.

Mr. DASCHLE. I yield 1 minute to the distinguished Senator from Massachusetts.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Mr. President, this vote is directly related to whether the Senate is really interested in covering all Americans who have insurance or whether whatever passes applies to only the 48 million persons who are included in the Republican bill.

In the House of Representatives, all of the leading Republican legislation applies to all patients with insurance through their private employers—the whole 123 million here. The proposals put forward by the House Republicans who happen to be doctors also cover the people in the individual market. But not the Senate Republican bill.

It is an extraordinary irony, but HMOs are found in all of these other categories—under the 75 million, the 15 million, the 25 million—not in self-funded employer plans. So the Republican bill does not even cover the individuals who first raised the whole question of whether their current coverage is adequate. Whatever we are going to do, Republican program or Democrat, let's make sure we provide protections to all patients. Every category here on this chart. That is what our amendment does.

But their amendment would leave out more than 100 million Americans like Frank Raffa, a fire fighter for the city of Worcester, Massachusetts. He puts his life on the line every day, but he and millions of others are left out and left behind with the Republican program. Let's make sure we are going to cover all of them, all the workers in this country.

The PRESIDING OFFICER. The time has expired.

Who yields time?

Mr. NICKLES. Mr. President, I yield 1 minute to the Senator from Missouri, Senator BOND.

The PRESIDING OFFICER. Before the Senator from Missouri starts, the Senate will be in order.

The Senator from Missouri.

Mr. BOND. Mr. President, the opponents of this amendment overlook the fact that the States are involved. The States do regulate health insurance. The States are taking care of those they can cover.

This amendment says we should not wipe out State regulation. It also completes the job of ending the tremendous inequity in our health care system which said formerly that self-employed people could only deduct 25 percent of their health insurance premiums. Thanks to the bipartisan support we have had, we say now, by 2003, that there will be 100-percent deductibility. Right now, however, there are 5.1 million uninsured, 1.3 million children. For the woman who is starting a new business, the fastest growing sector of our economy, she starts up an information technology business and she is not able to deduct 100 percent of health care insurance for herself and her family until 2003. She cannot afford to wait to get sick until 2003.

I urge my colleagues to support immediate deductibility.

The PRESIDING OFFICER (Mr. GORTON). The distinguished minority leader is recognized.

Mr. DASCHLE. Mr. President, I think the distinguished Senator from Pennsylvania had it right. We all support 100-percent deductibility for the self-employed. We just voted for it an hour or so ago. There is no question all of the Senate supports it. We are on record in support of it. The question is whether we should accelerate it. We just voted to accelerate it on this side on the Robb amendment. That isn't the question on this amendment. This amendment is about whether or not we offer 100 million additional Americans the patient protections under the Patients' Bill of Rights.

In order to clarify that, I ask unanimous consent that the deductibility language be added to both the Republican bill, S. 1344, and the Daschle substitute.

Mr. NICKLES. I object.

Mr. DASCHLE. I ask unanimous consent that at least the deductibility amendment be allowed as part of the Kennedy amendment as well.

Mr. NICKLES. I object.

The PRESIDING OFFICER. Objection is heard.

Mr. DASCHLE. That makes it very clear. This vote is about denying millions of Americans the right to patient protections, not about health and deductibility for self-employed businessmen.

I yield the floor.

The PRESIDING OFFICER. All time has expired.

Mr. NICKLES. Mr. President, I ask for the yeas and nays on the amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 1234. The yeas and nays have been ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

The result was announced—yeas 53, nays 47, as follows:

[Rollcall Vote No. 202 Leg.]

YEAS—53

Abraham	Frist	McConnell
Allard	Gorton	Murkowski
Ashcroft	Gramm	Nickles
Bennett	Grams	Roberts
Bond	Grassley	Roth
Brownback	Gregg	Santorum
Bunning	Hagel	Sessions
Burns	Hatch	Shelby
Campbell	Helms	Smith (NH)
Cochran	Hutchinson	Smith (OR)
Collins	Hutchison	Snowe
Coverdell	Inhofe	Stevens
Craig	Jeffords	Thomas
Crapo	Kyl	Thompson
DeWine	Lott	Thurmond
Domenici	Lugar	Voinovich
Enzi	Mack	Warner
Fitzgerald	McCain	

NAYS—47

Akaka	Edwards	Lieberman
Baucus	Feingold	Lincoln
Bayh	Feinstein	Mikulski
Biden	Graham	Moynihan
Bingaman	Harkin	Murray
Boxer	Hollings	Reed
Breaux	Inouye	Reid
Bryan	Johnson	Robb
Byrd	Kennedy	Rockefeller
Chafee	Kerrey	Sarbanes
Cleland	Kerry	Schumer
Conrad	Kohl	Specter
Daschle	Landrieu	Torricelli
Dodd	Lautenberg	Wellstone
Dorgan	Leahy	Wyden
Durbin	Levin	

The amendment (No. 1234) was agreed to.

Mr. NICKLES. Mr. President, I move to reconsider the vote.

Mr. LOTT. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 1233, AS AMENDED

The PRESIDING OFFICER. The question now is on agreeing to amendment No. 1233, as amended.

The amendment (No. 1233), as amended, was agreed to.

Mr. DODD addressed the Chair.

The PRESIDING OFFICER. The Senator from Connecticut is recognized.

AMENDMENT NO. 1239 TO AMENDMENT NO. 1232

(Purpose: To provide coverage for individuals participating in approved clinical trials and for approved drugs and medical devices)

Mr. DODD. Mr. President, I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Connecticut [Mr. DODD] for himself, Mrs. BOXER, Mr. HARKIN, Mr. KENNEDY, Mr. REID, Mrs. MURRAY, Mr. DURBIN, Mr. ROCKEFELLER, Mr. FEINGOLD, Mrs. FEINSTEIN, and Mr. DASCHLE, proposes an amendment numbered 1239 to amendment No. 1232.

Mr. DODD. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The text of the amendment is printed in today's RECORD under ''Amendments Submitted.'')

Mr. DODD. Mr. President, I offer this amendment on behalf of myself, Senators HARKIN, BOXER, FEINGOLD, FEINSTEIN, JOHNSON, ROCKEFELLER, KENNEDY, MURRAY, and REID of Nevada.

As I understand it, we will debate it briefly this evening, and then it will be one of the first orders of business tomorrow morning.

This amendment has two parts to it. It would ensure that patients have access to the best possible care in two areas—cutting edge clinical trials and medically necessary prescription drugs.

Until recently, health plans routinely paid for the doctor and hospital costs associated with clinical trials, and many still do. But a growing number of insurance plans are now refusing to pay, disrupting an arrangement that

immediately benefited individual patients and advanced our ability to treat future patients.

As my colleague from Vermont will recall from our debate in the Health and Education Committee, which he chairs, this amendment is a moderate one. It would require insurance plans to cover the costs of a patient's participation in clinical trials in only those circumstances that meet the following criteria: One, the clinical trial must be sponsored or funded by the National Institutes of Health, the Department of Defense, or the Veterans' Administration; two, the patient must fit the trial protocol; three, there is no other effective standard treatment available for the patient; four, the patient has a serious or life-threatening illness.

It seems to me that if a patient's situation meets those criteria, insurance plans ought not to deny access to clinical trials. This ought not to be a controversial proposal.

Let me lastly add that the plan's obligation is to pay only for the routine patient costs, not for the costs of running the trial that ought to be paid for by the sponsor of the trial—such as the experimental drug or medical device.

The cost of providing coverage for clinical trials is negligible. After all, similar routine patient costs for blood tests, physicians' visits, and hospital stays are covered for standard treatment anyway.

The Congressional Budget Office found that this patient protection would increase premiums a mere four-tenths of a percent over the next 10 years. That is less than 12 cents per person per month.

Many researchers believe even this minuscule amount is a dramatic overstatement of the cost. In fact, when the Memorial Sloan-Kettering Cancer Center, and the MD Anderson Cancer Center compared the cost of clinical trials to standard cancer therapies, both of these world-renowned cancer centers found that the average cost per patient actually was lower for those patients enrolled in clinical trials. So it actually can save money to give patients access to clinical trials, if you believe Sloan-Kettering and the Anderson Cancer Center.

The American Association of Health Plans—the trade association for the managed care plans—has urged its members to allow patients to participate in clinical trials and to pay the associated doctor and hospital costs. Let me quote from a news release of the American Association of Health Plans. They said:

> AAHP supports patients having access to NIH-approved clinical studies, and supports individual health plan linkages with NIH-sponsored clinical trials. AAHP also believes that it is appropriate for health plans choosing to participate in NIH research studies to pay the routine patient-care costs associated with these trials.

This is the very trade association of the insurance plans urging its members to allow access to clinical trials and suggesting they ought to pick up the cost

The release goes on to cite the benefits of participating in clinical trials for patients and for the advancement of medicine.

We are asking that health plans do nothing more than what they already said they want and they intend to do.

The Republican proposal? What do they say about the clinical trials? They say the managed care bill should study this issue further. With all due respect, further studies will only cause unnecessary delays. We already have answers to many of the questions they want to study. We know what hinders a patient's participation in clinical trials. It is the plans' refusal to pay for them. We know what the costs are. They are minuscule. And plans presumably have figured out how to differentiate between costs of running the trials and costs of patient care since many of them already are doing it.

All we would get from another year of delay is more patients with life-threatening conditions being denied access to research that can save their lives.

I know this does not have to be a partisan issue. Republicans have not only supported related legislation but some—including Senator MACK, and my colleague, Senator SNOWE who is on the floor, and Senator FRIST—have been leaders on this issue. Our good friend and colleague from Maine, Senator SNOWE, has authored excellent legislation widely supported, I might add, by patient groups which would broadly provide access to almost all clinical trials for all privately ensured patients. I commend her for that bill. Thirteen of our Republican colleagues have cosponsored the Mack-Rockefeller bill that would require Medicare to cover the cost of cancer clinical trials. The Representative from my State, Republican Congresswoman NANCY JOHNSON, has introduced a companion bill with several Republican cosponsors.

What I am offering has broad bipartisan support in a variety of legislative proposals. All we are saying is this Patients' Bill of Rights ought to include it.

Clearly, there is bipartisan interest in making sure patients all over this country with breast cancer, colon cancer, liver cancer, congestive heart failure, lupus, Alzheimer's, Parkinson's, diabetes, AIDS, along with a host of other deadly illnesses, have access to cutting-edge treatments. To allow a plan to deny a patient access to clinical trials is an outrage.

I hope this body will find it in its good judgment to adopt this amendment tomorrow when it comes up for a vote and to allow people to have access to these critical clinical trials.

The second part of this amendment deals with prescription drugs.

Nearly all HMOs and other insurance plans use a preferred list called a formulary to extract discounts from drug companies and to save on drug costs. Many of the best plans already take steps to ensure these formularies aren't unreasonably rigid by putting processes in place that allows patients access to nonformulary medicines when their own doctors say those drugs are absolutely needed. In fact, the HMO trade association supports this practice as part of its Code of Conduct for member plans.

Why would a patient need a drug that is not in the plan's formulary? Patients have allergies in some cases to drugs on the formulary. They may be taking medications that would have bad interactions with the plan's preferred drugs, or simply have a medical need for access to some product that is not listed in the formulary—rather commonsensical reasons.

Without access to a reasonable process for making exceptions to the formulary, patients may be forced to try two or three different types of older, less effective medications and demonstrate that those drugs don't work or have negative side effects before the plan would allow access to offer formulary prescription drugs.

No patient, in my view, should be exposed to dangerous side effects, or ineffective treatment, just because the cheaper drug in their plan that was chosen does not work as well as the one their doctor would recommend.

I was pleased that during our committee markup our chairman, who is on the floor, and our Republican colleagues agreed to support a portion of the protection in the Democratic Patients' Bill of Rights plan that relates to access to prescription drugs. I will point out that, as with the majority of provisions in the Republican bill, even its limited protection would be denied to more than 100 million Americans whose employers don't self-insure their own health care coverage.

In addition, their provision contains a significant loophole that needs to be corrected. The Republican proposal requires plans to provide access to drugs off the formulary. However, it also says that the insurers can charge patients whatever they want to get those off-formulary products, even if they are medically necessary, and even if the drug is the only drug that can save that patient's life.

This subverts the purported intent of the very provision the Republican bill proposes; and that is to ensure that patients have access to medically necessary care. If a determination has been made by a doctor and the plan that a patient needs that specific drug and no other, why should that patient be subjected to higher costs—conceivably even a 99-percent copay?

The issue is not about patients simply preferring one brand over another. Our concern is for patients for whom a certain product is medically necessary. It is inconceivable they should be charged more for the care they need just because it doesn't make the plans formulary. This amendment would remedy that situation.

Lastly, our amendment would also address another roadblock that patients encounter trying to get life-saving prescription drugs. That is the practice of a plan issuing blanket denials on the ground that a drug is experimental even when it is an FDA-approved product.

If there is any question in your mind why the plans would resort to such a practice, I think it's useful to listen to their own explanation. In a letter to the majority leader in July of last year, the American Association of Health Plans, Blue Cross and Blue Shield, and the Health Insurance Association of America wrote:

> If health plans are not allowed to deny coverage on the basis that the device is investigational, the health plans would have to perform a much more costly case-by-case review on the basis of ''medical necessity''.

They state the case for me.

In other words, according to the health plans themselves, their fear is that if they are prevented from issuing blanket, unfounded denials they might actually have to look at an individual patient's medical needs.

These two provisions of this amendment are critically important. Patients need access to clinical trials and they need access to prescription drugs. It doesn't get more basic than that.

Denying access to clinical trials doesn't just deny good care to the patient today who is desperately in need of a cure, but it denies state of the art health care to future patients as well, by impeding the development of knowledge about new therapies.

Senator MACK, Senator SNOWE, and many others have strongly supported legislation in this area. Some of their bills go further than my amendment does.

I hope tomorrow when the vote occurs we will have the support of a broad bipartisan coalition.

Mr. REID. Will the Senator yield?

Mr. DODD. I am happy to yield to the Senator.

Mr. REID. I say to my friend from Connecticut, isn't it true we spend billions of dollars at the National Institutes of Health, the Veterans' Administration, and the Department of Defense on medical research that can only be made effective if they have clinical trials?

Mr. DODD. That is correct. The process of finding cures starts with an unknown product first being tested in the laboratory. The second place it is tested is with animals. Third is the clinical trial before it is on the market for general use.

If insurers impede enrollment in clinical trials that phase of research development will be adversely affected and valuable, life-saving products will be delayed from getting on the market for general use by the public.

It is an excellent question.

Mr. REID. I say to my friend, all the money, the billions and billions of dollars, spent by the entities I previously talked about, the money we spend is basically worthless unless we can have clinical trials.

Mr. DODD. To answer my colleague from Nevada, the Senator is absolutely correct. This is a tremendous waste of taxpayer money. There are those, I suppose, who are only concerned about that issue. I appreciate the Senator raising the point because it is indeed a waste of money.

It is also a waste of human lives. I think that people watching this debate here on the floor of the Senate will ask the question: What did the Senate do when it had a chance to protect my family, my child, my wife or my husband, to give them access to the cutting edge technologies when my insurer says no. I think they will be outraged if we don't provide them this protection.

In addition to the monetary cost issue, which our distinguished friend from Nevada has raised, to cause a human life to be lost because we denied access to clinical trials, I argue, is an even greater loss.

Mr. REID. There have been some who say it is too expensive. The Senator is aware of plans that have cut off clinical trials because it is ''too expensive.''

What I hear my friend saying is, the real expense is in the pain and suffering of the families who suffer from Parkinson's, Alzheimer's, lupus, and all the other diseases that the Senator has outlined so clearly.

Is it not true that is where the real suffering comes and that is where the expense comes—in the pain and suffering to those people—if we don't allow the clinical trials?

Mr. DODD. I appreciate the question of my colleague.

He is absolutely correct. I will make a dollars-and-cents case. The cost is 12 cents per patient per month, a negligible cost.

As I mentioned in earlier remarks, when Sloan-Kettering Cancer Institute and the MD Anderson Cancer Center examined the issue of cost—two world-class cancer research centers—their conclusion was that clinical trials are actually less costly than the standard care that will be used in the absence of clinical trials. ''Less costly'' is their conclusion.

If your argument is we cannot do this because it costs too much, one estimate suggests 12 cents per patient per month, and two of the world-class cancer centers in the world think it is actually a lower cost using the clinical trials.

Mr. REID. The final question I ask my friend from Connecticut: Isn't it true that huge amounts of money will be saved if these clinical trials are proved effective? The Senator knows that half the people in our rest and extended care facilities are there because of Parkinson's and Alzheimer's.

Assume, for example, that these clinical trials would delay the onset of one of these two diseases or if some miracle would occur we could cure those diseases. Would that save this country money?

Mr. DODD. The cost in savings would be astronomical.

When we delay a product going from the research phase to general use because patients are shut out of clinical trials, not only do patients today suffer, but future patients suffer, and the costs to the health care system as a whole go up.

AIDS is a wonderful example of this—the AIDS clinical trials have saved literally thousands of lives. People are working today who would not have been able to do so had it not been for clinical trials that helped to develop powerful new drugs. Imagine if the treatments that exist today existed a few years ago, what a different world it would be and how many lives would not have been lost—productive citizens today who would make a contribution to our society.

I reserve the remainder of our time.

Mr. JEFFORDS. Mr. President, I commend my good friend on the committee for the work he has done in this area. This is an area where we have joined together. It will ensure that we have a change, a positive change in the clinical trial aspect. I want to work together with the Senator in that regard.

I also want to say this bill is not finished yet. We have places to go and time to spend to bring it to a better form than it is now. I look forward to continuing to work to improve the bill.

I reserve the remainder of my time.

Mr. DODD. How much time remains?

The PRESIDING OFFICER. The Senator from Connecticut has 29 minutes 33 seconds, and the Senator from Vermont has 49 minutes 15 seconds.

Mr. REID. Mr. President, I think we are ready to do wrap-up.

Mr. JEFFORDS. That is my intention.

Mr. REID. The time has stopped running on the bill for both the majority and minority.

Mr. McCAIN. Mr. President, this evening I cast several difficult votes regarding core principles facing this body as we work to ensure the health care rights of Americans are protected.

I voted for an amendment creating an external appeals process for patients who are denied medical care by their health plan. While I strongly support this initiative, I am concerned that this specific proposal needs further strengthening ensuring that the individual health care rights of Americans are the priority. I will be working with my colleagues on both sides of the aisle to strengthen the external appeals process, including access to reasonable legal remedies while ensuring that the external review process is conducted by unbiased and independent entities whose sole purpose is to protect the rights of American patients.

In addition, I support guaranteeing an individual medical care in an emergency room without prior approval from their HMO if the person believes that it is an emergency situation. However, I was forced to vote against an

amendment which provided this protection but then superseded state rights and created an opportunity for emergency rooms to begin providing a litany of treatments outside of the realm of the perceived emergency which could have negative financial repercussions.

Finally, I support providing American women with direct access to OB/GYNs and ensuring they receive quality health care while battling breast cancer. However, I was forced to vote against an amendment providing this critical access because it eliminated an important provision ensuring that health care costs do not skyrocket thereby causing thousands, if not millions of new Americans to lose their health care coverage.

Mr. CAMPBELL. Mr. President, today I take this opportunity to comment on the pending bill.

In my view, what we are discussing today is the most costly big-government health care plan since the Clinton health care reform plan was debated earlier this decade. We all know the fate of that attempt, and it is my hope we might now allow common sense to play a part in creating a Patients' Bill of Rights.

The demands on our health care system have changed dramatically in the past decade. So has our health care system. But, those changes have not affected all people evenly, and it's clear many people have had unfortunate experiences.

Going from the traditional doctor-patient relationship into a system where all aspects of care are subject to approval and authorization is understandably difficult. But, as the cost of quality care became an obstacle to access, the concept of managing care has evolved as the predominate method of insured medical service.

While health care in America, and our advances in medical technology remain the envy of the world, it would be a serious mistake to pretend that all are well-served by our present health care system.

The Federal Government, in an effort to give all Americans access to affordable care, has, in fact, encouraged participation in managed care plans. All federally-sponsored health care, which includes Medicare, Medicaid, the Federal Employees Health Benefit program and military health care, has experienced the emergence of managed care. Now we must deal with the issue of ensuring health care quality as a first priority. And we must do it in a way that will not raise costs of care or cause employers to stop offering health insurance.

While managed care has become the dominant delivery method of cost-effective healthcare in our nation, what is missing are standards that will ensure fairness to both patients and providers, and clarify what are often confusing medical and legal terms and hidden rules for both parties. The question before us now is how best to protect these patients while giving the health care industry incentives for finding efficient methods of delivering care.

All of us expect the highest quality health care for the citizens of this country, but, that care must be affordable. Anyone that believes having Congress dictate a costly, one-size-fits-all mandate will make health care more affordable or more available is, I believe, severely out of touch with reality.

That is why I am concerned about the pending legislation. This bill mandates new regulations which would increase premiums by 6.1 percent, not including inflation. It could raise the cost of a typical family's health insurance policy by more than $300 per year. That is not logical, responsible or acceptable. We have been down this road before with the ''catastrophic health'' bill of 10 years ago. The Senate passed it because people were told premium increases would be minimal. Then people got their bill. This pending bill will drive up the number of uninsured Americans. In my State of Colorado, it is estimated that this legislation would add more than 32,000 persons to the rolls of the uninsured. Our biggest health care problem already is that there are currently 43.5 million uninsured Americans. Who pays for their inevitable medical care? You, I, and every other taxpayer. It is clear that increased mandates increase costs, and that those increased costs reduce coverage.

It is no secret that higher health insurance premiums will force employers to drop optional medical coverage they offer employees. That should not be the intention of this legislation, but it is the reality. Every time a mandate raises the cost of insurance by one percent, more than 200,000 Americans lose their coverage.

Small businesses would drop coverage if exposed to the pending bill's liability provisions. Canceling coverage leaves patients exposed to expensive medical bills. That's not patient protection. We cannot pass legislation that forces employers to provide health care. They will close shop, because they can't afford it. The pending bill will lead to government-run health care. The bill's mandates could cost the private sector more than $56 billion, greatly exceeding the annual threshold established in the Unfunded Mandates Reform Act, which most Members of this body voted for.

Many States are currently developing patient-protection legislation through their State legislatures and assemblies. My State of Colorado has already established mandates concerning an independent external review process for denied claims, a ban on gag clauses, and direct access to OB-GYN services.

Despite that fact, the pending bill, in an attempt to tighten federal control over the entire U.S. health system, applies federal mandates to all health insurance products.

Mr. President, I believe it is time to put the brakes on the runaway one-size-fits-all mandates which are inflicting hardship on our most vulnerable citizens and legitimate health care providers. The time to protect patients and providers is before costly mandates are enacted into law.

Let us think ahead. We have already seen through our experience with the Balanced Budget Act of 1997, that well-intentioned solutions enacted by Congress can turn into unworkable, burdensome regulations when imposed on the entire health care system. We are discussing sweeping legislation which, if passed and enacted, will have significant consequences for all Americans and their health care. I believe we can best protect these Americans by making reasonable changes which give them more choices. Let's provide access to affordable, quality care without inventing unnecessary new federal mandates for an already top-heavy health care structure.

I believe the Republican Patients' Bill of Rights Plus will do just that. It will improve quality of care and expand consumer choice as well as protect patients' rights.

It will hold HMOs accountable for providing the care they promised. It places treatment decisions in the hands of doctors, not lawyers. And, patients have the right to coverage for emergency care that a prudent lay-person would consider medically necessary.

The purpose of our bill is to solve problems when care is needed, not later after harm has occurred. Common sense demands we act reasonably. More importantly, the future health care of hundreds of millions of Americans demands we act with their interests in mind.

I thank the Chair.

Mr. ALLARD. Mr. President, in the 1970s, the State of Colorado adopted a well-child care law, legislation concerning the treatment of alcoholism and mental health, as well as legislation concerning insurance coverage of psychologists. In the 1980s home health care, hospice care, and mammography screening legislation was passed into law. In the 1990s, those who represent the people of Colorado in the State House saw fit to pass laws concerning the coverage of nurses, nurse midwives, nurse anesthetists, nurse practitioners, psychiatric nurses, the continuation of coverage for dependents and employees, and conversion to non-group health care.

This decade the Colorado Legislature also passed consumer grievance procedures, children's dental anesthesia and general dental provisions, direct access to OB–GYN, direct access to midwives for OB–GYN, emergency room services legislation, a ban on gag clauses, prostate cancer screening, breast reconstruction, maternity stay, and mental health parity legislation. Last, but certainly not least, among State laws enacted in my home State is a law concerning independent external appeals

for patients and a comprehensive Patients' Bill of Rights, passed in 1997.

I am proud to have served in the Colorado State Senate, and I am proud to say that today I represent a state that has been responsive and aggressive in addressing health care issues and patients' rights.

At the same time, Mr. President, I am deeply troubled that there are those in this body who are advocates of Senator KENNEDY's Patients' Bill of Rights that would preempt a number of the laws that I just mentioned in the State of Colorado. In this country of 260 million Americans throughout the fifty states I believe that the people of those States are in the best position to make these specific decisions. I come from our nation's 8th largest State with a population of just 3.9 million people. I will not assume that any federal entity is more prepared to develop policy for Colorado than the people of Colorado, nor would I impose the policies unique to Colorado's needs on another State.

Something I find equally troubling is that in addition to infringing on the laws of the State of Colorado, the legislation that Senator KENNEDY and the Democrats have developed has the potential to increase health care costs, deprive 1.9 million Americans of health insurance who are currently covered, and cast heavy mandates down on individual states who are in a far better position to make these decisions for themselves.

I will speak today about a number of things I believe will enhance the quality of health care, increase access to care, and provide important protections for patients without unnecessarily placing mandates on individual states. These provisions are all part of a comprehensive package called the Patients' Bill of Rights Plus Act, which I feel properly addresses the needs of America's patients, physicians and health care providers.

The Patients' Bill of Rights Plus Act establishes consumer protection standards for self-funded plans currently governed by the Employee Retirement and Income Security Act (ERISA). 48 million Americans are currently covered by plans governed by ERISA—these are American health care consumers who are not under the jurisdiction of state laws.

Our bill would eliminate gag rule clauses in providers' contracts and ensure that patients have access to specialty care. The legislation also requires that health plans that use formularies to provide prescription medications ensure the participation of doctors and pharmacists in the construction of the formulary. Further addressing patient choice and access, health plans would be required to allow women direct access to obstetricians and gynecologists, and direct access to pediatricians for children, without referrals from general practitioners.

These provisions are important steps in removing barriers that may prevent patients covered under ERISA from receiving necessary and proper treatment in a timely manner.

As a former small business owner I have a keen understanding of the issues that confront the self-employed. I also have experience in balancing the wages and benefits you extend to an employee with a healthy bottom line. I think it is important that we remember throughout the course of this debate that employers provide health care benefits as a voluntary form of compensation for their employees. We must be wary of legislation that will increase costs and liability for employers in a way that may reduce the quality and scope of benefit packages for employees.

Our bill, the Patients' Bill of Rights Plus, would make health insurance deductible for the self-employed and increase the availability of medical savings accounts. I believe that each of these provisions would give greater power to the individual and make private insurance more affordable for families and individuals. Large corporations can claim a 100 percent deduction for health care and small business should be treated the same.

Medical savings accounts, otherwise known as MSAs, combine a high deductible and low cost catastrophic policy with tax free savings that can be used for routine medical expenses. We should increase the availability to all families who desire MSAs. These efforts will prove particularly helpful to those individuals working for small business, and those in transition from one job to another since MSAs are fully portable.

I want to stress that our legislation will not mandate these accounts for everyone, but will simply establish the accounts as an option to those who feel they will be best served by MSAs. I believe that medical savings accounts are particularly important for uninsured, lower income Americans. Allowing consumers to pay for medical expenses through these affordable tax-deductible plans, tailored to their needs, is a viable free-market approach to decreasing the number of uninsured in America. This is a question of providing greater choice for health care consumers.

The Patients' Bill of Rights Plus Act would also permit the carryover of unused benefits from flexible spending accounts, again increasing the number of options available to the consumers of health care.

In keeping with presenting more options to the consumer, The Patients' Bill of Rights Plus Act includes language that would require all group health plans to provide a wide range of comparative information about the health coverage they provide. This information would include descriptions of health insurance coverage and the networks who provide care so that consumers covered by self insured and fully insured group health plans can make the best decisions based on their needs and preferences.

One of the most contentious issues in health care has been the issue of malpractice liability, grievance procedures and the mechanism for the appeal of decisions made by managed care companies. My colleagues across the aisle are interested in taking the grievance procedure into a court of law, allowing a patient greater access to litigation as a means of challenging a managed care organization's decision.

Lawsuits and the increased threat of litigation will demand that more money to be funneled into non-medical administration and away from what patients really want—quality health care. Furthermore, making the courts a de facto arbiter of health care decisions seems to me to be less efficient and less effective in dealing with the interests of the patient. The Kennedy bill is an enormous gift for the trial lawyers in America who stand to profit by high cost, long-term cases. Patients, not lawyers, will fare far better under the Patients' Bill of Rights Plus.

I am also concerned that expanding medical malpractice liability will lead to more defensive medical decisions regardless of the merit of a particular treatment. High liability exposure and cost has driven countless physicians from their profession for years, particularly in high-need rural areas.

This is not a provision we can afford in rural areas of western States like Colorado that are already underserved.

Rather than take health care out of the doctor's office and into the courts, the Patients' Bill of Rights Plus Act establishes strict time frames for internal and external appeals for the 124 million Americans who receive care from self insured and fully insured group plans. Routine requests would need to be completed within 30 days, or 72 hours in specific cases when a delay would be detrimental to the patient. Rather than use the courts in cases of health care appeals our legislation would establish a system of independent, internal and external review by physicians with appropriate expertise. We are talking about doctors with years of experience and medical training making health care decisions, not legal arguments.

I believe that such a system will be more responsive and more tailored to the needs of every individual patient—and it will do so without creating unnecessary bureaucracy. It is also important to note that these internal and external appeals will cost patients and employers considerably less than the alternative proposal that is heavy on lawsuits, lawyers and litigation.

Another area of concern that I believe needs to be incorporated in any sensible managed care reform legislation is the inclusion of protections for patients from genetic discrimination. The Patients' Bill of Rights Plus Act would prohibit all group health plans and insurers from denying coverage or adjusting premiums based on predictive genetic information. The protected genetic information includes an

individual's genetic tests, genetic tests of family members, or information about the medical history of family members.

No one should live in fear of being without health care based on genetic traits that may not develop into a health problem.

Mr. President, I believe these provisions will empower the individual, not the lawyers or bureaucracies. I am committed to the notion that each individual American consumer of health care is in the best position to chose where his or her health care dollar is best spent.

An administrative issue involved in this debate that I am very concerned with is the effort to attempt to force all health plans—not just HMOs—to report the medical outcomes of their subscribers and the physicians who treat them. This makes sense for a managed care plan such as an HMO, but it would be virtually impossible for a PPO or indemnity plan to monitor and classify this data without becoming involved in individual medical cases.

I believe that if we require all health plans to collect and report data like this we will be requiring all plans to be organized like an HMO. This would significantly reduce the number of choices consumers and employers currently enjoy in selecting their health care.

The Congressional Budget Office recently determined that if S. 6, the Kennedy version of the Patients' Bill of Rights, were to pass that this country would see private health insurance premiums increase 6.1 percent above inflation. What appears to be a minor increase to health care premiums would have disastrous and immediate consequences around the country, adding 1.9 million Americans to the ranks of the uninsured. In my home state that translates to 32,384 people. In Colorado the average household would lose $203 in wages and 2,989 jobs would be lost by 2003 for this ''minor'' increase.

We are talking about people in Colorado losing their jobs and their health care coverage because Washington wants to do what the State of Colorado has been working on for the last thirty years.

The Congressional Budget Office determined that our bill, the Patients' Bill of Rights Plus Act, would increase costs by less than 1 percent. While I urge my colleagues to be wary of any potential increase in costs for the American people, I also believe that the Patients' Bill of Rights Plus, and not the current Kennedy bill, directly addresses health care quality issues and increases choice for consumers with a minimal cost.

Mr. AKAKA. Mr. President, I rise today to speak on a very important piece of legislation—legislation that is vital to the future of health care in this country, the Patients' Bill of Rights. Democrats have fought long and hard to debate this bill on the floor of the Senate and I am thankful for the opportunity to speak in support of the underlying measure.

Today more than 160 million Americans, over 75 percent of the insured population, obtain health coverage through some form of managed care. Managed care arrangements can and do provide affordable, quality health care to large numbers of people. Yet reports of financial consideration taking precedence over patients health needs deserve our attention. We hear stories and read news articles about people who have paid for health insurance or received employer-sponsored insurance, became ill, only to discover that their insurance does not provide coverage. Recent surveys indicate that Americans are increasingly worried about their health care coverage. 115 million Americans report having a bad experience with a health insurance company or knowing someone who has. This undermining of confidence in our health care system must be addressed. We must act to restore the peace of mind of families in knowing that their health insurance will be there when they need it most. We can accomplish this by establishing real consumer protections, restoring the doctors decision-making authority, and ensuring that patients get the care they need.

Some of the important issues that we are debating include the scope of coverage, definition of who determines ''medically necessity,'' protecting the doctor/patient relationship, access to care, and accountability.

True managed care reform cannot come from a narrow bill that covers only a certain segment of the population. Today much of the regulation of managed care plans comes form the states. However, federal laws such as the Employee Retirement Income Security Act of 1974 (ERISA) and the Health Insurance Portability and Accountability Act, combined with the various state regulations, form a patchwork of regulation for managed care plans. Some in this chamber believe that the protections we are considering should only apply to ERISA-covered plans and not to the 113 million Americans who have private insurance that is regulated by the states. They argue that these issues should be left to the states to address. Democrats believe that everyone deserves equal protection, regardless of where they may live or work. The Patients' Bill of Rights would not interfere with patient protection laws passed by the states, it would simply extend these patient protection rights to all Americans.

As managed care has grown, so has the pressure on doctors and other health care providers to control costs. Complaints receiving widespread attention include denials of necessary care, lack of accountability, limited choice of providers, inadequate access to care, and deficient information disclosure for consumers to make informed plan decisions. Mr. President, a strong Patients' Bill of Rights should address the shortcomings of managed care. S. 6 takes a comprehensive approach in dealing with these issues, which is why I am a cosponsor of the measure.

The dominance of managed care has undermined the doctor-patient relationship. Often tools are used to restrain doctors from communicating freely with patients or providing them with incentives to limit care. We need to ensure that insurers cannot arbitrarily interfere in the medical decision making. The Patients' Bill of Rights includes a number of provisions to prevent arbitrary interference by insurers. Our bill establishes an independent definition of medical necessity, prohibits gag clauses on physicians and other restrictions on medical communications, and protects providers from retaliation if they advocate for their patients.

The issue of who decides what is medically necessary is probably the most fundamental issue of this debate. We must empower patients so they receive appropriate medical treatment, not necessarily the cheapest treatment, not necessarily the treatment that an insurance company determines is appropriate, but the best treatment. Currently, many doctors are finding insurance plans second-guessing and overriding their medical decisions. Democrats believe that the ''medical necessity'' of patient care should be determined by physicians, consistent with generally accepted standards of medical practice. Doctors are trained to diagnose and make treatment decisions based on the best professional medical practice. We need to keep the medical decisions in the hands of doctors and not insurance company bureaucrats.

Families in managed care plans often face numerous obstacles when seeking access to doctors and health care services. Some of these barriers include restrictions on access to emergency room services, specialists, needed drugs, and clinical trials. S. 6 would ensure access to the closest emergency room, without requiring prior authorization. It would provide access to qualified specialists, including providers outside of the network if the managed care company's choices are inadequate, and direct access to obstetricians and gynecologists for women and pediatricians for children. S. 6 would also ensure access to drugs not included in a managed care plan's covered list when medically indicated and provide access to quality clinical trials.

Finally, the underlying bill allows consumers to hold managed care companies accountable for medical negligence. Currently, insurers make decisions with almost no accountability. Patients deserve the right to a timely internal appeal and an unbiased external review process when they disagree with a decision made by the insurer. Patients also deserve recourse when the misconduct of managed care plans results in serious injury or death. However, under ERISA plans, patients have no right to obtain remedy under state

law. These patients are limited to the narrow federal remedy under ERISA, which covers only the cost of the procedure the plan failed to pay for. S. 6 would ensure that managed care companies can be held accountable for their actions. It does not establish a right to sue, but prevents federal law from blocking what the states deem to be appropriate remedies. A strong legal liability provision will discourage insurers from improper treatment denials or delays and result in better health care.

Mr. President, only a comprehensive bill will guarantee patient protection with access to quality, affordable health care. We should not miss this important opportunity to enact meaningful legislation that is federally enforceable and will improve care and restore confidence in our health care system.

MORNING BUSINESS

Mr. JEFFORDS. Mr. President, I now ask unanimous consent that the Senate now proceed to a period of morning business with Senators permitted to speak for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

TRIBUTE TO DR. MARY E. STUCKEY, THE 1999 ELSIE M. HOOD OUTSTANDING TEACHER

Mr. LOTT. Mr. President, it is with great pleasure that I pay tribute to The University of Mississippi's 1999 Outstanding Teacher of the Year, Dr. Mary E. Stuckey.

Each year my alma mater The University of Mississippi, known as Ole Miss, recognizes excellence in the classroom with the Elsie M. Hood Outstanding Teacher Award during its Honors Day Convocation. Nominations for this honor are accepted from students, alumni, and faculty. A committee of former recipients then selects the faculty member who best demonstrates enthusiasm and engages students intellectually.

Dr. Mary E. Stuckey is an Associate Professor of Political Science. An 11-year veteran of the Ole Miss Political Science Department, Dr. Stuckey's teaching interests include the Presidency and political communications as well as American Indian politics. Her research focuses on Presidential rhetoric, media coverage of the President, and institutional aspects of Presidential communication. Dr. Stuckey is also working on several projects regarding depictions of American Indians in the media and in national politics. In addition to these areas of interest, she also teaches in the McDonnell-Barksdale Honors College.

Dr. Stuckey's research has earned her several prestigious grants. These include the President Gerald R. Ford Library, the C–SPAN in the Classroom Faculty Development, a National Endowment for the Humanities Fellowship, and the Canadian Studies Faculty Research. She has also published several studies such as ''The President as Interpreter-in-Chief'' and ''Strategic Failures in the Modern Presidency.''

A native of southern California, Dr. Stuckey earned a bachelor's degree in political science from the University of California at Davis. She then completed her graduate studies at the University of Notre Dame and joined the Ole Miss faculty in 1987.

Now, Mr. President, let me tell you that Dr. Stuckey and I probably will not agree on much when it comes to political issues. But three members of my current staff, Steven Wall, Beth Miller, and Brian Wilson, tell me she is outstanding in the classroom. They all agree that she is an equal opportunity challenger, regardless of political views, when it comes to the study of politics. She requires her students to use logic rather than emotions when advocating any viewpoint. Dr. Stuckey does not penalize her students when they don't share her views; rather she rewards academic scholarship.

The study of political science is essential to any society. And I believe it is even more incumbent on us, as Americans, to do so. Thomas Jefferson once said, ''Self-government is not possible unless the citizens are educated sufficiently to enable them to exercise oversight.'' He was right. Universities are an important institution to help instill in each generation an appreciation for the unique and honorable character required for our democratic republic. Americans want to learn from their past mistakes so they can strive to build a better society for their children and grandchildren. Dedicated and inspiring teachers, such as Dr. Mary E. Stuckey, this year's Elsie M. Hood Award recipient, are key to ensuring that our next generation of political leaders will have the necessary knowledge and character to make America strong.

ECONOMIC REFORMS IN RUSSIA

Mr. KERREY. Mr. President, I draw my colleagues' attention to an article that appeared earlier this year in Economic Reform Today. I ask unanimous consent that the full text of ''Safeguarding Russian Investors: Securities Chief Speaks Out'' be printed at the end of my statement.

The PRESIDING OFFICER. Without objection, it is so ordered.

(See exhibit 1.)

Mr. KERREY. Mr. President, Economic Reform Today is a quarterly magazine published by the Center for International Private Investment. CIPE is one of the core grantees of the National Endowment for Democracy and is dedicated to promoting democratic governance and market oriented economic reform. Their work has been particularly important in assisting the ongoing transition to free markets in the former communist countries of Eastern Europe and the former Soviet Union.

The article I will include in the RECORD, highlights Russia's continuing effort to implement political and economic reforms. This has been a painful process in Russia. However, it is my firm belief that Russia's transition to a free-market democracy will be measured in decades, not years. During this important time—CIPE and the other NED grantees—have been working to ensure that the Russian people have access to the information and resources necessary to make a successful transition.

Again, I encourage my colleagues to read this important article.

EXHIBIT 1

SAFEGUARDING RUSSIAN INVESTORS: SECURITIES CHIEF SPEAKS OUT

(If Russia is to gain economic stability and attract foreign investors it will need to respond better to the needs and concerns of investors. Dmitry Vasiliyev has made this the chief reform priority of the securities commission that he heads. He is one of the strongest voices in Russia today calling for more efficient and transparent markets to provide the necessary foreign and domestic capital to jump start Russia's newly privatized enterprises. In this interview with Economic Reform Today, Vasiliyev underscores the importance of establishing strong shareholders' rights as a cornerstone of economic reform)

ERT: You have made upholding shareholder rights one of the top priorities of the Federal Securities Commission (FSC). Why is this so important?

Mr. Vasiliyev: Protecting investors' rights is an important prerequisite for attracting foreign investment, and, unfortunately, Russia faces serious problems in this area. Although we are gradually improving the quality of corporate governance, Russia is losing billions of dollars in investments because of poor investor safeguards, both in corporate and government securities. This is reflected in the lower value of Russian stock prices as compared with those of other emerging market countries. Better protection of investors' rights will attract more investors and allow companies to raise more capital and lead to the development of new technologies and more production.

ERT: Can you gauge the damage that denying these shareholder rights inflicts on the Russian economy?

Mr. Vasiliyev: The Russian economy faces serious consequences unless it can offer adequate safeguards. Not only are foreigners reluctant to invest in Russia, but Russians do not trust it either. People are putting their savings into dollars because other forms of investment don't offer enough protection.

That's why we have concentrated our efforts on protecting the market from low-quality securities. Last year we denied registration to 2,600 issues; that is, we turned down 14% of all submitted prospectuses. That means we prevented 2,600 possible violations of shareholder rights. Of course we also had to cancel some issues that were already registered; for example, the well-publicized cases involving the largest Russian oil companies, such as Sidanko and Sibneft. Last week the Commission launched an investigation into the case of Yukos. We are determined to use all measure necessary to defend minority shareholders. In some cases the exchange or brokers themselves violate shareholder rights through manipulation. Our investigations have increased sevenfold in the last two years. We recognize, however, that we are only at the beginning of a long process.