

any committee. It hadn't passed out of any committee in either House, certainly not the two committees with jurisdiction over this legislation. Therefore, it was not within the scope of this conference committee to stick this provision in.

So, Mr. President, my point and the reason that I raise this point of order is that I think what was done really was a violation of the way the process is supposed to operate. On a very legal, technical point, it was a violation. This had not been dealt with by committee in either House.

Mr. President, I have to say, I was a college professor and used to teach political science courses, and I knew conference committees were called the third House of the Congress, but I had no idea that this kind of action could be taken, really, in the dark of night, not an open process, not accountable to the citizens of the country. It was the wrong thing to do, and it is for this reason that I raise this point of order and that I appeal the ruling of the Chair.

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

Mr. WELLSTONE. I reserve the remainder of my time, and I will yield on your time.

Mr. SANTORUM. In that case, I will yield to the senior Senator from Pennsylvania.

Mr. SPECTER. Mr. President, contrary to the statement by the Senator from Minnesota, this matter has been considered in the Judiciary Committee as part of the markup on the drug patent bill. It was on the floor as a part of the Hatch amendment, which was a part of the defense authorization bill.

This measure was also considered by the House, which passed a 2-year patent extension for this drug on separate occasions; in 1992 and again in 1996. It has been so considered as a matter of basic fairness. The FDA delayed action on this matter for some 97 months, contrasted with 27 months on the average.

This matter has been considered extensively. I raised it in open session in the Agriculture Subcommittee of the Appropriations Committee earlier this week. It had been in the House Agriculture appropriations bill and was dropped in conference. I do not vouch for the provision where it was added to the health care bill after conference. I do not know about that and was not a party to that.

But we have a very basic problem in America about research expenditures for drugs that benefit sick people. These drugs benefit everybody including the elderly, the young, and those not in either category. If we are going to expend a very substantial sum of money on research, there is going to have to be a reasonable return. We have a patent period, and the patent period was not honored in this case. The manufacturer here, Wyeth-Ayerst, is a major Pennsylvania constituent of Senator SANTORUM's and mine, employ-

ing thousands of people in the Philadelphia suburbs. If they are to be able to continue, they are going to have to have a reasonable return.

Those who added it to this bill did so because this is a health bill. One way or another, these sorts of matters must be considered. I am very sympathetic to generic manufacturers, and I have a very strong voting record for senior citizens on issues like this. But if we are to have the kind of research, productivity and the great miraculous advances, we are simply going to have to have a reasonable rate of return on the patent period that is realistic. That is why on the merits and as a matter of fairness, I have advocated this position publicly and do so today, because I think it is an appropriate and sound position.

I yield to my colleague from Pennsylvania.

Mr. SANTORUM. I think the Senator has articulated the arguments on the merits very well. This is an appropriate remedy. I just ask the Senator from Minnesota if he has ever heard of the drug Daypro. It is a competing drug that had the same problems going through the FDA as Lodine, the same problems, the same delay. But in the 1996 omnibus appropriations bill, Daypro got an extension. I don't recall the Senator from Minnesota objecting to that extension, asking for that to be removed. But they got one, too.

So what we have now is a competitive disadvantage. We have one company with a similar drug, a similar prescription, getting an extension and another drug with the same FDA problem not getting an extension. This is a health care bill. The Chair has ruled that it is within the scope of this bill. So I think what is going on here is, frankly, not a special interest, but simply a matter of fairness that we are trying to address. I think what has gone on here is really a lot of actions that—as the Senator said, this bill passed here in the Senate, passed in the House. It is not a new provision. It has had committee discussion. This thing is not anything new to any Member of this floor. We should have left it alone and created the fairness that this Senate acted on and the House acted on in the past.

Again, I agree with the Senator from Minnesota, and I don't agree with sticking things in conference that weren't originally there. I understand that objection. But this is not a red herring proposal. This is a sound proposal. This is a fair approach, and I think we are going to see either this or, frankly, the repeal of the Daypro. One or the other is going to happen again sometime in the next couple of months.

Mr. WELLSTONE. Mr. President, I appreciate working with both of my colleagues. For all I know that other provision was stuck in conference committee in the dark of night. I did not catch it. I really appreciate what you have said. I think we would probably

disagree maybe on the substance because I think by postponing the time that this can be generic. We really provide more cost to the consumers. But it seems like what you have said—and hopefully we can all agree on this—this should not have been stuck in the conference committee the way it was. It was not appropriate, and that is why I challenged the ruling of the Chair.

I think from the point of view of the way our process operates it is a huge mistake to legislate this way. That is why I hope that I will receive strong support on this challenge. And my understanding is that, if we prevail on the voice vote, this will become a successful concurrent resolution which will be a technical correction resolution that I introduced on behalf of myself, and also Senator KENNEDY from Massachusetts.

Again, I thank especially Senator DAVID PRYOR for really bringing this to my attention.

Mr. SPECTER. Mr. President, I would take strong exception to any language if it refers to anything which my distinguished colleague, I, or others in the advocacy of this position have done. We have spoken of it directly. I did so earlier this week in the conference, and we do so on the floor today.

We need medical research. We need these wonder drugs to be produced. It is a matter of fairness as to how we are going to compensate those who produce them. If we are to have them for the consumers, we will have to be able to pay for them. And I think ultimately we will have to take this matter up on the merits, and I think at that time we will see that it is an appropriate position which Senator SANTORUM, I, and others have advocated.

Mr. WELLSTONE. Mr. President, how much time remains on our side?

The PRESIDING OFFICER. The Senator has 36 seconds.

Mr. WELLSTONE. I say to my both my colleagues from Pennsylvania that they clearly are two Senators who are always more than willing to be strong and determined and honest in their positions in public.

This amendment is not at all aimed at the Senator from Pennsylvania. It is aimed at something that I think is wrong with this process.

I yield the floor.

The PRESIDING OFFICER. The question is, Should the decision of the Chair stand as the judgment of the Senate?

The ruling of the Chair was not sustained.

CORRECTING THE ENROLLMENT OF H.R. 3103

The PRESIDING OFFICER. The clerk will now report the concurrent resolution.

The bill clerk read as follows:

A concurrent resolution (S. Con. Res. 68) to correct the enrollment of H.R. 3103.

The PRESIDING OFFICER. Under the previous order, the concurrent resolution is agreed to.

The concurrent resolution (S. Con. Res. 68) was agreed to as follows:

S. CON. RES. 68

Resolved by the Senate (the House of Representatives concurring), that in the enrollment of the bill (H.R. 3103 entitled "an Act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance converge in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings account, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes", the Clerk of the House of Representatives shall make the following correction:

Strike subtitle H of title II.

Mr. KENNEDY. Mr. President, I wish to make a brief comment on the addition of the special-interest provision that was added in the legislation without knowledge of the Democratic conferees and, to my knowledge, Republican conferees.

I am pleased that a provision to benefit a particular pharmaceutical company will now be dropped from the very important health care legislation.

The provision was surreptitiously included in the conference report without the knowledge of the conferees. Clearly, it did not belong in this legislation.

I simply point out that the provision was rejected when previous efforts to put it into other bills were attempted. An initial attempt to include the special deal was rejected in the defense authorization bill. A second attempt was made to include it in the agriculture conference report, and that was rejected also. Now it has been rejected in the health reform conference, and we were right to reject it.

Let me just conclude by saying, strike three, this provision is out and good riddance.

I will highlight the points in the GAO report that was issued. It said that Lodine is a "me, too" drug which provides no significant health benefit or therapeutic breakthrough which would justify expedited review, such as AIDS or cancer.

FDA found that the Lodine submission was "piecemeal, voluminous, disorganized, and based on flawed clinical studies."

The Lodine submission to FDA did not contain "enough data to prove efficacy, until September 1989."

It has already received special consideration under the Waxman-Hatch amendments. We passed that to try to take into consideration companies that felt they had not been treated fairly before the FDA. We have included in the RECORD the excellent statement that has been made by both Senator CHAFEE and Senator PRYOR. First of all, we note that no hearings or deliberations of any kind have been held in either the House or Senate as to whether any public purpose would be served by granting this extension. Then, finally, the CBO says the patent extension will cost the Federal Government and taxpayers \$10 million. These

resources would be far better applied and are urgently needed under the submissions jurisdiction.

The other point I will mention, the Lodine patent extension includes language barring importation of active ingredients. This would prevent generic competitors from conducting the essential preclinical tests and clinical studies to prepare for marketing, as they are permitted and required under the 1984 act. This specific clause further extends the patent extension by as much as 5 years and market exclusivity by as much as 7 years.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996—CONFERENCE REPORT

The Senate continued with the consideration of the conference report.

The PRESIDING OFFICER. The Senate is now operating under control of debate time.

Who yields time?

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, as I understand by the previous agreements, we have divided up the time for the next few hours between the Kassebaum-Kennedy bill and also on the minimum wage legislation, but that there has been agreement to vote on these measures at 6 o'clock. So there is an expectation that it would be at 6 o'clock.

So I expect that during the course of the next period of time that we have between now and 6 that perhaps that time could be divided, if it is agreeable with Senator KASSEBAUM; that we might just divide the time between she and I until 6 o'clock.

Mrs. KASSEBAUM. I anticipate, of course, if there is more time allocated to us, that will take us past 6 o'clock. As you know, Senator DOMENICI and Senator WELLSTONE want a large share of that time to be equally divided. We will try to do so. But we will have to make sure that time is allocated to them.

Mr. DOMENICI. Mr. President, I think the Senators will be fair. But it seems to me that the spirit of the understanding would provide a portion of that time to the Senator from New Mexico. I think the spirit of it was that a portion of that time would go directly to the Senator from New Mexico.

Mr. KENNEDY. If we have 55 minutes, I suggest that we divide it between Senator KASSEBAUM and myself. And then we will allocate it to our Members between now and 6 o'clock, if that is agreeable.

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

Mrs. KASSEBAUM. Mr. President, I allocate to myself 5 minutes.

The PRESIDING OFFICER. The Senator from Kansas is recognized for up to 5 minutes.

Mrs. KASSEBAUM. Mr. President, today, we stand on the threshold of

passing long-overdue reforms to our Nation's health insurance system.

According to the General Accounting Office, the bipartisan conference agreement before us today will help at least 25 million Americans each year who now face discrimination and live in fear that their health insurance coverage will be canceled if they change jobs, lose their job, or become sick.

It was exactly 1 year ago today that the Senate Labor Committee passed the core provisions of this legislation by a unanimous vote. For many months prior to that time, Senator KENNEDY and I worked together with insurance companies, consumers, Governors, State regulators, large employers, small employees, and other to forge a bipartisan consensus which would bring us to this day.

Mr. President, it has been a long, and sometimes bumpy, road. But the spirit of cooperation and bipartisanship that began this process 1 years ago has allowed us to overcome very difficult obstacles that threatened—but never derailed—our drive to pass common-sense health reforms that would provide real health security.

While there has been a great deal of debate and polemics over the last few months about extraneous provisions, Senator KENNEDY and I have never lost sight of our primary goal. The heart and soul of the Kassebaum-Kennedy bill that passed the full Senate unanimously are firmly embedded in the conference agreement before us.

Mr. President, beginning July 1, 1997, every American who has played by the rules will be able to keep their health insurance coverage even if they change jobs, lose their job, or have a pre-existing illness.

Last night, the House of Representatives passed the Health Insurance Portability and Accountability Act by an overwhelming vote of 421 to 2. Today, we will have the opportunity to do the same and to send this bill to President Clinton for his signature.

This is a dramatic victory for the American people—not only because the bill will help millions of Americans with preexisting illnesses, but also because—I believe—the process of compromise, negotiation, and bipartisanship that was the hallmark of this bill will go a long way toward restoring Americans' faith that their Government can work to address their most pressing concern.

Depending on who was speaking yesterday, one would think that health reform was entirely the province of one party. But as Senator KENNEDY and I both know, this effort has been bipartisan from the start.

Senator KENNEDY and Representative ARCHER worked together to develop a compromise on medical savings accounts that broke a months-long impasse on the bill.

The majority and minority leaders, as well as Senator Dole, deserve much credit for breaking the gridlock over this bill.