It is very heartening to know that we have an agreement that will allow the open debate on this issue. Last year when the debate came up, there were no amendments and a cloture vote within 2 days. It was not a great opportunity for the body and for the members of the public to be involved in. So I think this is a great step forward.

I want to thank my leader, Senator DASCHLE, for his persistence on this. I want to thank the President for his absolutely relentless support of our legislation for over 2 years now. And I appreciate his involvement in this as well.

But overall, what I think we have seen here is a bipartisan ability to come together on timing. I hope it leads to a bipartisan ability to come together on a meaningful piece of legislation.

With that, I yield the floor.

Mr. MCCONNELL addressed the Chair.

The PRESIDING OFFICER. The Senator from Kentucky.

Mr. MCCONNELL. Mr. President, I too want to thank the distinguished majority leader for working with others who are interested in this legislation to create an atmosphere in which we can have an important debate on an issue of enormous significance to our country. I think it is a sensible and orderly way to give everyone an opportunity to have his or her say. I commend the majority leader and Senator MCCAIN as well for their good work to bring us to this point.

The PRESIDING OFFICER. Is there objection to the unanimous consent request of the majority leader? Without objection, it is so ordered.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

Mr. JEFFORDS. What is the pending business?

The PRESIDING OFFICER. There is now to be 4 hours of debate equally divided on S. 830. The Senator from Vermont controls half that time.

Mr. JEFFORDS. I yield to the Senator from Utah 5 minutes.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I ask unanimous consent that the RECORD reflect the fact that amendment No. 1182, as modified, which was adopted was a Hatch-Wyden amendment.

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

Mr. HATCH. Mr. President, there is an old saying, ''No good deed goes unpunished.'' And it applies only too well to those who tackle the job of shepherding the FDA legislation through Congress.

The legislation we are debating today has its foundation in the last Congress. From my experience, I know that FDA bills are inherently contentious and complicated—and that would be true even if my friend from Massachusetts, Senator KENNEDY, was not on the Labor Committee. Sometimes I believe that it was this FDA bill that drove our good friend Nancy Kassebaum out of the Senate.

So we should all take off our hats and thank JIM JEFFORDS for his efforts in forging this important compromise bill. The overwhelming votes on cloture and on the motion to proceed are testament to the fact that S. 830 is a solid piece of bipartisan legislation that will benefit the American public for years to come.

Every Member of this body understands only too well the necessity of having good staff. Our staffs work long hours in order to resolve very difficult issues. I commend the work of all of the staff involved in the development of this bill. I will defer to tradition and allow the chairman and ranking member to single them out when the bill achieves its final passage.

However, I do want to depart from tradition for a moment to compliment the work of Senator JEFFORDS' point person on FDA reform, Jay Hawkins. It is always safe to bet against the passage of FDA legislation, but Jay joined the Labor Committee this past winter and hit the ground running and has helped the chairman in crafting and bringing S. 830 through the committee and onto the floor.

Jay has worked hard, listened patiently to diverse viewpoints, identified and solved problems, and has exhibited sound judgment and tremendous energy throughout this process.

Unfortunately for Jay and his family, on August 20, his mother, Mrs. Donna Lotz Hawkins, died after a long battle with cancer. Jay's mom was a mountain climber, ocean swimmer, and distance runner who had many friends that will deeply miss her.

The loss of a parent can never be replaced. While I never met Jay's mom, as a parent I know that she must have been extremely proud of her son for all of his important work in the Senate.

It is only fitting that this bill, which has so much of Jay's imprint, promises to speed the development of the next generation of cancer treatments.

I just wanted to take these few moments to salute Jay and the chairman for their considerable efforts on the FDA bill, and I want to extend my condolences to the Hawkins family on the loss of his mother.

I yield the floor.

Mr. D'AMATO addressed the Chair.

The PRESIDING OFFICER. Who yields time?

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

Mr. D'AMATO. I thank the chairman and ask unanimous consent that I may proceed as in morning business.

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

(The remarks of Mr. D'AMATO pertaining to the introduction of S. 1203 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. KENNEDY. Mr. President, I yield such time as the Senator from Rhode Island might use.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. We have made great progress with respect to the Food and Drug Administration [FDA] bill. That is a tribute to Chairman JEFFORDS and the ranking member, Senator KENNEDY from Massachusetts, and all the members of the committee and the Members of the Senate participating in this debate.

However, there remains at least one issue of concern, one issue that was a subject of extensive debate today. That issue is a provision regarding the 510(k) approval process for class I and class II devices. As I mentioned previously, these class I and class II devices are serious medical devices. This is not a Band-Aid or gauze. These are lasers or biopsy needles or many other complicated, necessary medical devices.

As a result, we cannot, I think, assume that this is a small or inconsequential issue we are debating. It is a very important issue.

Essentially, the legislation that is before the Senate today limits the FDA from looking behind the stated use on the label presented by the manufacturer when they request approval to put a new product on the market. It is important, in certain cases, to make such a searching review beyond the proposed use by the manufacturer. It is particularly important in the case where there is strong suspicion that the label is either misleading or fraudulent or false. Although my amendment was not favorably considered earlier today, it would have given the authority to the FDA to look beyond the label in cases where they could show—and this is a very high standard of proof—that the label was false or misleading.

There is no other provision in this new legislation that would give the FDA such authority. Indeed, one could ask why the proponents of this legislation deliberately chose to remove the FDA's authority and to effectively prevent the FDA from conducting a thorough review of medical devices as they come on the market.

I have outlined, as many of my colleagues have, the detailed reaction of several sections of the FDA law. It is complicated, arcane legislative language.

I have tried to think of a more homely and mundane example which might illustrate the dilemma the FDA would be facing as it contemplates this new legislation. If the FDA were in the position of not approving medical devices but approving, for example, land transportation vehicles, they might be confronted with an existing model, perhaps a Ford Mustang. And say, for example, a new product such as an F–16 fighter plane is presented for review.

Both can move over the ground, both of them are fairly fast, and both of them have certain similar aerodynamic capacities. Both of them can carry passengers. So one could make the argument that the F–16 could be substantially equivalent in use as a ground transportation vehicle.

But I think anyone would have to say, upon looking at both of these devices, that there is a strong suggestion the F–16 can be used for something else. If the FDA, or in this example, the hypothetical agency, did not have the authority to ask the simple question: Will it be used to fly and can it fly? The hypothetical agency may not be doing the job.

That is a homely example to illustrate that the FDA is frequently confronted with devices that are presented as being substantially equivalent to existing devices. These new devices may be similarly labeled to that existing device, but they have the potential for other uses. If it is obvious that the device is for uses not listed on the label, the FDA should have the authority to make an inquiry into those other uses.

In fact, my suspicion is that in the development of new medical devices there is a long history of starts and stops. A history of contact with other individuals, many researchers working together, exploring different uses and alternatives, different materials. In that process, it is very likely that other issues are contemplated, evaluated and perhaps designed into the device.

Today we have a system where there is more incentive for approaching the FDA with a petition of a 510(k) approval because that is the fastest way to the marketplace. Even if there were uses that were discussed and contemplated, even if there are obvious uses that might become part of common practice, those may be dismissed in order to get this through the system quickly.

What we have done today by not adopting my amendment is effectively prohibit the FDA from making that searching inquiry into possible uses. The consequences can be severe to the public health.

Despite all of these issues we have discussed, this bill represents significant progress on many fronts. We are very, very close. I hope in the ensuing conference—or before we go to conference—that we could address this particular issue. It is an issue that has been highlighted by Secretary Shalala. It has been highlighted with respect to the potential for a Presidential veto. I hope we don't reach that point.

The hard work that has been done over many months by my colleagues, the hard work of many representatives of the industry, and the hard work of public health advocates I think will lead us, if we can get over this hurdle, to a bill that we will all be proud of.

In conclusion, today we have spent some time discussing the industry. We have spent some time discussing the FDA. There have been criticisms by Members with respect to both the industry and the FDA. Our job at this point is not to demonize or deify anyone. It is to get good laws passed. I believe this legislation can be approved and can succeed.

I note the majority leader is standing by, and I yield back my time.

VISIT TO THE SENATE BY THE EUROPEAN PARLIAMENT

Mr. LOTT. Madam President, I am pleased to welcome a delegation from the European Parliament to the U.S. Senate. The parliamentarians are in the United States for the 47th interparliamentary meeting.

Europe continues to move forward with economic integration and the European Parliament's role is increasingly important. As the European Union—like the North Atlantic Treaty Organization—expands, the role of the European Parliament will become even more important.

The United States and the European Union have the world's largest commercial relationship, with trade and investment approaching $1 trillion.

I believe increased interaction between our legislature and the European Parliament will serve the interests of both sides. I would like to add that I met with the U.S. Ambassador to the European Union, Mr. Vernon Weaver, earlier this summer and was impressed with the job he is doing to protect American interests in Brussels and across Europe.

I urge my colleagues to greet this delegation, led by Mr. Alan Donnelly of the United Kingdom.

Madam President, I ask unanimous consent that a list of all of the delegation be printed in the RECORD.

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

EUROPEAN PARLIAMENT DELEGATION FOR RELATIONS WITH THE UNITED STATES

(47th EP/US Congress interparliamentary meeting, 21–26 September 1997, Washington DC)

LIST OF MEMBERS (15)

Mr. Alan Donnelly, Chairman, PSE, United Kingdom.
Mr. Bryan Cassidy, 1st Vice-Chairman, PPE, United Kingdom.
Mr. Lucio Manisco, 2nd Vice-Chairman, GUE/NGL, Italy.
Ms. Nuala Ahern, V, Ireland.
Ms. Mary Banotti, PPE, Ireland.
*Mr. Jacques Donnay, UPE, France.
*Mr. Willi Görlach, PSE, Germany.
Ms. Ilona Graenitz, PSE, Austria.
Mr. Fernand Herman, PPE, Belgium.
*Mr. Mark Killilea, UPE, Ireland.
Ms. Elly Plooij-Van Gorsel, ELDR, Netherlands.
Mr. Barry Seal, PSE, United Kingdom.
Mr. Michael Tappin, PSE, United Kingdom.
Mr. Josep Verde I. Aldea, PSE, Spain.
Rapporteur on Transatlantic Trade and Economic Relations, Ms. Erika Mann, PSE, Germany.

NOTE—Abbreviations:

PSE: Group of Party of European Socialists.
PPE: Group of the European People's Party (Christian-Democratic Group).
UPE: Union for Europe Group.
ELDR: Group of the European Liberal Democrat and Reform Party.
GUE/NGL: Confederal Group of the European United Left—Nordic Green Left.
V: Green Group in the European Parliament.

RECESS

Mr. LOTT. Mr. President, I ask unanimous consent the Senate stand in recess for 5 minutes so we may greet our guests from the European Parliament.

There being no objection, the Senate, at 4:58 p.m., recessed until 5:06 p.m.; whereupon, the Senate reassembled when called to order by the Presiding Officer (Ms. SNOWE).

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

Mr. KENNEDY. Madam President, we are making substantial progress on the FDA bill, and I applaud that progress. We have worked out a number of key issues on a bipartisan basis since the committee markup in June. We have worked out the issues on fast tracking some innovative opportunities for dealing with the special challenges we are facing. We built on the fast tracking that we have done on AIDS drugs, and we are trying to do more in the areas of cancer and Alzheimer's, following what has been an important initiative at FDA for getting drugs out faster. We have even worked out differences on the off-label uses of various pharmaceuticals and devices and what information and studies will be required in terms of safety and efficacy. We have worked out the early consultation between device manufacturers and the FDA.

We have been working toward reducing the total development time. A key element in our negotiations has been going upstream and working with the pharmaceutical companies, as well as the manufacturers, in shaping and formulating their applications so that they will move more rapidly through the approval process. Many of these initiatives were worked out by Dr. Kessler. We have put them into legislation under the leadership of Senator JEFFORDS and others on the committee. We have settled the issues of cosmetics, after good debate and discussion. We have also worked our third-party review pilot programs and timeframes for some of the drug approvals. Each one of these issues was worked out in a way that protects the public health.

This process continues now with further debate today and tomorrow on what I, and others with me, consider to be the most significant threat to the public health remaining in the bill. These other areas that are complex and difficult, where a wide variety of different positions had divided the committee in a significant way. We have