

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: Confederation 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