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

been able to make important and significant progress in ways that advance public health. I believe that we have advanced the interest in the public health. This final issue remains and has been identified by the President of the United States and the Secretary of HHS as being the No. 1 public health risk within this legislation. We had a good debate on that issue earlier today and a real engagement of the differing ideas. I find that we were able to make important progress. The Members realize and recognize what is really at stake. We were unable to win the majority of the Members, but we have a substantial group of Members who are likewise concerned about the public health issues.

We have heard from the various consumer groups and they are the ones that will benefit the most from breakthrough devices. If you read through their concern and opposition to the provision in the legislation and their strong support for the Reed amendment, you understand why we are so concerned about this particular provision.

The House is in the process of taking up legislation dealing with the same subject matter, although they have reached a stalemate with regard to the extension on PDUFA. PDUFA, which I certainly support, provides the additional resources for the FDA to get the kind of trained disciplined personnel that represents the top of our research technology to work very effectively in the evaluation of these various products.

As the prime sponsor of that proposal here in the Senate, with my friend and colleague, ORRIN HATCH, we are clearly strongly in support of PDUFA. We tried to take similar action with regard to the medical device industry, but we were unable to do that. But we were able to accomplish it with the pharmaceutical industry, and it is necessary to have this extension.

The House will take up the FDA. We will continue to work with the administration, and with the leaders of the Energy and Commerce Committees in the House to make sure the compromises reached in the Senate are retained or improved. We will work to make sure that the medical device issue that we have been debating on the Senate floor is fixed.

We believe that the Food and Drug Administration should not be faced with a situation where a device is submitted with a label that contains false and misleading information that would effectively deny FDA an opportunity to review the device on its real uses. And deny them the authority to require the medical device company to provide information relevant to the safety of that medical device.

There is nothing that we have heard that changes my very view that the interests of the American consumer and the American public are best protected by strengthening the lead agency for safety—the Food and Drug Administration. The agency to which all Americans turn when they find that there is tampering with pharmaceuticals, or they are concerned about the importation of pesticides on grapes from Chile, or they are concerned about drugs and medical devices. We saw that across the country this last week with the fen/phen tragedy.

Now we are being asked to reduce the protections for the American people by prohibiting this lead agency, with all its expertise, from protecting the public when it comes to medical devices. We are handcuffing them from being able to reach out and protect the American public when a medical device is falsely labeled. That is a serious error on our part.

A great deal of discussion has taken place in the committee and out here on the floor of the U.S. Senate as to the FDA's ability to approve medical devices in a timely manner. We heard it expressed this morning. We heard. ''Just look how bad the FDA really is.'' We have to accept this provision because it is going to make such a difference to the patients that need these medical devices.

Let us look at what the record has been with regard to the FDA.

If you go through the GAO study on the FDA and its approval record, the progress that has been made in the recent time is truly remarkable. I have it here. This shows the review times that have been decreasing, starting in 1994, continuing 1995, and 1996. This is the General Accounting Office.

The premarket notification 501, the median FDA review time for notification as judged to be equivalent devices already on the market has dropped consistently from 199 days to 95 days in 1996. Look at that difference between 1993 and 1996. The time reduced from 199 days to more than half for the medical devices that are the substantial equivalent.

Here is the premarket approvals. Those take longer than the premarket notifications because the FDA reviews the substantial amount of evidence to determine if the devices are safe and effective. The median time for PMA has dropped from 766 days in 1993 to 280 days in 1996. Again, a 40 percent reduction of the time—a dramatic improvement in the most complicated medical devices that are new; to convince the FDA with the range of different new technologies that are coming and that are being implanted in people. We have reduced that time for clearance on the newest devices that have to be tested carefully and evaluated in terms of their safety. We have dropped the time by about 35 or 40 percent. Approval times have been reduced and we still have the best safety record. We are seeing dramatic improvement in approval time for the most complicated medical devices, and we are seeing dramatic improvement in approval times for the kinds of medical devices that are substantially equivalent. And we still have a strong safety record. But that isn't enough for the medical device industry. They are refusing to support an amendment which would permit the FDA to look at the safety features of medical devices that ought to be looked at.

It would be an entirely different matter if these improvements had not been made. At least you would have an argument to say you needed dramatic changes in the approval process. But the time it takes for the newest kinds of medical devices are improving dramatically.

We heard on the floor of the Senate, ''Well, we have to be able to get these devices out there because all of us are aware of how fast those devices are being approved in Europe. If we do not accept this provision, all our medical device companies are going to go abroad. We are going to lose jobs. This is an issue of jobs. We will take a chance with the health of the American people on this so we can keep our industry here and protect our public.''

Well, let's look at the facts on this one. We have just had the GAO report of June 1997 showing the remarkable progress that is being made in terms of approving these devices while still doing comprehensive examinations of the complex safety issues. They can evaluate the new kinds of safety information provided by the medical device industry, and do it in a timely way, and protect the public. That is what Senator REED and myself believe should be done with regard to this provision.

Madam President, this is a May 12, 1997 document by the World Medical Device Diagnostic News.

This is April 21, 1997.

I will include the relevant parts in the RECORD. But I am reading now:

> France calls on EU to tighten device controls. In a letter to the European Council of Ministers, the French government has called for tighter controls over high-risk medical devices. The government is particularly concerned about implantable devices and other products that fall into the high-risk categories, class 3, class 2.

The letter which was sent to other EU member states has not been released publicly. It forms part of the French campaign of ever-increasing intensity for more stringent relations on medical devices. France is also questioning the validity of the European approach to the regulation of products that pose a high risk to health.

Then in another section talking again about the European Union, industry experts speculate the French might argue on the basis of the results and the question of medical device directors being unable to cope with the high-risk products.

These are storm warnings with regard to the use of high-risk products—storm warnings from our European friends about what is happening over there with their medical device industry. Then we heard here, ''Well, those may be high risk but we are only looking at low risk devices.'' Low risk? The list of the products that are being suggested as low risk: Ventilators, fetal

cardiac monitors, imaging devices, MRI ultrasound, x-ray. Who wants to take chances about whether the ultrasound that an expectant mother is having is going to do the job or not? We think that is a low risk? We don't think that mother ought to be able to get satisfactory information about the adequacy of the protection and the soundness of x rays and CAT scans and ultrasound and MRI's, imaging devices. Low risk? Anesthesia machines. Low risk? We have the storm warnings about what is happening in our own country.

Here is the February Business Outlook for the Medical Device Link. Here is their cover story February 1997:

With the improvements in FDA product review performance, despite an ever more challenging domestic market, device company executives are more optimistic than ever.

They talk about the FDA being cited by many as the leading source of their pessimism.

While nearly as many blamed the disconcerting restructuring of health care providers, two years later—that is now. This is going back to 1994 and 1995.

''* * * two years later device company executives report a substantial improvement in FDA's performance, particularly in the 510(k) product approval times.

This is the medical device industry document. It continues.

In fact, this year's survey conducted last October marks the highest business climate ratings ever in the 5-year history of the survey.

The highest degree of approval rating ever in the 5-year history.

It is going well, my friends. We do not have a Shiley Heart Valve tragedy today. We don't have a Dalkon Shield tragedy today. It is working in terms of protecting the public. But the industry is demanding changes in providing the protection. Why? This is what the industry is saying about the FDA. ''The impact of FDA's internal reforms and review time is more significant than might appear. The agency has not only reduced the approval delays that slowed newer products but, perhaps more importantly, has greatly reduced uncertainty as to the timeliness of future product introductions.''

I will include the appropriate amount of this. I will not take up the whole record, although it is a fairly short document.

It continues along: Respondents' rating of the current business climate for the medical device. Here are the results. A substantial majority of medical device executives said, medical device industry, good or excellent.

Then it has executive ratings of device industry business climate, 1993 to 1997: 58 percent good or excellent. Last year it was 58 to 11. Find me an agency of Government where those who are being covered by the regulators are saying 58 percent approval, 11 percent disapproval. An examination of this review shows that it was down just in 1995, 37 to 23—37 percent approval, 23 percent disapproval. Now that disapproval has gone from 23 to 12 to 11 in 1997 and the 37 is up to 58 in 2 years. This is the reflection of those who are involved in medical device businesses.

''Expectation of respondents for business conditions in the medical device and diagnostic industry,'' again, going up, enormously favorable.

''One important cause of this year's improved outlook is the clearly perceived improvement in relations with the FDA. As shown in figure 5''—that will be in the RECORD—''the decline in complaints about the agency mirrors the increase in positive business outlooks.''

You could not get a greater endorsement. You could not find better support for an agency that is being regulated. You could not see a more dramatic improvement in how that agency has been dealing with those that it is required to police. And all while still protecting the public health, all being done to protect the public health. As the Secretary of HHS and the President of the United States said, of all the different provisions, this is the one that puts the public health at risk. All against a background of a device industry that is saying things have never been better.

Several committee members have expressed concerns that the FDA will try to think of every possible off-label use for a device and harass the industry to death. There is no justification for that attitude. It is good rhetoric, but it just defies any kind of understanding about what is happening in the medical device industry today. The medical device manufacturers and personnel find that their relationship with the FDA is improving significantly in terms of how they are being treated, the times that are involved, the way that the agency has been considering various applications like the ones we have been talking about. The public health is being protected, but we are being asked to change it.

How many times around here do you hear, ''If it is not broke, why fix it?'' Well, this is the attempt to try to fix something that is not broke. And we are not talking about widgets here. We are talking about real health implications to the American public.

Why should we take a chance on people's health when those medical devices are being carefully tailored and designed technologically to do something that is different than is on the label? It just defies me. That is the issue.

So, as we go on through this survey report, talking about international markets: ''Just as outlooks on business are influenced by market segments, so, too, they are affected by geographical markets. In fact, large companies have a clear advantage over small ones in entering foreign markets. Of the companies surveyed, 91 percent were selling to the United States, just over half were doing business in Europe and Canada, while 36 to 40 percent were in Latin America. Of the largest companies surveyed within the various''—$50 million in annual revenues, 90 percent or more were involved in the survey and they show here when asked what markets offered them the best prospects in 1997, more respondents, 80 percent, named the United States than any other market. This are the medical device companies from Central and South America talking about what they believe the greatest opportunity for market expansion is in the United States, and they are going to have to meet the strict requirements that are being put out by the FDA. They think, even going through those requirements for safety and ensuring the public is going to be protected, that there is this dramatic opportunity for growth.

And it just continues. If we go through the Medical Economics magazine of this year, January, it talks about the enormous explosion of the various devices, talking of the demand for devices to treat arteriosclerosis, enlarged prostates, infertility and many others creates a worldwide market of $120 billion, including about $50 billion in the United States. That's growing by 8 percent annually. Feeding this demand are technologies that offer new ways to treat disease, allow doctors to treat illness more quickly, effectively and safely. The coronary stint, for example, created a submarket that exploded from $220 million globally to more than $1 billion in 1996. Sales of this device are growing 30 to 40 percent.

I used that as one of the examples here the other day. This is a $1 billion industry. We are talking about the power of this industry to put pressure on Congress, with this kind of economic power, that pressure is dramatic. To resist that kind of pressure when it is contrary to the protection of the public health I think is enormously important.

What we are saying is simple and fundamental. That is, the proposal that is being advanced here will permit the medical device industry to submit various medical devices to the FDA and the FDA will be limited to examining only the uses listed on the label of the medical devices. If it is substantially equivalent to a medical device that's been approved, all the company has to be able to show is that it has the same kind of safety protections that the earlier device had, even though—even though—it is the intention of the medical device manufacturer to use that medical device for an entirely different purpose and market it for an entirely different purpose, the FDA is prohibited from examining the safety features.

Maybe those safety features are such that they will significantly improve the health and well-being of the person that is using the medical device, but we ought to make sure at least that the agency has the information that would justify that utilization. All this is happening against a background which demonstrates that the medical

device industry is happier with the FDA than at any time in the history of the 20 years, 23 years, of medical device legislation. Happier that there has been a dramatic improvement in approval timeframes, important improvement in terms of safety. We are taking that excellent record and risking it with this particular provision. It does not make sense.

This makes absolutely no sense at all. We strongly believe that this provision has to be altered or changed. We have missed the opportunity to do that on this particular legislation, but we will have further opportunities to do so in the near future.

It is amazing to me, as we went through consideration and as we were able to make progress on so many other items while advancing public health, but the medical device industry does not want to deal with this one. They felt they had the votes. They had them this afternoon. But this is a long road. It is a long road, the completion of this whole process, and we are going to fight every step of the way. We have seen a variety of different options that would attend the kind of concerns that the medical device industry has put expressed, which we and the FDA and the administration were prepared to deal with, but the device industry is unprepared and unwilling to do so.

So if they are unwilling, we are unwilling at least to roll over. There are a variety of different procedures which we will have to resort to in order to make sure that this threat to the public health of the American people does not go forward over the objections of those who are in the best position and do represent the patients and the consumers.

By accepting this change in the protections available to the American public at this time, we are not saying that the health of the American people is going to be advanced. If this particular provision remains unchanged, a provision which effectively handcuffs the FDA, it is the bottom line of the medical device companies that will be enhanced. And ethical companies and the protection of the American people will suffer.

That makes absolutely no sense. It is basically and fundamentally wrong, and we will continue the battle ahead.

APPROPRIATIONS ''TRIGGER''

Mr. COCHRAN. Madam President, as chairman of the Appropriations Subcommittee with funding jurisdiction for the Food and Drug Administration, I am compelled to state my opposition to the appropriations mandate in this bill. While this bill reauthorizes prescription drug user fees for the next 5 years, it also states that the FDA cannot assess those fees unless the appropriation for FDA salaries and expenses is at least equal to the appropriation for fiscal year 1997, adjusted for inflation.

The Appropriations Subcommittee will continue to balance the needs and requirements of all agencies and activities under its jurisdiction within the total amounts available for discretionary appropriations. Any member of the Senate who disagrees with the committee's recommendations is free to seek to change the allocation of resources proposed in the bill.

However, annual appropriations decisions should not be predetermined by the establishment of arbitrary appropriations ''floors'' and ''ceilings'' in authorization bills. In this particular case, the bill seeks to dictate that FDA's salaries and expenses appropriation be ''held harmless'' against inflation—that for each of the next five fiscal years, the appropriations be at least equal to the current appropriations level, adjusted for inflation. If not, FDA cannot assess prescription drug user fees.

Madam President, I am certain that each agency and program which receives appropriations would like to secure a similar protection against inflation. However, this is unrealistic in the current budget environment and inconsistent with the levels available for discretionary appropriations under the bipartisan budget agreement.

Industry paid fees are expected to supplement rather than supplant FDA spending for drug approvals. For this reason, I understand the industry's desire to make sure that FDA maintains its current level of effort relative to the drug approval process. However, as I indicated, it is unreasonable to attempt to guarantee FDA protection against inflation at the possible expense of other programs and activities. It would be difficult for me as chairman of the Appropriations Subcommittee of jurisdiction to predict what agency or program restructuring might occur over the next 5 fiscal years, what a program or agency's future resource requirements might be, or the fiscal constraints the subcommittee might face in each future year.

Mr. President, it could be that the minimum mandated appropriations level in this bill is met in each of those years. However, it is just as likely that it would not be. The Appropriations Committee will continue to do its work by considering the needs of every program and agency within its jurisdiction within the total resources available to it. It will not feel constrained to meet the proposed appropriations ''trigger'' for the collection of prescription drug user fees if it remains in this bill.

I do not think it is the intent of the Labor and Human Resources Committee or the Senate to set an arbitrary mandate that might result in a situation during the course of the next 5 years where these fees may not be collected. I believe this would undermine the existing drug approval process and run counter to the interests of the federal government, the industry, and the American public. The issues and concerns I raise are similar to those expressed by Senators GREGG and MCCONNELL in the additional views they incorporated in the committee's report accompanying S. 830.

Madam President, I am hopeful that the committee take this issue seriously and will work in conference to remove this appropriations mandate and possible impediment to the continued success of the Prescription Drug User Fee Act.

Madam President, 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. JEFFORDS. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. KENNEDY. Madam President, I am prepared to yield the remainder of our time this evening.

Mr. JEFFORDS. Madam President, we are not prepared to at this time, so 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. DASCHLE. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

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

MILITARY AIR CRASHES

Mr. DASCHLE. Madam President, on Friday afternoon of last week, I was shocked and saddened to learn that a B–1B bomber had crashed near Alzada, MT, during a routine training mission over the Powder River military operations area. The bomber was assigned to Ellsworth Air Force Base in South Dakota, and all four crew members aboard the aircraft were killed.

I wish to extend my deepest sympathies to the families of those courageous individuals. They died in the service of their country, and I know my colleagues join me in honoring their memory and their sacrifice.

The B–1 accident was the sixth military air crash in 7 days. Although there is no apparent connection between the accidents, Secretary of Defense William Cohen rightly asked the Air Force and the other branches of the Armed Forces to implement a 24-hour safety stand down to allow those who fly and maintain U.S. military aircraft to focus on safety.

Despite the rash of accidents that occurred in recent days, the past year has been a relatively safe year for the Department of Defense.

Fifty-five military aviation accidents occurred this year compared to 67 last year, 69 in 1995, and 86 in 1994. Although this appears to be a good trend, the Pentagon must strive to improve its safety record even further, and they are doing that.

I commend Secretary Cohen for implementing a safety stand down and am confident it will yield positive results.