

Could you clarify your intent in this area?

Mr. JEFFORDS. Enforcement authority is not covered by the preemption provision of the bill, so a State's embargo and other enforcement authority would not be affected.

Mrs. FEINSTEIN. For nonprescription drugs, California law requires comprehensive and annual inspections of manufacturers. Federal law requires limited inspections on no timetable. DHS maintains that the "State's requirements for drug manufacturer licensing and the annual inspections may be considered a requirement in addition to the Federal requirement."

What is the chairman's intent in this bill, as it addresses licensing and inspections by States?

Mr. JEFFORDS. As I said previously enforcement authority is not covered by the national uniformity provisions. Thus, drug manufacturer licensing and inspection in the States would not be affected.

Mrs. FEINSTEIN. My State has expressed concerns about advertising, saying that State law has advertising restrictions, that is prohibition on false and misleading advertisement, advertising of unproven remedies, that may be preempted. Could you elaborate on the bill's intent in the drug advertising area?

Mr. JEFFORDS. The national uniformity provisions would not affect traditional drug advertising laws because this bill does not address the authority of the Federal Trade Commission Act. State laws that prohibit false and misleading advertising or to prohibit unsubstantiated claims for non-prescription drugs, for example, would not be affected. Traditional advertising issues relating to claims substantiation, fair balanced and truth are outside the scope of national uniformity.

Mrs. FEINSTEIN. I thank my colleague. I hope that this discussion will clarify the true intent of the authors of this bill and provide some clarification of the State's authority to protect the public health under this bill.

VOTE ON AMENDMENT NO. 1130, AS MODIFIED

The PRESIDING OFFICER. The question is on agreeing to the committee substitute, No. 1130, as modified. The yeas and nays are ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

The result was announced—yeas 98, nays 2, as follows:

[Rollcall Vote No. 255 Leg.]

YEAS—98

Abraham	Bryan	Craig
Akaka	Bumpers	D'Amato
Allard	Burns	Daschle
Ashcroft	Byrd	DeWine
Baucus	Campbell	Dodd
Bennett	Chafee	Domenici
Biden	Cleland	Dorgan
Bingaman	Coats	Durbin
Bond	Cochran	Enzi
Boxer	Collins	Faircloth
Breaux	Conrad	Feingold
Brownback	Coverdell	Feinstein

Ford	Kerrey	Robb
Frist	Kerry	Roberts
Glenn	Kohl	Rockefeller
Gorton	Kyl	Roth
Graham	Landrieu	Santorum
Gramm	Lautenberg	Sarbanes
Grams	Leahy	Sessions
Grassley	Levin	Shelby
Gregg	Lieberman	Smith (NH)
Hagel	Lott	Smith (OR)
Harkin	Lugar	Snowe
Hatch	Mack	Specter
Helms	McCain	Stevens
Hollings	McConnell	Thomas
Hutchinson	Mikulski	Thompson
Hutchison	Moseley-Braun	Thurmond
Inhofe	Moynihan	Torricelli
Inouye	Murkowski	Warner
Jeffords	Murray	Wellstone
Johnson	Nickles	Wyden
Kempthorne	Reid	

NAYS—2

Kennedy

Reed

The amendment (No. 1130), as modified, was agreed to.

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

The PRESIDING OFFICER. Without objection, the motion to lay on the table the motion to reconsider is agreed to.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The majority leader.

UNANIMOUS-CONSENT AGREEMENT

Mr. LOTT. Mr. President, I ask unanimous consent that the scheduled cloture vote be vitiated with the previous debate limitation still in effect.

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

Mr. LOTT. In light of the earlier consent with respect to debate time on the FDA bill—I believe Senator JEFFORDS got the unanimous-consent request agreed to a few moments ago—there will be no further votes this evening. The Senate will begin, now, up to 4 hours of debate on the FDA bill. The concluding 4 hours of debate will begin at 12 noon on Wednesday. Therefore, final passage will occur at approximately 3:45 on Wednesday, of the Food and Drug Administration reform bill.

I guess I should put that in the form of a request, Mr. President.

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

UNANIMOUS-CONSENT AGREEMENT—CAMPAIGN FINANCE REFORM

Mr. LOTT. Mr. President, I ask unanimous consent the majority leader, after notification of the Democratic leader, must turn to S. 25, the McCain-Feingold campaign finance reform bill, prior to the close of the first session of the 105th Congress, and Senator MCCAIN will immediately be recognized, then, to modify the bill, and it be in order that the majority leader immediately offer an amendment relative to campaign finances. I further ask unanimous consent that it not be in order for any Senator to offer any legislation regarding campaign finances prior to the initiation of this agreement.

The PRESIDING OFFICER. Is there objection?

Mr. DASCHLE. Reserving the right to object.

The PRESIDING OFFICER. The Democratic leader.

Mr. DASCHLE. Mr. President, this is the same unanimous-consent request propounded last Friday. The difference is that I have now had the opportunity to consult with my colleagues, and also to consult with the President and those in the White House who have a great deal of interest in our progress on this legislation.

The President has just sent Senator LOTT and me a letter, indicating his desire to either keep us here or bring us back if we are not sufficiently successful in meeting the goals that we have all indicated we share with regard to the completion of the work on the McCain-Feingold bill.

Given his assurances that he will call us back or keep us here—and I certainly hope that that is not necessary because I think there is plenty of opportunity for us throughout the month of October to bring this legislation to the floor and have a good debate—we certainly would not object.

As I indicated on Friday, I had two concerns, one, that we would run out of time and, two, that I had not had the opportunity to discuss this matter, and we were precluded from offering the amendment to any other legislation in the event that we would have run out of time. Now there is no concern for running out of time because the President will see to it that we have whatever length of time we need to complete our work.

So Mr. President, I am very pleased that we have been able to make this progress, and we have no objection.

The PRESIDING OFFICER. Is there objection?

Mr. DASCHLE. I ask unanimous consent that the letter sent to me by the President be printed in the RECORD.

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

THE WHITE HOUSE,

Washington, September 23, 1997.

Hon. THOMAS A. DASCHLE,
Democratic Leader, U.S. Senate, Washington, DC.

DEAR MR. LEADER: Senators McCain and Feingold have pledged to bring their campaign reform legislation to a vote. When that happens, the American people will be watching. I encourage you to act responsibly and support passage of this long-overdue, bipartisan legislation.

This measure is of the utmost importance, and it deserves full consideration on the Senate floor. If any attempt is made to bring this bill up in a manner that would preclude sufficient time for debate, I will call on Congress to stay in session until all of the critical elements are fully considered.

There is a real need for reform. The amount raised by both political parties is doubling ever four years. And as candidates are forced to spend ever greater amounts of time raising every larger amounts of money,

the people's business suffers. We have an obligation to restore the public trust.

The bipartisan measure that Senators McCain and Feingold intend to bring to the floor is balanced and effective. It addresses many of the most pressing needs for reform. It does not include every reform that I believe necessary. But it is an important first step—and it represents the only real opportunity to enact meaningful reform in this Congress. Any attempts to attach amendments that would make it unpalatable to one party or another are nothing less than attempts to defeat campaign finance reform. And a vote to filibuster this measure is nothing short of a vote to maintain the system that favors special interests over the public good. For years, the special interests and their allies have filibustered reform. But this year, the American people will hold accountable those who vote to maintain the status quo.

Despite formidable odds, the Congress faces the best opportunity in a generation to enact campaign finance reform. Let us work together in a bipartisan spirit, as we have throughout this legislative session, to thwart special interests who seek to smother reform and deny the will of the people. I urge you to support the bipartisan efforts embodied in the McCain-Feingold proposal, permit the Senate to debate their bill, and vote to enact these needed changes to our political system.

Sincerely,

BILL.

Mr. LOTT. Mr. President, it is the same unanimous-consent request I offered last Friday. I thought it was a fair procedure within the bounds of the 105th Congress' 1st session to take up consideration of campaign finance reform. I still think it is a fair procedure. I indicated last Friday it was never my intent to try to have this come up on the last day or the last week. I do not think that would be in anybody's interest. And I did not intend to do that. I said at the time I did not intend to do that.

So I am glad we have this worked out. We will work now to try to determine a time to bring up consideration and debate of this issue in a way that will allow us to have time to discuss it freely but also give us time to look at other issues that we hope to have completed before the end of the session.

With regard to the President's letter, I have not had an opportunity to read the letter yet. I am always glad to have a communication from the President. I do not feel threatened or intimidated by the letter because we still have an awful lot of work to do together on appropriations bills. I am still hopeful that we can have the ISTEA follow-on transportation infrastructure bill passed. And we hope to even consider the fast-track legislation.

So the President has a lot of issues that he would like for us to work with him on. We would be glad to do that. And we intend to do that. However, we do not intend to be threatened or intimidated on this or any other issue.

The PRESIDING OFFICER. Is there objection?

Mr. MCCAIN addressed the Chair.

The PRESIDING OFFICER. The Senator from Arizona.

Mr. MCCAIN. Reserving the right to object, and I will not object, first of all,

I want to thank the majority leader for his willingness to take up this issue.

As I said on Friday when he made it very clear to all that we would take up this issue in a timely fashion under the conditions of the unanimous-consent agreement, as he stated, I thought it was eminently fair.

There are other issues that are before the Senate that need to be resolved. And over time I have great confidence that the majority leader will bring up this issue so that it can be adequately addressed.

As far as the letter from the President is concerned, let me just say, Mr. President, we all know that the President can call Congress into session all he wants to. He cannot make them act. And I see from time to time, as we address this issue, the seeking of some kind of political advantage and leverage here in this debate.

Let me make one thing perfectly clear, the only way we are going to achieve meaningful campaign finance reform is by sitting down together in a bipartisan fashion. We do not need letters from the President of the United States now. What we need is meaningful and serious negotiations between all parties committed to meaningful campaign finance reform. I intend to work with my colleagues on both sides of the aisle to achieve that.

Again, I want to thank the majority leader because he told me a long time ago that this issue would receive the serious consideration that it deserves, and he has confirmed that confidence with the unanimous-consent agreement today.

Mr. KERRY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KERRY. Mr. President, I will not object either. I just want to ask the majority leader a couple questions.

Mr. President, I ask, is it possible for the majority leader to share with us any little bit deeper what his thinking might be as to when he thinks it might actually come? I know he cannot be precise, but is there some variation here in the course of the next 3 weeks, Mr. President?

Mr. LOTT. Well, we need to look at the conference reports on appropriations bills. We need to look at the continuing resolution, if one is needed. I presume it will be. We need to look at what progress is being made with regard to the ISTEA or the highway transportation bill. And we need to look at when we will need to schedule fast track. And we will need to consider when we are going to have an opportunity to take up serious product liability.

So there are several issues that we feel like, I think on both sides of the aisle, we must do this year, and one way or another—or should do—and we will look at all of that. It is not my intent to drag this out to the end of the session because I would like for us to be—if I had my way, I guess the last thing we would do would be probably

the fast-track legislation in one form or another and to deal with it up or down. That would be my thinking what we would do last, not because I am pushing it off to the end but because we have to have some hearings, it has to be marked up, go to Finance and I think Banking and two or three other Committees. That is what looks like will probably come up toward the end of October or early November.

So it is my thinking that we would want to do it before then. I will try to, you know, make sure everybody has an input here. We have Senators on both sides that have interest. We have chairmen that have interest. It is not my desire to have this come up in the congestion at the end.

I want to find a window. I can see a possibility of one before long where we can take this up and consider it for a period of time that everybody might be comfortable with.

Mr. KERRY. Mr. President, I thank the majority leader for the breadth of that. I think it is very helpful to have that on the RECORD.

Secondly, I want to ask him just with respect to my own understanding of the request, the first amendment is the amendment from Senator MCCAIN.

Mr. LOTT. The original McCain-Feingold.

Mr. KERRY. Followed immediately by an amendment from the majority leader; is that correct?

Mr. LOTT. No. Followed by the modified McCain-Feingold bill.

Mr. KERRY. With a second degree?

Mr. MCCAIN. Substitute.

Mr. LOTT. My amendment would be a first-degree amendment after the McCain-Feingold modification.

Mr. KERRY. Mr. President, if I could ask, in furtherance of the effort here to keep the bipartisanship and discussions going, would it be possible in the near term for us to learn the content of that other amendment, of the amendment of the majority leader, so that we might be able to have something competent to be able to meet on and discuss?

Mr. LOTT. We have not made a final decision. We have a number of options we are reviewing. It could be an amendment or it could be an amendment in the nature of a substitute. And we are looking at both of those possibilities. But before we bring it to the floor, we will notify the Members of what our intent would be on that.

Mr. KERRY. I thank the majority leader.

Mr. FEINGOLD addressed the Chair.

The PRESIDING OFFICER. The Senator from Wisconsin.

Mr. FEINGOLD. Let me take a moment, and reserve the right to object, to thank both of the leaders for coming together on this issue. It is of tremendous importance to everyone here in this body and to the American people. And I think they both have an extremely difficult task in dealing with an issue like this that is of such personal importance to each Member of the Senate.

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 ACCOUNT- ABILITY 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.