quipped, ''In a campaign, if you haven't heard a good rumor by noon, you better start one.'' Needless to say, Wiley knew how to have fun in serious situations, and he always got the job done.

Wiley's outstanding work and invaluable knowledge were not the only reasons he was well loved by Mississippians. Many benefited from his tireless work as an ambassador for his beloved Mississippi State University. Wiley was a servant of the people, and he was one of them.

He is best described as the kind of person who never met a stranger or knew an enemy. He reached out to individuals at all levels, and his friendliness was contagious. Quite simply, everyone liked Wiley.

I understand that the church in Jackson couldn't hold all those who showed up yesterday to pay tribute and show appreciation for Wiley. To anyone whose life he touched, this is no surprise.

There is not a story that can be told or a memory brought to mind about Wiley that wouldn't bring a smile to the faces of those who knew him, which is a tribute in itself to his character. Wiley will be sorely missed, but more importantly, he will be fondly remembered.

I am sure all my colleagues in the Senate join me in extending condolences to the members of his family, to his friend Senator COCHRAN, and to the many others who loved him.

I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I know we all join in expressing those feelings about Wiley. They were so adequately and eloquently expressed. We appreciate that.

UNANIMOUS-CONSENT AGREEMENT

Mr. JEFFORDS. Mr. President, I ask unanimous consent that when the Senate reconvenes at 2:15 there be an hour for debate only on the FDA bill to be equally divided between Senators JEFFORDS and KENNEDY, and immediately following that hour the Senate will resume the Interior appropriations bill.

The PRESIDING OFFICER. Is there objection?

Mr. ASHCROFT. Reserving the right to object, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

The PRESIDING OFFICER (Mr. ASHCROFT). The Chair, in his capacity as a Senator from the State of Missouri, asks unanimous consent that the order for the quorum call be rescinded.

Without objection, it is so ordered.

For the pending request for unanimous consent, no objection being heard, without objection, it is so ordered.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate stands in recess until the hour of 2:15 p.m.

Thereupon, the Senate, at 1:25 p.m., recessed until 2:14; whereupon, the Senate reassembled when called to order by the Presiding Officer (Mr. COATS).

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with consideration of the bill.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. I yield 10 minutes to the Senator from Connecticut.

Mr. DODD. Mr. President, I thank the Chair and I thank my colleague from Vermont, the chairman of the committee.

Let me begin these brief remarks by commending all of our colleagues on the Labor and Human Resources Committee. This has been a long process, 2½ to 3 years. The Presiding Officer is a member of this committee as well and all have worked very hard, I think, to bring a bill which I think most would agree is a very good bill.

There obviously still are some issues that will have to be resolved, but this has been a very fine product that has been assembled by both Democrats and Republicans for the first time in several decades of reforming the Food and Drug Administration and the processes by which we bring important pharmaceutical products and medical devices to patient groups and individuals across this country in an efficient, safe, and expeditious fashion.

Let me begin as well by thanking our colleagues for their overwhelming support earlier today of the cloture motion to proceed with this bill. Mr. President, 94 Senators, of both parties, loudly and clearly told us they are ready to move forward to reauthorize PDUFA and begin debating the other critical reforms this bill contains.

There is no Federal agency with a more direct or significant impact on the lives of the American people than the Food and Drug Administration. The foods that we serve our family, the medicines we take when we are sick, even the drugs we give our pets are all approved and monitored by the Food and Drug Administration. We must not lose the opportunity that we have before the Senate today to enact legislation that ensures that the FDA has the authority it needs to bring safe and effective products to the American people quickly, efficiently and safely.

I again thank both Senator JEFFORDS and Senator KENNEDY for their perseverance on this issue. Time after time they have been willing to return to the bargaining table after many others would have just walked away. With open minds and good faith they have extensively negotiated this bill line by line.

Mr. President, we have now come to a point where issues on which Members were previously completely polarized—third-party review of medical devices, off-label dissemination of information, health claims for food products, the number of clinical trials needed for drug approval, and just today, national uniformity of cosmetics—we have now reached agreement.

I don't know that any of us would have thought unanimity possible on these provisions even a month or two ago. Yet here we are, this afternoon on this day, with full agreement on all but a handful of issues, or less.

I know we have a better bill for all the arduous negotiations that have occurred. As an example of how far we have come, let me just briefly describe third-party review of medical devices. The bill would expand the pilot program currently administered by the FDA. This is a program, I should note, that is supported by the FDA as a way to make more efficient use of its resources.

In last year's debate on this issue, which many may recall as being one of the more acrimonious, we were told that this provision was a nonstarter, no room for compromise, subject closed.

This year, I am pleased to say a spirit of bipartisanship and compromise has prevailed. Senator HARKIN, Senator KENNEDY, and Senator COATS, the Presiding Officer, worked diligently to draft language that ensures that higher risk devices are not inappropriately included in this pilot program and that strong conflict of interest protections are in place.

Late last week, again on an issue that appeared unresolved, national uniformity for cosmetics, we have reached agreement. Senator GREGG of New Hampshire has offered what I think is a very reasonable compromise. In the area of packaging and labeling, States can continue to regulate where the FDA has not acted. Conflicting State requirements that could confuse consumers will be removed. But where the FDA has not chosen to act, where it does not have either the manpower nor the authority to protect the public, States can still play their historic role in regulating cosmetics.

This is the kind of effort, Mr. President, made over and over again on this bill—some 30 times just since the markup 2 months ago that we have made improvements in this legislation. A great many of us take pride in the product that we have created —a bill that would speed lifesaving drugs and devices to patients and that clearly retains the FDA as the undisputed arbiter of the safety and effectiveness of the products.

I will speak about some of the positive reforms contained in this bill, as well.

At the heart of this bill is the 5-year reauthorization of PDUFA, the Prescription Drug User Fee Act, a piece of legislation remarkable for the fact

that there is unanimous agreement that it really works. PDUFA has set up a system of user fees which drug companies pay to the FDA. These fees have enabled the agency to hire more staff. As a result, drug approval times have been cut almost in half, getting new and lifesaving therapies to patients more quickly.

In addition, by improving the certainty and clarity of the product review process, S. 830 encourages U.S. companies to continue to develop and manufacture their products in the United States, not an insignificant matter. The legislation emphasizes collaboration early on between the FDA and industry during the product development and product approval phases. This will prevent misunderstandings about agency expectations and we think should result in quicker development of approval times.

Mr. President, in addition, S. 830 establishes or expands upon several mechanisms to provide patients and other consumers with greater access to information and lifesaving products. For example, the legislation will give individuals with life-threatening illnesses greater access to information about the location of ongoing clinical trials of drugs.

Based on a bill originally championed by Senators SNOWE of Maine and DIANNE FEINSTEIN of California, I offered an amendment in committee, which I was pleased to see adopted, to expand the existing AIDS database to include trials for all serious or life-threatening diseases.

Experimental trials offer hope for patients who have not benefited from treatments currently on the market. Currently, patients' ability to access experimental treatments is dependent on their spending large amounts of time and energy contacting individual drug manufacturers just to discover the existence of trials.

Mr. President, this is not a burden that we should place on individuals already struggling with chronic and debilitating diseases. This database will provide one-stop shopping for patients seeking information on the location and the eligibility criteria for studies of promising treatments.

Mr. President, I am particularly pleased that this legislation incorporates the Better Pharmaceuticals for Children Act, legislation originally introduced by our former colleague from Kansas, Senator Kassebaum, and now cosponsored by myself and Senator DEWINE of Ohio, along with Senator KENNEDY, Senator MIKULSKI, Senator HUTCHINSON, Senator COLLINS, and Senator COCHRAN.

This provision, Mr. President, addresses the problem of the lack of information about how drugs work on children, a problem that just last month President Clinton recognized publicly as a national crisis.

According to the American Academy of Pediatrics, only one-fifth of all drugs on the market have been tested for their safety and effectiveness on children. This legislation provides a fair and reasonable market incentive for drug companies to make the extra effort needed to test their products for use by children.

It gives the Secretary of Health and Human Services the authority to request pediatric clinical trials for new drug applications and for drugs currently on the market. If the manufacturer successfully conducts the additional research, 6 extra months of market exclusivity would be given.

I recognize that there are a few matters unresolved in this bill despite the best efforts of all involved, and we will need to hold votes on those issues. One issue, which I plan to discuss further when we debate the bill this week, involves section 404 of the bill, which relates to the FDA's medical devices. This provision, the so-called labeling claims provision, clarifies current law by stating that while reviewing a device for approval, FDA should look at safety and efficacy issues raised by the use for which the product was developed and for which it was marketed.

Again, this is current law. Unfortunately, in a few instances the FDA has inappropriately expanded the scope of its review by requiring manufacturers to submit data on potential uses of the product. Some have raised concerns that under this provision a manufacturer could propose a very narrowly worded label for a device and that the FDA would be barred from asking for information on other obvious uses.

I don't believe this is the case. The FDA retains its current authority to not approve a device if features of the device raise new questions of safety and efficacy. Clearly, if a bad actor device manufacturer attempted to get a misleading label past the FDA, the agency would have full authority to disapprove the product.

Again, I urge, on this matter, that some common ground be sought to see if we cannot resolve this, but I do believe the present legislation is more than adequate to protect the concerns that have been raised about a use for a device beyond what its intended purpose would be.

I was pleased to join Senator JEFFORDS, the chairman of the committee, as the first Democratic cosponsor of this bill. I thank him again for the hard work and long hours that he and his staff, as well as Senator KENNEDY, Senator MIKULSKI, Senator WELLSTONE, Senator COATS, Senator GREGG and others, have contributed.

Mr. President, this has been a long process, and while there are still some outstanding issues, I think this committee deserves a great deal of credit for having been open to the suggestions of others. There are about 50-some-odd amendments that are kicking around that may be offered. I don't know how many will actually survive the germaneness test when they are raised, but I hope, for those who are bringing up new matters here that we have not had a chance to look at, that they would reserve those unless there is an overwhelming need for them. In many cases, if the matters had been brought before the committee earlier, we might have been able to handle them.

We have a few days left to get the bill done. PDUFA goes out of existence on September 30. We have been 2½ years at this now. My hope is we will not delay this to such a degree that we lose a historic opportunity to make a difference. When it takes 14 to 17 years to get some cancer treatments approved, there is something fundamentally wrong with that kind of a process. We ought to be able to make it far more efficient than that and also be able to provide people with the safety that they demand. It is a wonderfully encouraging thing in this country, when we think how many places we go and how many products we ingest and how many products we apply to our bodies and to our children and families, that we have a high sense of confidence that when we do that, it is safe and, by and large, efficient and effective. We don't want to lose that.

We also believe in this day and age with all the technology available to us that we ought to be able to not give up on safety or efficacy and be able to move that process forward.

I thank my colleague from Vermont for yielding.

Mr. KENNEDY. Mr. President, I yield 7 minutes to the Senator from Illinois.

Mr. DURBIN. I thank the Senator from Massachusetts for yielding.

We can all remember 2 years ago when there was a debate on Capitol Hill about closing down the Federal Government. Rush Limbaugh and people like him went on the radio and said, ''Go ahead and do it, no one will notice. No one will notice if you close down these Federal agencies. They are just a drain on the Treasury and our tax dollars.''

But the agency that we are talking about today is an agency you would notice immediately—immediately—because the Food and Drug Administration, as small as it is by Federal standards, is one of the most important. There is not a single thing you buy in the drugstore or look at in your medicine chest at home that the Food and Drug Administration has not taken a look at to make sure it is safe for you, your kids, and your family.

That is why this FDA reform bill is so critically important to this Nation to make sure we make this agency more efficient. I want to salute the Senator from Vermont and the Senator from Massachusetts. They have had their differences on issues, but I think most Senators, Democrats and Republicans, agree reform is needed. This bill is a step in the right direction.

It is in that spirit that I will offer several amendments. Let me tell you about two that I think people should take notice of. If you went out today and decided to buy a car for your family—a few years ago I went out and

bought a Ford—you will have your name and address entered into a computer. If at some later date something is found wrong with that car, the brakes are faulty or there is some mechanism on the door that is not safe, they will notify you, they will track you down, and they will send you a notice. A lot of Americans have received them, ''Come on in to our shop, and we will fix your car.'' That is reasonable. None of us want to drive an unsafe vehicle.

My amendment says is it not now reasonable, when it comes to heart valves and pacemakers and items like that, that we do the same thing? If you or your loved one is told by the doctor you need a pacemaker, you think long and hard about it but say, ''Doctor, if you think that is what I need to live, so be it.'' You go through the surgery, and everything works out just fine. Wouldn't you like to be on a list somewhere so that if a defect is found in that pacemaker 6 months, a year, or 2 years later, that you can be notified? That is what my amendment says. Track and surveillance, find the customers that use the products. If there is a change, let the customers know, let the people know, so they can go back to their doctor, back to the hospital. I don't think that is unreasonable.

The second thing is we want to move some of the drug surveillance, for example, and drug approval off the Food and Drug Administration campus and take it to third-party reviewers. Now, this is being done in Europe and other places. It is not unreasonable that we would go to a laboratory and say, ''You do the testing, you read the results; you tell us whether this drug is ready for the market.'' I think that is a reasonable thing for us to try to do, under supervised circumstances. But my amendment says let us make certain, absolutely certain, that this third-party reviewer does not have an economic interest in the drug company seeking approval. Would you trust a reviewer who just happened to have a thousand shares of stock of the company making the product that he is deciding whether it will go to market or not? Would you have second thoughts if that person was being offered a job by the same company whose drug he is reviewing just happened to get a vacation in the Caribbean last summer at the expense of the same company?

Conflict of interest statutes are important here. If we are going beyond the Federal Government and we are going to have private laboratories doing this, for goodness sakes, let's be certain that their judgment and decisions are based on sound science and not on financial gain. That is what my second amendment will do.

I think these will move us along toward making the FDA an even better agency. There are a lot of critics of the Food and Drug Administration. I have worked closely with this administration for over 12 years. Some of the finest people in Government are working out there. Sometimes they are frustrated that we wish they would bring things to market more quickly. Did you read the newspaper this morning? Occasionally, things are moved to the market that aren't safe. Thank goodness, the FDA can say it is time to take the item off the market, or decide the benefits are not outweighed by the problems this drug creates. We have to keep this agency strong and independent and above political criticism. The two amendments which I will be offering on the floor are an attempt to do that.

I thank the Senator from Massachusetts for yielding.

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. Mr. President, how much time do I have?

The PRESIDING OFFICER. The Senator from Massachusetts has 25 minutes, 20 seconds under his control.

Mr. KENNEDY. I yield myself 20 minutes, Mr. President.

The PRESIDING OFFICER. The Senator is recognized for 20 minutes.

Mr. KENNEDY. Mr. President, I thank my colleague and friend from Illinois for reminding us how important this debate is here on the floor of the U.S. Senate. We are talking about the agency of Government that has the prime responsibility for protecting the health of the American consumer. We all have an interest in making sure that medical products are available earlier. Every one of our families have benefited from the innovation and resourcefulness of the medical device industry and from the advances of pharmaceuticals. I doubt there is any Member of the body that has not. So all of us want to be able to make sure that medical advances will be available to the American public.

We are in a situation today where the United States through the FDA is leading the world, in terms of approving new drugs as well as medical devices. That has changed from recent years. I think all of us have seen some very dramatic and important progress made in recent years. As I have said many times before, I want to give a tribute to the chairman of our committee who has worked tirelessly on this issue. He has brought together those individuals on our committee and outside that have differing views, all struggling to try and advance the interest of the public health. I think he has made remarkable progress in moving us forward to where we are today. But there are important remaining items that I hope we can dispose of in the Senate within a reasonable time period so that the process could move forward. I take exception from the understanding of the language that has been included in this bill with regard to ensuring that the consumers of medical devices and users of medical devices have the kind of protection that has been referred to here by my friend and colleague, the Senator from Connecticut, and others.

I have here, Mr. President, a letter from the Secretary of Health and Human Services, which indicates that they have four major concerns with this particular legislation. One of them was the area of cosmetics. Another area is environmental considerations, and another area is device manufacturing procedures. But the other important area is the one that I am going to address here today, and that is what I call the safety issue, the fen/phen issue as it applies to medical devices.

The Secretary, speaking for the President of the United States, has identified this as being a major issue. So when others gather around and say, ''Look, we have debated this and discussed it, why are we bringing these matters up in this debate at this time?'' The reason that we are bringing it up is, as the Secretary of Health and Human Services has recognized, there are very powerful health consequences we ought to take note of and deal with and that we ought to alter and change.

It isn't only the Secretary of HEW. Here is the National Women's Health Network, who points out:

> The network is extremely concerned with the section 404, which prevents FDA from requiring medical device companies to perform complete reviews on the safety and effectiveness of a medical device. This must be amended to give FDA the authority to verify that the label is not false or misleading. Section 404 is a serious danger to women's health, which must be fixed before S. 830 is acted upon by the Senate.

Then the Patients' Coalition indicates a similar concern. It outlines probably eight or nine major issues and section 404 is one of them.

The Consumer Federation of America wrote:

> We are writing in support of your amendment to change section 404 to prevent serious injuries to patients and consumers from medical devices with false or misleading labels.

This isn't just the Senator from Massachusetts that is saying this. Here is the Secretary of HEW saying it. Here are the primary groups defending women's health and consumers' health, all who have joined in recognizing the dangers that this particular provision provides, and why it is so important that we are going to change it and alter it.

The Consumer Federation says:

> Section 404 has been crafted to permit medical device manufacturers of class II devices to limit FDA's review of the safety and effectiveness of a device based upon conditions of use listed on the label. Even if it were clear from the device's technical characteristics that its real use would be for risky purposes, FDA would be prevented from looking beyond the conditions of use on the label.

There it is. That is what the issue is. The Consumer Federation understands it. They are pointing out that 404 was crafted to permit the device manufacturers of class 2 devices to limit FDA's review of the safety and effectiveness of a device based upon conditions of use listed on the label. Even if it were clear from the device's technical characteristics that its real use would be for

risky purposes, FDA would be prevented from looking beyond the conditions of use of the labels.

That is what we are addressing, Mr. President, and why this is important. Mr. President, all we have to do is look at today's newspapers. Look at this morning's newspapers, the Washington Post, Wall Street Journal, all across the Nation, talking about the off-label use of pharmaceuticals, those pharmaceuticals that were used on an off-label basis. That is similar to the issue we are talking about here today with regard to medical devices, the off-label use of medical devices.

But the issue that we have before the Senate this afternoon is more insidious. Why? Because it says that if a medical device company is submitting an application for a certain use, FDA can't look at any other uses even if there is a clear intention—and we are glad to spell out what that criteria would be—for example predominant use—to use the device or market the device for another use. That is what we are interested in—having FDA look at the safety and efficacy of a use clearly intended by the design of the medical device.

I am going to illustrate this in just a few moments. The issue is whether the FDA has the authority to look at whether that medical device has been tested for the off-label use, which is the clear intention of the medical device company. And the answer is, no, they cannot. This isn't off-label use of two products that are being put together and then prescribed by various medical professions. This is the guardian of the American public, the FDA, that is being denied the ability to look beyond the label at the technological differences of a device in terms of safety and effectiveness. That is the issue.

Now, there are those that say—and we heard the argument by my friend from Connecticut—that FDA inherently retains that power. If they do, let's spell it out. If we spell it out, we haven't got a problem. But the Secretary of HEW does not believe they have the inherent power. The Consumer Federation doesn't believe they have the inherent power. The various patient groups don't believe they have the inherent power. The various groups that are out there protecting the public, virtually none of them believe they have the inherent power. If they have it, let's spell it out. We can work that language out. We have been attempting to do that for a considerable period of time, but we have not been able to do so.

The answer on the other side is, well, we can't anticipate every possible use that a medical device might have and we are not going to submit safety data for every possible use and that FDA shouldn't get in the minds of various doctors using that medical device, for whatever purpose. That is not the argument. That will be the argument you will hear out here on the floor of the Senate. That isn't what we are talking about.

We are talking about a limited number of medical device companies that will go to FDA and abuse this process because they are able to get through the process with a label that in so many respects matches a previously approved one, but the medical device has an entirely different technology that clearly indicates a different intended use. That is what we are talking about.

For example, the new lasers that are being approved by the FDA labeled as general lasers that are for cutting various tissue, but clearly designed to treat prostate cancer. We want the FDA to be able to say, if you are going to use that for prostate cancer, we want to make sure that it is safe and efficacious. We don't want to permit the medical device industry to submit false and misleading statements.

That is a powerful statement. But I daresay if they are going to submit a statement that says they are going to use a particular medical device for one purpose and FDA can demonstrate that the company has intended the device for another purpose, and they are already involved in, advertising and promoting that particular medical device in countries all over Europe for an entirely different purpose, I say that is false and misleading. The Members of the U.S. Senate are going to have a chance to decide whether or not they are going to stand and say we will not permit the medical device industry to submit false and misleading information on labeling. We will see how that vote will go.

We include false and misleading under what they call the PMA's, which means the various medical devices that have to go through a more elaborate procedure. We have protections against false and misleading advertising on that. But we are going to say that the American public shouldn't be assured that when the medical device industry submits a particular product, that they do not submit information that is false and misleading. And what we mean by that is that they have an intention to use that various medical device for an entirely different purpose for which there have not been adequate safety standards established or safety records advanced. That is the issue, Mr. President.

That is a very, very important health issue. It is a very important one. You can say it is only one section out of a whole piece of legislation, but it is very important. First of all, let me review very quickly about how medical devices are approved in the FDA, so that we understand and put this into some criteria.

I want to go through examples of some of the problems that we are facing today. I'd like to let the American people make judgments and decisions about whether they think adequate safety information should be available for digital mammography and digital diagnostic x rays. Let the American people judge whether these devices should be used in surveying women who may have cancer when they haven't been approved for that.

Mr. President, let's get back to where we are today. In the light of today's revelations about fen/phen should we be thinking about a provision in this bill that would allow device manufacturers to get their products approved for off-label use on the basis of a false and misleading label.

There are two stories in the Wall Street Journal—one yesterday and one today—as well as one in the Post today, which tell us why the Senate should give a resounding ''no'' to this fen/phen device division.

The first article explains in detail how an unscrupulous drug company engaged in a broad conspiracy to illegally promote the use of a product for treatments that have not been shown to be safe and effective. This conspiracy involved the laundering of money, deceptive deals, and hospital physicians' coercion of honest employees who objected to these corrupt practices. Fortunately, companies which engage in these kind of fraudulent practices are the exception rather than the rule. But it is precisely the exceptions that make a strong FDA so critical.

The second story outlines the tragic results of off-label use of two approved drugs, dexfenfluramine and fenfluramine. These two drugs, used in unapproved combination for weight reduction, were found to have caused irreversible heart damage in thousands of women. In addition, there are early revelations that fenfluramine phentermine, known as fen/phen, had also caused severe heart damage.

This is truly appalling—women receiving medical assistance for weight reduction, assistance they have been led to believe was entirely safe but which has not been tested adequately for that use—ended up suffering severe heart damage.

The provision that is before us, rather than increasing protection for American consumers against products that have not been safe and effective, would actually reduce those protections. It would permit a device manufacturer to design a product for one use and falsely claim on the label submitted to the FDA that the device was for a different use. The FDA would be barred from protecting consumers. It would require the FDA to accept the manufacturer's label at face value. The FDA under this legislation has to accept the labeling that the manufacturer has put forward, even if it were false or misleading. Fen/phen should teach us that the American consumers deserve to be protected against unsafe product uses. But the provision before us goes in exactly the opposite direction. That is why the President has threatened to veto it. That is why a broad coalition of consumer health groups oppose it. And that is why the Senate should reject it.

Mr. President, as we know, there are two categories of medical devices. Let me give a brief explanation of how the

FDA regulates and clears medical devices for marketing. It will help clarify the need for this amendment.

Under the current law, the manufacturers of new class I and class II devices get their products onto the market by showing that they are substantially equivalent to devices already on the market. For example, the manufacturer of a new laser can get that laser onto the market if it can show the FDA that the laser is substantially equivalent to a laser that is already on the market.

Similarly, the manufacturer of a new biopsy needle can get that biopsy needle onto the market by showing that it is substantially equivalent to a needle already on the market. These manufacturers are obligated to demonstrate substantial equivalence to the FDA by showing that the new product has the same intended use as the old product, and that the new product has the same technological characteristics as the old product. If the new product has different technological characteristics, these characteristics must not raise new types of safety and effectiveness questions in order for the product to still be substantially equivalent to the older product.

So, if the product is substantially equivalent and doesn't raise new safety effectiveness questions, it moves on through. The logic of the process for bringing medical devices onto the market is simple. If the product is very much like an existing product, it can get to market quickly, but if it raises new safety or effectiveness questions, those questions should be answered before it gets on the market.

This process for getting new medical devices on the market, commonly known as the 510(k) process, is considered by most to be the easier route to the market. That process accounts for how 95 percent of all devices get to the market. Devices that are not substantially equivalent class I or class II devices already on market must go through a full premarket review. Thus, device manufacturers have an incentive to get new products on the market through the 510(k) process. In fact, well over 90 percent of the new devices get on the market through the submission of a 510(k) application. Section 404 of the bill prohibits the FDA from requiring safety and effectiveness data on any device following the 510(k) route except for uses the manufacturer chooses to put on the label, even if the label is false and misleading—even if the manufacturer says, ''We are just going to use it for cutting tissue, we are not going to use it for prostate cancer,'' knowing full well that they intend to use it for prostate cancer. All the world knows that they are going to use that device for prostate cancer. The FDA is prohibited from saying, ''Let us see where the safety is.'' Where is the safety information on that? That, Mr. President, is the issue.

Let me give you a few more examples.

On the biopsy needle for breast tumors, the needle is labeled for performing a biopsy. But the design clearly indicates that it is designed to remove tumors. Here you have a case where you have a small needle with a very narrow opening at the one end which is used for testing a biopsy of a particular tumor. Now the manufacturer comes in with a much broader needle, a much wider needle, and says, ''Look, our needle is for the same thing, just to biopsy the tumor.'' The design clearly indicates that it is built to remove tumors. Under the bill language, FDA could not ask for safety and efficacy data for the needle's use for tumor removal, even though that is clearly indicated by the designer of the device. The company comes in, and says, ''Look, we have a biopsy needle right here. Sure, ours is a little larger. But this biopsy needle is really absolutely intended to do the same thing as the others out there and, therefore, we are substantially equivalent,'' even though they are out there advertising that this needle can be used for removing a tumor. They don't have to provide any safety information about how safe or effective that device is for the removal procedure.

There is also the ''laser for cutting'' issue. The labeled use is for general cutting. But the laser has been adapted specifically and clearly to cut prostate tissue. Under the bill language, FDA could not ask for safety and efficacy data for cutting prostate tissue.

Digital mammography is currently approved and labeled for diagnostic x rays—which are used to confirm the suspicion of a breast tumor. If digital mammography is clearly going to be used for screening, based on the design of the instrument, which requires a higher degree of accuracy, FDA should be able to look at the effectiveness of that technology for that use. Without this assurance, too many women may undergo biopsies or be misdiagnosed. But this bill would prevent FDA from asking for the data needed to protect women.

Orthopedic implants—plates and screws for long bones—some implants are made to be removed after the bone has healed and, therefore, labeled for short-term use. But if the FDA determines from the design of the device, or from the particular materials that the implant will clearly be left in the patient on a long-term basis, FDA should be able to ask for safety and efficacy data. For example, how does the bone react to having the implant there over a long period of time? Is the bone weaker? But this bill would prevent the FDA from asking these questions.

Mr. President, I can go on, and will go on when we have the more general debate. But these stories exemplify the issue. The issue is safety. The issue is protecting the safety of the American consumer in regards to the use of medical devices which clearly demonstrate that the dominant use of those medical devices differs from what is put on the label.

It would surely seem to me that men and women of reason would be able to work this out in a spirit of order to provide those protections. But we have been unable to do so. Being unable to do so we should understand the real implications. As when you have the off-label use of fen/phen, and the concern of the American people and all of the newspapers all over the country. You would think that here in the U.S. Senate we would be thinking about how we are going to provide further protections for the American people instead of fewer protections. Here in this particular medical device provision, we are hamstringing the FDA and its ability to gather data on safety and efficacy when it is so clear that the devices are going to be used for in a manner that differs from the one claimed.

That is why many of us—not only the administration, but many public health groups and organizations that represent women—have been so concerned about this issue.

I withhold the remainder of my time.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. Mr. President, I yield myself 10 minutes.

The PRESIDING OFFICER. The Senator is recognized to speak for 10 minutes.

Mr. JEFFORDS. Mr. President, I think I would like to talk a little bit about where we are right now in the process.

We had an agreement this last weekend which would have allowed us to dispose of this bill without the necessity of going through the cloture process. But then fen/phen happened. All of a sudden the Nation is alarmed and concerned, and reasonably so. But to bring the pharmaceutical fen/phen issue into the device issue is disingenuous. The situation with fen/phen is that two different, approved drugs were used in combination on the basis that doctors found out that when used in combination they were more effective in achieving their purpose of reducing weight. It was determined by some astute doctors who noted that there were some problems being caused with respect to heart valves that there was a relationship between those problems and the drug combination. This was brought by the doctors to the attention of FDA, and the FDA immediately alerted the marketplace and called for a prompt in-depth evaluation. On the basis of further data the companies voluntarily removed them from the market.

Now we are talking about a very, very different issue when it comes to the device issue discussed by the Senator. For instance, let's go back to fen/phen. If a drug company had to test its drug in combination with every other drug that is on the market with which it might reasonably be expected to be used in combination, it would take decades before anything would be approved. Right now I have had a whiplash. I am taking two different drugs to

manage the injury. But I don't think anybody has done a study to figure out whether Ibuprofen and the other drug I am taking is going to create some problem for me. I hope they don't spend all of that time researching that question because we would never get anything approved. That is certainly the case with the devices, we must not allow the FDA to endlessly question device manufacturers about how physicians might or might not use their product in the future, especially if the manufacturer does not seek permission to market or promote for that use.

Again, we had an agreement going into this week that we would argue this device thing out, and then we would vote on it. Now that is off because of fen/phen. So we are now in the a post-fen/phen situation.

But let us remember that we just had a vote. It was 94 to 4 that we ought to go forward. Why? Last week we were delaying consideration over 6 pages of a 152-page bill, we are now talking about 2 pages of a 152-page bill. I agree that section 404 is an important issue. We need section 404 to correct problems at FDA.

Also, I am concerned that my good friend from Massachusetts is getting into an emotional argument about the security of people in this Nation, and that somehow we are threatening their security by this particular provision—I have been chastised in my own State, and perhaps the country, saying I am threatening the lives of all Americans with this bill. That is life in politics. You have to take that.

Let me talk about the issue that we have with respect to the devices.

While the past has been marked by advances for both patients and the economy, the present is increasingly troublesome, and the future is by no means assured. For both premarket-approved products and the 510(k) product—that is, nearly identical products—the FDA's review requirements have become more burdensome and are taking more time. This has resulted in the delay of approving new devices. That is the issue here. Should we have to wait years to get something which will help us, help our health, help save our life, because FDA wants to explore hypothetical uses of the product by physicians, acting on their own initiative?

This has resulted in the delay of approving new devices. Furthermore, the current regulatory system is not keeping pace with medical innovation. U.S. patients face delayed access to the newer, more advanced generations of devices. In some cases, Americans are going abroad to take advantage of these technologies. U.S. device firms are themselves moving production and research facilities to other countries.

A study conducted by Medical Technology Consultants, MTCE Ltd., found that patients in the United States wait up to three times as long as their European counterparts for Government approval of new medical devices. The study also found that higher risk, breakthrough medical devices were approved in Europe within 80 to 120 days, provided the manufacturer has passed an EU facility inspection, which is completed within 120 days. Similar devices take an average of 773 days to be approved in the United States. New lower risk devices entered the European market with no delay once a manufacturer has passed the initial facility inspection. Similar devices take an average of 178 days to be approved in the United States.

The FDA already takes four times as long to approve breakthrough medical devices as is allowed by U.S. statute—it has to do them faster—according to the Health Industry Manufacturers Association, HIMA. The approval times for these devices have nearly doubled since 1990. The FDA's record on approving incremental improvements to existing devices is similar, with approval times also nearly doubling since 1990. Manufacturers will not continue to research and develop devices in the United States—they will all be overseas—if they face such egragious delays. Patients presently have to wait for devices stuck in the FDA's pipeline, and manufacturers have little incentive to bring new devices into that pipeline in the first place.

According to another study conducted by the Wilkerson Group, a New York-based independent consulting firm, FDA delays in approving devices will lead to the loss of U.S. jobs to nations where approval processes are more streamlined—an estimated 50,000 jobs over the next 5 years. Governments in Ireland, the Netherlands and elsewhere have already begun to highlight the impediment of FDA regulatory delay in their marketing materials to attract United States businesses overseas. Such actions will erode our Nation's medical research infrastructure over time.

So we are going to be getting them all from Europe. That is not going to help us obtain better health care for our citizens.

I would say one of the problems we have had, and the reason we have PDUFA and everything else, is to try to help the FDA be more efficient and effective in getting through their duties. It is important that we become more effective and efficient in reviewing these devices. I point out we here in this country have a wonderful record, but it can be a better record.

Certainly another thing I would like to point out—why are the patients' representatives in favor of amendments that we have and consumers opposing them at times? Because consumers, obviously, are looking at it from a different perspective. They are not ill. They don't need it. So they say, ''Don't do anything that might hurt us. It is better to be safe and take a long time and delay it, than it is to put it on the market.'' That's fine. But if you are a patient, you say, ''Hey, wait a minute. I am willing to take a little risk. I am willing to take a little risk. I'm in bad shape.'' So you have to keep those things in mind when you listen to the arguments. In most all the cases, the patients certainly are on one side, in a sense, and the consumer is on the other.

With that, I reserve the remainder of my time.

Mr. KENNEDY. Mr. President, how much time remains?

The PRESIDING OFFICER. The Senator has 2 minutes.

Mr. KENNEDY. I yield 1 minute to the Senator from Rhode Island.

Mr. REED. I thank the Senator from Massachusetts for yielding time. Very briefly, what we have done in the overall FDA law is create an incentive for companies, under section 510(k) to get approval of class I and II devices, to go out and pick out existing devices and say the new device is substantially equivalent. This, I think, provides pressure for companies to go out and simply say we are going to do exactly what these other devices do, even though their new design might have many more capabilities. This is not an academic problem.

Take, for example, the issue of a biopsy needle. Typically these needles are very small. They remove a very small amount of tissue, about the size of a pencil tip. If the FDA was presented with a new biopsy needle that was claimed to be simply for biopsy of tissue but in fact removed 50 times that amount of tissue, a much, much larger bit of tissue, the suspicion would be that this is not just for biopsies, it's actually to remove the lesion. Yet under this law, today, as we speak, they could not look behind that claim on the label. They could not look behind it and say, give us some data about the removal of lesions. This is a serious public health problem. That is what we are addressing today. I hope, with Senator KENNEDY's direction and leadership, we can resolve this along with Senator JEFFORDS and his colleagues. I yield the remainder of my time.

Mr. JEFFORDS. I yield to the Senator from Indiana 2 minutes.

Mr. COATS. Mr. President, I don't intend at this particular point to get in a specific discussion over section 404. I just urge—clearly, there is a differing point of view. We heard from Senator DODD from Connecticut, who was involved in the drafting of the bill; and Senator JEFFORDS from Vermont, the committee chairman, explained this. This was someone who was directly involved in the 404 question and has been drafting the language and negotiating the language. This is clearly an issue we are going to have to address. The committee debated it. There has been negotiation subsequent to that. We are now in a position where we are going to have to agree to disagree. I just urge the Senator from Massachusetts, at the earliest possible time—I know it can't be done today given the problems we

have with scheduling the Interior appropriations bill—to bring the amendment to the floor and then let us have the debate and then let the Senate work its will by vote and then go forward. Hopefully, this is not something that is going to further delay passage and then implementation of FDA reform.

Every day we delay, many things happen, most of them bad. No. 1, we move ever closer to September 30, at which time the PDUFA, the drug prescription user fee which is used to provide the individuals with the resources necessary to expedite drug approval, expires. That expires on September 30. The House has yet to act on this. They are waiting for the Senate to act. We are trying to wrap up appropriations bills. The clock is ticking and we need to move forward with this so we can allow the House to go forward, get into conference, get the bills back here.

I wonder if I can ask additional time from the Senator from Vermont? Maybe an additional minute or two. I don't know how much time is left.

Mr. JEFFORDS. The Senator can have whatever time he wants.

Mr. COATS. I thank the Senator from Vermont.

Mr. President, it is going to be extraordinarily difficult for us to finish our business on this bill, unify the different positions between the House and the Senate, and get the legislation to the President of the United States before September 30 so we do not have to lay off people at FDA, so we do not have to further delay review of devices and drugs and health-saving and health-improving and lifesaving products for the American people. That is what all this is about, is expediting the process; not to short-circuit the process but just to bring some efficiencies to the process.

The United States lags dramatically behind our foreign competitors. But more important than that, we have American citizens who are being denied access to health-improving and lifesaving drugs and devices because of this huge backlog at FDA. So, we can continue to go through these debates, as the Senator from Vermont said, 2 pages out of 150 pages—an important part but a small part of the entire, overall reform bill.

I hope we can come to some reasonable agreement in terms of bringing forward amendments; where there are disagreements, agreeing to a time limit on debate of those amendments, let each side present their case and then let the Senate vote on the matter and then move forward. Delay, delay, delay simply postpones what is, or at least what I believe is, inevitably going to happen and what should happen. That is that a majority of the Members of the U.S. Senate, on a bipartisan basis, and a majority of the Members of the U.S. House of Representatives, on a bipartisan basis, and the vast majority of the American people, want to see changes in the current FDA so they can bring lifesaving devices and drugs and health-improving devices and drugs safely but efficiently to the marketplace so that people can utilize those without having to get on a plane and go to Mexico or a foreign country, so we do not have to keep shifting manufacturing facilities and jobs out of the United States into areas which have a more reasonable and effective review process.

Many of us thought the device section was resolved and closed and that—at least last week it was presented that the only remaining item left on the agenda was the cosmetics. We went through great drama here over the problem with cosmetics. Now cosmetics has been agreed to. All of a sudden we are back onto devices. Many of us are concerned that even if this issue is resolved, we will suddenly have a new issue appear that will further delay the steps that we need to take here in the Senate to move this legislation forward.

So, I ask our colleague from Massachusetts if we could at least set some schedule here to ensure that we do not go another week, that at least this week we complete debate on the amendments, move to final passage, and then allow the House of Representatives to begin their process. I am not asking him to respond. It's just a plea here that we have spent 2½ years, and each day we delay we run into problems with reauthorization of PDUFA and we run into serious, considerable delay in terms of bringing in the processes which will allow us to more efficiently do the work, the legitimate work, of the Food and Drug Administration.

How much time is left? I will be happy to yield whatever time is remaining back to the Senator from Vermont.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I just say to my good friend from Indiana, as well as the Senator from Vermont, I think if we could work this particular provision out we would probably be able to end this legislation today—tonight. I think this is really the last remaining major issue.

I know the Senator mentions the cosmetic issue and then this new issue was raised. This was one of the four items that were identified in the President's letter. I have identified this issue previously. We had a brief discussion on section 404 during the cosmetic debate.

But this, I believe, is really the last issue. There are other issues that other colleagues have spoken about, but I urge early time considerations if we are able to resolve this legislation. I shall try to do the best I can to continue to work on these issues.

If I can ask consent to have 1 more minute and then 1 more minute on his side, too? I ask unanimous consent to have 1 more minute on either side.

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

Mr. KENNEDY. We will try to work with the Senator hoping that we might now be able to work something out that will meet both the legitimate objectives that the Senator has and the concerns that I have discussed and share with the administration. I am not suggesting that FDA read the minds of all the device companies and determine every conceivable way that a device might be used. Instead that they be limited to the very narrow case where there is a predominant or dominant use or clearly defined use that would be intended that was not on the label. Perhaps an advisory group could make these decisions. I am not interested in trying to anticipate every possible use, just in those very narrow areas which I think pose a threat.

I will try to explore a compromise with both the Chair and the Senator. We are going to the Interior bill and then come back to the FDA reform bill, but as I indicated to Senator JEFFORDS earlier I thought there could be a very timely disposition of all of the remaining amendments.

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. KENNEDY. I thank the Chair.

Mr. JEFFORDS. Mr. President, I ask unanimous consent for 1 minute.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I will say, we will continue to cooperate to bring this to an expeditious ending. I thought we had that agreement. I am ready to enter another one. I hope by the time the Interior bill is over, we will have one. I urge us to work together. I yield back whatever time I have.

Mr. COATS addressed the Chair.

The PRESIDING OFFICER. The Senator from Indiana.

Mr. COATS. Mr. President, I am not sure what unanimous consent is required.

The PRESIDING OFFICER. One minute, I believe.

Mr. COATS. Mr. President, I ask unanimous consent for 1 additional minute to respond to the remarks of the Senator from Massachusetts.

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

Mr. COATS. Mr. President, the Senator from Massachusetts offers expediting of this process. No one wants to keep delaying it. We have been in negotiation for months, if not years. This particular item has been discussed, debated, turned upside down, dissected. I think we are at the point where the best way we can expedite this is simply to have the amendment offered, have the debate, let the Senate work its will. There are Members on both sides who are willing and able to present the case, and then let the Senate work its will.

Having said that, this Senator has on two occasions now responded to the Secretary of Health and Human Services, who personally called and asked

that I look at new language. I said I will be happy to look at new language, but it just seems every time we look at new language and make a concession, there is another issue that pops up. We made 30 some concessions. We don't want to have 31 and then 32.

I appreciate the offer of the Senator from Massachusetts, and we will continue to operate in that spirit.

The PRESIDING OFFICER. The time of the Senator has expired.

DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 1998

The PRESIDING OFFICER. The clerk will report the Interior appropriations bill.

The bill clerk read as follows:

A bill (H.R. 2107) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 1998, and for other purposes.

The Senate continued with the consideration of the bill.

Mr. KENNEDY. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. GORTON. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

AMENDMENT NO. 1188

Mr. GORTON. Mr. President, what is the order of business?

The PRESIDING OFFICER. The Ashcroft amendment is the pending business.

Mr. GORTON. Mr. President, I understand that the proponents of the Ashcroft-Helms amendment are not willing to vote on that amendment today and wish that vote to take place tomorrow so that they have a greater opportunity to discuss it both here on the floor of the Senate and in public. I am firmly of the opinion, because that is the amendment that deals with the National Endowment for the Arts in the most radical fashion, that it should be voted on first, because if it is defeated, there are other amendments, including one sponsored by the Presiding Officer, that may get a fairer and broader view if they are voted on in an appropriate sequence.

So I intend, and I believe the majority leader intends, to try to see to it that all Members who wish to speak on the National Endowment for the Arts and any of the four amendments that have been offered and spoken to so far have the opportunity to do so and that, at an appropriate time tomorrow, we vote first on the Ashcroft-Helms amendment, second on the Abraham amendment, third on the amendment of which the Presiding Officer is the sponsor, fourth, the amendment of Senator HUTCHISON of Texas, with I hope relatively small or short debate times in between the amendments, hoping that people will have had the ability to say all they wish to say about them in the course of discussing all of them together. There is no agreement at this point that this will be precisely the procedure, but I think it is likely.

In the meantime, for the remainder of the afternoon, we are open for business. There are two controversial provisions relating to Indian matters. I am attempting to get the other Senators, in addition to myself, to the floor as soon as possible to consider those. They will not require a vote but will take a certain degree of discussion.

I have been told that Senator BUMPERS will be willing to present one or more amendments this afternoon, to have them debated and perhaps to have a vote by early this evening. Assuming that he and/or his staff are within hearing, I hope that he will come to the floor as soon as possible and present his amendment and will notify his opponents or ask us to notify his opponents of the fact that he is doing so, so that we can talk about them.

We should not waste this afternoon, Mr. President. If we get some business accomplished today, there is still a very real possibility that we can finish debate on the Interior appropriations bill by tomorrow evening and go on to other questions. The debate so far has been healthy. I look forward to any Member who wishes to come to the floor and propose an amendment. With that, I yield the floor.

Mr. DOMENICI. Will the Senator yield?

Mr. GORTON. Yes, I will be happy to.

Mr. DOMENICI. Mr. President, I want to ask the Senator a question. I think he knows I am interested in the two Indian issues, and I gather at some point he is going to try to get the three or four Senators who have been working on this with him here?

Mr. GORTON. I asked, or caused to be asked, Senator CAMPBELL, chairman of the Indian Affairs Committee, Senator MCCAIN, yourself, Senator STEVENS, and Senator INOUYE to gather together as soon as most of us can make it. I think the lead in that is Senator CAMPBELL as chairman of the Committee on Indian Affairs. As soon as we can arrange that, even if we are on something else, I will see if we can interrupt and get this part of the bill completed.

Mr. DOMENICI. I thank the Senator very much. I yield the floor.

Mr. GORTON. For the time being, Mr. 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. SPECTER. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. SPECTER. I ask unanimous consent that I be recognized for 10 minutes to speak as if in morning business.

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

NEED FOR INDEPENDENT COUNSEL IN CAMPAIGN FUNDRAISING PROBE

Mr. SPECTER. Mr. President, the competency and appearance of integrity, if not the integrity itself, of the Department of Justice was called into sharp question when Attorney General Reno, FBI Director Freeh, and CIA Director Tenet briefed the Senate Intelligence Committee last Wednesday and the Senate Governmental Affairs Committee on Thursday.

In last week's briefing, the CIA Director advised that an individual, referred to here as ''X'', who had been identified in many news accounts as a major foreign contributor to political campaigns and campaign committees, has made significant contributions as part of a plan of the Government of China.

The CIA Director further advised that the CIA obtained that information about ''X'' from the FBI, and it only put the FBI information on ''X'' together with the news reports on ''X'' after an analysis which was made following a request by Senator BENNETT at the July 1997 FBI–CIA briefing of the Governmental Affairs Committee.

The FBI Director advised that the information about ''X'' had been in the FBI files since September or October of 1995 on one report and since January 1997 on a second report. The FBI Director advised that the Governmental Affairs Committee was not told about that information at the July 1997 briefing because the FBI did not know it had the information.

These disclosures raise a fundamental question of whether the FBI deliberately withheld the information or was not competent enough to know what information it had in its own files. Either alternative is a strong indictment of the FBI.

With the new information on ''X,'' the question is: Where do we go from here on dealings with the Department of Justice and the FBI?

When the FBI Director said the FBI did not know the FBI had the information on ''X'' in its files, based on my extensive dealings with Director Freeh, I accept and believe that he personally did not know the FBI had the information in its files. Frankly, I am not so sure that others in the FBI did not know of the import of that data.

This matter obviously adds fuel to the fire on recent questions about the FBI and Director Freeh's leadership of that agency. There are questions on many matters, including the FBI laboratory, the FBI's handling of the interrogation of Mr. Richard Jewel in the Atlanta pipe bombing case, the FBI allowing White House people to look at confidential personnel background files, and the FBI's handling of the Ruby Ridge incident after Judge Freeh became director, as well as before.