package is worth having. I hope we will continue to try to come to a conclusion today, if at all possible.

We will be completing work also this week on the Commerce, State, Justice appropriations bill as well as the Department of Transportation appropriations bill.

Previous agreement was entered into also last week to complete action on S. 39, the tuna-dolphin bill, early this week. So we expect that sometime in the next 2 days we will have a 30-minute time for debate and possibly a recorded vote, but a vote of some sort on the compromise that was worked out on that issue last Friday.

At 5 p.m. this afternoon, the Senate will begin consideration of the Transportation appropriations bill. We hope to get most of the work done on that appropriations bill tonight, done tonight. There will be no rollcall votes today.

Tomorrow morning the Senate will be scheduled to have a series of votes, or we were scheduled to have a series of votes with debate beginning at 8:30 and votes occurring, I believe, beginning at 9:30, on the Commerce, State, Justice appropriations bill, but we understand that there is a memorial service for Justice Brennan that will be held on Tuesday morning, so it may be necessary to delay these votes and, as always, Members will be notified exactly when that will be. There will be some stacked votes, I don't know right now whether it's 2, 3, or 4, with relation to Commerce, State, Justice. But it will be later in the morning or in the early afternoon, so we can accommodate Senators who would like to attend the memorial service. Then we can complete action on the bill.

I had hoped we would have agreement on the spending and on the tax relief bill early enough that we could actually get started on it on Tuesday morning. It looks like we will not be able to do that, but we still want to get the final votes on the State, Justice, Commerce appropriations bill as soon as we can and be prepared to move swiftly to the budget agreements once they are reached.

I thank all Senators for their cooperation. I know this will be, again, a hectic week. But I believe we can complete 2 more appropriations bills which will put us at 10, leaving only 3 that we would have to work on when we return in September. That is an incredible pace, and I am very pleased with the cooperation that we have had in getting that done. I hope we can continue that. We also, again, hope to complete action on two or three other bills; most important, the budget agreements. When that is completed, of course, we would then have an opportunity to turn to the Executive Calendar also.

Mr. President, I would like to hear from the distinguished Senator from Vermont as to what is the state of negotiations regarding the Food and Drug Administration reform package. I know he has worked very hard on it. We hope to get that done this week. I would be glad to hear his impressions of how we are going to do that.

Mr. JEFFORDS. Mr. President, I would be happy to enlighten the body as to where we stand. It is my understanding we have an agreement. However, it appears an objection will be raised if we try to move forward at this time. So, I would just alert everyone that I believe we have an agreement and that we will be able to move forward this week.

There are, as is always the case when you go to bring a measure forward, people who decide suddenly they want to be involved in the process. We will try to accommodate them. I know there are several Members who are out of the country right now and will be back later today. So, I don't intend to call up the FDA Act at this time, but I will, with the indulgence of the President, move forward, I suppose as in morning business, and discuss where we are on the bill.

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. If there is no objection, there will now be a period of morning business.

The Senator from Illinois.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

Mr. DURBIN. Mr. President, I would like to say at the outset that I have the highest respect for the Senator from Vermont. The Senator has done a great deal of work on one of the most important pieces of legislation which we will consider during the course of this Congress. Although I am not a member of his committee, I have an abiding interest in the Food and Drug Administration. For 12 years in the House I was a member of the subcommittee which funded the Food and Drug Administration. I was called on many times to get involved in issues related to this important agency.

It is an extraordinary agency. By Federal standards it is tiny. About $1 billion each year out of our $1.6 trillion budget is spent on the budget of the Food and Drug Administration. Yet every one of us, every American family, depends on the Food and Drug Administration. Many of the products which we take for granted are reviewed by them for safety so that our families can use them and feel confident that the product is safe for that use. Thus, when there have been efforts to reform the Food and Drug Administration, I have been very attentive. Some people are looking to reform the Food and Drug Administration for selfish reasons. Others are looking to reform the Food and Drug Administration for the right reasons. I believe the Senator from Vermont falls in the latter category. I believe he is trying to reform the FDA for the right reasons.

He and I may have a few differences of opinion, I think very few, and I hope that we have a chance, when this bill comes to the floor, to actually address them and perhaps, in the quiet of an off-the-floor conversation, we may come to an agreement on each of these items that I would like to discuss. But I salute him for the hard work which he has done in a bipartisan fashion to bring this matter to the floor.

It is my understanding, perhaps the Senator from Vermont could enlighten us, that the bill itself was not ready for consideration, was actually in draft form for Members' offices to read, until this weekend. And, if that is the case, although I would like to see us move on it this week, I'm sure we would all like at least a few moments to go through it and to reflect on the different changes that are proposed and the impact that they would have on this important agency.

Mr. JEFFORDS. If the Senator will yield?

Mr. DURBIN. I would be happy to yield for a question.

Mr. JEFFORDS. The bill itself has been ready for about a month and has been under examination for a month. In order to be able to proceed most efficiently and effectively in the amendment process, we have been working with Members—and you have asked us to do so today—to take into consideration possible changes in the bill. We had many requests of that nature over the past month, and we have accommodated, to my knowledge, every one of those requests and have been and are ready to proceed, with the understanding that certain amendments would be offered. Some of those amendments would be accepted and some of those would be disagreed with.

But we are under the exigencies of time here. This is such an important bill. We started negotiations, the Senate did, last year, under Senator Kassebaum. The bill was voted out of the committee by a very substantial vote. However, there were strong objections raised to it and problems with the House. So we started again this year with the bill and we have been working for several months, now, ironing out these difficulties and problems.

It was my understanding we had a consensus. That is why we are here on the floor this afternoon. On the other hand, now we understand that some others have reasons that they would like to participate. We have no problem with that. The problem is not ours, in the sense of the committee. The problem is time on the floor. We have just 1 week left before we go into recess in order to accomplish the major bills, the reconciliation and budget matters, and we will have only a limited amount of time. So, for us to proceed and get this finished by the end of the week, which is important, it is going to take agreement by those who now want to participate in order to have a timely process where we can bring this to conclusion.

I look forward to working with my colleague—I know he will cooperate

with us so that this very important piece of legislation can get passed out. The House is waiting to move until we move. Also connected with it is the Prescription Drug User Fee Act, PDUFA, which is very important to get passed because that expires at the end of September. So we must move ahead. I thank the Senator for giving his time.

Mr. DURBIN. If the Senator from Vermont will continue to yield for the purpose of a question, then it is my understanding we will not proceed to the bill itself today, that we will wait?

Mr. JEFFORDS. I am not proceeding to the bill at this time. I am hopeful and wait patiently with great expectations that at some point after having discussed with you and perhaps communicated with the minority leader that we will be able to move forward with the bill in a way that will utilize the time today effectively so that we can complete this bill by the end of the week. But I do not intend to call it up at this particular moment.

Mr. DURBIN. I thank the Senator from Vermont and pledge my cooperation to consider any amendments which might be necessary to be debated on the floor in a timely manner, sensitive to the limited time we have this week. He is correct, that if we do not move on this user fee question, it will expire and create great problems and complications at this important agency. We don't want that to happen. I share with him the belief that we can and should move this bill forward this week, and I look forward to working with him.

PRIVILEGE OF THE FLOOR

Mr. DURBIN. Mr. President, I ask unanimous consent that Anne Marie Murphy of my staff be accorded the privilege of the floor for the duration of debate, when it starts, on S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

PRIVILEGE OF THE FLOOR

Mr. JEFFORDS. Mr. President, I ask unanimous consent that Sean Donohue and Chris Loso, fellows with the Committee on Labor and Human Resources, be permitted the privilege of the floor during all Senate consideration of S. 830, the Food and Drug Modernization and Accountability Act.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. JEFFORDS. Mr. President, as we have just discussed, I am going to proceed so that my colleagues and those interested in this legislation can better understand the nature of this legislation and the importance of it, and, hopefully, later in the day, we will be able to proceed in an orderly manner through the amendment process.

The legislation is to modernize the Food and Drug Administration, and we authorize the Prescription Drug User Fee Act, which will, upon enactment, streamline the FDA's regulatory procedures. This modernization will help the agency review medical devices and drugs more expeditiously and will let the American public have access sooner to newer, safer and more effective therapeutic products.

I am disappointed that some of my Democratic colleagues are not desirous of proceeding at this time, but I will do my best to accommodate them and also to move forward on this bill. I am especially chagrined, given the months of bipartisan negotiating that has led to this bill. Each major provision—all of the drugs and medical device provisions of this measure—represents long-sought agreements with the minority and with the FDA itself. I do not understand this continued delay.

In particular, Senator KENNEDY has played a key role in reaching this agreement, and I wish to applaud his willingness and tenacity in working through several difficult issues to reach a consensus on this legislation.

In addition, Secretary Shalala and the FDA itself has worked diligently to reach reasonable, sensible agreements. This is a good, bipartisan measure that represents moderate yet real reform. It has been agreed to by the minority and the administration.

There is no reason for further delay, and I am going forward today with the expectation that before the end of the day, we will be moving forward on this bill.

On June 11, prior to the committee markup of S. 830, I received a letter from Secretary Shalala outlining the Department's key concerns. This was sometime ago. In her letter, the Secretary stated:

> I am concerned that the inclusion of non-consensus issues in the committee's bill will result in a protracted and contentious debate.

Before and since our committee markup, we have worked hard to achieve a consensus bill. The measure before us today accomplishes that goal. Bipartisan staff and Members have worked diligently with the agency to address each of the significant non-consensus provisions raised by the Secretary.

In her letter, Secretary Shalala expressed her feeling that the legislation would lower the review standard for marketing approval. Key changes have been made to the substitute to address these concerns. With respect to the number of clinical investigations required for approval, changes were made to assure that there is not a presumption of less than the two well-controlled and adequate investigations, while guarding against the rote requirement of two studies.

We made it very clear you don't have to do two, although it is quite acceptable for you to do two, but you shouldn't look at it as being required. It is not necessary.

The measure clarifies that substantial evidence may, when the Secretary determines that such data and evidence are sufficient to establish effectiveness, consist of data with one adequate and well-controlled clinical investigation and confirmatory evidence.

Concerns were raised also about allowing distribution of experimental therapies without adequate safeguards to assure patient safety or completion of research on efficacy. Changes to accommodate those concerns were made. They are in the substitute. We tighten the definition of who may provide unapproved therapies and gave FDA more control over the expanded access process.

Other changes will ensure that use of products outside of clinical trials will not interfere with adequate enrollment of patients in those trials and also give the FDA authority to terminate expanded access if patient safeguard protections are not met. The provision allowing manufacturers to charge for products covered under the expedited access provision was deleted also.

In mid-June, the Secretary argued that S. 830 would allow health claims for food and economic claims for drugs and biologic products without adequate scientific proof. In response, Senator GREGG agreed to changes that would allow the FDA 120 days to review a health claim and provide the agency with the authority to prevent the claim from being used in the marketplace by issuing an interim final regulation.

In addition, the provision allowing pharmaceutical manufacturers to distribute economic information was modified to clarify that the information must be based on competent and reliable scientific evidence and limited the scope to claims directly related to an indication for which the drug was approved.

This bill was further changed to accommodate the Secretary's opposition to the provision that would allow third-party review for devices.

Products now excluded from third-party review include Class III products. These are products that are implantable for more than 1 year, those that are life sustaining or life supporting, and also products that are of substantial importance in the prevention of impairment to human health.

In addition, a provision advocated by Senator HARKIN has been incorporated that clarifies the statutory right of the FDA to review records related to compensation agreements between accredited reviewers and device sponsors.

I want to point out that we have been working hard with Members, the Secretary, and others who brought problems to us, and we believe we have all of those taken care of, but we understand now we will have to do some more work today.

Finally, the Secretary was concerned about provisions that she felt would burden the agency with extensive new regulatory requirements that would detract resources from critical agency

functions without commensurate enhancement of the public health. This legislation now gives FDA new powers to make enforcement activity more efficient, adds important new patient benefits and protections, and makes the review process more efficient.

First, we give FDA new powers and clarify existing authority, including mandatory foreign facility registration, seizure authority for certain imported goods, and a presumption of interstate commerce for FDA-regulated products. Those are all important changes to help clarify the powers of the FDA.

Second, to assist patients with finding out about promising new clinical trials, we established a clinical trials database registry, accessed by an 800 number. Patients will also benefit from a new requirement that companies report annually on their compliance with agreements to conduct postapproval studies on drugs. This was an important provision that we added, working with Senator KENNEDY.

Third, FDA's burden will be eased by provisions to make the review process more collaborative. Collaborative reviews will improve the quality of applications for new products and reduce the length of time and effort required to review products. We also expressly allow FDA to access expertise at other science-based agencies and contract with experts to help with product reviews. This is very important to bring about more efficient and effective utilization of resources.

Lastly, by expanding the third-party review pilot program for medical devices, we build on an important tool for the agency to use in managing an increasing workload in an era of declining Federal resources.

In closing, I echo another part of Secretary Shalala's June 11 letter:

> I want to commend you and the members of the committee on both sides of the aisle on the progress we have made together to develop a package of sensible, consensus reform provisions that are ready for consideration with reauthorization of the Prescription Drug User Fee Act. . . a protracted and contentious debate . . . would not serve our mutual goal of timely reauthorization of PDUFA and passage of constructive, consensus bipartisan FDA reform.

I can't tell you how pleased I am that we have been able to work with the Secretary and come to this point now where we have few—I don't believe we have any disagreements—with the Secretary. Although we have some further matters we may have to discuss.

From the beginning of this process, all of the stakeholders have been committed to producing a consensus measure, and we have accomplished that goal. There is agreement on this bill, and I urge my Democratic colleagues to allow this important measure to move forward.

Before yielding the floor, I would like to commend the members of the committee. I have never worked with a group that has worked as hard as the members of my committee have to bring about a consensus. This has been night-and-day work for weeks. We have some outstanding Members on both sides of the aisle that have done outstanding work to bring us to this point. I could name them all, and I will eventually as we go forward, but I know standing and ready to go is one of those who has been of invaluable service to this committee. That is Senator FRIST. With his knowledge as a physician, his intelligence and ability to communicate in a way that brings about consensus, we have moved forward on some incredibly important goals for being able to assist our doctors in their pursuance of good health for all of us.

With that, Mr. President, I yield the floor.

Mr. FRIST addressed the Chair.

The ACTING PRESIDENT pro tempore. The Senator from Tennessee.

Mr. FRIST. Mr. President, I rise to speak on the issue of a bill which I am very hopeful will be considered shortly, and that is the Food and Drug Administration Modernization and Accountability Act of 1997. I came to the floor expecting, as we all had anticipated, that this bill would be considered today in the bipartisan spirit that has, in many ways, been reflected by working together over the past 2 years on a bill that will modernize the FDA, will strengthen the FDA and will, what I guess I care most about, improve patient care for the thousands, for the hundreds of thousands of people who will benefit from having speedier access to effective drugs, to effective therapies, to effective devices.

I am very excited about the bill, yet I am very disappointed now that my colleagues on the other side of the aisle have presented a situation where this bill cannot be considered today.

I am hopeful that over the course of today we will be able to reach some sort of agreement. I had thought we had reached that agreement, but obviously we have not, much to my disappointment and, I think, to the detriment of the United States and all those people who could benefit from having a strengthened FDA.

A comment was made earlier that the bill has not really been considered by a number of people. Again, that is a bit disappointing. The bill before us today really represents over 2 years of work conducted in committee and with people off of the committee that we just heard our distinguished chairman mention—2 years of work with one objective; that is, to modernize the Food and Drug Administration. I do want to emphasize the bipartisanship in committee, in the Human Resources Committee.

This bill was considered, was marked up, and the bill, with a 14 to 4 vote, passed out of committee to be taken to the floor. Throughout this process, our distinguished chairman, who we just heard from on the floor, has worked with the minority staff, with the minority Senators as well as the majority. Both Senator JEFFORDS and the majority, and Senator KENNEDY and the minority on the committee have negotiated in good faith to move forward.

During the months—and really this has gone on for months, in effect, for 2 years as we debated and discussed a very similar bill—but during the months leading up to committee passage—again, it has gone through the committee with a vote of 14 to 4—and continuing up to today, there have been a series of meetings between the FDA, between industry, between the administration and the committee staff, all gathered together in a bipartisan spirit, legislative and executive branch, working together to clarify provisions, to outline and to resolve those concerns between the various parties. And with a bill that is this major, that will impact every single American both in the current generation and in the next generation, it takes that working together, negotiating across the table, listening to everybody's concerns.

I am delighted—up at least, I thought, until 15 or 20 minutes ago—that those provisions had been discussed, that the debate had been outlined with negotiations and compromise carried out to where we have a very strong bill that will benefit all Americans.

The chairman of the committee, through which this passed again with a strong bipartisan vote, pointed out the importance of passing FDA reform over the next 6 to 7 days, or I guess the remaining 5 days now, when he referred to the expiring authorization of what is called PDUFA. This is favored.

The reauthorization, which is expiring—the authorization is expiring—the reauthorization is supported by the FDA, it is supported by the U.S. Congress, it is supported by the administration, and it is supported by industry. This law has been a great success. It must and will be extended for another 5 years. It is an integral part of the FDA reform and modernization bill that I hope will be introduced this week.

If in some way this aspect of the bill is blocked, despite the fact that both sides—that all sides—want it to move forward, there is the potential that as many as 600 FDA reviewers that are employed because of PDUFA, which speeds up, which accelerates the approval process to get drugs out to the American people, could be at jeopardy. That must be addressed this week. Furthermore, patients awaiting the drugs that will be approved at an expedited rate of PDUFA will wait and wait and wait if this is not continued.

PRIVILEGE OF THE FLOOR

Mr. President, at this juncture, I ask unanimous consent that privileges of floor be granted to a member of my staff, Dr. Clyde Evans, during the period between now and 3 p.m., Monday July 28.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. FRIST. Mr. President, I would like to speak to a specific aspect of the bill that reflects, I think, the bipartisan spirit, the working together to the benefit of individual patients or future patients, to the benefit of children today, of hard-working men and women across this country. It has to do with the whole topic of dissemination of scientific medical information. This aspect of the Food and Drug Administration Modernization and Accountability Act of 1997 is a very important one, but one that has been contentious in many ways and in many people's minds has been the most contentious part of the FDA bill.

It all stems back to legislation that was introduced by my distinguished colleague from Florida, Mr. MACK, and myself 2 years ago. It focuses on the fundamental aspect which is so important to the practice of medicine today, to the delivery of care today, and that is to allow a free flow of good, accurate information that can be used to benefit people who need health care and health care services. It focuses on the dissemination of scientific medical peer-reviewed information to physicians and other health care providers.

As I said, this is an important aspect of the bill which I hope will be introduced. It will result in more scientific information on uses of FDA-approved drugs in an off-label or extra-label manner. Again, these are products that have already been approved by the FDA, but they are used very commonly in fields such as pediatric medicine, the practice of delivering care to children today while they are in the hospital, used very commonly in the treatment of cancer therapy. As much as 90 percent of all of the uses of drugs in oncology or the treatment of cancer are used in what is called an off-label or extra-label manner.

These provisions, which are a part of the underlying bill, represent a lot of hard work, as was implied by the distinguished chairman, a lot of bipartisan support which has been demonstrated especially over the last 2 months but really over the last 6 months.

Specifically, I want to thank my colleagues on both sides of the aisle, Senator MACK, who I mentioned, Senator DODD, Senator WYDEN and Senator BOXER, all of whom have remained throughout committed to this issue and have demonstrated real leadership in their bipartisan working together to come up with a piece of legislation that will be to the benefit of all Americans. I, too, want to express my appreciation to Secretary Shalala for her willingness to work, along with Senator KENNEDY, on what had been considered, as I mentioned, one of the most contentious issues initially of FDA reform. Now we have a bipartisan consensus agreement among all parties in this body with the FDA and with the administration.

The information dissemination provisions do represent a compromise, a balanced compromise, but they really ultimately respect the importance of physicians receiving up-to-date, independently derived scientific information, as well, at the same time to pursue, when possible, getting those prescribed uses ultimately approved on the label by the FDA. Thus, we have to address the dissemination of information. But what we have come to by these very careful, balanced negotiations is this linkage to actually improving and reforming the supplemental application process. The goal among almost all of us is to get as many of these uses today on the label.

Now, what does off-label mean? Off-label scares people. As a physician, as someone in my thoracic oncology practice, as someone who routinely every week treated cancer patients, I have some responsibility to define for my colleagues what off-label means. Off-label scares people. Is it somebody going in some secret closet and pulling out a medicine and using it? No, it is not. That is why extra-label is probably a better term. But right now off-label is something that we in the medical profession understand is used routinely in the pediatric population and, as mentioned earlier, for inpatient hospitalization. Probably 50 percent of all pediatric drugs prescribed are off-label. So it is not a term to be scared of or to fear.

In off-label use, it is simply the use of a drug which has been approved by the Food and Drug Administration in a way that has not yet specifically been indicated on the label. It might be using that drug in a combination with other drugs for an intended benefit. It might be a different dosage of that drug. It really comes down to the standpoint that the halflife of medical knowledge is moving quickly. We all know that.

We know how fast science is moving, how fast medical information is changing. That change is skyrocketing and accelerating over time. Clearly, you have an FDA which, and appropriately to some extent, has to be very careful, has to rely on large clinical trials, and has not been as good historically in the past as we would like for it to be in terms of approving over time. That FDA cannot approve every single use of every single drug in the field of health and science which is moving at skyrocketing speed, accelerating speed.

An example, aspirin, has been used off-label for years to prevent heart attacks. People generally know today taking a baby aspirin today or an aspirin every other day is effective in preventing heart attacks in certain populations. But right now, if you read on the label, there are certain limitations as to the use of aspirin. It is not specified that aspirin can be used prophylactically to prevent heart attacks today.

Another example which reflects the importance of off-label or extra-label use in a world where science is moving very quickly is that of the use of tetracycline. When I was in medical school, even 10 years ago, the whole theory of ulcer disease was based on a component of acid. Acid clearly plays a very important role, but what we did not know—in fact when I first heard it myself when I was a resident, I said, ''No way; impossible.'' But what was figured out is that antibiotics can help cure ulcers because the etiology of ulcer disease, of certain types of ulcer disease, is based on a bacterium.

Well, we know that today. Yet tetracycline and the use of tetracycline, a very common antibiotic which is used for many other reasons, does not have an on-label use for the treatment of ulcers. Yet there are thousands of people right now taking tetracycline to treat their ulcer disease—that is an extra-label use, an off-label use—under the law, of course. With 90 percent of my oncology patients using off-label-use drugs, with 50 percent of my pediatric patients using off-label drugs, with tetracycline, physicians are allowed legally, of course, to use and prescribe drugs for off-label uses.

In addition to being a thoracic oncologist—and I will have to add that I was codirector of the thoracic, which is chest, oncology cancer treatment; and lung cancer is the No. 1 cause of cancer death in women today—that for the medical treatment of thoracic cancers, of lung cancer, well over 95 percent of the treatment is off-label today.

In my field of heart and lung transplant surgery, many of my patients are alive today, of the hundreds of patients whom I have transplanted, because of the off-label uses of FDA-approved drugs. Then, in my routine heart surgery practice, where I have put hundreds of mechanical valves in patients over the last several years, there is another great advantage of off-label drugs.

About 40 years ago, the first mechanical heart valves were put in to replace defective valves scarred by rheumatic heart disease. These mechanical valves are replaced routinely. This started in the early 1960's, about 40 years ago. But it was not until March 31, 1994, just 3 years ago, that the off-label use of Coumadin, the blood thinner which all these patients are on and have been on for the last 35 years, that it was ultimately approved for on-label use, according to FDA.

It has been clear in the literature and among my colleagues that Coumadin, this blood thinner, is not only important, but lifesaving for those who have received medical valves. So dissemination of information is important. It is important for physicians to be able to have the latest information, to have the free flow of information. Why? In order to best treat, using the latest techniques and the most effective therapy, the patients who come through their door that they treat in the hospital. Dissemination of information,

with appropriate balance and disclosure, will allow sharing of this type of information with physicians and with other people who can take advantage of it.

Let me just close with one further explanation about why it is important. We are talking about this information going to people who are trained to consider this information. Right now, there are barriers there, which means if I were a physician practicing in rural Tennessee, I am not likely to be going to Vanderbilt or the local academic health center and participating in conferences every week. If I am in rural Tennessee, where do I get my information? I get it from what I learned in medical school, but there is a problem with that because we already said the half-life of medical knowledge is shorter and shorter, with the great discoveries that we have today. I am most likely to read medical journals. Yes, there are many, many journals that it is important for me to read to keep in touch with. I could search the Internet. But to be honest with you, your typical physician is so busy today delivering care, it is very unlikely that they are going to sit down at a computer terminal in rural Tennessee and go to the Internet and get information.

In fact, last year, in testimony before the Labor Committee, Dr. Lindberg at the National Library of Medicine testified before the committee, and explained how vast this literature is out there. He was talking about MEDLINE, which is the primary medical database that is used, in which all of the peer-reviewed journals are placed on this computerized data base. He explained the challenge that physicians have today in the following way:

MEDLINE contains more than 8 million articles from 1966 to the present. It grows by some 400,000 records annually. If a conscientious doctor were to read two medical articles before retiring every night, he would have fallen 550 years behind in his reading at the end of the first year.

Now, in medicine, where one's health and one's life is in the hands of the physician, I don't see how people can argue about free and appropriate dissemination of information to best benefit that patient, to take care of you as an individual. Yet, there are barriers there. We, probably unintentionally, over time, have created barriers that now we need to take down, to allow the appropriate and balanced dissemination of information to be to the benefit of that physician who is going to be seeing my colleagues, their children and their spouses in the future. More information, I feel, is better, as long as it's balanced, peer-reviewed, and safeguards are built in to make sure that it is not used for promotion.

Mr. President, I will yield the floor soon. This is an issue that I really want to just underscore this day because it represents bipartisanship, working together with the distinguished colleagues on both sides of the aisle. It started from a bill that was introduced in the Senate by the Senator from Florida [Mr. MACK], and myself. It has been greatly improved. How? By sitting around the table with the administration, with the FDA, with colleagues on both sides of the aisle to the point that we, when we pass the overall bill, will be able to improve the health care of individuals across this country.

I feel this is one of the most important aspects of this bill. Again, I call on my colleagues on both sides of the aisle to come together so that we can bring up the underlying bill and pass it to the benefit of all Americans.

I yield the floor.

Mr. WYDEN addressed the Chair.

The ACTING PRESIDENT pro tempore. The Senator from Oregon is recognized.

Mr. WYDEN. Mr. President, I strongly urge my colleagues to join today in bipartisan support for this important piece of legislation. In doing so, I want to commend Chairman JEFFORDS, in particular, and Members on both sides of the aisle, because this bill, in my view, meets the central test for good FDA reform legislation. An FDA reform bill ought to keep the critical safety mission for the Food and Drug Administration, while at the same time encouraging innovation—innovation that is going to produce new therapies and save lives. This bill meets that twin test.

This bill is a result of, as several of our colleagues have noted, much debate and an extraordinary effort to build consensus. I am proud to have played some part in that effort as a Member of both the House of Representatives and the U.S. Senate, having introduced, more than 2 years ago, H.R. 1472, the FDA Modernization Act, which contains several of the key ingredients of the legislation before us today.

Mr. President, from the time we get up in the morning until the time we go to bed at night, we live, work, eat, and drink in a world of products that are affected by decisions made at the Food and Drug Administration. Perhaps no other Federal agency has such a broad impact in the daily lives of average Americans.

Food handling and commercial preparation often occurs under the agency's scrutiny. Over-the-counter drugs and nutritional supplements, from vitamins to aspirin, are also certified by the agency.

Life-saving drugs for treatment of cancer, autoimmune deficiency, and other dreaded diseases, are held to its rigorous approval standards.

Medical devices ranging from the very simple to the complex, from tongue depressors to computerized diagnostic equipment, all have to meet quality standards at the FDA.

These products that are overseen by the FDA are woven deeply into the fabric of our daily lives, and the agency's twin missions of certifying their safety and effectiveness is supported by the vast majority of Americans.

Yet, balancing those missions against the time and expense required by companies to navigate the FDA approval system has often been difficult and controversial. In the last Congress, radical transformation of the agency, even ending the agency as we know it and replacing it with a panel of private sector, expert entrepreneurs, became a goal of some.

At the very least, reforming the Food and Drug Administration at the beginning of the last Congress looked to be an exercise fraught with partisan political turmoil, and destined for ongoing gridlock.

But while there was focus on the extreme ends of the argument—those folks arguing for no changes against Members demanding wholesale dismemberment of the agency—a broad, bipartisan group of Members of Congress developed.

With the help of Vice President GORE's Reinventing Government Program, Members of Congress from both political parties developed practical, bipartisan solutions to the critical management issues that the FDA approval process presents.

I sought to mobilize this bipartisan movement with H.R. 1472, introduced in June 1995. Some in my party thought I had gone too far, too fast. But I am gratified that many of the elements of this legislation, strengthened in this legislation, are going to be considered by the Senate.

These include, first, a streamlining of approval systems for biotechnology product manufacturing. It is clear that the rules for biotechnology, so central to health care progress, have not kept up with the times. This legislation will allow biotechnology to move into the 21st century with a realistic framework of regulation.

The bill allows approval of important new breakthrough drugs on the basis of a single, clinically valid trial.

It creates a collaborative mechanism allowing applicants to confer constructively with the FDA at critical points in the approval process.

It sets reasonable, but strict, timeframes for the approval of decisionmaking.

It reduces the paperwork and reporting burden now facing so many small entrepreneurs when they make minor changes in the manufacturing process.

It establishes provisions for allowing third-party review of applications at the discretion of the Secretary.

It allows manufacturers to distribute scientifically valid information on uses for approved drugs and devices, which have not yet been certified by the Food and Drug Administration.

Each of those areas, Mr. President, was in the legislation that I introduced more than 2 years ago, and with the bipartisan efforts that have been made in this bill, each of them has been strengthened. I am especially pleased that Senators MACK, FRIST, DODD, BOXER, KENNEDY, and I could offer the provisions of this legislation relating

to the dissemination of information on off-label uses of approved products.

This provision will allow manufacturers to distribute scientifically and clinically valid information on such uses following a review by the Food and Drug Administration, including a decision that I proposed more than 2 years ago, which may require additional balancing material to be added to the packet.

Here is why that is important. Manufacturers with an approved drug for ovarian cancer may have important, but not yet conclusive, information from new trials that their drug also may reduce brain or breast cancers. That data, while perhaps not yet of a grade to meet supplemental labeling approval, may be critically important for an end-stage breast cancer patient whose doctor has exhausted all other treatments.

That doctor and that doctor's patient have the absolute right to that information. It is time for this policy of censorship at the Food and Drug Administration to end. I believe that, with the legislation that will come before the Senate, it will be possible for health care providers to get this critical information and do it in a way that protects the safety of all of our citizens.

This legislation is going to save lives, not sacrifice them. It is going to mean that more doctors and their patients will have meaningful access to life-saving information about drugs that treat dread diseases like HIV and cancer.

It will mean that biologic products will have a swifter passage through an approval process which no longer will require unnecessarily difficult demands with regard to the size of a startup manufacturing process.

It will mean that breakthrough drugs that offer relief or cures for deadly diseases, for which there is no approved therapy, are going to get to the market earlier on the basis of a specially expedited approval system.

Mr. President, legislation, indeed laws, are only words on paper. Mr. President, we must also have a new FDA Commissioner who is committed to the changes in S. 830, just as committed to those changes as former Commissioner David Kessler was committed to the war on teenage smoking.

This bill goes a long way to making sure that the Food and Drug Administration is prepared to meet the challenges of the 21st century. But we also need to make sure that at the FDA, at that agency, there is a new commitment at every level to carry out these changes.

I believe that it is possible to keep the mission of the Food and Drug Administration—that all-critical safety mission, a mission that Americans rely on literally from the time they get up in the morning until the time they go to bed at night—while still ensuring that there are opportunities for innovation in the development of cures for dread diseases.

Mr. President, I also want to conclude by thanking a member of my staff, Mr. Steve Jenning. For several years now, he has toiled on many of these provisions with Members of Congress on both the House side and the Senate side, to help bring about this legislation. He has, in my view, done yeoman work, and I want to make sure that the Senate knows about his efforts. I know my colleagues in the House are very much aware of him.

So we all look forward, on a bipartisan basis, to seeing S. 830 come to the floor. It is a bill that is going to make a difference in terms of saving lives. The Senate needs to pass it and needs to pass it this week.

Mr. President, I yield the floor.

Mr. JEFFORDS addressed the Chair.

The ACTING PRESIDENT pro tempore. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, first of all, I want to thank the Senator from Oregon for his support and for his very effective presentation. I know there are so many of us here who want to work together. In fact, just about everybody does. That is why it is of such concern to me that we now find ourselves in a position where we can't proceed. I know of the Senator's immense assistance in helping us in this matter, and I appreciate what he has said.

Mr. President, I think it would be wise at this point, while we are biding time in the hopes of being able to move forward, to answer the questions that many people have: Why are we here? What is the big deal? What is so important? Why are we anxious to get moving and to get this piece of legislation passed?

I would like to go through some of the problems that we have right now with the FDA because it is our lives and our health that are at stake here. The time delays that occur because of the various problems at the FDA that we are trying to correct mean that new therapies that would be essential to your life and health, proceed so slowly that many, many people are deprived of the hopes and dreams we all have of a good health and a good life.

Let me provide some examples. By law, FDA is required to review and act on applications for approval on drugs within 180 days. Now, that 180 days was not just pulled out of the air. That was looking at the normal processes you would be able to do it in 180 days. According to FDA's own budget justification for fiscal year 1998, it takes the agency an average of 12 months longer than the statute allows to complete this process. It takes, on average, a year and a half for a process that should take 6 months.

Since the 1960's to the 1990's, complete clinical trials, that is, the time required by FDA to show for efficacy of drugs, has increased from 2.5 to nearly 7 years. Between 1990 and 1995, the FDA average approval time, that is, the time after the clinical trials have been completed, was about 2.3 years.

Today, only 1 in 5,000 potential new medicines is ever approved by the FDA. According to a recently published study, from the beginning of the process to the end, it takes an average of 15 years and costs in the range of $500 million to bring a new drug to market.

Why does this process take so long? Before FDA even gets involved in the process, innovators spend an average of 6½ years in early research and preclinical testing in the laboratory and with animal studies. Long before human tests begin, a summary of all the preclinical results is submitted to the FDA. This document, known as the investigational new drug application, or IND, contains information on chemistry, manufacturing data, pharmacological test results, safety testing results and a plan for clinical testing in people.

If the FDA judges the potential benefits to humans to outweigh the risks involved, the stage is set for three phases of clinical trials to begin. Taken together, the three phases of clinical trials in human populations average about an additional 6 years.

Phase I clinical trials focus on safety. During about a 1-year period, very low doses of compound are administered to small groups of healthy volunteers. Gradually, they are increased to determine how the bodies react to the different levels.

Phase II clinical trials last about 2 years; that is, 2 additional years. They involve 100 and 300 patient volunteers, and focus on the compounds effectiveness. These are blinded trials that are held in hospitals around the country where they compare the innovator compound with a so called placebo—that is the control group is not given anything. The effect of the innovator drug is compared with effect on those who received the placebo. Three out of four prospective drugs drop out of the picture as a result of the data collected during these phase II trials.

Phase III trials involve one or more clinical trials where researchers aim to confirm the results of earlier tests in a larger population. Phase III lasts from 2 to 5 years and can involve between 3,000 and 150,000 patients in hundreds of hospitals and medical centers. These tests provide researchers with a huge database of information on the safety and efficacy of the drug candidate to satisfy FDA's regulatory requirements.

The amount of data required to file for the next new phase, new drug application, or NDA, is staggering. The application for new drugs typically runs to hundreds of thousands of pages in length. For example, in 1994, the NDA for a groundbreaking arthritis medication contained more than 1,000 volumes of documentation that weighed 3 tons. It included data from clinical tests in roughly 10,000 patients, some of whom had been taking new medication 5 years.

During the NDA review process—which can last an additional 2½ years, Government officials have extensive

contact with the company. They visit the research facilities and talk to the doctors and scientists involved in the research. In addition, FDA officials visit and approve the manufacturing facilities and review and approve all the labeling, packaging and marketing that will accompany the product.

Well, that is good and we want the FDA to be thorough, but things can be done more efficiently and more effectively. If we cannot reduce these times based on the consensus agreements in this bill—then a lot of people will lose the timely availability and the utilization of these breakthroughs.

What does this reducing of overall time mean for Americans? If we can reduce this overall time, it means quicker access to safe and effective lifesaving drugs.

I want to point out that the FDA, when it reviewed priority applications, has been able to make breakthroughs in AIDS and elsewhere by just being more efficient.

Also, for instance, to give you an example of review process delay, over 12 million type-2 diabetics had to wait almost 2 years for a new machine to be approved. Almost 2 million American women with breast cancer had to wait almost 2 years in excess of what should have been required for this review process.

So when that you have that kind of delay, you know you have to have reform, and that is why we are here. Some may argue that the long period of review and approval time is the price we pay for ensuring drug safety and efficacy. But that long delay does not hold true for all drugs. We know the FDA can significantly reduce its approval times because it has already done it. We have, for instance, with respect to the AIDS therapies, the so-called protease inhibiters that were approved in a matter of months. FDA can do more to ensure that they receive timely attention, and S. 830 will help FDA do so for all promising therapies. FDA is aware of this, and that is why they have been working to help simplify the law, simplify the process, simplify the procedures, so that we can get these drugs to market on time without in any way infringing upon the necessity to protect the health of our people.

So as we proceed, I will review these issues in a more definitive manner. But as we await removal of an objection to proceed, I just wanted to remind people that there are real, valid, deep concerns that we are facing here. Our goal is to make sure the health of our Nation can improve and that people will be able to have access to the innovative therapies that will benefit their lives.

Mr. President, I yield the floor.

Mr. FRIST addressed the Chair.

The PRESIDING OFFICER (Mr. THOMAS). The Senator from Tennessee.

Mr. FRIST. Again, I would like to commend the chairman of the Labor and Human Resources Committee for the outstanding work he has done in shepherding through the committee and now, hopefully, later today bring to the floor an act which will modernize and strengthen the FDA and will be to the real benefit of all Americans to make sure that health care services are given in an expeditious way to the American people.

As I mentioned in my earlier comments in the Chamber, a central aspect of health care today is the dissemination of information to physicians, to health care providers so that both will know, understand and have access to and be able to use appropriately that information to serve their patients, the so-called off-label or extra-label provisions I introduced this morning, and I want to share once again my delight in the fact that in a bipartisan way, working with Senators KENNEDY, WYDEN, BOXER, MACK, myself, and the distinguished chairman, we have come together and worked with the administration and the FDA to address this very important issue of dissemination of information.

As I mentioned, off-label uses are really prominent in health care today. The American Medical Association estimates the off-label or extra-label use of drugs that have already been approved by the FDA to be in the range of 40 percent to 60 percent of all prescriptions. Of all prescriptions written today, 40 to 60 percent are estimated by the American Medical Association to be off-label, and there have been very few problems associated with this off-label appropriate use. In treating hospitalized children, it has been estimated that over 70 percent of the drugs are prescribed to be off-label, and that can vary anywhere from 60 to as high as 90 percent, and for diseases such as cancer the figure can be as high as 90 percent.

As a lung cancer surgeon—I mentioned earlier the treatment of lung cancer today—the medical treatment of lung cancer involves well over 80, more in the range of 90, percent of all medical treatment being off-label. And that is that the drugs already approved by the FDA are used either in a dosage or in a combination with other drugs that have not yet been approved or studied through the FDA process. That can be improved in lots of ways and that is part of the underlying bill, to strengthen the FDA by making the approval process more efficient. People ask me frequently, why aren't all uses of drugs, if they are really effective, if they are really valuable, if they really improve patient care, why aren't they on the label?

A goal of all of us, I think, is to get as many on the label as possible. But in answering that question, I first cite the American Medical Association's Council on Scientific Affairs, which met this spring to consider all of these issues and to make recommendations regarding information dissemination and what we call the supplemental approval process; that is, a drug has been approved for a specific indication at a specific dose and if it is discovered through medical science that a different dose or another medication is in order, why can't you get that in a supplemental way on the label. The AMA's Council on Scientific Affairs, in explaining why there are currently so many medically accepted, commonly used, unlabeled uses of FDA-approved drugs, states:

> The simple answer is that FDA-approved labeling does not necessarily reflect current medical practice.

In their comments, they go on to explain that manufacturers may not seek FDA approval for all useful indications for a whole range, a whole host of reasons, including:

> The expense of regulatory compliance may be greater than the eventual revenues expected—e.g. if patent protection for the drug product has expired or if the patient population protected by the new use is very small.

The point is, if you have a drug in your pharmaceutical company and you know it is good, yet it will benefit very few people in a population and you know it is going to cost you millions and millions of dollars and years and years of trying to put through these clinical trials, what incentive do you have when the benefit is to such a few number of patients out there? Thus, we need to lower that barrier, make the supplemental approval process for these extra-label or off-label uses easier, lower that barrier.

Patent protection. Once a manufacturer has invested a lot of money and time in clinical trials and meeting the regulatory requirements of the Food and Drug Administration, they are protected for a period of time through the patent, but once the patent expires, what then is their incentive to go out and get this off-label use put on the label when they have to go through so many hoops, through what all of us know is an inefficient process today?

The good news is that the underlying bill addresses the supplemental process. It links off-label use or dissemination of information about off-label use to a future application.

Now, the supplemental process—and what I am even more excited or equally excited about is it makes that supplemental process more efficient, with more incentives for the manufacturers to seek what is called a supplemental new drug application.

Going back to the AMA's Council on Scientific Affairs, they say:

> A sponsor also may not seek FDA approval because of difficulties in conducting controlled clinical trials. ([For example,] for ethical reasons, or due to the inability to recruit patients).

''Finally,'' and again I am quoting them:

> . . . even when a sponsor does elect to seek approval for a new indication, the regulatory approval process for the required [Supplemental New Drug Application] is expensive and may proceed very slowly.

In fact, they continue to explain a little bit later, that the past review

performance for SNDA's, Supplemental New Drug Applications, is

. . . unexpected because the SNDA should be much simpler to review than the original [New Drug Application], and suggests the FDA gave much lower priority to reviews of SNDAs.

The point is, we need to improve the underlying supplemental new drug application process and this bill does that as well. I am very hopeful that this bill can be brought to the floor because you can see the number of good things that are in this bill that will speed and make more efficient the overall approval process with safeguards built in that will protect the American people from dangerous drugs, the unnecessary side effects of drugs or devices.

The underlying bill, again pointing to the real advantages of getting this bill to the floor, includes additional incentives for manufacturers to seek supplemental labeling, including added exclusivity for those seeking pediatric labeling. Again, encouraging—and we know, if you look back historically, we as a nation have not done very well, in terms of aiming labeling for the pediatric population, a place where these drugs are so critical, are so crucial for our children, my children, your children. We need to do better there and this bill addresses that.

Also, the underlying bill requires that the FDA publish performance standards for the prompt review of supplemental applications. It requires the FDA issue final guidance to clarify the requirements and facilitate the submission of data to support the approval of the supplemental application. And it requires the FDA to designate someone in each FDA center who will be responsible for encouraging review of supplemental applications and who will work with sponsors to facilitate the development of—and to gather the data to support—these supplemental new drug applications. Moreover, the Secretary, as specified in the bill, will foster a collaboration between the Food and Drug Administration and the NIH, the National Institutes of Health, and the professional medical societies and the professional scientific societies, and others to identify published and unpublished studies that could support a SNDA, a supplemental new drug application. The point is to improve that communication, that working together. Finally, in the bill, the Secretary is required to encourage sponsors to submit SNDA's or conduct further research based on all of these studies.

Again, this drives home the point that the underlying value of this bill dictates that it be brought forward to the floor, that it be debated, that it ultimately be passed and taken to the American people—all of these provisions which I cited—to improve the FDA's commitment to the SNDA process, to improve the agency's communication with manufacturers regarding the requirements for SNDA's, and the requirements that in most cases the manufacturers submit approved clinical trial protocols and commit to filing a SNDA before disseminating scientific information about off-label uses—all will improve the number of supplemental indications pursued by manufacturers.

To be certain of the impact of all of these provisions, the dissemination provisions sunset after a completion of a study by the Institute of Medicine to review the scientific issues presented by this particular section, including whether the information provided to health care practitioners by both the manufacturer and by the Secretary is useful, the quality of such information, and the impact of dissemination of information on research in the area of new uses, indications, or dosages. Again, special emphasis in the bill is placed on rare diseases and is placed on pediatric indications.

Indeed, limiting information dissemination to off-label uses undergoing the research necessary to get it on label has been a real subject of negotiation and compromise in this bipartisan discussion with the FDA and the administration and representatives from Congress. However, the point is that we have done that. It is now ready to be brought to the floor, to be talked about among all of our colleagues if they so wish. Those negotiations and those compromises have been carried out. It is time now to bring that to the floor. We have worked to accommodate many other concerns of our fellow colleagues in the U.S. Senate, concerns among the FDA and other organizations. The provisions outlined in the amendment have changed a great deal from the original bill that was proposed by Senator MACK and myself during the 104th Congress, and it makes it a better bill, a stronger bill, one that I think will benefit all Americans.

In general, in the bill, manufacturers will be allowed to share peer-reviewed medical journal articles and medical textbooks about off-label uses with health care practitioners only if they have made that commitment to file for a supplemental new drug application within 6 months, or if the manufacturer submits the clinical trial protocol and the schedule for collecting the information for this new drug application, this supplemental new drug application. If those criteria are met, manufacturers will be allowed to share peer-reviewed medical journal articles and medical textbooks.

I have to comment on peer review because it is important. That means the types of materials that are submitted, that a manufacturer may submit to a physician—remember the physician already has 4 years of medical school, several years of residency, is trained to at least read that peer-reviewed article. If that peer-reviewed article is sent, that dissemination of information will facilitate, I believe, the overall care of patients—broadly.

In addition, the FDA will review whatever proposed information is to be sent out by a manufacturer to a physician. They will have 60 days to review that peer-reviewed article or that chapter out of a textbook. The manufacturer—and it is spelled out in the bill—must list the use, the indications—the indication, or the dosage provisions that are not on the label. The manufacturer must also disclose any financial interest. The manufacturer must also submit a bibliography of previous articles on the drug or the device. And, then, after all that submission, if the Secretary determines that more information is needed, she may require the manufacturer to disseminate other information in order to present an objective view. In other words, we are not allowing manufacturers to send out articles which have any sort of bias or conflict of interest. These are peer-reviewed articles with safeguards built in to make sure that there is not an undue bias.

The safeguards against abuse also ensure that the information is accurate; it is unbiased when it is presented to that practitioner. Manufacturers must inform the Secretary of any new developments about the off-label use, whether those developments are positive or whether they are negative. And, in turn, the Secretary may require that new information be disseminated to health care practitioners who previously received information on a new use. This really should go a long way to ensure that health care practitioner—the person who is in rural Tennessee—is fully informed, with peer-reviewed articles, cleared of any conflicts of interest, with the FDA having had 60 days to make sure that balance is there.

There are a number of benefits to this amendment. Patients will gain from better and safer health care because their physician will be more knowledgeable about potential treatments. That is the most important thing for a physician. Again, as I am in this body I want to keep coming back, again and again, to what is important to physicians and to our health care system. It is simply one thing and that is the patient; that the patient has access to the very best health care, the very best device to treat their cancer, to treat their underlying heart disease, to provide the patient with the very best possible care.

There will be a number of charges, and there have been in the past, about this freedom of information, allowing dissemination of extra-label information. One is—and we heard it last year and we built into the process, I think, very strong provisions to prevent this—but critics would say if you allow people to use drugs and devices off-label—remember, that's the standard of care right now—but if you allow information to be disseminated by a manufacturer, then what incentive does that manufacturer have to go out and jump the hurdles of a SNDA, the supplemental new drug application process?

Pharmaceutical companies are going to be committed to completing a SNDA in this bill. They have a greater incentive to continue research and clinical trials on their projects. The additional benefits of receiving approval for new indications include product reimbursement. Frequently you are not reimbursed for a medicine unless it is FDA approved. The incentive to get that approval is there if we have an appropriate barrier. Another is less product liability. Many people believe if it is on the label and you use that drug, that gives you some protection from product liability and therefore these manufacturers have an incentive to get that supplemental new drug application approved. Also, active promotion of the product for the new use.

I also heard in the debate last year before the committee this whole idea of what peer review is. It is misunderstood by people broadly, but the concept of peer review is that I, as an investigator, submit my data and my studies to the experts in the world who are not necessarily—who are not, in fact—at my institution, not a part of my research team. They are objective. There is no conflict of interest. They review the study, they review the protocol, they review how the study was carried out, and decide is this good science or is this bad science. And that is what peer review is. Typically, journals that are peer-reviewed have objective boards that look at this data and either put on their stamp of approval—they don't necessarily have to agree with everything, but they have to say it is good science and the study was conducted in an ethical and peer-reviewed manner.

So peer review is important. We have worked, again in a bipartisan way, in this bill, with the American Medical Association's Council on Scientific Affairs to agree on the definition of a quality peer-reviewed journal article in order to ensure that high scientific standards are guaranteed; if a manufacturer sends out an article, it has been peer reviewed. And we spell out in the bill that manufacturers will only be allowed to send out peer-reviewed articles from medical journals listed in the NIH, the National Institutes of Health, National Library of Medicine's Index Medicus. These medical journals must have an independent editorial board, they must use experts in the subject of the article, and must have a publicly stated conflict of interest policy. Again, building in, as much as possible, the concept of educated scientifically objective peer review.

Last, manufacturers will not be allowed to advertise the product. They will not be allowed to make oral presentations. They will not be allowed to send free samples to health care practitioners. In other words, sending a health care practitioner, a physician, an independently derived, scientifically significant peer-reviewed journal article is not promotion. As a physician, I know, reading a peer-reviewed article—you see a lot of peer-reviewed articles—does not necessarily change my prescribing habits. As a physician, I am trained through medical school and residency and my years of practice to assimilate that information, reject what I don't agree with or what I don't think is good science and use, if I think it is in the best interests of my patient, what is suggested.

In closing, let me simply say that I am disappointed that an objection has been made to bringing to the floor the large bill that will strengthen the FDA. It is important that we do so. It is important that we extend PDUFA, which is the approval process supported by the private sector, working hand in hand with the public sector, which has been of such huge benefit to patients. We should do so because we will be able to get better, improved therapies for the treatment of cancer, pediatric diseases, blood-borne diseases, to the American people in a more expeditious way, and that translates into saving lives.

We need to bring this bill to the floor now. We have bipartisan support. We have debated it. It was approved in a bipartisan way through the Labor and Human Resources Committee. If we do so, we will be doing a great service to the American people.

I yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I, again, want to thank Doctor —Senator FRIST who is a cosponsor of this bill and has lent his incredible expertise to this effort. I especially thank him for his leadership, with Senators MACK, BOXER, and WYDEN, for their work in solving the off-labeling provision. Their collaboration shows the broad base of support this provision now has. Off-labeling was one of the most contentious provisions in the last Congress. To come up with a solution of that issue is a tremendous step forward. I want to talk a little bit, before I wind things up here, about the broad base of support we have.

Senator DEWINE, for instance, joined with Senator DODD in offering important amendments to establish incentives for the conduct of research into pediatric uses of existing and new drugs.

Senator HUTCHINSON had an amendment to establish a national framework for pharmacy compounding with respect to State regulations which allowed us to move forward on another very contentious and important issue.

I also want to praise and thank Senator MIKULSKI for being a cosponsor of this legislation, and the importance of her help on PDUFA, of which she was a primary sponsor. We all benefit from Senator MIKULSKI's determination to bring FDA into the 21st century, not just for the benefit of her own constituents, but for all of us.

I also would like to point out that we had contributions by Senator DODD in the area of patient databases. He worked very closely with Senator SNOWE and Senator FEINSTEIN. We are grateful for their leadership in these areas. Senator DODD has been a tremendous asset in helping to enact broad-based reform this year. He has been of steady, continual assistance to us.

Also, the tremendous difficulties that we had with third-party review provisions during the last Congress have undergone substantial revision since it was first debated. Senator COATS in particular has shown incredible leadership on this issue. This was a very difficult area and Senator COATS has been magnanimous in his willingness to spend many hours in bringing about consensus. I certainly appreciate his work.

Senator WELLSTONE's contributions to the area of reforming medical device reviews shows the breadth of the philosophical collaboration we had on these issues. Senator WELLSTONE introduced his own legislation to reform the medical devices approval process and many of his provisions are included in this bill.

Also, of course, Senator KENNEDY has been of incredible help, as he has been on so many issues. He has worked hard and I thank him for the number of hours that he and his staff put into this bill to make sure we arrived at a consensus.

I also thank Senator GREGG for working so hard on radio-pharmaceuticals, on streamlining the process for reviewing health claims based on Federal research, and on establishing uniformity in over-the-counter drugs and cosmetics. The latter issue—cosmetic uniformity—is still giving us some trouble.

But Senator GREGG has just been incredibly hard-working and effective with this bill in handling four different issues.

Also, the two amendments that Senator HARKIN had on the third-party review for medical devices and also his work in other areas has been a very great help and a demonstration of the broad philosophical support that we have and how we are working together to bring about a consensus, hopefully, before the end of the day on the remaining issues.

Mr. President, before I cease, I would like to take care of a couple of housekeeping matters here.

PROVIDING FOR THE USE OF THE CATAFALQUE

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of House Concurrent Resolution 123, which was received from the House and is agreed upon by both parties.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report.

The assistant legislative clerk read as follows: