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:

A concurrent resolution (H. Con. Res. 123) providing for the use of the catafalque situated in the crypt beneath the rotunda of the Capitol in connection with memorial services to be conducted in the Supreme Court Building for the late honorable William J. Brennan, former Associate Justice of the Supreme Court for the United States.

The Senate proceeded to consider the concurrent resolution.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the resolution be agreed to; that the motion to reconsider be laid upon the table; and that any statement relating to the resolution appear at the appropriate place in the RECORD.

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

The concurrent resolution (H. Con. Res. 123) was agreed to.

AUTHORIZING USE OF CAPITOL GROUNDS

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 130, SEnate Concurrent Resolution 33.

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

The assistant legislative clerk read as follows:

A concurrent resolution (S. Con. Res. 33) authorizing the use of the Capitol Grounds for the National SAFE KIDS Campaign SAFE KIDS Buckle Up Car Seat Check Up.

The Senate proceeded to consider the concurrent resolution.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the resolution be agreed to; that the motion to reconsider be laid upon the table; and that any statements relating to the resolution appear at the appropriate place in the RECORD.

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

The concurrent resolution (S. Con. Res. 33) was agreed to, as follows:

S. CON. RES. 33

Resolved by the Senate (the House of Representatives concurring),

SECTION 1. USE OF CAPITOL GROUNDS FOR NATIONAL SAFE KIDS CAMPAIGN SAFE KIDS BUCKLE UP SAFETY CHECK.

The National SAFE KIDS Campaign and its auxiliary may sponsor a public event on the Capitol Grounds on August 27 and August 28, 1997, or on such other date as the Speaker of the House of Representatives and the President pro tempore of the Senate may jointly designate.

SEC. 2. TERMS AND CONDITIONS.

(a) IN GENERAL.—The event authorized under section 1 shall be free of admission charge to the public and arranged not to interfere with the needs of Congress, under conditions to be prescribed by the Architect of the Capitol and the Capitol Police.

(b) EXPENSES AND LIABILITIES.—The National SAFE KIDS Campaign and its auxiliary shall assume full responsibility for all expenses and liabilities incident to all activities associated with the event.

SEC. 3. EVENT PREPARATIONS.

(a) STRUCTURES AND EQUIPMENT.—Subject to the approval of the Architect of the Capitol, the National SAFE KIDS Campaign and its agents are authorized to erect upon the Capitol Grounds any stage, sound amplification devices, and other related structures and equipment required for the event authorized under section 1.

(b) ADDITIONAL ARRANGEMENTS.—The Architect of the Capitol and the Capitol Police Board are authorized to make any other reasonable arrangements as may be required to plan for or administer the event.

RECESS

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate stand in recess until the hour of 3 p.m.

There being no objection, at 1:37 p.m., the Senate recessed until 3 p.m.; whereupon, the Senate reassembled when called to order by the Presiding Officer (Ms. COLLINS).

MORNING BUSINESS

The PRESIDING OFFICER. Under the previous order, the hour of 3 p.m. having arrived, there will now be a period of morning business. The first hour of morning business is under the control of the Democratic leader or his designee.

In my capacity as a Senator from the State of Maine, I suggest the absence of a quorum.

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. BAUCUS. Madam President, I ask unanimous consent to speak for 10 minutes in morning business.

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

TRADE WITH CHINA

Mr. BAUCUS. Madam President, this week the United States Trade Representative will conduct a set of talks on China's accession to the World Trade Organization. Their results will have a great effect on our trade policy for years to come. So this afternoon I want to take a few minutes to discuss the reason these talks are important, the state of United States-China trade, and a strategy that can help improve the situation.

The reason these talks are important is simple. China is a big market, a big exporter, and a country with which we have a large and difficult trade agenda. By virtue of population, only India equals China as a potential export market. And China's economic growth, at nearly 10 percent a year throughout this decade, is unmatched in the world.

Much of this growth has come from trade. Twenty years ago, China barely participated in world trade. It is now the world's sixth largest trader and is now our third largest source of imports after Canada and Japan. If you count Hong Kong together with China, the figures are even more impressive.

But our American export performance to China is very poor. The Commerce Department reports $11.7 billion in goods exported in 1995, $12 billion in 1996, and on track for the same level this year. Adding exports of services, the total is about $2 billion larger, but the trends are no better.

By contrast, our exports to the rest of the world have grown by 18 percent since 1995. So despite China's size, despite China's economic growth, our export performance is weak and China's importance as an export market relative to other countries is rapidly declining.

We should be doing much better than this. There are two reasons for our weak performance. The first is that many of our own policies appear designed to cut our exports to China. And the second, larger problem, is Chinese protectionism.

We will start with the first point. Because while bringing down trade barriers takes a lot of work and hard negotiations, we can fix our own mistakes pretty easily. And let me offer three examples.

First, we bar trade promotion programs like the Trade Development Agency, OPIC, and sometimes the Eximbank from operating in China. The Senate took a good step forward by passing my amendment last week showing the Asian Environmental Partnership to work in China, but we have a very, very long way to go.

We refuse to sell nuclear powerplants to China. This is foolish enough when we see that France and Japan are pushing nuclear powerplant exports in our absence. And it is almost surreal when you consider that we are actually giving nuclear powerplants to North Korea.

We have an antiproliferation law that embargoes electronics exports if China sells missiles. That is, if China misbehaves, we sanction ourselves. This will not work. If we are serious about reducing the trade deficit, if we want a trade policy that creates jobs in America, we cannot routinely prevent ourselves from exporting.

That is part of the solution, but not the whole solution. Because while fixing our mistakes are important, structural economic issues and Chinese trade barriers do much more to cut our exports.

To date, we have used our own domestic trade law to solve our problems, section 301 and Special 301, to bring down trade barriers, the antidumping and countervailing duty laws to fight dumping and subsidies. This policy won some results, and if necessary we should continue using it into the future. But it is a slow and frustrating policy which addresses individual, specific problems rather than the full spectrum of trade barriers. We need a more comprehensive approach. And we have it in China's application to enter the World Trade Organization.

WTO rules address most of our China trade problems, from tariffs and quotas