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Senate

The Senate met at 12 noon, and was called to order by the President pro tempore [Mr. THURMOND].

PRAYER

The Chaplain, Dr. Lloyd John Ogilvie, offered the following prayer:

Thank You, dear God, for the anchor of hope in You that we have for the storms of life. When we lower our anchor, we know it will hold solid in the bedrock of Your faithfulness in spite of the billows of adversity and blasts of conflict. We are able to ride out the storms of difficulty and discouragement because we know You will sustain us. We share the psalmist's confidence, ''I wait for the Lord, my soul waits, and in His word I do hope.''—Psalm 130:5.

Our hope is not in the supposed reliability of people, the presumed predictability of circumstances, nor the imagined security of human power. Our hope is in Your grace and truth. We know You will never leave us nor forsake us.

Keep us anchored today so we won't drift from our commitment to serving You. We claim Your destiny for our life. And throughout this day, may we feel the tug of the anchor and know that we are indeed secure. In the name of our Lord and Saviour. Amen.

RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader, the senior Senator from Vermont, is recognized.

Mr. JEFFORDS. Thank you, Mr. President.

SCHEDULE

Mr. JEFFORDS. Mr. President, today the Senate is resuming consideration of S. 830, the FDA reform legislation. Under the consent agreement, there will be 4 hours of debate prior to a vote on final passage of the bill. Some of that debate time may be yielded back. Therefore, Senators can expect a rollcall vote on passage of S. 830 between 3:45 and 4 o'clock this afternoon.

Following that vote, the Senate may begin consideration of the D.C. appropriations bill. Additional rollcall votes may occur throughout the day as the Senate considers the last of the appropriations bills. The Senate may also consider any of the available appropriations conference reports.

I thank my colleagues for their attention.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER (Mr. SMITH of Oregon). Under the previous order, the Senate will now resume consideration of S. 830, which the clerk will report.

The legislative clerk read as follows:

A bill (S. 830) to amend the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to improve the regulation of foods, drugs, devices and biological products, and for other purposes.

The Senate resumed consideration of the bill.

The PRESIDING OFFICER. Under the previous order, there will now be 4 hours of debate to be equally divided between the chairman and the ranking member.

Mr. JEFFORDS. Mr. President, this is, hopefully, the final moments of debate on the FDA reform bill. There is no Senator who has been of more help and assistance, not only to the committee but to her constituents, than the Senator from Maryland. Thus, I am pleased that the one who will be opening the debate today is that Senator. So I yield her such time as she may consume; and may she consume a lot of time.

The PRESIDING OFFICER. The Senator from Maryland is recognized.

Ms. MIKULSKI. Mr. President, thank you.

Mr. President, in a few hours we will be voting on the final passage of the FDA Modernization and Accountability Act.

I am so pleased that this day has finally arrived. I thank the chairman of the Labor Committee, Mr. JEFFORDS, for all of his incredible patience, persistence, dedication, and attention to really lead the mission to move FDA into the 21st century. I thank him for his heartfelt devotion to accomplishing this mission and for never giving up. I also want to thank his staff for their hard work and for the bipartisan, nonpartisan way in which they worked.

Let me also acknowledge the tremendous contribution of the ranking member, Senator KENNEDY. There is no doubt that this is a better bill and FDA will be in better shape because of his efforts.

Mr. President, I have worked on FDA reform for a number of years. When I was a Member of the House of Representatives, we embarked, on a bipartisan basis, to ensure consumer protection, to prevent dumping of drugs that did not meet our standards into Third World countries.

Then coming to the Senate, I joined with my colleague from Massachusetts, Senator KENNEDY, and with the Senator from Utah, Mr. HATCH, in fashioning something called the Prescription Drug User Fee Act, otherwise nicknamed PDUFA. What PDUFA did is provide, through a user fee mechanism, the ability to hire 600 more people at FDA to analyze the safety and efficacy of pharmaceuticals to move them to the marketplace.

Because of PDUFA and the great legislative idea of Kennedy-Hatch, FDA was able to hire more people to examine products that were being presented for evaluation and get them to clinical practice more quickly.

The leadership of Kennedy-Hatch on PDUFA has not only stood the test of time, but it has shown that we can expedite the drug approval process while maintaining safety and efficacy.

But while PDUFA made a huge difference, it became clear that PDUFA was not enough. More staff operating in an outdated regulatory framework without a clear legislative framework was deficient.

That is when we began to consult with experts in the field of public health, particularly those involved in drugs and biologics on where we needed to go. While we were considering this, the world of science was changing. We were experiencing a tremendous revolution in biology. We went from basic discoveries in science, particularly in the field of chemistry and physics, to a whole new explosion in biology and genetics and biologic materials. We also went from a smokestack economy to a cyberspace economy in which the very tools of information technology could enable us to improve our productivity.

It became clear that we needed an FDA with a new legislative framework and a new culture and a continued commitment to the traditional values of safety and efficacy. This is when we began to put together what we called the sensible center on FDA reform. One often hears about partisan bickering. One often hears about prickly relationships between the two parties. But I tell you, thanks to the leadership of Senator Kassebaum, who initially chaired this initiative, we, Republicans and Democrats, worked together because we never wanted to play politics with the lives of the American people. What we wanted to do is to make sure the American medical community and the world medical community had the best clinical tools at their disposal to help save lives.

We saw the reform of FDA accomplishing two important policy goals—saving lives and at the same time generating jobs in our own American economy in the fields of pharmaceuticals, biologics, and medical devices.

Senator Kassebaum took important steps forward. Senator JEFFORDS assumed that mantle and brought us to this point today.

What will this bill do? Why is it so important? It gives, first of all, a clear statement on what is the mission and purpose of FDA—to save lives with pharmaceutical and biologic products and to maintain the safety of our food supply. This bill does not deal with the food safety issue, but it sure does focus on those things that normally would take place in clinical practice.

Why is it so important? It streamlines the regulatory process, it reauthorizes that very highly successful PDUFA, to make sure we have adequate staff, and it creates an FDA that rewards significant science while protecting public health.

It means that new lifesaving drugs and devices will get into clinical practice more quickly. It will enable us to produce products that we can sell around the world saving lives and generating jobs.

What is so great about pharmaceuticals, biologics, and medical devices is that they are translingual, they are transcultural. When you need a new drug and it is approved by FDA, whether you live in Baltimore or whether you live in London or whether you live in Bangladesh, you need it. If you then use a medical device, you know if it is safe in Maryland, it will be safe in Moscow or Malaysia. This is why this will offer us a whole new opportunity in exports.

I am really proud of FDA. I am proud of all the people who work at FDA, and under very Spartan resources. Why? Because it is known as the gold standard around the world for product approval. We want to maintain that high standard, and at the same time we want to make sure that the FDA is ready to enter the 21st century.

This legislation will be the bridge to the future, maintaining the evaluation of safety and efficacy with the new tools to be able to participate in a 21st century science environment and a 21st century economy. This bill sets up a new legislative and regulatory framework which reflects the latest scientific advancements. That framework continues the FDA's strong mission to public health and safety, but it sets a new goal for FDA—enhancing public health by not impeding innovation or product liability through unnecessary red tape that only delays approval.

There is an urgency about reauthorizing PDUFA. Its authority expires at the end of this month. PDUFA has enabled FDA to hire 600 new reviewers, and to cut review times from 29 to 17 months over the last 5 years. If we fail to act now, it means the people who have been working on behalf of the American people and the world will get RIF notices. We cannot let them down, because we do not want them to let the American people or the world down. We risk losing talented employees and slowing down the approval process.

Delay will hurt dedicated employees, but more importantly it will hurt patients. Patients benefit the most from this legislation. Safe and effective new medical tools will be helping patients live longer lives or get better quicker.

We are not just extending PDUFA. We are improving it. Currently, PDUFA only addresses something called the review phase of the approval process. Our bill extends PDUFA to streamline the early drug development phase as well.

What does this mean? New innovations. We are going to be able to allow for electronic submissions. We want to improve productivity. Instead of carloads of paper, stacks and stacks of material not being able to be utilized in an efficient way being deposited at FDA, companies will be able to make those electronic submissions. This reduces not only paperwork but actually provides a more agile way for scientific reviewers to get through the data in a way that improves efficiency while they are analyzing efficacy.

Updating the approval process for biotechnology is another critical component of this bill. Biotechnology is one of the fastest growing industries in our country. In my own State of Maryland, there are 143 of these companies. They are working on everything from AIDS to Alzheimer's to Parkinson's disease, to breast and ovarian cancer, as well as new immunizations for children.

These are absolutely vital areas of endeavor. We want to be able to help them develop these new areas, go through a submission at FDA to make sure they are safe, and get new products out there doing their job of improving people's health.

The job of FDA is to make sure that safe and effective products get to our patients. Our job, as Members of Congress, is to fund scientific research through NIH and other Federal laboratories and extramural research at great institutions like the University of Maryland and Johns Hopkins and at the same time to provide FDA the regulatory and legislative framework to evaluate new products to make them available to doctors and to patients.

That is why I am fighting for this. There have been many issues raised in this debate. Some have been very robust. Some have even been prickly. But I tell you, I want to absolutely say that I am on the side of FDA. I am absolutely on the side of safety. I am absolutely on the side of efficacy. I believe this is what this bill does.

This legislation should not be a battle of wills, it should not be a battle over this line item or that line item. It should be really a battle over what is the best way to make sure the American people have from their physicians and other clinical practitioners the best devices and products to be able to save their lives.

Mr. President, my dear father died of Alzheimer's. He was in the final stages when I became a U.S. Senator. He was so ill that he could not come to that marvelous night in my life when I won the general election and knew I would be the first Democratic woman ever elected in her own right. I spoke to my father that election night, via TV because he could not be there, to thank him for what he did for me and my sisters. With Alzheimer's, I watched my father die one brain cell at a time. It did not matter that I was a U.S. Senator, it did not matter that I was helping fund research at NIH, my father was dying.

My father was a modest man. He didn't want a fancy tombstone or a lot of other things, but I vowed, I promised, in my heart of hearts I would do all I could to find a cure for Alzheimer's. I would do all I could for those people who have Alzheimer's or other forms of dementia or other mind diseases. While I did that, I promised also that I would do all I could to make sure those tools moved to the clinical practice as fast as they could.

Every one of us has faced some type of tragedy in our lives where we look

to the American medical, pharmaceutical, biological, and device communities to help us. I have done that so many times. I am grateful to the medical communities in the United States of America.

When my own mother had one of her last horrible heart attacks that was rapidly leading to a stroke there was a new drug that was so sophisticated that if it was administered quickly could help her avoid having a stroke. It required informed consent, because even though it was approved it was so dramatic in the way it thins the blood, almost to a hemophilia level, that you needed consent on the scene.

I heard all of the medical pros and cons of that. I was advised by a great clinician at Mercy Hospital and I gave that approval because my mother was not conscious and not able to do that. And guess what? That new drug approved by FDA, developed in San Francisco, got my mother through her critical medical crisis with the hands-on care of the Sisters of Mercy at Mercy Hospital. My mother did not have a stroke because we avoided the clotting with the help of this new dramatic drug.

I give praise and thanksgiving to God for that and the ingenuity of the American medical community that enabled my mother to stay with us 100 more days so she could be back at home, have conversations with us, her grandchildren, and so she could, even in her final days, continue a telephone ministry that she had. She was a member of a parish group called the Cheer Up Club where other shut-ins called each other. Let me tell you, the best ''Cheer Up Club'' I can belong to is right here in the U.S. Senate when we pass FDA reform to make sure that when a physician works with a patient or a family they are cheered because they have these new tools.

Mr. President, I thank you for the time given to me to speak today. If I seem a little emotional, you bet. I love my family, as so many of us do, and this is why I so rely upon the American medical community and FDA to make sure that the best pharmaceutical, biological, and medical devices are available to the American people and also to the people of the world.

I look forward to voting for final passage and having a conference report to bring back.

Mr. JEFFORDS. I thank the Senator from Maryland for a most eloquent and moving personalized statement, as well as her efforts that have gone on to improve the FDA for all of us.

Mr. KENNEDY. Mr. President, I also join in expressing great appreciation to the Senator from Maryland in terms of the FDA reform.

She speaks very eloquently, passionately, and emotionally about the family's personal experience with the breakthroughs of modern medicine and what it can mean to those afflicted by the scourge of so many of these diseases.

I must say I join with Senator JEFFORDS in saying that no one on the committee has been as tireless in pursuit of FDA reform as the Senator from Maryland. As a tireless advocate for FDA, she has brought great knowledge and understanding to achieve the goals that she has outlined here and I think all of us pay tribute to her.

I want to thank her, as well, for commenting positively on the work of the people at the agency. There are many individuals at FDA who could, at the drop of a hat, go to the private sector and other areas and be better off financially. But who, because of their commitment to the public, are trying to do a job they believe in and are willing to serve the public.

Ms. MIKULSKI. I thank the Senators from Massachusetts and Vermont for their very kind comments.

I also thank you for the cooperation of your staff, and wish to acknowledge the role of Lynne Lawrence and Roberta Haeberle.

But let's get FDA the right staff that they need.

Mr. JEFFORDS. Mr. President, before yielding to the Senator from New Hampshire I would like to say he has spent as much or more time than anyone on this legislation and has had the very difficult chore of working in this very controversial area of uniformity. It is so essential that this Nation have uniformity so that when they buy a product they can know with the assurance of the FDA that the product they are getting is one that will be safe and helpful. Many, many hours the Senator has spent working on this issue, as well as the bill generally. I praise and thank him.

Mr. GREGG. I thank the chairman of the committee.

Mr. JEFFORDS. I yield such time as the Senator from New Hampshire desires.

The PRESIDING OFFICER (Mr. ROBERTS). The Senator from New Hampshire.

Mr. GREGG. I wish to join with others in stating my admiration for the chairman's efforts here in getting this bill forward. He understates his role if he thinks somebody has worked harder than he. He is clearly the person who has put the most time in this and developed an excellent bill.

That is the point. The bill reported out of the committee came out of the committee with a huge vote, 14–4, a very definitive statement by the committee which has a fair number of experts, one of whom you just heard, Senator MIKULSKI from Maryland, on various parts of this bill, a fair number of experts who understand the importance of bringing the FDA into the 21st century.

Why is it important? I think the statement has been made over and over again here in the last few days, but I think it needs to be made again. The fact is this involves people's lives. We have spent a lot of time on this bill and we have had a lot of votes on this bill. We had an 89–5 cloture vote on September 5; a 94–4 cloture vote on September 17; and yesterday, a 98–2 vote in favor of the bill. At some point, people should be willing to say enough is enough. It was inappropriate to delay this bill as much as it has been delayed.

This is about people's lives. The capacity to get these drugs out, to get these devices out, to give people the ability to use these various pharmaceutical treatments and various device treatments which are in many instances going to save lives and in almost all instances going to improve lives, is critical.

I have a situation in New Hampshire. An attorney named John Hanson wrote to me about a friend of his who, regrettably, has ALS, or Lou Gehrig's disease. This is a horrible disease. It is a disease that eats away at your capacity as an individual to function. Although your mind stays sharp, the rest of your body fails. Every day that goes by is a critical day to this individual, every day that goes by.

Now, the FDA had a product before it called myotropin which is waiting for approval. The people who have ALS are very interested in getting this drug, but they can't get it because the FDA has taken the position that it is not yet available on the market.

Why is that? It is because of this long lead time of bureaucratic activity that is the wrap-up period for the approval of drugs. Regrettably, as a result of that long lead time, which can be years and years and years, many people are unable to get these drugs which are so important to them. In a case like ALS, of course, it really is the individual who should have some option in being able to choose whether or not to use a drug. That individual has a pretty stark choice before them—die as a result of the disease you have; or maybe have a chance of surviving as a result of taking a drug which maybe has not had years of review but has only had a few years of review.

So the issue is how do we get the FDA to approve these drugs, approve these devices in a prompter manner, in a manner which doesn't give up any of the need for making sure that the drugs are safe and that they work, making sure that the devices are safe and that they work, but does give up the bureaucracy which has for so long and so often stifled a prompt review process.

So this bill which the Senator from Vermont has brought forward today really does attempt to overcome what you might call the culture of overcautiousness which has become, regrettably, the culture of the FDA. It is an attempt to say to the FDA in a very definitive way, listen, we understand the importance of what you do, we understand that you are sincere and committed individuals. But we also understand there is another part of this formula that is called getting the drugs to the patients, getting the devices to the patients.

So, let's start working as a team to get these things out quickly. To accomplish that, a number of proposals were put forward to make the FDA work more effectively and make the drugs and devices which are distributed across this country more understandable in their usage and also more readily available when they work.

We have heard a lot of discussion, of course, about section 404. I note that the Senator from Massachusetts has another group of lists up there on section 404 of people involved in this issue. One thing that has been mentioned is that this new section 404 may in some way be tied into the fen/phen issue. Well, it is not. Section 404 is a device section. It is not a drug section and does not apply to drugs or drug manufacturers. Using that as an example, which just recently occurred, is truly a red herring. The purpose of section 404 obviously is to try and get these devices out in a more prompt and efficient manner.

Now this language was put together after a lot of work and a lot of negotiation, a lot of discussion, with all the different parties involved. I know the Senator from Vermont was actively involved, the Senator from Indiana was aggressively involved. My sense is that everybody who had a legitimate concern about section 404 had a fair hearing before the committee, and the committee decided that the compromise language which was put in the bill—and believe me, it was compromise language—on section 404 was the most effective and appropriate way to go. The committee decided it by a 14–4 vote.

I hope this Congress and this Senate specifically would give considerable respect to the efforts that were made at the committee level on this specific issue. I do think in this instance the Senator from Massachusetts is just plain wrong. His position is not consistent, in my opinion, because he has brought in debate over drugs with the medical device issue, but more importantly, it is not the position which was adopted by a vast majority of the members of the committee, because we understood the importance as a majority in the committee, 14 people who voted for this, of getting out some major reform in the FDA laws which would allow for a prompter approval process without giving up any of the issues of safety or effectiveness of the drugs or the devices that are being involved here.

I congratulate the Senator from Vermont again for moving forward. It appears we may actually be getting to the end of the day on this bill relative to passage. I hope we would not see any more of this delay tactic as we move down the road because every day that gets delayed potentially costs a life, and certainly causes people who need these drugs, need these devices, a tremendous amount of anxiety on top of a situation which in almost every instance is already filled with extraordinary anxiety because of the type of disease or problem they have. So let's get on with doing the business of the Senate and pass this bill.

Mr. JEFFORDS. Mr. President, I want to take a moment to thank the Senator from New Hampshire again for the incredible amount of work he has done, and I hope we heed his advice.

I yield the floor.

Mr. KENNEDY. Mr. President, I yield as much time as he needs to the Senator from New Mexico.

The PRESIDING OFFICER. The Senator from New Mexico is recognized.

Mr. BINGAMAN. Mr. President, I thank the Senator from Massachusetts and I wish to speak as in morning business for up to 10 minutes.

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

(The remarks of Mr. BINGAMAN pertaining to the introduction of S. 1210 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. KENNEDY. Mr. President, we are moving on in the consideration of FDA reform. I would like to review where we are, where we have come from, and where I believe we ought to go on this important issue that is intimately tied to the public health and safety of the American people.

I would just like to remind our colleagues and others about the importance of this agency. We will be debating about section 404 of the FDA legislation that is before us. It might sound like a small, narrow provision in a complicated piece of legislation, but its implications are profound in terms of potential impacts on the health and safety of millions of American people.

Senator REED, myself, and others have attempted to make the case that we are unnecessarily risking the health of the American people. We are doing this because we are effectively permitting false and misleading information to be placed on the labels of medical devices that are submitted to the FDA for review. We are doing this and at the same time, tying the hands of the FDA to look behind those labels and into the real purpose of the medical device. We are creating a loophole that will allow companies to submit their products under a protocol they know will allow for quick approval, but whose clear intention is to market the device for uses that are different from those they listed when they went through the approval process.

Over the last few days, we have reviewed the most prominent example of this issue when we talked about the biopsy needle of U.S. Surgical Co. We discussed how they were able to get approval for the device by telling FDA that it was substantially equivalent to a device they already had on the market. But, in reality, the biopsy needle that was on the market excised an amount of tissue that was less than the size of the lead in a pencil, and the new device they submitted to FDA removes a piece of tumor that is 50 times larger than would be removed with the existing needle biopsy device.

It is quite clear from the evidence that we are able to advance on the floor of the Senate, both the correspondence we received from doctors about marketing practices and a promotional videotape, that this device was being promoted for an entirely different purpose than the one U.S. Surgical listed on the label it submitted to FDA. Due to this maneuvering, we did not have the proper kind of safety information available to the principal agency of Government that is charged with protecting the safety and health of the American people.

I cannot understand why we, by way of this legislation, are denying that Federal agency the opportunity to adequately protect the American people. And it isn't just me, 35 other Members of the Senate, more than a third of the Senate, indicated a similar position with their votes yesterday. Virtually all of the consumer groups are with us as well.

I have illustrated on this chart some of the organizations that are working to protect patients, that listen to patients, and that understand the need of patients, and that stand with us on this issue. They are virtually unanimous in their concern about this particular provision.

I have in my hand articles about the FDA which have been published over the period of the last 2 days. This is an agency that is on the cutting edge of many health-related issues. It is charged with many different responsibilities that have enormous impacts on the lives and well-being of American people.

Here we have on September 22 a major article: ''Doctors want approval to inject themselves with live virus''—HIV. This will be a decision the group will seek approval. From whom? From the FDA.

Here is another—''FDA sets rules on supplemental labels.'' The FDA published final rules yesterday aimed at making * * * manufacturers put more information on labels.

Why are they doing that? To protect the American public. They have responsibilities for that.

FDA acts to get more women in drug studies. That is very appropriate and very important to do.

FDA moved [yesterday] to force drug companies to stop excluding young women from studies of promising new medicines out of fear they will get pregnant, curbing the research.

And, again:

FDA told the drug companies to include women in all stages of drug tests.

Then it goes on about the importance of having women represented in drug trials so we can understand how they will affect women. That can't be learned from studying the effects on men because of the metabolic and other differences between men and women.

Here is another example of FDA looking out after public health issues, and the impact of pharmaceuticals on our population.

On September 23 here is the long story in the New York Times.

Thirty-seven years later, a second chance for thalidomide. Officials at the agency announced today they intend to approve thalidomide for use in leprosy patients, as long as the New Jersey . . . company seeking market approval adheres to conditions, including elaborate restrictions intended to keep the drugs away from women who might be pregnant.

Here is the FDA looking after what? Looking after a possible cure for leprosy and making sure that women who are expecting are protected from thalidomide.

What is the role of the agency? Looking after the women and children—looking at trying to find some cure for leprosy.

What is another role of the FDA? Trying to make sure that all members of our population are included in the review of various pharmaceuticals.

Here is a story on E. coli bacteria. We remember the stories across the country a little over a year ago and the dangers that were posed in terms of the health of the American people. This has no direct connection with the issue surrounding FDA reform except that it, too, comes against a background of years of determination, —the ''meat industry and anti-regulatory forces to block long overdue improvements in the way the Government monitors the meat safety.''

Here is an example of an editorial advising us to be cautious in our rush to regulatory reform. Let's not override safety.

That is what this editorial is about—the same message we are delivering today—in our rush to reach these thoughtful and important reforms, let's not override safety.

This editorial involved a different issue—E. coli and meat products. It may be E. coli today, but it may be an unsafe medical device tomorrow.

Again, on the 23d, FDA. The approval of thalidomide, lawsuits filed against the fen/phen, and many other articles. The FDA published a rule on the 23d—from the Washington Post:

Final rules aimed at making supplemental manufacturers put more information on the labels. The rules restrict the use of the term ''high potency,'' requiring products such as vitamins, minerals, herbs, and amino acids to be labeled as dietary supplements and labeled also to provide information about serving size.

What is the agency doing in each of these cases that made the newspapers over the past few days? Protecting the American public. In each and every example that we have cited FDA is trying to protect the American public on a wide variety of issues.

We are talking today about doing the same thing with regard to medical devices, protecting the public from false and misleading labels. That is the issue. It is not the only issue, but the Senator from Massachusetts, the Senator from Rhode Island, for the patient advocacy and consumer groups, it's the primary issue. There hasn't been a single patient advocacy group that has been advanced by those that are opposed to our position here during the course of this debate. Not one. Why? Because they cannot find any. Why? Because this provision is a direct threat to the health and safety of the American consumers. And virtually every group that has studied it, that has reviewed it, understands that.

That is where we are. We want to let the American people know the importance of the FDA. Let them know how it is out there trying to provide protection for the American people. That is what we believe should be the case on the provisions that we have been discussing here, with section 404.

Because of the Senate vote yesterday tabling the Reed amendment, the FDA reform bill still includes the provision that seriously threatens the public health—the provision that must be removed before this legislation becomes law. This provision encourages device manufacturers to lie to the FDA and forces FDA to approve medical devices that have not been adequately tested to assure that they are safe and effective. Weeks ago, the Secretary of HHS identified this provision as one that would lead her to recommend a veto if it were not removed. Despite what some of my colleagues say, this is not a new issue. The Secretary identified it last June, identified it again in July, and identified it again in September as one of the administration's principal concerns.

It is virtually the only technological issue that remains to be resolved on this bill. Every major public health and consumer organization that has taken a position on this provision strongly opposes it.

While the Reed amendment was defeated yesterday, I anticipate the bill itself will be adopted by the Senate today. This is not the end of the story. There are many procedural steps that must be taken before the bill becomes law, including action by the House, reconciliation of the bills passed by the House and Senate, and the signature of the President. There will be many more opportunities for debate before this bill can even go to conference. I believe that in the end the public interest will prevail.

I intend to discuss this provision during the course of today's debate on the bill. I would like to begin by reviewing the reasons we embarked on an FDA reform bill in the first place and how much we have been able to improve the original bill.

As I mentioned earlier, there are few more important agencies of the Federal Government than the Food and Drug Administration. The FDA is responsible for assuring that the Nation's food supply is pure and healthy. The FDA provides a guarantee that the drugs and devices we rely on to cure or treat diseases are safe and effective. It wasn't always that way. Medical device legislation was adopted in the mid-1970's.

If it does its job well, the FDA can speed medical miracles from the lab bench to the patient's bedside. And if the agency does its job poorly, it can expose millions of Americans to unsafe or ineffective medical products and jeopardize the safety of our food.

The record of the FDA in moving these various medical devices through the process and moving them from the manufacturer onto the market is improving. We have seen significant and dramatic improvement over the period of the last 3 years. In the premarket notification process known as 510(k), which about 95 percent of all the medical devices come through, the median review times have dropped from 199 days to 93 to 85 days, meeting the standard of 95 percent of all of those submitted. That is extraordinary progress. And for the more complicated, newer devices, the breakthrough kinds of devices, which account for only 5 percent of submissions, review times have been reduced to about 40 percent of the time between 1993 and 1996.

This is the record. That is why there is within the medical device industry, general support for the steps taken by the agency.

Here is the Medical Device and Diagnostic Industry magazine of this year.

With improvements in FDA product review performance, despite a more challenging domestic market, device companies are more optimistic than ever. Company executives report a substantial improvement in FDA performance, particularly in 510(k) product approval times.

This is the Medical Device and Diagnostic Industry magazine commenting on the performance of the FDA in terms of its approval ratings.

This year's survey of medical device manufacturers marks the highest business climate ratings ever.

Here we have the industry magazine talking about how effective the FDA is in moving these devices through the process expeditiously. And now, even with this information, we are undermining the ability of that agency to provide adequate protections for public health and safety.

(Mr. COATS assumed the chair.)

Mr. KENNEDY. If the agency was not doing a good job, if we were seeing these bureaucratic delays denying patients products, at least there would be an arguable position. But what we are talking about here is the industry's own assessment about the effectiveness of the agency. They are pointing out how hopeful and optimistic they are about the recent performance of the agency in quickly approving devices.

Not only have they made progress in moving them expeditiously, but now a number of the medical manufacturers want to diminish the existing power of the FDA to assure proper safety. The American people must ask why. We do not have the kind of problems that we had years ago with the Dalkon shield and the Shiley heart valve. We do not have the kinds of problems that we had

with earlier medical device tragedies. What we have now is an excellent record of safety and effectiveness with devices, and it is against that background we find some in the medical device industry want to make it even more profitable for themselves, and to do so at the risk of the public.

Continuing along with the survey:

The overall results of the survey indicate widespread satisfaction with the medical device business climate. A substantial majority of the survey respondents characterized business conditions for the device industry as good to excellent. One important cause of this year's improved outlook is perceived improvement in relationships with the FDA. The declining complaints about the agency mirror the increase in positive business outlooks. Much of this improvement is no doubt due to the dramatic decrease in the last 2 years of 510(k) product approval times which the FDA has made a lead focus of its internal reforms.

Ray Larkin, President and CEO, Nelcor, Purett & Bennett, Pleasanton, CA, underlines the extent of the improvement of the FDA: ''As critical as I may have been a year ago, I think they have made significant improvements in the product approval and the compliance side. The whole regulatory environment is improving.''

This is what industry itself is saying about the FDA. This is not just those of us who are opposed to this particular provision. This is the industry itself. How many times have we heard, ''If it is not broke, why fix it.'' And here we have the wide approval by the regulated industry itself. And yet some here in this body want to deride this progress and put the American public at risk by denying the agency the ability to review important information about safety and effectiveness when the information on the label is false and misleading.

And here is Medical Economics of this year.

The demand for devices has created a worldwide market of $120 billion including $50 billion in the U.S.

That's growing by 8 percent annually.

A healthy industry, thank goodness, because I think all of us know the importance of these medical devices when they are safe and effective. But we have to make sure they are safe and effective. We do not want to compromise the current superb safety record.

An extensive study was conducted by the Medical Device Diagnostic Industry magazine this year that showed that the executive rating of device industry business is at an all-time high—58 percent favorable, 11 percent unfavorable. ''Expectations of the medical device business conditions.'' The best that it has been in any time in recent years. All the measures indicating that the medical device industry is doing well, that the public is being served, safety is being addressed.

Even with regulatory protections for safety, the speed with which these devices are being approved has been improved, nonetheless we are being asked to alter those conditions. We are being asked to handcuff the FDA from being able to look at that medical device that may meet the safety standard substantial equivalence but it clearly intended to be used and marketed for another purpose. A purpose for which safety and effectiveness data have not been gathered or evaluated.

Let's get back to the fundamentals. The main purpose of the FDA reform bill was to reauthorize the Prescription Drug User Fee Act of 1992 known as PDUFA. PDUFA is one of the most effective regulatory reform programs ever enacted. Under PDUFA, the pharmaceutical industry pays the user fees that cover part of the cost of FDA's drug approval and regulatory functions. And with these additional resources the FDA has been able to hire additional personnel so that drugs can be reviewed more promptly. As important as these additional resources were, equally important were the specific performance targets for speedier drug review negotiated between the industry and the FDA as part of the PDUFA agreement.

This is where the industry, working with the agency, said, well, if we give support for this and it becomes law and they get the additional resources to hire the personnel, can we reach these target timeframes for approval, and the agency agreed to that. And we had extraordinary accountability. We found a 90 to 95 percent compliance with those goals. The industry establishing the support for the PDUFA fee resulted in important and dramatic progress made. The combination of performance targets, additional resources, and the leadership of Dr. Kessler, the former FDA Commissioner, has created a regulatory revolution at the FDA.

Listening to some of the speeches we have heard during the course of this debate, you would think the FDA was a regulatory dinosaur mired in the past, cumbersome and bureaucratic, imposing unnecessary and costly regulatory burdens on industry and denying patients speedy access to lifesaving drugs.

That is a myth that those who want to destroy the FDA in the interest of an extreme ideological agenda or in the interest of higher profits and at the expense of the patients, would love you to believe. It is not true. The FDA's regulatory record is the envy of the world, and it sets the gold standard for protection of patient health and safety.

Over the last few years, in partnership with Congress and the administration, the FDA has responded to growing criticisms of delays in approving new products by taking impressive steps to improve its performance. The Prescription Drug User Fee Act of 1992 was one of the most effective regulatory reform programs ever enacted. The bill established a new partnership between the industry and the agency. The industry agreed to provide the additional resources. The agency agreed to a measurable performance standard to speed the review of products, and every goal set by the legislation has not only been met but been exceeded.

So today the FDA is unequaled in the world for its record in getting new drugs to market quickly, without sacrificing patient protection. In fact, last year average review times in the United States were twice as fast as in Europe. Fifteen new drugs were approved in both the European Union and the United States. In 80 percent of the cases, the United States approved the new drugs either first or at the same time as the European Union. More companies chose the United States for the introduction of breakthrough drugs than any other country.

That is the current record. In addition to speeding the review times, the FDA has taken far-reaching steps to reduce unnecessary burdens on industry and modernize its regulatory processes. More needs to be done, but these steps have added up to a quiet revolution in the way FDA fulfills its critical mission. When the prescription drug user fee was originally passed, the device industry refused to agree to the user fees that would give the FDA additional resources and performance standards that have contributed so much to the agency's outstanding record on drugs and biologics. But even in the device area, the recent FDA achievements have been impressive.

I think it is fair to say that following passage of PDUFA, the primary priority of the FDA was to implement that commitment and contract with the pharmaceutical industry. And I do think that the agency gave that a higher priority than it did moving ahead in terms of the medical devices.

I think that is probably a fair criticism. But once PDUFA had been effectuated, the priorities shifted to the medical device industry.

I remember the debate on PDUFA quite clearly. I welcomed the opportunity to join with my colleague, Senator HATCH, and others in the adoption of PDUFA, and I remember the efforts we made in the area of the medical device industry to do exactly the same thing. But we were unable to get the device industry to agree to that. I think it is unfortunate. Any fair evaluation in terms of the FDA in looking over the period of the time since the passage of the PDUFA, the changes in the way that the agency worked in advancing and accelerating the consideration of pharmaceuticals and biologics would understand that they get the priority. It has been only in recent years that the device industry has received attention, with the results which I mentioned just a few moments ago.

The so-called 510(k) application devices, which are approved on the basis of substantial equivalence to a device already on the market, account for 95 percent of the device submissions. The FDA has virtually eliminated its backlog. Last year it reviewed 94 percent of these devices within the statutory timeframe compared to 40 percent just 4 years ago—dramatic improvement. And we haven't compromised safety in the process. Why are we now attempting to undermine the health and the

safety of the American public? Why are we risking it?

Mr. President, even in the area of class III devices, which is where most problems remain, the FDA has improved its performance substantially. According to a study by the GAO, median review times dropped 60 percent between 1991 and 1996. A recent survey of device industry executives reported that the business climate for the industry is the best in a 5-year history of the survey. The sponsor of the survey attributes the favorable response in large measure to the improvements at FDA and concludes:

The agency has not only reduced the product approval delays that slowed new product introductions, but, perhaps more importantly, has also greatly reduced both executives' and investors' uncertainty about the timeliness of future product introductions.

That is the conclusion of the General Accounting Office. That is not the conclusion of those of us who are trying to say look, the system is working, the devices that are getting into the FDA are being approved in record time, they are getting out to benefit the people and we have a solid safety record.

We are being asked here to walk away from that safety record. We are being asked here, for the first time since we passed serious medical device legislation 25 years ago, to take steps backward in the area of protecting the American public.

In a recent FDA report, the agency sets new targets for even quicker review of the class III devices while still giving assurances that we are going to continue to protect the public. The agency is doing a good job now. It will be doing an even better job in the future. There is no justification for weakening the FDA power to protect the public—not based on the myth that it is denying patients prompt access to needed new products.

If you listened to this debate for the past days, the other side's description of the FDA may have been accurate 5 years ago or 10 years ago, but does not reflect where the FDA is today. And that is not just my opinion, but it is what we hear from the General Accounting Office, and what we have the industry itself saying.

The most important aspect of this bill is the reauthorization of PDUFA. The new PDUFA program was negotiated between the FDA and the industry. It expands existing programs by setting additional performance standards and puts special emphasis on expanding early cooperation between the FDA and industry so the drug development process, not just the regulatory process, can be stepped up. The agency has been creative in anticipating the possibility of major new drug breakthroughs. They have been working with the industry in new ways to help shape and formulate the way the industry effects its application so it can be approved in more expeditious manner. This is because we are not just interested in drug approvals but also development times.

We had a long debate about how we were going to reduce the number of days: 180, 360, 120, or 90 days—for the approval on these various issues. That was taking our eye off the ball. What is important is development time. In our own review of FDA, what makes the most difference reducing total approval time is reducing development time. The agency has been doing really excellent work. In addition to PDUFA, there are a number of other provisions changing the way the agency does business, particularly in the area of medical devices. As originally introduced, the bill included many extreme provisions that posed significant threats to public health. It was important that these provisions be modified before the legislation could be allowed to move forward. I compliment Senator JEFFORDS and the other members of the committee, Republicans and Democrats alike, on their willingness to compromise on these unacceptable proposals over the months we worked on the bill. I would like to review a number of these provisions for the Members of the Senate so they understand the changes this legislation makes and the pitfalls that have been avoided. These compromises must not be undone as the bill moves further through the legislative process. I am proud the progress that has been made. We have reached constructive compromises on more than 20 items.

I have here the letter that was sent to the chairman by the Secretary of Health and Human Services in June, June 11, as the committee was considering the FDA reform. In this, the Secretary mentions, ''Unfortunately, the Chairman's substitute to S. 830, also includes a number of provisions which as drafted do not reflect consensus and about which I have very significant concerns.''

I will not take the time of the Senate now to review those. But basically they include some 20 different provisions. I ask unanimous consent to have those printed in the RECORD.

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

SECRETARY OF HEALTH AND HUMAN SERVICES,
Washington, DC, June 11, 1997.

Hon. JAMES M. JEFFORDS,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

DEAR SENATOR JEFFORDS: For the past several months the Administration has been working with the Senate Labor and Human Resources Committee on legislation to improve the performance and accountability of the Food and Drug Administration (FDA or the Agency), while preserving and enhancing the Agency's ability to protect and promote the public health. I appreciate the efforts that you, Senator Kennedy, and the other members of the Committee have made in this regard and believe that considerable progress has been made toward these goals.

The Food and Drug Administration Modernization and Accountability Act of 1997, S. 830, includes approximately 20 provisions that represent significant consensus reforms. Among the provisions that we all agree on are those that set forth the Agency's mission, codify reforms to the regulations of biotechnology products, provide expedited authority for the adoption of third party performance standards for device review and for the classification of devices, and streamline submission requirements for manufacturing changes and marketing applications for drugs and biologics.

I must emphasize that these provisions represent very significant reform, on which all parties have worked hard to reach consensus, and which I hope will not be jeopardized by insistence on other provisions on which we have not reached agreement.

Unfortunately, the Chairman's substitute to S. 830, also includes a number of provisions which as drafted do not reflect consensus and about which I have very significant concerns. Also, the current version is not ''balanced'' in that it does not take advantage of significant opportunities to strengthen current law so FDA can more effectively protect the public health. The most significant of the non-consensus provisions, summarized on the enclosed list, would undermine the public health protections that the American people now enjoy, by: (1) lowering the review standard for marketing approval; (2) allowing distribution of experimental therapies without adequate safeguards to assure patient safety or completion of research on efficacy; (3) allowing health claims for foods and economic claims for drugs and biologic products without adequate scientific proof; (4) requiring third party review even for devices that require clinical data; and (5) burdening the Agency with extensive new regulatory requirements that will detract resources from critical Agency functions without commensurate enhancement of the public health. Another significant nonconsensus item is the set of adjustment provisions in sections 703 and 704, which together require significant increases in FDA's appropriations levels over FY 1998 through 2002 (almost $100 million above the FY 1998 Budget with levels rising thereafter). We recognize that the ability of the FDA to commit to specific performance goals under PDUFA depends on the resources it will have available. We would support a user fee proposal that is consistent with our FY 1998 Budget proposal, but we are concerned that the proposal to collect user fees in this legislation imposes additional pressure on the fixed level of the discretionary resources agreed to under the Bipartisan Budget Agreement.

We note the inclusion of the provision on pediatric labeling in the most recent version of the Committee mark. We believe it should be revised to assure a more appropriate system for testing drugs for pediatric use before they are prescribed for children.

I want to commend you and 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 (PDUFA). We are interested and prepared to continue working with the Committee to reach consensus on additional issues—and have proposed acceptable alternative approaches to many of the objectionable provisions. My concern is the time for reauthorization of PDUFA is running perilously short. As I indicated in my recent letter to you, I am concerned that the inclusion of non-consensus issues in the Committee's bill will result in a protracted and contentious debate. This would not serve our mutual goal of timely reauthorization of PDUFA and passage of constructive, consensus bipartisan FDA reform.

A copy of this letter is also being sent to the ranking Minority member, Senator Kennedy, and the other members of the Senate Labor and Human Resources Committee.

Sincerely,

DONNA E. SHALALA.

Enclosure.

S. 830 (CHAIRMAN'S SUBSTITUTE)

A. Major Concerns:

1. Cumulative Regulatory Burdens/No Provisions to Promote Public Health.—Many new regulatory burdens are being imposed on FDA (list enclosed) and little that can be advanced as promoting public health.

2. Third Party Review of Devices (Sec. 204).—Expansion of FDA's existing pilot project for review of medical devices (includes devices that require clinical data) by organizations accredited by FDA.

3. Approval Standard for Drugs/Biologics/Devices (Secs. 404/409/609/610/611/619).—Effectiveness standard for drugs and biologics needs further clarification; for supplements (applications for new uses) lowers standard such that they might not ever require a single investigation; limits FDA authority to evaluate clinical outcomes for devices; and lowers approval standard for radiopharmaceuticals, including PET drugs.

4. Health Claims For Foods (Sec. 617).—Health claims not approved by the FDA but consisting of information published by authoritative government scientific bodies (e.g., NAS or NCI) would be permitted for use by companies in the labeling of food products, even if it is very preliminary.

5. Expanded Access to Investigational Therapies (Sec. 102).—Would allow drug and device companies to sell an investigational product for any serious disease or condition without FDA approval and without appropriate protections for clinical investigations.

6. Device Modifications (Sec. 601).—Would allow companies to make manufacturing changes that affect a device's safety and effectiveness without FDA agreement.

7. Health Economic Claims (Sec. 612).—Would allow industry to discuss health economic claims given to managed care organizations under a lower evidentiary standard and without FDA review, even if the claim compared the safety or efficacy of two drugs.

8. Pediatric Labeling.—Would provide an incentive of six months of market exclusivity to encourage pharmaceutical companies to conduct necessary clinical trials for FDA approval of their products for children; doesn't assure that necessary labeling for children will be included; and might undercut FDA's ability to use other means such as regulations.

B. Other Significant Concerns:

1. Expanded Humanitarian Use of Devices (Sec. 103).

2. Device Collaborative Determinations/Review (Secs. 301/302).

3. Limitations on Initial Classification Determinations (Sec. 407).

4. Evaluation of Automatic Class III Designation (Sec. 604).

5. PMS (Sec. 606).

C. Currently In The Bill—No Language Provided Yet:

1. Off-Label Use of Drugs (floor amendment expected).

2. Drug Compounding (amendment expected).

Mr. KENNEDY. They are listed here. There are 20 items, major concerns about the cumulative aspect of the regulatory burdens, the various kinds of advisory committees, the advisory committees and the regulatory burdens that would have added to the complexity, and even the process of considering new drugs. The basic concerns the administration had on features of the third-party review, the approval standard for some of the drug and biologic devices, limits that were put on the FDA to evaluate some of the clinical outcomes for devices, and the lower approval standards that were included in some radio-pharmaceuticals.

They had some concerns about the health claims for foods and expanded access to investigational therapies, which allow drug or devices companies to sell investigational products for any serious disease without FDA approval and without appropriate protections for clinical investigators. The device modification allowed the companies to make manufacturing changes that affected devices' safety and effectiveness without ever notifying the FDA; the health economic claims that would allow industry to discuss health economic claims given to managed care organizations under a low evidentiary standard and without FDA review.

There was pediatric labeling, and the whole question on the humanitarian use of devices and collaborative determinations. There were also some concerns about off-label use of drugs, drug compounding.

If you look at the improvements in the bill and the compromises worked out here, 19 of the 20 have been worked out to the satisfaction of HHS and the FDA. There may be some groups that do not feel that certain provisions are worked out adequately. But I am prepared to defend those compromises. There is only one that remains. That is the provision that we are addressing here. Whether we are going to permit false and misleading labeling on a particular product and deny the FDA the right to look behind that label in order to protect the safety of the families of America. There were 19 accepted, only one remains—but it is an important one.

Why is it, if we are able to work out 19 of the 20, can't work out this one? The Senator from Rhode Island offered an excellent amendment yesterday saying, ''OK, we will go along with the existing language that is in the bill. But we will also add the language that nothing in the label will be false and misleading.'' False and misleading; that was defeated. Those Member who voted against it, I expect, will have to explain to their constituents why they would resist an amendment that said we should not permit the medical manufacturer to submit something false and misleading.

Members are saying that this has been a long process that has taken a good deal of time. This measure was considered in the last Congress and now again in this Congress. We could have acted on these measures. We could have acted before June 11 and not dealt with any of the outstanding health and safety issues. But the fact of the matter is, we took the time, we listened to the arguments of the FDA and the Department of Health and Human Services, the people who are charged with protecting the American people. We worked out the 19 of the 20. Everyone gave a little, took a little, but 19 of those 20 have been worked out. Not this particular provision. It took time to work out those compromises. I think the time spent was well worth it. This is a much better bill than would have come out of that committee or on the floor in June or July or August, or even the early part of September.

What were those steps that we took? First of all, we preserved the States' oversight of the safety of cosmetics. This compromise assures that the States will be able to continue to regulate the safety of cosmetics. The Gregg proposal in the underlying bill would have barred the States from any regulation whatsoever of cosmetics, even though the FDA has neither the authority nor the staff to regulate these products. The compromise allowed the States to continue their regulation unless a specific inconsistent regulation has been issued by the FDA in a particular area. We went through that debate. We found the examples, particularly with regard to the State of California, how they were able to protect their consumers. In some cases there were carcinogens in the products and the manufacturing company changed the formula and were able to get right back out there and produce the product and have record sales.

The toluene that was in lipstick, which is related to another carcinogen that was related to some birth defects with children was altered and changed.

We have had important studies that have been done up in Seattle, WA, at the University of Washington and other medical centers, about some of the potential dangers of use of talcum powder on small infants and its relationship to ovarian cancer.

These were studies, scientific studies that were done by the States, that are directly related to protecting health and safety. The FDA does not provide for that kind of protection. Nonetheless, there was an effort to preempt States from protecting health and safety. We were able to defeat that. I think that was important. I believe the consumers in those States think so.

Second, the safeguard for off-label use of drugs. This important compromise will allow companies to circulate reputable journal articles about off-label use of drugs but will ultimately enhance the public's health and safety because the FDA will be given the opportunity to review, comment on, and approve articles which the companies circulate. The compromise also requires the companies to undertake studies on the safety of their drugs for the specific off-label use and submit applications to the FDA for approval for their drugs for these uses within 3 years. That was not in the legislation prior to this compromise. We saw the steps that were taken to meet the safety standards.

Currently, companies are circulating articles without reviewing them for off-label use, without seeking review or approval by the FDA, and without conducting the studies which would lead to an ultimate FDA approval or disapproval of the drug.

We wanted to make sure that the companies were going to conduct the safety standards for the use of those particular drugs. We were able to work that out. Again, to protect the American public.

Expanding access to drugs for patients and fast track approval. The fast track approval—this is one of the most important new initiatives in the legislation—will provide the same streamlined availability for drug treatments for patients with any life-threatening disease now available to patients with cancer or AIDS. It is a major breakthrough for patients who have life-threatening diseases.

We were moving through the measures in the bill and pointing out in June of last year that the Secretary of HHS identified 20 major areas that we ought to review and work through in trying to accommodate some of the health and safety concerns.

Effectively, we have resolved 19 of those. The only unresolved matter, according to the letter from the HHS, is the provision on section 404.

What I was trying to do is to point out a number of these areas where we have made important progress and to mention the safety provisions that had been worked out and included in a bipartisan way.

I was mentioning the expanded access to drugs for patients on the fast-track approval. We have had more than 17 different pharmaceuticals or drugs that have been identified for fast-track procedure. We are taking what has been the practice of the FDA and actually demonstrating by legislation, the importance of this particular procedure. We are trying to make the progress available to all those that have life-threatening diseases by giving authority to those researchers who believe the opportunities for fast-tracking these various pharmaceuticals will benefit the American public.

That has been successful for AIDS and cancer, and now we are encouraging its use for other life-threatenting conditions.

We have also expanded access for drugs under investigation for patients who have no other alternative. So an individual who might not otherwise qualify for various clinical trial protocols can get access to a drug if they have no other alternative. If this is the last gasp, the last hope that they will be able to have access to some of the modalities that might not have been particularly identified for this particular illness or sickness but their medical professionals believe they should have access, and we are moving in that direction. I think that gives a degree of hope to many of those who really wonder if they have any hope at all in trying to get some of the modern kinds of breakthrough drugs

We have accepted the Snowe-Feinstein piece of legislation that will give individuals who have a particular life-threatening illness or sickness the opportunity to tap into the NIH database to find out what clinical trials are taking place. This is a very, very important additional provision, and I commend our Senators who are not on the committee but who have been interested and involved in this. That is very, very important.

Mr. President, another area that we reviewed is the streamlining of the FDA procedures. The concern initially was in the areas of contracting out of various functions of the FDA. We talk about not only timeliness but also about the importance of preserving quality. We have to make sure that we are not only interested in timeliness, but we are also concerned about the quality.

We have also, in this streamlining of the FDA procedures, worked out how we were going to try to review third-party review. That was worked out in a way which I think has virtual broad support. It permits 70 percent of all the devices that would be eligible to be reviewed. But in the areas that are the very significant higher level of class II—a limited number of class II and class III will remain outside of that particular protocol so that we will have a chance to review the results of the research that will be done. We have accelerated the time for that review, so the information will come back in quicker and we will be able to evaluate the results of that particular process.

Mr. FRIST addressed the Chair.

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

Mr. FRIST. It is a real pleasure for me to take a few moments and reflect on my interpretation of where we are today and the significance of the bill that is before us.

It was 1938, not that long ago, that Congress passed the Food, Drug and Cosmetic Act. And at that time the primary mission was defined fairly clearly to be to protect the public health by safeguarding Americans from unsafe and ineffective products.

Over the past 60 years, the FDA has truly done an excellent job on the whole in fulfilling this mission to make sure that food is safe and wholesome and that drugs and medical devices are safe and effective for treating disabilities and the diseases that have plagued us over the years.

You can look back and cite numerous, numerous examples that recall the FDA's important role, their vigilance in protecting the American public from unsafe drugs. Think back to Thalidomide. We think back to the FDA's quick response to the Tylenol tampering case as evidence of the effectiveness that that very important Government entity plays that affects each of our lives in ways that many of us do not realize.

But during this same period of time, the United States has been the most innovative nation in the world, particularly in the arena of medical research. I think back to my dad, who is 86 years of age, who practiced medicine for 55 years. I remember when I was a very young boy traveling with him as he would make house calls, and now to think how much things have changed over that period of time in terms of antibiotics, antiviral agents, vaccines, treatments for diseases that when I was a child were devastating to large populations. You look at hepatitis B, chicken pox, polio, many forms of cancer, the list goes on of what we can treat today.

We have developed important new surgical procedures. As a surgeon who has been in the medical field for the past 20 years, I have had the real privilege to watch fields unfold that were nonexistent even when I was in medical school. I think of certain types of tissue transplants, lung transplants, which I was doing routinely before coming to the Senate, that 15 years ago were not done at all.

I think of the new medical device implants like little stents we can now place in the coronary arteries which feed the heart, which were nonexistent 10 years ago; the artificial joints, the hips, the knees.

Thanks to the new biomedical drugs and products, we have new protocols for treating everything from AIDS, where we demonstrated tremendous success in the last year, to the treatment of other diseases like cystic fibrosis.

However, in recent decades the FDA, which has never had in writing a clear mission statement to guide its hand, has become too bureaucratic, too top heavy, with excessive regulation. I say this again out of tremendous respect for the FDA, having seen firsthand the tremendous successes of that agency.

To address this problem the FDA, to its credit, has been very aggressive in undertaking a number of reforms internally that have reduced the regulatory burden on industry and have improved patient access to new therapies.

However, it is clear that much, much more needs to be done. In the past, medical discoveries typically reached the patient in a relatively short period of time. Again, when my father first started the practice of medicine, it took an average of anywhere from 7 to 8 years for a new drug, a new pharmaceutical agent to pass through the entire discovery and approval process. Now, although in certain areas there has been tremendous improvement, it takes anywhere from 10 to 15 years to go through that discovery process and through that approval or disapproval process. Everybody agrees that is too long. Everybody agrees that you can have the same or improved standards if we streamline, if we coordinate, if we modernize the Food and Drug Administration.

That is what this bill is about, not a lowering of standards, not putting devices or pharmaceutical agents out on the market that have not gone through that eye of the needle of disciplined, very high standards that we all expect of the Food and Drug Administration.

Unfortunately, up-to-the-minute advances in medical science, advances that are occurring at increasing speed, are not making it to our marketplace as quickly as they should. Many times these advances are going overseas.

Too often you see that a drug that is in this long pipeline, and we know it is a potential benefit, all of a sudden moves overseas. It moves overseas for trials, for ultimate approval too often. Many times the manufacturing of that drug or of that device also follows it overseas.

I think the FDA regulatory structure simply has not kept pace with the rapid rate at which scientific discovery is being made. In too many cases, which I personally hear among investigators in the academic community and the private sector, the FDA has become a barrier, a barrier instead of a partner, to innovation and to access to medical therapies. It is that concept of dropping down the barrier and facilitating that partnership with very high standards that this bill achieves.

I mentioned U.S. biomedical research moving overseas. The implications are significant. It is very hard to put a price tag on this in the short term. But if we drive our very best biomedical science, our very best biomedical research off our shores to other countries, over the long term it is to the detriment of our health care, to our quality of life, and to our economy. Our once almost impenetrable edge in a U.S. dominated market can be lost forever if we do not act responsibly now.

I find my fellow doctors often travel to Europe to train, to study, to see, not the general foundation of medical knowledge of which we have the best in the world, evident by people from all over the world coming here to study medicine, but for innovative, breakthrough therapies. Too often today the therapies, the technologies, the research is moving overseas, and, therefore, even my colleagues go overseas to learn something that they should be learning right here in this country.

In the future, as medical science moves away from the contemporary practice of just treating overt symptoms when somebody comes in with a complaint, an organ failure, to a medical field where we begin to fabricate organs, where we do transplants, where we diagnose and treat disease at the molecular level, at the genetic level, playing off the tremendous success we have seen in the human genome project, a project that I might add as an aside is coming in under budget and much quicker than we would have ever anticipated even 6 years ago, the possibilities for new drugs, new devices, new methods of patient treatment are virtually limitless.

Thus, we need a structure to address these great breakthroughs, this great innovation, that is up to date, that is modernized, that is well organized, that is disciplined, that is coordinated. That is what this bill achieves. With the explosive growth in technology, the FDA needs to better use the considerable genius and talent of non-Government scientists and researchers.

There is always a great fear when we approach this issue of so-called contracting out because people can paint the picture that only Government people, only Government scientists have the ethics, have the honesty, have the integrity to be able to make decisions, to be able to look at clinical data and say what is best, what is dangerous, what is a benefit to the patient.

That is just not right. We have many good people in the private sector. In truth, because science is moving so fast and is so complicated, so intricate, it is almost absurd for us to expect that we can hire in the Federal Government all of the research scientists necessary to be able to conduct studies, look at studies, interpret data from the studies. Almost by necessity, because of the speed with which science is developing, we need to reach out and access many very, very good experts that are in the private sector.

One of the greatest complaints against the FDA that I hear is a feeling that the FDA has not been willing to collaborate and partner with others in the private sector, it might be industry, might by academia, it might be the academies, it might be individual scientists. People come in and say, ''You know, I sat down with the FDA,'' but there is a real feeling of an adversarial relationship rather than a collegial relationship.

We need to make fundamental changes in this regard at the FDA. We need to build upon the successes in protecting the American public by reenergizing the process. We need to revitalize the process of product approval, speeding approval where appropriate, meeting high standards, improving and enhancing communication between the FDA and the public it serves, nurturing, not stifling, research and innovation. And, yes, we need to draw upon the untapped scientific excellence outside the FDA, at all times remembering that the FDA has the final say as to whether or not to accept the conclusions from that partnering with outside individuals and agencies.

The bill before us today, S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997, does represent a bipartisan effort, including significant input from the Food and Drug Administration aimed at making the FDA more efficient. The bill was passed out of the Labor Committee on June 18 with a bipartisan vote, again, 14–4. On September 23, the Senate overwhelmingly approved the substitute amendment by Senator JEFFORDS.

I want to take this opportunity to commend Senators JEFFORDS, COATS, DODD, and MIKULSKI and my other colleagues on the Labor Committee, Senator KENNEDY, all for their tireless efforts and commitment to modernizing the FDA.

But to the American people I hope we have sent a signal that we can accomplish a very good bill, yes, a first step, but a very good bill in updating an organization, in updating a Federal agency which will affect the lives of every American in a positive way.

I do urge my colleagues later today to support this bill. But I also ask that we all view this legislation and discussion as an ongoing commitment to improve the agency, not just a one-shot change in the agency, which we will put aside and come look at again in 10 years, but realize this needs to be an ongoing process with continued oversight.

The Prescription Drug User Fee Act, commonly known as PDUFA, has been commented upon today. It has been one of the great successes in the relationship between the FDA, industry, and the American people. This bill is much more than just a reauthorization of PDUFA. It is also about improving the FDA and fostering, better communication and partnering with the private sector.

I am a cosponsor of this bill because I believe it is a needed step in the right direction. We need to continue the debate, to look at both short and long-term investment of resources in order to move the agency forward in areas of regulatory research, professional development, collaboration between Government, academia and the private sector. I hope to continue working with my colleagues in a bipartisan manner to further improve FDA in the following years.

The Senator from Massachusetts was going through a number of the items in the bill and talking about the work on both sides of the aisle in pulling together areas that were contentious initially. I want to thank him formally, and his staff, for working together on what I consider a very important aspect of this bill that has to do with dissemination of scientifically, peer-reviewed medical literature to my colleagues, to people in the health care profession, about the uses of drugs, both on-label and off-label.

As a physician, I understand the need for this up-to-date sharing of more information than is currently allowed today. Off-label uses have been in the news recently, both in terms of pharmaceuticals, and we have talked a lot about it in terms of devices recently.

I think it is very confusing to the American people what off-label use of medicines is. In truth, about 90-percent of all cancer therapies are off-label today. So if you have cancer, there is a 90 percent chance you will be receiving off-label medicine. When we say off-label, it doesn't mean the medicines are bad. Sometimes it means those are the most effective, and in cancer therapy, it does mean they are the most effective, up-to-date modern therapy to

have if you want your cancer treated. The American Medical Association has estimated between 40 and 60 percent of all prescriptions are for off-label uses, and up around 50 to 60 percent for the pediatric population, which means if your child is sick today medical therapy is likely to be off-label.

Why? It only makes sense. The FDA can't study every use for every drug in every combination of drug available. It is impossible to do today.

I want to acknowledge the tremendous work by Senator MACK on this particular provision during the last few years. I have had the opportunity to work with him over the last 2½ years on this specific provision of dissemination of information. I want to thank Senators DODD, WYDEN, and BOXER, and Senator KENNEDY for his work in negotiating with us in order to allow the inclusion of this important provision which will be to the benefit of all Americans in S. 830.

The bill before the Senate today will help meet the need for increased access to scientific and technical expertise that is currently lacking at the FDA. I touched upon this. It is that whole concept of interagency collaboration with Federal agencies and with the private sector. We will see more collaboration with the National Institutes of Health, more collaboration with the Centers for Disease Control, the National Academy of Sciences.

The bill allows the FDA to contract with outside reviewers and expand its current third-party medical device review pilot program which has been very successful to date. Everyone agrees that it has been successful, which in turn will help conserve FDA resources, so that those resources can be used in other areas. Because the FDA always retains the final authority to approve or disapprove new drugs or medical devices reviewed by outside experts, the FDA always has the final authority, and it will not impede nor weaken the FDA's ability to safeguard the public health. To help alleviate the confusion and frustration that many feel today in working with the FDA, the bill codifies evidence requirements for new drug and medical device application submissions, it improves communication between the agency and industry. After almost 60 years, the FDA will be held and made accountable by giving it a specific mission statement and requiring the FDA to develop a plan of action to meet its requirements under law.

Again, we talk a lot about the specific provisions of the bill. The bill as a whole, once it is passed, will be of benefit to every American, to every consumer, to every patient. Thanks to the bipartisan efforts of Senators SNOWE, FEINSTEIN, and DODD, individuals with serious life-threatening disease will be able to access new clinical trial databases providing expedited access to investigational therapies.

Imagine yourself being in a situation of having a disease which somebody says is not treatable, it is incurable. Where do you turn today? Nobody knows. There is no central repository, no database for sharing information of where the most up-to-date clinical trials exist. There will be after this bill is passed.

This bill will also expand the fast-track drug approval process for new drugs intended for the treatment of serious or life-threatening conditions. It puts a focus right on those conditions that we know people are dying from every day. Let's focus in that particular area, make sure we get potential drugs to market if they are safe, sooner than the 15 years that we are averaging over the last decade from beginning to the initial discovery to final placement on the market. The bill itself will provide access to investigational therapies for patients who have no other alternative but to try an unapproved investigational product.

Consumers will also benefit from this bill. The Senator from New Hampshire talked earlier this morning about national uniformity. It is critically important. We have not talked much about that in terms of food and drugs over the last several days. The uniformity aspect of over-the-counter drugs, the uniformity there will have a huge impact. Again, touching people in all sorts of ways. It will keep prices down, it will provide the consumer with a unified and consistent information for self-medication.

Another benefit to consumers, if the health claim information for food, published by the NIH or the CDC, Centers for Disease Control, or other Government, well-respected scientific bodies, will be allowed to appear on food labeling, giving the consumer accurate information, educating the consumer, empowering the consumer when they make their dietary choices.

In closing, Mr. President, this bill is a good bill that will benefit all Americans now and into the future. Medical science, moving at skyrocketing speed, offers promise of not just longer, but healthier lives, a higher quality of life. In the not-too-distant future, medical science and medical technology will not just thwart the assaults of infectious agents, but will eliminate many of the ailments of modern life.

The FDA must facilitate, not complicate, that endeavor. We need a new model for a new century. It is time to update the FDA. This bill accomplishes that reform, that modernization. It will give a starting point for a model that will facilitate, not stifle, the medical progress of mankind.

I yield the floor.

Mr. JEFFORDS. Mr. President, I would like to express my sincere appreciation to Senator FRIST, especially for his most recent discussion.

We have been concentrating on one small part of this bill—small in the sense of the number of pages or words relative to the rest of the bill, and by outlining and expressing the tremendous advancements we made in many of these areas in this bill, which has kind of gotten lost in the dialog, especially in the off-label use which has been a very contentious issue. But I think the resolution which you and Senator MACK, working with Senator KENNEDY, myself and others have come up with is a tremendous step forward in preventing such things that have occurred in fen/phen and things like that, and making sure we exchange knowledge and that we work together to improve what can be improved.

I deeply appreciate the comments of the Senator and all the work the Senator has put into this bill. Your expertise and your knowledge has been a reward to us and has given us confidence that we have done the right thing. You have done a fantastic job and it is deeply appreciated. I yield the floor.

I see the Senator from Delaware on the floor. I would be glad to yield to him for the time that he might take.

The PRESIDING OFFICER (Mr. GREGG). The Senator from Delaware is recognized.

Mr. BIDEN. I thank my colleague. With the permission of the Chair and my colleagues, I will take about 12 minutes, if I may.

Mr. President, the purpose of this FDA reform bill we are considering today is obviously to streamline the process for approving drugs so that they are available to people who need them more quickly. I support the bill and I look forward to its becoming law.

But, Mr. President, I rise today to speak to several amendments and several points that were, quite frankly, made nongermane as a consequence of the cloture vote, so I will pursue this at another date. I rise today to discuss the problem of drugs that do not get to the market, even though we need them desperately, because there are insufficient financial incentives for pharmaceutical companies to develop these drugs that we need to get to the market. In particular, I am speaking about medicines to treat addiction to illegal drugs like cocaine and heroin, so-called pharmacotherapies—that is, drugs that would be able to be developed and used to combat addiction to cocaine and heroin and other scheduled drugs.

Since 1989, when I first offered a comprehensive report, which—I don't know whether I am going to burden the RECORD with it, but I will point it out to my colleagues. It was a report entitled ''Pharmacotherapy: A Strategy for the 1990s.'' Since that time, I have argued that a key component of our national drug strategy should be the development of these pharmacotherapies that would act as antigens or antagonists to the effects of the illegal drugs being purchased on the streets.

These medicines are critical for turning around addicts, particularly addicts who are difficult to treat with traditional methods. Getting these addicts off of drugs is one of the most important efforts we can undertake to reduce the harm done to our Nation by the drug epidemic—because these

treatment-resistant addicts commit such a large percentage of the drug-related crime, we would, if we could find some of the answers, significantly impact on and increase the safety of all Americans.

In my 1989 report, I posed the question: ''If drug use is an epidemic, are we doing enough to find a medical 'cure' for this disease?'' The obvious answer, as the report concludes, is, no, we are not. If, for example, everyone who was victimized by a drug addict who has knocked them on the head or hurt them or robbed them or burglarized their home, and everyone who is addicted to drugs had a rare disease instead of the victims of drug addiction, or of being addicted to drugs, we would have a multibillion dollar national campaign to find a medical cure for it, as we rightfully are attempting to do with AIDS, breast cancer, or cancer generally. But there is precious little going on, although there is a lot of potential in the area of developing medicines, drugs, to combat drug addiction.

Based on my report, I offered legislation with Senators KENNEDY, MOYNIHAN, and others, enacted into law in 1992, which created the Medications Development Program of the National Institute of Drug Abuse and commissioned a major study by the National Academy of Science on pharmacotherapies.

This study highlighted the promise of the medical research that I referred to. In fact, in recent years, there have been a number of promising advances that give hope that effective medicines could be developed if we dedicated a sufficient amount of energy and resources.

One example of this promising research is the recent development of a compound that appears to immunize laboratory animals against the effects of cocaine. Let me say that again. There is a compound that has been developed in a laboratory that appears—it hasn't gone through clinical trials—to be able to immunize laboratory animals against the effects of cocaine. The compound works like a vaccine by stimulating the immune system to develop an antibody that blocks cocaine from entering the brain.

Now, this is pure conjecture on my part. Let's assume that that was able to be developed and it worked for human beings. What an incredible impact it would have on the United States of America. What an incredible impact it would have not only on the addicts, but on those of us who are victims of the addicts. I want to remind everybody that over 60 percent of all the violent crime committed in America is committed by people who are addicted. At the moment they are committing the crime, they are high, they are on a drug or a substance. Just think what a difference that would make.

Now, there are at least eight new medicines with promising potential, beyond the one that I mentioned, to treat drug addictions which are at various stages of research and development. By the way, I commend to my colleagues the report put out by the Institute of Medicine called the ''Development of Medications for the Treatment of Opiate and Cocaine Addiction.''

Now, of the eight promising medicines that are out there, one is LAAM, a treatment for heroin addiction, the first new medicine since methadone was approved in the early 1970's. Others are Naloxone, Naltrexone, Imipramine, Desipramine, Carbamazepine, Burprenorphine, and Diltiazem. These are all medicines identified by the various studies—in this case, by the Institute of Medicine—that in fact have promising capacity to deal with either blocking the effect of the drug when it is ingested by an addict or someone attempting to use it for the first time, or it has the effect of causing that person to be sick and not wanting to take the drug again. Not a silver bullet that cures everything, but every single drug expert I have spoken with indicates that if these could be developed, they would be significant tools in aiding in the recovery of addiction and preventing addiction.

The National Academy of Sciences study also outlined the key steps we have to take to fully realize the promise of pharmacotherapeutic research. Yet, almost a decade after my original report, almost a decade after Senators KENNEDY, MOYNIHAN, myself and others moved to change the law in 1992, despite promising research, despite the tremendously important gains that such medicines would mean for our national effort against a drug epidemic, despite the fact that it's clear what steps we have to take to speed and encourage the research in this area, despite all this, we are still not doing enough to encourage the development of medicines to treat drug addiction.

That is why I have come to the floor today, Mr. President—to discuss three amendments I had offered to the FDA reform bill. These amendments sought to take three different approaches to addressing our critical need to develop pharmacotherapies to deal with our drug epidemic.

First, I believe we should reauthorize the Medications Development Program of the National Institute of Drug Abuse and increase its funding to $100 million by the year 2002. I might add, every time we identify serious and pernicious diseases like breast cancer, prostate cancer, or AIDS, what do we do? We all immediately know that if we spend more money on research, we will attract more brilliant women and men into the field to find the answer because they have funding to do their research, and we increase exponentially the prospects that we will find a cure or find something to mitigate against the ravages of the disease. But not all people instinctively reach that conclusion. Why don't we reach that conclusion about drug addiction when the medical community says there are so many promising avenues we could go down? It would be different if the National Academy of Sciences and researchers and experts said, ''You know, there isn't any promise here, there is nothing we should bother to do, there is nothing we can do. This is like trying to be able to go warp speed in our Challenger.'' Well, that would be one thing. But that is not the case. That is not the case.

Currently, the program I have referred to at the National Institute of Drug Abuse receives about $67 million. Increasing that level by 50 percent over the next 5 years is the very least we should be doing in light of the savings in crime reduction, reduction in health care costs, and other expenses that would be eliminated or diminished if we could effectively treat drug addiction with medicine.

Yet, despite the progress being made by Government and university researchers, the Federal Government cannot solve this problem by itself, even if the amendment I proposed were not out of order or were accepted.

Private industry has not aggressively developed pharmacotherapies for a variety of reasons, including a small customer base, difficulties in distributing medicines to the targeted population, and fear of being associated with the notion of substance abuse.

There are two major, major drug companies in my State—Zeneca and Du Pont Merck. They have a number of brilliant researchers. I have visited their laboratories.

They say to me what every other drug company says. ''OK. BIDEN, how many addicted drug people are there in all America?'' I believe the number is estimated at 5.6 million people. Let's say we spend $200 million, $300 million, $500 million, or $700 million developing it. They say, ''Say we go out and spend all this money. And let's say we come up with a cure or a silver bullet. How do we get that to the 5.6 million people who need it? They don't have the money to buy it. Are you going to guarantee us that you will buy it? Are you going to guarantee us they will take it? What are you going to do? Our return on investment is de minimis. We will lose money in all probability, even if we come up with a silver bullet,'' which they are not suggesting they will.

Conversely, if they come up with a silver bullet for prostate cancer, or a silver bullet for breast cancer, the world would beat a path to their door to buy it. That is one of the reasons they don't want to get into the game, even though they acknowledge that these are promising opportunities.

Second, none of these companies, or anyone I named—Lilly, Squibb, any of them—wants to be known as the company that deals with drug addiction. It is bad public relations.

So for these and many other reasons, private industry has not really gotten

into the fray. We need to create financial incentives to encourage pharmaceutical companies to develop and market these treatments. And we need to develop a new partnership between private industry and the public sector in order to encourage the active marketing and distribution of new medicines so they are accessible to all addicts who need treatment.

My amendments sought to create these incentives in two ways.

First, I believe we must provide additional patent protections for companies that develop drugs to treat substances abuse. Under my bill, pharmacotherapies could be designated ''Orphan Drugs'' and qualify for an exclusive 7-year patent.

These extraordinary patent rights would increase the market value or pharmacotherapies—providing a financial reward for companies that invest in the search to cure drug addiction.

This provision was contained in a bill introduced by Senator KENNEDY and me which passed the Senate in 1990, but the provision was dropped in conference. It was also contained in the pharmacotherapy bill I introduced last year and the youth violence bill I introduced this year.

In addition, I proposed an amendment which would provide a substantial monetary reward for companies that develop medicines to treat drug addition and shift responsibility for marketing and distributing such drugs to the Government—a ''Biden Bounty'' as some have called it.

This approach would create a financial incentive for drug companies to invest in research and development but enable them to avoid any stigma associated with distributing medicine to substance abusers.

To qualify for the award, a pharmaceutical company would have to demonstrate that the new medicine meets strict guidelines—developed by the National Academy of Sciences—that the medicine effectively treats cocaine or heroin addition.

At a minimum, the guidelines will require the producer of the drug to conduct a controlled, long-term performance test which demonstrates that: Patients—addicts—will actually take the medicine; addicts will continue taking the medicine for as long as it takes to cure the addition; a significant percentage of those who receive treatment refrained from using cocaine or heroin for at least 3 years; and the medicine has a reasonable cost.

So, it is real simple—if a medicine meets the National Academy of Science test and it is approved by the Food and Drug Administration, then the Government will purchase the patent rights for the drug from the company that developed it.

So this bounty that would be made available to them is literally a reward. A reward, not unlike if I were a billionaire and say, ''I will give any company $100 million if they found the cure for cancer, or for any cancer.'' It is the same notion.

The key reason the Government must not only reward companies with a bounty for developing medicines, but also purchase the patent rights is due to the stigma problem identified by the National Academy of Sciences report. This stigma problem is the legitimate concern of companies that they not be identified as the drug addicts company.

I would also note, that if a company does want to market and distribute the medicine, they do not have to sell the patent to the Government. But if they don't want to they can sell the patent to Government, and we market it.

The purchase price for the patent rights is established by law: $100 million for a drug to treat cocaine addiction and $50 million for a drug to treat heroin addiction, figures recommended by the Tufts University Center on Drug Development.

So the way it works. You develop a patent. You don't want to be distributing it because you don't want to be known as that company. The Federal Government would pay you $100 million for the patent after it has demonstrated that it works, and it was effectively done, and we would be the one engaged in the business of doing it. We can pay all of this money to buy cops, we can pay all of this money for prisons, and pay all of these other moneys for other things. It is a reasonable expenditure for taxpayer dollars, in my view, to deal with the problem and scourge of drug addiction.

Once the Government has purchased the patent rights, then the Government would contract out the production of the drug and distribute it to the existing clinics, hospitals, State and local governments, and other entities qualified to operate drug treatment programs.

This is not a radically different process from how our military procurement works: The Pentagon specifies what they want a fighter plane to be capable of—how fast, its stealth capabilities, what kind of weapons, et cetera; then the powers of the private sector are unleased because the Government will buy the best plane which meets the specifications.

If my colleagues doubt that any such medicine could ever be developed, fine.

If you are right, the Government will never spend the money.

But, if I am right—just imagine the promise—in terms of reduced drug abuse; reduced crime; and reduced health care costs.

The bottom line is that—this joint public/private endeavor I seek will harness the most important engine of innovation the world knows—the private sector.

The three pharmacotherapy amendments I offered were directly related to the purpose of the FDA reform bill and I hoped they would be accepted. Nonetheless, I understand that for procedural reasons, my amendments were out of order and could not be offered for a vote.

Still, I urge the Labor Committee to hold hearings on the topic and consider this legislation as soon as possible. And, I put my colleagues on notice that I will be back to offer these amendments on the next appropriate legislation.

In closing, I would observe that America's drug epidemic is reduced each and every time a drug abuser quits his or her habit. Fewer drug addicts mean fewer crimes, fewer hospital admissions, fewer drug-addicted babies and fewer neglected children. The benefits to our country of developing new treatment options such as pharmacotherapies are manifold.

Each dollar we spend on advancing options in this area can save us 10 or 20 times as much in years to come. The question should not be—''can we afford to pursue a pharmacotherapy strategy?'' But rather, ''can we afford not to?''

I urge my colleagues to join me in promoting an important, and potentially ground breaking, approach to addressing one of our Nation's most serious domestic challenges.

A lot of the scientific community says that there are great promising medicines out there but which the companies will not move on for the reasons I have stated. We should be doing all that we can for our own safety's sake.

I thank my colleagues. I yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I yield to the distinguished Senator from Ohio who has worked tirelessly on this bill as well as the bill we reported out of committee by unanimous agreement relative to the work force improvement. So I yield to him 6 minutes.

The PRESIDING OFFICER. The Senator from Ohio.

PRIVILEGE OF THE FLOOR

Mr. DEWINE. Mr. President, let me first make a unanimous-consent request that my congressional fellow, Jan Burrus, be granted floor privileges during the duration of this debate.

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

Mr. DEWINE. Mr. President, I wish to make some comments about one particular element of this year's FDA reform bill—one that I believe is especially important and valuable.

I want to thank Chairman JEFFORDS and my colleagues for including in this bill a revised version of the Better Pharmaceutical for Children Act (S. 713). Senator DODD and I introduced this bill earlier this year because an overwhelming majority of pharmaceuticals currently on the market have not been tested for safety or effectiveness in children.

In fact, Mr. President, a shocking 80 percent of the drugs that are on the market today have never been tested for children.

We need to provide our young people with prescription drugs that have been studied for their effects on children's

bodies and appropriately labeled with doses suitable for young ages. Too many children today are taking adult-size drugs because we don't have a comprehensive strategy to test drugs to determine appropriate dosages for children.

Children deserve better than this. Children deserve he same assurance adults have—that the drugs they take are safe and effective.

Section 618 of the FDA reform bill includes a modified version of the bill Senator DODD and I have worked so hard on. It provides an additional 6 months of market exclusivity to drug manufacturers who complete requested or required pediatric studies on drugs that are useful for children. This exclusivity will act as financial incentive for manufacturers to do research on their products for young patients.

As our legislation with incentives came close to final passage, the FDA proposed a rule to mandate pediatric studies. The rule was proposed last month and would require pediatric studies for most new drugs and for many drugs that are already on the market.

When the administration released its new regulation, I applauded their decision to join Senator DODD and myself in trying to fix this problem. I offered to work with them in a bipartisan way to combine the proposals for the benefit of the Nation's children. The legislation before us today does just that, and in essence combines our bill along with the administration's proposal.

We have adapted the legislation that Senator DODD and I originally introduced so that it will work with the FDA's regulation. To ensure that we do the best that we can for children, we have combined the two approaches to this problem: the financial incentives from the better pharmaceuticals for children bill and the mandates from the proposed FDA rule.

We're now moving in the right direction. This combined approach may not yet be perfect, but we can still work on it. I have extended an invitation to all interested parties to continue to work toward a better compromise between now and conference. The most important thing is to get it right. I think this compromise between a market-based approach and mandates goes a long way toward that.

Time is of the essence in ensuring that children and their doctors have the information they need to safely and effectively use pharmaceuticals. Providing market incentives to manufacturers will help speed this process along.

In closing, Mr. President, I would like to again congratulate Chairman JEFFORDS for the tremendous job that he has done over a long period of time in bringing this bill to the floor. This is a good FDA reform bill. The ''Better Pharmaceuticals for Children'' section is only one of many creative, practical steps this bill makes and takes in the right direction.

The reform bill makes commonsense changes that will help patients get access to new medical technologies. At the same time, Mr. President, it maintains assurances that products are safe and that they are effective.

Again, I applaud Chairman JEFFORDS for this bill. I look forward to its speedy passage.

Mr. JEFFORDS. Mr. President, I thank the Senator for his excellent comments and praise him again for his work.

Mr. President, the goal of this legislation is to ensure a strong and efficient FDA.

The modernization and revitalization provision included in S. 830 makes for a better FDA—not a weaker one, as some have suggested.

Like many of my colleagues, I have had the opportunity to meet with industry groups here in Washington, and with consumers, patients, and physicians—both here and at my home in Vermont. All of these interested parties have made important points about how to modernize the agency while ensuring that its stellar standards for public safety remain as strong as ever. Though the large industries regulated by FDA are by and large not present in Vermont, all of us use their products. The people and the patient advocates in Vermont have told me that more needs to be done to ensure their timely access to the best therapies available.

I believe we have accomplished that with this bill.

Mr. President, I yield the floor.

FOOD LABELING REFORMS

Mr. MCCONNELL. Mr. President, I want to thank Senator JEFFORDS and Senator KENNEDY for the inclusion of my two amendments in S. 830. My amendments address specific food labeling reforms that benefit both consumers and the food and agriculture industry.

First, the Nutrition Labeling and Education Act of 1990 [NLEA] requires that any nutrient content claim on a food label be accompanied by a referral statement—''See Back Panel for Nutrition Information.'' The original intent of this provision was to help educate consumers about the presence and location of nutrition information on food products. Based on the NLEA's success, today few consumers even notice this generic referral statement because most individuals immediately look to the mandatory Nutrition Facts panel to obtain nutrition information.

My proposal seeks to improve the effectiveness of this consumer notice by requiring a referral statement only in those instances where the FDA identifies that a food contains a nutrient at a level that could increase the risk of a health condition for vulnerable persons.

For example, if a food label states that the product is low in fat, but the FDA finds that the sodium content could prove harmful to persons with high blood pressure, the referral statement would state—''See Nutrition Information Panel for Sodium Content.''

Through the continued use of a specific referral statement, persons who may find themselves at risk from potentially harmful levels of some nutrients would be reminded where to find detailed nutrition information. My proposal simply removes the requirement for a generic referral statement whose purpose is now fulfilled by active consumer use of the Nutrition Facts panel.

My second proposal addresses a keen concern for American consumers today—food safety. The much publicized outbreaks of E. Coli 0157:H7, cyclospora, and salmonella have captured the attention and apprehension of Americans, particularly parents, who are concerned about the inadvertent exposure to food pathogens.

Since the 1960's, food irradiation has presented a safe, simple, and inexpensive process to kill harmful pathogens in many foods. Today, this approved food safety technology promises to reduce the incidence of many food borne illnesses which threaten the health of millions of Americans, especially the very young and the very old.

The food irradiation process is quite straightforward. Food is exposed to a carefully measured amount of intense radiant energy which kills parasites and micro-organisms. Food irradiation is not a cure-all, but it can be an important food safety tool. Broader use of FDA-approved irradiation promises a significant step forward in improving our Nation's food safety. Dr. Michael T. Osterholm of the Minnesota Department of Health eloquently sets forth the argument in favor of food irradiation's use in his May 1997 editorial in the New England Journal of Medicine. I ask that the text of his editorial be printed in the RECORD after my statement

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

(See exhibit 1.)

Mr. MCCONNELL. In addition to the FDA, the World Health Organization, the American Medical Association, and the U.S. Department of Agriculture agree that food irradiation presents no health risk, and have endorsed irradiation as a method to prevent food borne diseases. Today, more than 35 countries have approved irradiation as a safe food treatment technology.

Despite their well-documented food safety benefits, few irradiated foods are marketed in the United States. Why? Because the current labeling requirements render the foods virtually unmarketable. FDA regulations require that irradiated foods prominently and conspicuously bear the international radura symbol and the phrase ''treated with irradiation'' or ''treated by irradiation.'' Clearly, public notice of irradiation is necessary for informed consumer choice. However, the degree of prominence for the current irradiation labeling creates a false impression among many consumers that the irradiation statement is a warning. This

unintended labeling result must be corrected. Targeted improvements in the labeling will provide consumers with clearer information on irradiation's approved use and provide a simple means to further food safety in our Nation.

My amendment simply requires irradiated foods to bear an appropriate disclosure requirement and specifies that the FDA-approved disclosure need not be more prominent than the ingredient statement. The intent of my amendment is for the FDA to revise its irradiation disclosure requirement to assure that consumers do not misinterpret this disclosure as a warning.

Clearly, the FDA should have the authority to require appropriate disclosure of food irradiation. However, the use of a disclosure design that discourages the utilization of this government-approved technology compromises efforts by the FDA and food processors to improve food safety in our Nation.

Mr. President, two dozen well-known and well-respected food and agriculture groups—such as the American Farm Bureau Federation, the National Cattlemen's Beef Association, and the Institute of Food Technologists—have endorsed this targeted change as a means of promoting greater use of irradiation as a food safety tool. I ask that the text of their letter of support be printed in the RECORD at the conclusion of my remarks.

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

(See exhibit 2.)

Mr. MCCONNELL. I want to emphasize that even with this amendment FDA would retain full authority to regulate all aspects of irradiation on food, including products on which it can be used, what dose can be used, and the content and placement of irradiation labeling. Under my amendment, the FDA can still use the current radura symbol and the disclosure statement. No information would be hidden from consumers. In the same manner that the FDA alerts purchasers to the presence of allergens, the FDA has the ability to inform consumers of the use of food irradiation. I also want to emphasize that this modest labeling improvement does not diminish the need for the FDA, USDA, the food industry, and consumer groups to work together to improve the public's understanding of how food irradiation works and its potential benefits to public health.

Mr. President, I believe that the inclusion of these amendments in S. 830 demonstrates the U.S. Senate's interest in food safety and effective labeling. Again, I greatly appreciate the consideration that the chairman and ranking member of the Senate Committee on Labor and Human Resources have given to these targeted food labeling reforms.

EXHIBIT 1

[From the New England Journal of Medicine, May 29, 1997]

CYCLOSPORIASIS AND RASPBERRIES—LESSONS FOR THE FUTURE

(By Michael T. Osterholm)

One hundred years ago, Osler observed that to know syphilis was to know clinical medicine. Today, to know and appreciate the many clinical, microbiologic, and public health aspects of the outbreak of cyclosporiasis associated with raspberries that Herwaldt and colleagues describe in this issue of the Journal[1] is to know foodborne disease in the modern world. The investigation conducted by Herwaldt et al. illustrates the changing epidemiologic characteristics of foodborne disease in this country.

Two of the key factors that have contributed to these changes are the substantial alterations in the American diet over the past two decades and the globalization of the food supply.[2] Although the promotion of a ''heart-healthy'' diet (high consumption of fruits and vegetables and low consumption of fat) may be improving cardiovascular health, it has led to a new range of problems for the gastrointestinal tract. Infectious-disease specialists frequently remind persons traveling to developing countries to reduce the risk of traveler's diarrhea by eating only foods that can be boiled or peeled. Yet seasonally, up to 70 percent of selected fruits and vegetables consumed in this country come from developing countries. One does not need to leave home to contract traveler's diarrhea caused by an exotic agent. Although produce from U.S. growers is also a source of pathogens, fruits and vegetables from developing countries are cause for additional concern. Many developing countries are just entering the global produce market. The first raspberry vine was planted in Guatemala in 1987, yet approximately 20 percent of all fresh raspberries sold in May 1996 in the United States came from Guatemala.

Emerging or reemerging infectious agents are another factor associated with the changing epidemiologic characteristics of foodborne disease. *Cyclospora cavetanensis* is such an agent. When an emerging foodborne agent is first recognized, there are typically many unanswered questions about the epidemiologic characteristics of the infection and its prevention. Furthermore, clinicians need to be aware of the clinical presentations associated with new agents. For example, a patient presenting with a diarrheal illness of five or more days' duration, severe fatigue, and loss of appetite should be evaluated for cyclosporiasis regardless of whether the patient has traveled to a foreign country or consumed contaminated water. Clinical laboratories now need to be proficient at performing routine examinations for a wide variety of emerging agents. Moreover, public health officials need to be aware of the importance of initiating and maintaining population-based surveillance for these types of agents. Today, the resources for conducting surveillance are severely limited at the state and local levels.

A serious problem posed by new agents such as *C. cayetanensis* is our lack of understanding of their biology. Herwaldt et al. emphasize the potential role of contaminated water. However, there appears to have been only limited consideration of the role that birds or other animals may have had in contaminating the berries. Recent evidence suggests that eimeria, a recognized coccidial parasite in birds, may be very similar to *C. cayetanensis*, if not the same agent.[3, 4] Eimeria has long been recognized as an important cause of diarrheal disease in birds. Consumption of berries by birds is a major cause of crop loss and results in frequent contamination of the berries. The use of high-quality water for irrigation and pesticide spraying and other good management practices will not solve the problem of *C. cayetanensis* contamination if birds play a major part in that contamination. A similar outbreak of cyclosporiasis in Florida during the spring of 1995 was only later recognized as likely to be associated with Guatemalan raspberries. Yet no outbreaks were documented in association with the fall harvest and shipment of Guatemalan raspberries in 1995 or 1996. The season migration of wild birds in Guatemala needs to be evaluated as a possible explanation for the patterns seen with berry shipments and outbreaks of disease in the United States. One test of this hypothesis will be whether there is another outbreak of cyclosporiasis associated with this year's spring shipment of raspberries from Guatemala.

I believe that one of the unfortunate lessons of the outbreak in the spring of 1996 came from public announcement of the apparent association between a product and an illness without sufficient epidemiologic evidence. The implications of this lesson reach far into the future. When an outbreak occurs, public health agencies are often under pressure to act quickly. The public has come not only to expect a quick response but also to demand it. The Texas Department of Health and the Houston Department of Health and Human Services investigated a cluster of cases of cyclosporiasis among 20 participants at a May 9, 1996, conference in Houston. On June 8, these agencies issued a press release summarizing the results of their epidemiologic investigation. In that announcement, they concluded that the consumption of fresh California strawberries was associated with the illness. The need to warn the public is legitimate, but it must be weighted carefully against the possibility of being wrong, which will result in economic loss for the falsely accused industry, as well as weaken the confidence of both industry and the public in future public health warnings. Confusion about the actual cause of this outbreak persisted for more than six weeks, until additional epidemilogic studies conducted by state and local public health agencies, the Centers for Disease Control and Prevention, and health officials in Canada concluded that raspberries from Guatemala were the source of the outbreak.[5]

We need to establish well-defined criteria for evaluating the quality of epidemiologic data from investigations of outbreaks, particularly when the etiologic agent is not readily isolated from the implicated food product. Furthermore, when a widely distributed product is implicated in an outbreak, we must ensure that before public announcements are made, all available epidemiologic and microbiologic evidence and information on product distribution are reviewed quickly and that the conclusion is supported by federal, state, and local experts in foodborne disease.

On January 25, 1997, President Bill Clinton announced an important new initiative to improve the safety of the nation's food supply, including improvements in our ability to detect foodborne outbreaks and coordination of the local, state, and federal responses. However, we already have the means of virtually eliminating the problem of cyclosporiasis associated with fruit and vegetable consumption—namely, irradiation. The use of ionizing radiation for food pasteurization has been extensively evaluated and is supported by the World Health Organization, the Food and Agriculture Organization, the International Atomic Energy Agency, and various other international agencies,

Footnotes at end of article.

scientists, and government officials.[6] Irradiation provides the greatest likelihood of substantially reducing bacterial and parasitic causes of foodborne disease associated with numerous foods, including fresh fruits and vegetables. However, the food industry remains reluctant to use this technique out of fear of incurring the wrath of activist groups that wrongly proclaim that irradiation is unsafe or seriously compromises the quality of the food product. The time has come to use irradiation; we must not let any group use arguments without a scientific basis to keep such an important technique from the marketplace. This may be the most crucial lesson to be learned from the story of cyclosporiasis and imported raspberries.

FOOTNOTE REFERENCES

[1]Herwaldt BL, Ackers M–L, Cyclospora Working Group. An outbreak in 1996 of cyclosporiasis associated with imported raspberries. N Engl J Med 1997; 336:1548–56.

[2]Hedberg CW, MacDonald KL, Osterholm MT. Changing epidemiology of food-borne disease: a Minnesota perspective. Clin Intect Dis 1994;13: 671–82.

[3]Relman DA, Schmidt TM, Gajadhar A, et al. Molecular phviogenetic analysis of Cylospora, the human intestinal pathogen, suggests that it is closely related to Eimeria species. J Infect Dis 1996;173:440–5.

[4]Garcia-Lopez HL, Rodriguez-Tovar LE, Medina-De la Garza CE, Identification of Cyclospora in poultry. Emerg Intect Dis 1996;2:356–7.

[5]Update: outbreaks of Cyclospora cayetanensis infection—United States and Canada, 1996. MMWR Morb Mortal Wkly Rep 1996;45:611–2.

[6]Monk JD, Beuchat LR, Doyle MP. Irradiation inactivation of foodborne microorganisms. J Food Prot 1995;58:197–208.

EXHIBIT 2

JUNE 10, 1997.

Hon. MITCH MCCONNELL,
Committee on Labor and Human Resources, U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR MCCONNELL: We are writing to advise you of our enthusiastic support for an amendment you may offer to FDA Reform legislation regarding labeling of food products under the Federal Food, Drug, and Cosmetic Act. We understand that your amendment is intended to remove labeling impediments that discourage consumer acceptance of irradiation as a technology designed to strengthen food safety and expand the availability of safe and affordable food products.

Irradiation is a simple and inexpensive process used since the 1950s to kill harmful pathogens in many foods, but is rarely used today because of FDA's label disclosure requirements. Irradiated food products must prominently bear the international ''radura'' symbol and the phrase ''treated with radiation'' or ''treated by irradiation.'' These bold labeling requirements more prominent than required warning statements, render the foods virtually unmarketable. Again, we understand that your amendment would require irradiated foods to bear an appropriate disclosure requirement, but specifies that the disclosure need not be more prominent than the ingredient statement. In this way, concerned Americans may be assured that food that has been irradiated will be marked as such but the prominence of disclosure will not be so bold as to create the false impression that the irradiation statement is a warning. Broader use of irradiation and other pathogen-reducing technologies promises a significant step forward in further improving food safety.

We enthusiastically support your irradiation prominence-of-disclosure amendment. It would provide for labeling policies that encourage the use of FDA-approved food safety and agricultural production technologies.

Sincerely,

American Farm Bureau Federation, American Feed Industry Association, American Meat Institute, Animal Health Institute, Apple Processors Association, Chocolate Manufacturers Association, Florida Fruit And Vegetable Association, Food Distributors International, Institute of Food Technologists, Millers' National Federation, National Cattlemen's Beef Association, National Confectioners' Association, National Fisheries Institute, National Food Processors Association, National Meat Association, National Pork Producers Council, National Turkey Federation, Northwest Horticulture Association, Produce Marketing Association, U.S. Chamber of Commerce, United Egg Producers, United Egg Association, United Fresh Fruit & Vegetable Association, and Western Growers Association.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

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

The PRESIDING OFFICER. The Senator from Massachusetts has 30 minutes.

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

Mr. President, I will just review quickly the work that was done by the committee.

As I outlined earlier, there were 20 major proposals that were made by the Secretary in June. We have addressed 19 of those. The one remaining proposal we have not addressed is the one that brought about the Reed-Kennedy amendment which was defeated yesterday, and the one which virtually all of the consumer groups feel ought to be altered and changed before we get to final resolution and passage of this legislation.

I reviewed some of the other provisions and the changes that were made as a result of bipartisan efforts, which I think are important and significant improvements, and also provide additional kinds of protection.

I mentioned the fast tracking of the various products, and the ability of individuals who do not have expanded access to drugs still under investigation for patients who have no alternatives, the inclusions of the Snowe-Feinstein bill that will help to expand opportunities by using the NIH database, and some of the streamlining of the FDA procedures.

I will mention just a final few.

One concerned the improved consultation between manufacturers and the FDA. Prior to this provision, if there were any changes being implemented by manufacturers with these medical devices, they had to be cleared.

We have changed that so that manufacturers can make adjustments and changes that are not going to affect issues of safety in order to make their production more efficient. But we also have some protections for safety included in there.

The environmental issues. The original bill would have eliminated all the environmental impact statements from FDA applications. I didn't think that was what we were doing when we were extending PDUFA. We made adjustments and changes on that to ensure that those environmental impact statements will be preserved.

The strengthening of the safety protections of the various medical devices. FDA will still require device manufacturers to file supplemental applications when they are making changes that affect safety and effectiveness of the devices, but we have made efforts to streamline that provision.

The tracking of various devices after approval. Under the initial bill, there was a termination of tracking of medical devices. We had a good debate on this. I thought the Senator from Illinois [Mr. DURBIN] made a strong case for continuing postmarketing surveillance of medical devices. We have now compromised and said that we permit the FDA to make the judgment. We have found that a principal reason for postmarketing surveillance was a safety factor, a belief that if you track the various medical devices and are able to get information that shows that those medical devices may pose a danger to the people, you should be able to notify others who might have used a similar kind of device to give those individuals protections as well.

Initially it was thought that by having that kind of review, you could advance these medical devices because you are going to have a pretty good evaluation of those medical devices as they affect people by having tracking mechanisms rather than just attempting to evaluate safety and effectiveness prior to the time that the medical devices are actually utilized. So it was an attempt to speed up the process that the tracking provisions were put into effect initially. Now they are enormously important because if we find out that people do have adverse impacts from these medical devices—and we have tracking mechanisms—we can protect not only those individuals but also others who might have the same kind of device implanted in them.

We worked out a compromise, and I think the public interest is protected. It would not have been if we had not worked it out.

The tightening of the process for FDA approval of medical devices. We have 180 days for these devices. What we are saying is at the end of 100 days the FDA indicates the deficiencies in those devices but still has 180 days to be able to make a final judgment. But it does give an earlier indication to the medical device manufacturer about the potential problems that they are going to face.

Recordkeeping by distributors of devices. In the initial bill, they wiped out all of that information. So if there was an adverse impact from the medical device, the distributors would not have collected the information and the FDA

would not know about it. What we have done is maintained that the distributors have to keep the information which they have with regard to adverse impacts from devices. They do not have to report it to the FDA, but they have to keep it. And then if there is some kind of indication about adverse impact, the FDA will be able to pursue it. It saves a good deal of paperwork. And, it still adequately protects the public.

We have made many changes in a bipartisan effort to improve and strengthen the bill. We have safety standards for drugs to ensure that the alternative use of a drug is going to meet high safety standards. That is an improvement.

Health care economic information. When pharmaceuticals are given or sold to health care organizations, there is going to be complete information given in terms of alternative treatments for individuals, and this is a very important element.

Health claims for food products. In the initial proposal, this legislation which was to extend the PDUFA to ensure faster consideration of pharmaceutical drugs, was effectively going to eliminate any FDA rule on health claims for food products. There was an example where the industry was leaning on us again in order to undermine the kind of information that would be given to consumers on these various food products, the health claims.

I was around here in the late 1980's when we passed the legislation with regard to food labeling to make sure that the consumer was going to have the right information as to the health assets a particular food might provide, and our committee wanted to effectively eliminate those advances. We were able to maintain them. I think that was important. Those are some of the items. And in each and every instance, the public health was enhanced, with the exception of one—404. There is the record. I could have taken more time and gone into greater detail. And there can be no review of any of those 19 that would bring one to a different conclusion except for the one that we are talking about here. That is the only one that was brought out in the June 11 letter by the Secretary of HHS that said you have to address it because of the compelling need to protect the public.

That is the one that every consumer group has said, why don't you address that the way you did the other 19? You worked out bipartisan agreements on all of the other 19 proposals and enhanced the public protection. Why can't you do it on this one?

Well, we have been unable to. But we still hear from some of our colleagues about what a long process this has been, that we could have passed this in June, you would not have passed it without those health protections. I think that we protected the public with the one exception—and that stands out.

We have gone over the FDA's impact on the lives of the consumers of this country. How in so many different ways it impacts and affects our lives and how they have taken action in each and every one of those circumstances to protect the public health. I have gone through in detail about how the medical device industry is prospering. They have a more positive attitude than they have ever had.

Now what they are going to do is restrict the protection of the public health with this particular provision, and it is wrong. The issue is clear. Will medical devices be approved on the basis of false and misleading labels? All we needed was to add the words ''false and misleading'' to the bill. This bill would have gone through unanimously. But we were defeated on the amendment that would have prohibited false or misleading labels. When our colleagues go back home and they are asked in their town halls, why were you for permitting medical device companies to submit false information? I hope they have a good answer, because I cannot think of one, not when the industry is making the progress it is making and is having record sales, and safety is still being protected.

Will dangerous medical devices that have not been tested for safety and effectiveness be foisted on the American people?

Will unscrupulous companies like U.S. Surgical Corp. be rewarded for deceiving the FDA?

Will there be a higher value placed on the profits of the powerful than the health of the American people?

Section 404 of the FDA bill requires the FDA to approve a medical device based on the use identified on the label submitted by the manufacturer, even if that label is false or misleading. It prevents the FDA from requiring the manufacturers show that their product is safe and effective for the purpose for which it will be really used as opposed to the purpose falsely claimed on the label. It stands 20 years of progress toward safer and more effective medical devices on its head.

Nothing better shows the need for the Reed-Kennedy amendment than the recent history on the Advanced Breast Biopsy Instrumentation system device developed and marketed by the U.S. Surgical Corp. This attempt to mislead the FDA and foist an untested machine on women with breast cancer shows why it is critical that section 404 not be passed in its current form.

The U.S. Surgical Corp. submitted their new machine to FDA for approval based on a label claim that it was to be used for biopsy of breast tissue suspected of being malignant. This is a common procedure used in mammograms or other diagnostic techniques to identify suspicious looking areas of the breast that may indicate malignant tumors. If the biopsy of a small piece of the suspicious material indicates a malignancy, surgery would normally follow to remove the cancerous tissue.

But U.S. Surgical's label claim was false. One of the models of the machine was designed to excise a piece of tissue 50 times as large as previous biopsy instruments—the size of a piece of hot dog as compared to the size of the tip of a lead pencil. It was clearly designed to be used to excise small tumors, not just to perform a biopsy. But the machine was not tested to see whether it was safe and effective for this purpose. The company was, in effect, proposing to subject women with breast cancer to surgery with a machine that might have been less effective in treating their illness than existing therapies. It placed the company's profits first and the patient's needs last.

Because FDA initially relied on U.S. Surgical's false and misleading label, the device was subjected only to an engineering review and was cleared for use on February 1, 1996. Had the product been honestly labeled, FDA would have reviewed it using a multidisciplinary team and required the company to present genuine clinical data in support of the application.

On March 29, 1996, the FDA obtained a copy of a promotional videotape that U.S. Surgical was distributing to physicians to try to sell their product.

We have a copy of it right here, Mr. President, and the videotape clearly describes the device as appropriate for surgically removing small lumps of cancerous tissues. Let me quote some extracts from this slick production.

U.S. Surgical is entering a new millennium in breast surgery by combining advanced stereotactic technology with minimally invasive surgery.

Unlike needle biopsies where small samples of the lesion are removed for pathological analysis, the ABBI system removes the entire specimen.

If the specimen proves to be cancerous but pathology reports the entire margin is clear, it is up to the clinical judgment of the surgeon to decide to remove additional tissue or if the procedure can be considered complete.

The ABBI system—

Which is the needle I referred to—

allows surgeons to provide the benefits of a minimally invasive technique to breast surgery. . .. Benefits to the patient include: Reduced physical and emotional trauma as a woman undergoes only one versus two procedures.

Minimally invasive breast surgery. A new standard of patient care offered only by United States Surgical Corp.

Here is their advertisement: ''The latest technique is minimally invasive breast biopsy.''

And here is the language included in the videotape that says minimal invasive breast surgery. And we heard out on the floor, well, U.S. Surgical Corp. did not have anything to do with promoting this. ''A new standard of patient care offered by the United States Surgical Corp.''

It is clear that this company has designed this machine for breast surgery, not just biopsy, and is promoting it for this use despite the false and misleading label submitted to the FDA.

Here is what a distinguished physician, Dr. Monica Morrow, professor of surgery at Northwestern University, had to say about the company's machine:

I am writing to express my feelings regarding the importance of the FDA's mandate to evaluate ''behind the label'' uses of devices and drugs.

The need for such evaluation is clearly exemplified by the marketing strategy for the U.S. Surgical breast biopsy device (ABBI). This device was approved for use as a diagnostic instrument. However, the company video clearly depicts the use of the device for definitive breast cancer therapy.

No clinical trials using the accepted techniques for comparing cancer treatments have been conducted to validate this claim, and without such trials, the device could potentially pose a significant risk to patients. In addition, other claims regarding improved cosmetic outcome and patient acceptance are similarly unsubstantiated. The indications for the uses of devices and drugs should be determined by appropriate clinical and scientific data, and not by their appeal as marketing gimmicks.

This video was dropped off in my office by a company representative as part of an effort to interest me in purchasing this equipment.

When the FDA became aware that the company was promoting the device for this unauthorized purpose, it also became aware that it had made a mistake in clearing a device that was clearly designed for a purpose not stated on the label—tumor removal—without adequate clinical testing. The FDA then acted to require the company to include a strong cautionary label that the device was only to be used for tissue sampling, not tumor excision. And it required it to submit clinical data on its use for the original claimed purpose of biopsy. Based on this revised label and the new clinical data, the FDA recleared the machine for breast biopsy on September 24, 1996.

And it further required the company to conduct studies on the safety and effectiveness of the machine for tumor removal, studies which are ongoing.

Evidently the company sees its potential now, and now is doing the studies which it didn't do before on the removal of the breast. Now they are doing it, after the FDA caught them promoting this device for that purpose.

We have listened out here, ''This is just another machine. This is just another biopsy machine.'' And we find the clearest example of a case where it gets approved for one purpose, it is promoted and used for another purpose. When it is caught by the FDA, they did submit additional clinical information for the removal of breast—and they are doing it now. They didn't say, Tumor removal? We never thought we were going to use it for tumor removal. Why is the FDA suggesting that we had ever intended to use it for that, but, OK, there is an idea, we will go out and conduct the clinical studies.

Let's be realistic here, they had intended to use it for an alternative use. They promoted it for an alternative use. And they never supplied the FDA with the safety information on that alternative use.

How much time do I have remaining?

The PRESIDING OFFICER. The Senator has 10 minutes.

Mr. KENNEDY. Mr. President, U.S. Surgical's public response to this sorry record of profiteering at public expense is a disgraceful attempt to avoid responsibility for its unacceptable behavior. It claimed it had not produced the video—even though the video carries the company log and it is impossible to watch it without it being clear that the company paid for it, produced it, and wrote the script.

It claimed that it had not distributed the video, even though there is no reason to produce a promotional video except to distribute it, and even though Dr. Morrow has written that the video was delivered to her office by a company representative trying to convince her to buy the U.S. Surgical machine. And, according to the Associated press, a company spokesman said that ''the label * * * makes clear that the biopsy divice is 'to be used only for diagnostic breast biopsy and is not a therapeutic device.' '' But as the history of this machine makes clear, that clear disclaimer is only on the label because the FDA stepped in and stopped the company from its illegal promotional efforts.

If section 404 is passed in its current form, the FDA will be handcuffed in its efforts to protect the public against untested and potentially harmful—even fatal—devices. Under current law, the FDA is able to require that the company develop data to show that the new device was safe and effective for removing tumors—the real use intended by the company, not the false and misleading use submitted on their proposed label. When the FDA made a mistake and inappropriately cleared the device, it had the authority to go back to the company and warn that it would revoke their approval unless adequate warnings were placed on the label and necessary clinical testing was performed.

But under section 404 of the FDA reform bill, the FDA would be forced to approve the new device without such evidence. Unscrupulous companies will not only be allowed but encouraged to submit misleading labels, because they will gain a competitive advantage over companies that play by the rules.

American women do not want to die from breast cancer because companies are allowed to sell devices that may be unsafe and ineffective. No Senator would want their own wife or mother or daughter to be subjected to such an untested device, solely because a greedy company wanted higher profits.

Supporters of this measure claim that FDA will still have the power to require that dangerous devices be shown to be safe and effective before they are sold. They point to the language of the statute that says a device approved as substantially equivalent must meet two tests. First, it must have the same intended use as the predecessor device. Second, ''the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical information if deemed necessary by the Secretary, that demonstrates that the device is safe and effective as a legally marketed device, and does not raise different questions of safety and efficacy that the predicate product.''

What their argument ignores is the first part of the test—the intended use test. Today, the FDA can look at the device and say, from the technical characteristics of the product, that it is obvious that it has been redesigned so that it is primarily for a different use than the older device. But under the amendment, they would be barred from doing this. They would be forced to accept the manufacturer's word as to the intended use of the device—even if that label were false and misleading, even if the manufacturer was lying. That is what happened with U.S. Surgical and the biopsy machine that was really designed to treat breast cancer. Under the current law, FDA could require that U.S. Surgical show their device was safe and effective for treating breast cancer. Under the amendment, they could not.

This is not just my opinion. It is the reason that the administration has singled out this provision as possible grounds for a veto. It is the reason it is opposed by a broad coalition of consumer and public health groups. It is obvious that the only reason that the proponents of this provision are not willing to compromise is that they want to hamstring the FDA for the benefit of the industry. How else can they possible justify requiring FDA to evaluate a device based on a false and misleading label.

If allowed to stand, this provision will give unscrupulous companies a license to lie to the FDA. It will penalize ethical companies who are truthful and do the necessary testing to prove that their products are safe and effective.

Most of all, it will put the health of America people at risk so that a greedy few may profit.

The issue goes far beyond products to excise breast cancer. If applies to lasers to treat prostate disease, stents to place in carotid arteries, imaging systems to detect breast cancer, and a host of other treatment for dread diseases.

A few days ago, the public was made aware of the tragedy that resulted from the use of diet drugs in ways that had not been approved by the FDA as safe and effective. This so-called off-label use of fenphen may well have caused serious and irreversible heart damage in tens of thousands of women who thought the drugs were safe.

The legislation before us would actually encourage the use of off-label, unapproved uses of medical devices. It can fairly be called the fen-phen device provision.

It is shocking that this shameful provision has been so cavalierly included in this bill. It is incomprehensible that reputable device manufactures are not prepared to support a compromise that allows the FDA to look behind labels that are false or misleading.

Medical devices can heal, but they can also main and kill. The history of medical devices is full of stories of unnecessary death and suffering.

But thanks to the authority the FDA now has, there are also many stories of lives saved by the vigilance of the FDA. What is incomprehensive about the bill before us is that it would take backward—in the direction of less protection of public health rather than more. The whole history of device regulation has been to provide the public greater protections.

Two decades ago, the Dalkon shield disaster led to the passage of a law giving the FDA greater authority over medical devices. At the time, this birth control device went on the market, the FDA has no authority to require manufacturers to show that devices are safe and effective before they are sold. In 1974, an FDA advisory committee recommended that the Dalkon shield be taken off the market—after almost 3 million women had used it.

The device was found to cause septic abortions and pelvic inflammatory disease. Hundreds of women had become sterile, and many required hysterectomies. According to the manufacturer's own estimates, 90,000 women in the United States alone were injured. The manufacturer, A.H. Robbins, refused to halt distribution of the device, even though the FDA requested it, while the issue was reviewed by the advisory committee.

The Shiley heart valve disaster was so serious that it led to the enactment of further legislation. This mechanical heart valve was approved in 1979. It was developed by the Shiley Co. the Shiley Co. was subsequently sold to Pfizer, which continued marketing the value. It was taken off the market in 1986 because of its high-breakage rate.

By that time, as many as 30,000 of these devices had been implanted in heart patients in the United States. One hundred and ninety-five valves broke and 130 patients died. Thousands of other patients who had the defective valves in their hearts had to make an impossible choice—between undergoing a new operation to remove the device, or living with the knowledge that they had a dangerous device in their heart that could rupture and kill them at any moment. Depositions taken from company employees indicated that cracks in defective valves may have been concealed from customers.

Before the defective valve was withdrawn, the manufacturer had tried to introduce a new version with a 70 degree tilt instead of the 60 degree tilt approved by the FDA.

The increased tilt was intended to improve blood flow and reduce the risk of clotting. The FDA's review found that the greater tilt increased the likelihood of metal fatigue and valve breakage, and the new version was not approved for use in the United States. Four thousand of the new devices were implanted in Europe. The failure rate was six times higher than for the earlier valve—causing at least 150 deaths.

In another example of a human and public health tragedy involving a medical device, the firm Telectronics marketed a pacemaker wire for use in the heart.

Twenty-five thousand of these pacemakers were marketed, beginning in 1994, before it was discovered that the wire could break, cause damage to the wall of the heart, or even destroy the aorta.

Another device disaster is toxic shock syndrome from superabsorbent tampons. Most women would not think that a tampon could kill them or a change as minor as increasing the absorbency of the material used could have life-threatening consequences. About 5 percent of toxic shock syndrome cases are fatal. As a result of this problem FDA began requiring testing of the absorbency of all types of tampons. Women deserve protection. FDA should be strengthened, not crippled.

The case of artificial jaw joints—referred to as TMJ devices—are another tragedy that devastated tens of thousands of patients, mostly women. These devices were implanted to assist patients with arthritic degeneration of the jaw joint, most with relatively mild discomfort. But the impact of the new joints, sold by a company called Vitek, was catastrophic. The new joints often disintegrated, leaving the victims disfigured and in constant, severe pain. To make matters worse, Vitek refused to notify surgeons of the problems with the joints, and FDA had to get a court order to stop distribution of the product. Similar problems were experienced with Dow Corning silicone jaw implants.

In yet another example, the FDA was able to block a device that involved a plastic lens implanted in the eye to treat nearsightedness. The device was widely marketed in France, but the FDA refused to approve it for use in the United States. Long-term use of the device was later shown to cause damage to the cornea, with possible blindness.

The angioplasty catheter marketed by the Bard Corp. turned out to be a dangerous device that the company sold with a reckless disregard for both the law and public health. The device was modified several times by the corporation without telling the FDA in advance, as required by the law. The company was prosecuted and pleaded guilty to 391 counts in the indictment, including mail fraud and lying to the Government.

Thirty-three cases of breakage occurred in a 2-month period, leading to serious cardiac damage, emergency coronary bypass surgery, and even death.

Devices as simple as patient restraints used in nursing homes and hospitals have been implicated in 231 injuries, including 128 deaths.

The list goes on and on.

These tragedies resulted in expanded powers for the FDA to protect the public against dangerous devices and greater vigilance on the part of the agency. But this bill steps backward by forcing the FDA to try to protect the public with one hand tied behind its back.

This bill actually forces the FDA to approve devices based on false and misleading labels.

Under the provision, the FDA cannot look behind the manufacturer's proposed use to demand appropriate safety and effectiveness data, even if it is obvious that the device has been designed for an altogether different use than the manufacturer claims. I have already discussed the dangers of a breast cancer biopsy needle that would have been used to treat breast cancer without adequate evidence that it was effective. There are many other examples of the kind of dangerous devices that could be foisted on the American public, if the provision of the bill allowing false and misleading labels is allowed to stand.

Surgical lasers are increasingly used for general cutting, in place of traditional instruments such as scalpels. In a recent case, a manufacturer called Trimedyne adapted the laser in a way that indicated it was clearly intended for prostate surgery. But it submitted an application to the FDA saying that the laser was only intended for general cutting. The label was clearly false, and the FDA was able to require adequate safety data before the product was allowed on the market. But under this bill, the FDA would be forced to approve the product, without requiring evidence that the device is safe and effective for prostate surgery.

Prostate surgery is a very common procedure affecting tens of thousands, if not hundreds of thousands of older men.

Failed surgery can result in permanent incontinence and other devastating side effects. Do we really want surgical tools to be used to treat this common illness that may not be safe and effective? If this legislation passes unchanged, that is exactly the risk that large numbers of patients needing prostate surgery could face.

A further example involves digital mammography, an imaging technology that is becoming an alternative to conventional film mammography. The new device is approved for better diagnostic imaging of a potentially cancerous lump in the breast that has already been detected. But it is not known whether the new machine can be used effectively in screening for breast cancer when there are no symptoms.

Under this bill, if a manufacturer seeks approval for a digital mammography machine that is clearly designed for breast cancer screening, not just for diagnosis, the FDA would be prohibited from requiring data to show that the machine is effective for screening. Does the Senate really want to support legislation that could result in women dying needlessly from undetected breast cancer? That is what this device provision could cause.

Another example involves the large number of patients who have suffered serious fractures and who benefit from orthopedic implants that help the broken bones to heal. In some cases, these implants are designed to be removed after the healing is complete. In other cases, to avoid further surgery or to strengthen the bone, the implants are left in place.

Under this legislation, a manufacturer of plates and screws approved for short-term use could modify them in a way that clearly shows they are intended for long-term use. The FDA would be prohibited by this bill from looking behind the false and deceptive label and requiring the manufacturer to show that the device will not degenerate or weaken the bone during long-term use.

Pedicle screws are a clear example of just such behavior by manufacturers. Originally designed to hold long bones in place after a fracture, they were modified by the manufacturer so that they could be used to make the spine more rigid, with the goal of reducing painful back problems. But the many manufacturers of these screws did not present safety and effectiveness data to the FDA for this new use.

The result: the screws sometimes broke and sometimes caused spinal fractures. Reoperation rates ranged from 14 to 52 percent—and patients suffered permanent pain and disability. This is exactly the kind of unethical behavior by manufacturers that this bill encourages.

Other examples in the way that this provision could allow unsafe and ineffective devices abound. A stent designed to open the bile duct for gallstones could be modified in a way that clearly was designed to make it a treatment for blockages of the carotid artery. Without adequate testing, it could put patients at risk of stroke or death. But under this bill, the FDA would be prohibited from looking behind the label to the actual intended use of the device.

Still another example involves contact lenses, which can be approved for either short- or long-term wear. Extended wear contact lenses can be left in the eye overnight, and sometimes are worn for weeks. Under this bill, a manufacturer could take contact lenses approved for short-term wear, and modify them in a way clearly intended for long-term wear. The FDA would have to approve the modified lenses based on the false and misleading label for short-term use. Unsuspecting patients could suffer corneal ulcers and even blindness.

The vast majority of medical device manufacturers meet high-ethical standards. Most devices are fully tested and evaluated by the FDA before they are marketed.

But as many examples make clear, if the FDA does not have adequate authority to protect innocent patients, the result can be unnecessary death and injury to patients across the country. There is no justification—none whatever—for Congress to force the FDA to approve devices with false or misleading labels. And there is certainly no justification for giving a competitive advantage to unscrupulous companies who will exploit this gaping loophole in the law.

Companies that hope to benefit by weakening the FDA are powerful and profitable. They believe they have the votes to push this disgraceful provision through the U.S. Senate. Today, they probably do have the votes.

But if the American people truly understand what is at stake, I do not believe they will permit this dangerous provision to become law. When the vote comes on Tuesday, we will see how many Senators are willing to stand with the American people—and how many are willing to vote in favor of false and misleading labeling.

The legislation we are considering has many constructive elements. But it does not deserve to go forward unless this disgraceful provision is removed. False or misleading labels should have no place in approval of medical devices. Unscrupulous manufacturers do not deserve a free ride at the expense of public health.

I intend to continue to fight to modify this provision so that public health can be protected, and I believe that we will ultimately be able to reach a compromise that will not sacrifice the public interest to the profits of greedy manufacturers. We have been successful in assuring that every other objectionable provision of this bill has been modified so that the public health is protected. This provision must be changed as well.

Here are some significant advances in the FDA bill and compromises worked out on S. 830 since the committee markup on June 18.

First, preserving State oversight of safety of cosmetics. This compromise assured that the States will be able to continue to regulate the safety of cosmetic products. The Gregg proposal in the underlying bill would have barred States from any regulation whatsoever of cosmetics, even though the FDA has neither the authority nor the staff to regulate these products. The compromise allows States to continue their regulation unless a specific inconsistent regulation has been issued by the FDA in a particular area.

Second, safeguards for off-label use of drugs. This important compromise will allow companies to circulate reputable journal articles about off-label use of drugs but will ultimately enhance the public health and safety because the FDA will be given the opportunity to review, comment on, and approve articles which the companies will circulate. The compromise also requires companies to undertake studies on the safety of their drugs for the specific off-label use and submit applications to the FDA for approval of their drugs for these uses within 3 years. Currently, companies are circulating articles without reviewing them for off-label use without seeking review or approval by the FDA and are also never conducting the studies which would lead to ultimate FDA approval or disapproval of the drug.

Third, expanding access to drugs for patients and fast track approval:

Fast track approval. This is one of the most important new initiatives in the legislation. Fast track approval will provide the same streamlined availability for drug treatments for patients with any life-threatening disease now available only to patients with cancer or AIDS.

Expanded access to drugs still under investigation for patients who have no other alternatives. The compromise combines protections for patients with expanded access to new investigational therapies, without exposing patients to unreasonable risks.

Providing access for patients to information about clinical trials for serious or life-threatening diseases. This compromise will assure that patients suffering from serious or life-threatening diseases will have available to them information about ongoing clinical trials relating to these diseases.

Fourth, streamlining FDA procedures. In order to expedite some product reviews, the compromise authorizes the Secretary to contract out to third-party reviewers when it will improve timeliness, but not when it will reduce quality. For medical devices, the compromise establishes in law an already existing pilot program for reviewing devices by outside third parties. The compromise limits the review only to low-risk class I devices and specifically excludes higher risk devices that are life-sustaining or if the device was not shown to be appropriate could cause substantial impairment to human health. The FDA will not have to expend resources on unnecessary reports which may be duplicative of other reports already required to be filed by the agency.

Fifth, improved consultation between manufacturers and FDA. The compromise increases the requirements on the FDA to consult with device manufacturers and specifically to work toward achieving agreement on what set of data needs to be provided by the device manufacturer before approval can be granted. In addition, the device manufacturers are required to supply progress reports to the FDA, and in particular, report significant deficiencies in the device which have developed during the review period.

Sixth, environmental issues. The original bill would have eliminated environmental impact statements from FDA applications. The compromise ensures that the bill does not undermine environmental protections provided by the Environmental Protection Act.

Seventh, strengthening safety protections of medical devices:

Safety and effectiveness of devices. The FDA will still require device manufacturers to file supplemental applications when they are making changes to

their manufacturing procedures which may affect the safety and effectiveness of the devices.

Tracking of devices after approval. The compromise ensures that FDA can require surveillance of products after they have been approved for as long as needed to protect the public health.

Tightening up the process for FDA approval of medical devices. The FDA will now be required to accept the classification made by the manufacturer unless questions are raised within a specific period of time. The compromise also tightens up timeframes within which the FDA must make a final decision on a device application.

Recordkeeping by distributors of devices. The compromise requires limited recordkeeping by device distributors so that patients using devices will be readily identifiable if there is a health problem.

Eighth, other issues:

Safety standards for drugs. Supplemental applications for drug approvals need to meet the same safety standards as the original application.

Health care economic information. Only valid and supportable health economic claims may be made by drug manufacturers.

Health claims for food products. This compromise assures that the Nutrition Labeling Act is not undercut or weakened, and that any health claims by food manufacturers have to be substantiated.

Mr. President, we want to be able to give the FDA the authority, when it is clearly indicated as a result of the technological changes in that medical device that an alternative use is intended, to look in behind the proposal and examine the safety data that would indicate that device is going to be safe, for the American public to be protected.

That is the issue. We have had too many medical device tragedies in this country. It has not been that long ago, whether it is the Dalkon shield or the Shiley heart valve, or even the adjustments in absorption level in tampons that produced toxic shock and resulted in the deaths of women—there have been too many medical device tragedies. We have been able to avoid them in recent times. The industry is doing well. We are having new breakthrough technologies.

We have reviewed 19 of the 20 key elements that have been raised by those who have been most concerned about the safety and security of the American people. We have addressed them and advanced the public's interest in protecting the health of the American people with the exception of this provision.

It would be wrong and a major mistake to permit this legislation to be passed without making that change.

I reserve the remainder of my time.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. Mr. President, I yield such time as he may consume to the Senator from Indiana, who has been somewhat involved in this issue. I am sure he may have a few things to say.

Take as long as you like.

Mr. COATS. Mr. President, I thank the Senator from Vermont. I have been listening carefully to the words of the Senator from Massachusetts. I have clearly come to the conclusion the only remaining problem with the entire 215-page bill is section 404. We have had considerable debate about that yesterday and today. The Senator said this is the last remaining piece. The Senator correctly pointed out, of the 20 items that he was interested in, 19 have been resolved. That is an awfully good batting average, 19 out of 20. Yet the Senator says the bill cannot go forward until the last one is resolved.

We had a debate on this. The Senator passionately presented his case, but it was not persuasive. Mr. President, 65 Members of the Senate did not agree with the Senator from Massachusetts. We had the vote. That issue has been dispensed with. I know the Senator is upset that his view did not prevail, but it did not prevail, despite lengthy and passionate argument to the contrary.

But, putting that aside, I hope we can take the Senator at his word, that this is the only part of the bill that remains of concern to him. I have word the FDA lobbyists are currently trying to work the House to undo the negotiations, some of the negotiations on some of those 19 items. I trust the Senator, having acknowledged that those have been negotiated fairly and addressed, would support us in maintaining the language that is in the Senate bill when this bill goes to conference, and not encourage any kind of modification of that or weakening down of that agreed-upon compromise.

I assume that means section 406 is satisfactory and there is nothing more we need to do with it, based on the Senator's remarks. I am pleased we can go forward on that basis.

I also heard the Senator say that basically everything is fine at FDA, that this revolution that has taken place under Dr. Kessler solved the problem, admitting there were problems before but we really don't need to do anything more. To quote him, he said, ''If it ain't broke, don't fix it.'' FDA is improving as we speak. Everything is going fine at FDA.

The reason why we are here is that everything is not going fine at FDA. It has not for 20 years. We have been attempting to reform the process at FDA for the past 20 years and there are some reasons for that. It is not fine because there clearly have been delays that have resulted in impaired health and safety of Americans.

You know, there are two edges to this sword. There are two sides to this issue. One side is making sure that we have a Food and Drug Administration that follows careful procedures before approving drugs and devices, because clearly that is in the best interests of the health and safety of Americans. There is no one on this floor, as Senator DODD said yesterday, who does not want to maintain a vital FDA, with the authority to review drugs and to review devices and to make sure, to the best of their ability, that those drugs and devices promote the health and promote the safety of Americans.

They will not always be perfect, as we have learned in this discussion. They make mistakes. Sometimes politicians lean on them to approve things that should not be approved and they approve them only to find out later that they should not have approved them. Maybe they should not be subject to that political pressure. They should not. None of us, whether we are for or against a particular drug or device, should be involved in the scientific process of approving or not approving a drug. But we can involve ourselves in requiring that the FDA do what is necessary to avoid the bureaucratic delays, avoid the inefficiencies, and make itself a more efficient administration. I will talk about that in just a moment.

But let me talk about the other side of this issue. Let me talk about the patients and the consumers, the Americans whose health and safety and whose lives have been jeopardized or lost because of inefficient FDA bureaucratic delays. We talk about those who have been impacted by drugs that have been approved, in some people's view, too quickly. What about those whose health and safety has been impaired and who have died because the drugs have not been approved quickly enough? A very prestigious institution, the Hudson Institution, has done a seminal study on that issue and put out a report in November of 1995 titled, ''The Human Cost of Regulation. The Case of Medical Devices and the FDA.''

I hope my colleagues will read this to understand the other side of the issue, the rest of the story. I will just quote briefly from it.

> When policymakers weigh the costs and benefits of our current policies governing the production of new medical technologies, persons who die from the absence of a device that should have been available should count as much as the victims of a defective device.

We have heard a lot here about victims of defective devices, but we have not heard very much about victims of devices that have been unnecessarily delayed that could have saved patients' lives, that could have improved their safety.

Mr. KENNEDY. Will the Senator yield just for a question?

Mr. COATS. I will be happy to yield to the Senator for a question.

Mr. KENNEDY. What is the date of that particular study? I did refer to recent studies. I was just interested in the date.

Mr. COATS. November 1995. I will quote further:

> Although these improvements are certainly laudable, they are not worth the human costs of the FDA's approval system.

Rather than protecting public safety, in some cases the FDA's system for approving medical devices actually endangers lives.

Let me cite some examples: Coronary stents. Coronary stents are simply a wire mesh tube that holds the artery open to facilitate the flow of blood to the heart muscle. During angioplasty, which nearly 400,000 Americans a year undergo, before the coronary stent was developed 15 percent of patients undergoing that operation had a blood vessel collapse and had to go into emergency bypass surgery, which placed them at greater risk, and a lot of lives were lost. The coronary stent, however, became an alternative method of treatment for most of these patients and reduced dramatically the amount of collapsed blood vessels and dramatically the lives that were lost.

You would think that, given the importance of this technological breakthrough, the FDA would have given expeditious handling to the application for approval of the stent. Sadly, for thousands of Americans who died when they could have benefited from this stent, this was not the case. It took 9 months for the device's developers to obtain permission from the FDA to even begin preliminary phase I clinical trials. These trials took another year. Then the manufacturer conducted phase II trials for 9 months, and based on those results requested immediate permission to begin the final phase III trials.

The FDA rejected this request. The manufacturer appealed and then again requested permission to begin phase III trials. Three more months and the FDA came back and said no, you can't start. In the meantime, the manufacturer had repeated a whole series of phase II trials again. Finally, 7 months later, the manufacturer completed the first segment of phase III after the FDA finally granted permission, and on and on it went for another 15 months.

Four months later the FDA's advisory panel of medical experts said OK, we will issue the order granting approval—excuse me. They recommended the order to grant approval. It then took the FDA 12 months to comply with their medical experts' request to order the approval of the stent.

The Hudson Institute estimated the number of lives lost, and it is an estimate. But, based on a very thorough study, and it is all documented here in this report, they estimated that the lag time attributable to the FDA cost Americans 2,888 lives. That is the other side of the story.

We hear about mistakes, and, yes, mistakes are made. We are all humans after all. We hear about mistakes, and the Senator from Massachusetts has detailed and had his charts up about individual patients who have been injured, or had their health jeopardized through FDA approval of a product and then the fact that product was not everything that it was billed to be. But we have not heard anything said about the 2,888 patients who died because of FDA bureaucracy and inefficiency in approving a lifesaving medical device.

Let's assume that only 25 percent of that delay was due to FDA. We are still talking about 1,570 lives. That is the other side of the story.

I could go on and on. The omnicarbon heart valve, the left ventricular assist device, the heart transplant procedures, all of these, just dealing with the heart—delays because of FDA inefficiency.

That is why the committee has been so insistent on moving forward with reform. That is why the committee has said, no, everything is not fine at FDA. Yes, we appreciate the fact that they are doing a little bit better since they taxed the pharmaceutical industry to provide the funds to hire the researchers to expedite the approval of drugs. But they have not done better with devices.

The statements that the Senator has made were wrong. We have not had improvement in the way that devices are handled. High-risk and novel device review times in 1995 increased from 348 days to 773 days; if you count the days in FDA hands, 247 to 606. That is on average.

I could go over example after example. In fact, in the budget this year, in responding to that, FDA said we are actually going to slow down, we are actually going to have to slow down review times with respect to device submissions. The agency itself predicted that they would complete 6 percent fewer reviews but review them 20 percent slower. Part of that is our fault. We are not giving them the resources that they need to speed up the process.

But there is another part of this story that we have not heard from the Senator from Massachusetts. That is the testimony of the then-Commissioner of FDA, Dr. David Kessler. The Senator this morning said that under the revolution that is taking place under the leadership of Dr. Kessler, everything now is just hunky-dory.

Well, we had Dr. Kessler before our committee. Dr. Kessler did not say everything was hunky-dory. Dr. Kessler did not say everything was fine. In fact, Dr. Kessler pretty much threw up his hands and said, ''I can't control the agency. I can't administer this agency.'' In an astounding statement to Members of Congress, he said, ''It's only under pressure from the Congress that we have been able to expedite and move things here.'' He said, ''I'm at a loss to do this, but you keep the pressure on.''

Well, if we listen to the Senator from Massachusetts, we would take the pressure off. Then they probably would revert to the same old ways. It is a bureaucracy that has not been administered well under the previous Commissioner. Let us hope the current acting Commissioner or the new Commissioner can do a lot better job than the previous Commissioner. The previous Commissioner seemed more intent on pursuing a political agenda than he did in approving drugs and approving devices that save the lives and improve the health of Americans.

To respond to a question from a Member of Congress, to make the statement that, ''The only way we can improve is if you put pressure on us,'' probably explains the sudden rash of approvals that have come out of FDA. Why? Because we have a reform bill in the process. They have gotten the message. They have gotten the message that Congress will no longer tolerate this delay.

They heard it not just from Republicans, not just from people who so-called represent the device industry or the pharmaceutical industry or the business side, they have heard it from Republicans and Democrats, liberals and conservatives, people on both sides of the aisle.

How did we possibly get out of that Committee on Labor and Human Resources, probably as divided philosophically as any committee in the U.S. Senate, how did we possibly get 14 out of 18 votes? We got it because liberals, Democrats, Republicans, conservatives, all came to the same conclusion. The conclusion was: FDA needs reform, and it needs it now.

We have delayed several weeks here, and even months here, simply trying to get this thing through the Congress. We have had two filibusters. We have had untold procedural tricks and gimmicks, all perfectly within the rules but designed to delay the process. We have had one objection after another.

It was not that long ago when the Senator from Massachusetts was down on the floor saying, ''If we can just fix this cosmetic''—he had his pictures up with problems with the cosmetic and food industry. ''That doesn't go to the heart of the problem; the FDA's drugs and devices, that part is fine. That part is settled. We just have to fix the cosmetic part.'' And so we said, ''OK. We'll fix it.'' And Senator GREGG negotiated a compromise with the Senator from Massachusetts and the Senators from California, and others, and we eliminated that concern.

All of a sudden, when we were told that that is all we needed to do to move this forward, all of a sudden a new issue comes popping up, not one that was offered by amendment in the committee. If it was the primary, the No. 1 priority of the President and the Secretary of Health and Human Services, you would have thought the Senator from Massachusetts or someone would have offered an amendment in committee. But no, it was then the next thing to delay the bill, the next cause celeb, the next throw down the gauntlet, the next draw down the line in the sand, the next ''we can't move forward,'' the next ''this bill is totally worthless without a fix here.'' Fix 19 out of 20. Actually it was 34. The Senator miscounted. Since markup—14–4—since markup, 30 sections of this 60-section bill have been altered. And 34 provisions—as I hold this here in my

hand—of negotiations trying to get the Senator to allow us to move forward with this bill.

The Wall Street Journal today in an op-ed piece calls this a timid bill. It has been watered down. It has been watered down substantially. A lot of us would have liked to have gone a lot farther than we have been able to go with this bill. We had provisions which would allow outside help for the agency, third-party accreditation. Only over the strenuous objections and resistance of the Senator from Massachusetts were we able to move forward with that.

Yet, the FDA had its own pilot program going on that. This is the medical device equivalent of the PDUFA, of the user fee. Let us get some outside help from accredited agencies that FDA certifies, not that DAN COATS selects, not that some device company selects, but that FDA selects. We gave FDA the authority to go out and find scientific laboratories and testing laboratories that met their standards and, under their standards, would be able to assist them in the process of speeding up the review time of devices. Then we built in all kinds of—all kinds of—FDA authority to select the companies, to make sure that there was no conflict of interest, to oversee the process, to withdraw it at any time, to have a final veto over the approved product. Those are just some of them. I have five pages in this bill here of accredited party participation, restrictions that go to FDA to make sure that process is valid, to make sure it has integrity, to make sure it is not a loophole.

Here we are trying to do something that helps FDA, that helps speed the approval of devices that can save lives and improve health. We give FDA all kinds of authority, and we still have to negotiate as if this was going to destroy FDA. Every latest thing we saw, and then something else comes up. ''This is going to destroy FDA.'' FDA retains plenty of authority here, but it gets some help in the reform business and gets a strong message from Congress to ''get your act together, get a Commissioner that knows how to administer as well as how to politic.''

I am more exercised than I usually get on this legislation. We have all tried to be patient as we have worked through this process. But more than one person on this Senate floor can get indignant and upset when people's safety and health and lives are in jeopardy. And there is more than one way that people's safety, health and lives are in jeopardy. Delay of this bill, obfuscation, resistance also jeopardize people's health and safety and lives. To suggest that those of us who do not agree that the Senator's 20th item that he wants compliance with is something that is going to destroy FDA, undermine the entire device section of FDA, put Americans at risk of their health and safety and maybe even their lives, I do not think that is a responsible charge.

I think the obvious answer to that is, delay puts just as many, if not more, people at risk. The Hudson study certainly points that out. What does that mean? It does not mean that we should have no FDA reform. It does not mean we should necessarily have the FDA reform I think we should have. But it means we should have FDA reform. It means we ought to move forward without an ill-conceived attempt to destroy the whole bill.

I do not think the opposition here has been designed to make this a better bill. I think the opposition—and I think it has been made clear with the Senator's statement this morning that everything is fine at FDA, hunky-dory, it is not broke, it does not need to be fixed, it is improving as we speak, with revolutionary changes under Dr. Kessler. I do not think anybody believes that. Well, maybe two people. We had a vote yesterday 98 to 2. Sixty-five people voted for the so-called provision that the Senator said would absolutely kill the bill. And then 33 more joined with those 65 in voting for the bill, even though the Senator's point did not prevail.

So 98 to 2 is a pretty good indication that there is a solid belief here for reform and the solid need for reform. I just hope now we do not have to go through this same tortuous delay process in the House of Representatives where the hard work that has been accomplished here is undermined by those foes of any change in FDA, the status quo people. ''Everything's fine. Let us just keep it as it is. Let's just keep denying Americans the health and safety improvements. Let's keep denying them an efficient FDA.''

Anybody who can stand up and defend efficiency and the effectiveness of this Government-run monopoly has not had very much experience with the private sector. All we are trying to do here is—not strip FDA's authority; there is a public function for that. We are trying to give them some help in accomplishing what I think, what 98 of us at least believes needs to be accomplished.

I am glad I do not have to vent my spleen any more than I already have on this because we are nearing final disposition of this in the Senate. It goes to the House. We will have a contentious conference. I think those who do not want FDA reform will continue to resist this. As I said yesterday, the clock is ticking. If we want funds to provide for the expedited review of drugs, we have to complete this very shortly. September 30 is the date on which it runs out.

We are not going to go forward with PDUFA funds, appropriations or reauthorization unless it includes the reforms that are in this bill. I think that has been made clear. And I think 98 people made that clear yesterday.

I will tell you what. I am reluctant to put this whole Hudson study in. It is several pages. It would be at considerable cost to the taxpayers. I ask unanimous consent that excerpts, some portions, of the Hudson briefing paper be printed in the RECORD so it is not so voluminous. But it is available in my office for anybody to review it.

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

[Excerpts from the Hudson Briefing Paper, Nov. 1995]

THE HUMAN COSTS OF REGULATION: THE CASE OF MEDICAL DEVICES AND THE FDA

(By David C. Murray)

* * * * *

GIANTURCO-ROUBIN CORONARY STENTS

The development of coronary stents has revolutionized the treatment of certain heart conditions related to a severe blockage in or collapse of a coronary artery, the vessel that carries blood to the heart muscle. A sent is basically a wire mesh tube. The surgeon places the stent over an uninflated balloon on the tip of a long guide wire, inserts it into the body through a major blood vessel, and snakes it through the blood vessels into a coronary artery. Next, he anchors the stent inside the artery by inflating the balloon. Then he deflates the balloon, leaving the stent in place to hold the artery open and facilitate the flow of blood to the heart muscle. During the next few weeks, the lining of the artery grows over the stent, anchoring it permanently in place.

Several other interventional techniques, including angioplasty, can treat blockages of a coronary artery. During angioplasty, the surgeon inserts an angioplasty balloon into the coronary artery and expands the balloon next to the blockage, thereby compressing the blockage into the artery wall and allowing blood to flow freely through the artery.

During angioplasty, the coronary artery may collapse, preventing the flow of blood to the heart muscle. This occurs in 2 to 4 percent of the 400,000 such operations performed in the U.S. each year. Unless the flow of blood is restored, the patient suffers a heart attack. Before the development of stents, the surgeon could restore the flow of blood to the heart in about half of all patients by performing an emergency coronary artery bypass graft (CABG) surgery. This operation was quite risky, resulting in the death of approximately 15 percent of patients undergoing the bypass operation.

The coronary stent, however, became an alternative method of treatment for most of these patients. In fact, at hospitals that evaluated the stent during clinical trials, only 8 percent of the patients suffering from abrupt closure of the artery needed to have the bypass surgery. Of those that did require the bypass surgery, only 5 percent died. At the time the clinical studies were done, the late 1980s and early 1990s, there were approximately 350,000 angioplasties done per year in the U.S. Based on these numbers, it is estimated that roughly 1,300 Americans died each year from abrupt closure before the stent was available. Had the stent been approved for use at that time, it is estimated that only 70 Americans would have died per year from abrupt closure, resulting in roughly 1230 lives being saved per year.

Given the importance of this technological breakthrough, one would assume that the FDA would have given expeditious handling to the application for approval of the stent. Sadly for the thousands of Americans who died when they could have benefited from the stent, this was not the case. It took nine months for the device's developers to obtain permission from the FDA to begin preliminary, or Phase I, clinical trials. These trials took another year. The manufacturer then conducted Phase II trials for nine months and, based upon the results of these trials,

requested immediate permission to begin the final Phase III trials.

The FDA rejected this request. The manufacturer appealed and again requested permission to begin Phase III trials. After three more months, the FDA said no. In the meantime, the manufacturer had begun a second set of Phase II trials. The manufacturer appealed again, and after another three months, the FDA finally granted permission for the Phase III trials to begin. Seven months later, the manufacturer had completed the first segment of the Phase III trial and requested permission to expand it. After another seven months, the FDA granted this request; this trial was completed in another 15 months. Four months later, the FDA's advisory panel of medical experts recommended approval of the device, but the FDA did not issue the actual order granting approval until another 12 months had passed. At last, on May 28, 1993, more than six and a half years after the initial application to begin the clinical trials, the FDA approved the device for use in the U.S.

Obtaining approval in Europe was quite another matter. Belgium first approved the device in June 1992, after only a few months of review. Several other European countries quickly followed suit. On the face of it, there appears to be only an eleven-month lag between the European and FDA approval dates, but the whole approval process in Belgium took only a few months, compared with two years for the formal review of the data by the FDA and four and a half years for the clinical trials.

One could argue that the European approval process was a ''free rider'' on the clinical trials the FDA mandated, thus making this comparison unfair. The Europeans did use much of the clinical data generated for the FDA approval process, but the Europeans have a streamlined process for facilitating clinical trials, with the go-ahead generally granted in fewer than 60 days. It is unlikely that it would have taken nine months just to get the clinical trials under way in Europe, as it did in the U.S., just as it is unlikely that the manufacturer would have encountered so many delays in expanding the clinical trials. Indeed, manufacturers who move their clinical trials to Europe cite regulatory flexibility in designing and conducting clinical trials as their primary reason.

Given the complexity of the situation, it is worthwhile to create a range of estimates for the human costs of the FDA's regulatory delays in approving the coronary stent. At an absolute minimum, the delay in approval time between Belgium and the U.S. was 11 months. Using the estimated loss of 1,230 lives per year, the minimum human cost of the 11-month delay is approximately 1,128 lives (11/12 times 1,230). This estimate, however, does not include the delays associated with the FDA's design and oversight of the clinical trials.

TABLE 1.—ESTIMATED NUMBER OF LIVES LOST DUE TO REGULATORY DELAY IN APPROVING THE CORONARY STENT

Regulatory Phase	Time lag (months)	Percent of Lag Attributable to the FDA			
		25%	50%	75%	100%
Investigational Device Application	7	182	365	547	718
Begin Phase III trials	5	130	260	391	521
Expand Phase III trials	5	130	260	391	521
Clinical Subtotal	17	442	885	1,329	1,760
Approval Lag	11	1,128	1,128	1,128	1,128
Total	27	1,570	2,013	2,457	2,888

Taking these delays into account substantially increases the human costs attributable to the U.S. system. Table 1 provides varying estimates of the number of lives lost due to FDA regulatory delay. The estimates vary according to whether the FDA is assumed to be 25 percent, 50 percent, 75 percent, or 100 percent responsible for the delay at each phase of the approval process. The lags in clinical trials in the table are the time in excess of 60 days that it took a manufacturer to obtain FDA permission to proceed to the phase in question. The table estimates FDA responsibility for the 11-month lag between European and FDA approval at 100 percent for all scenarios.

It seems reasonable to estimate that between 1570 and 2888 lives were lost in the U.S. due to the regulatory lags imposed by the FDA for this device. It is readily evident that delay does have a heavy price.

IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

As mentioned earlier, implantable-defibrillators have saved the lives of tens of thousands of Americans, many of whom would have survived only a short time had they not received the implant. The U.S. first approved implantiable defibrillators for use in 1986; CPI, then a subsidiary of Eli Lilly and Company, first brought them to market. The original defibrillators were so large that they could not be implanted in the chest; instead the surgeon placed them inside the patient's abdomen. To connect the defibrillator to the patient's heart, the patient needed a thoracotomy, which involves cracking the sternum and opening the chest. The surgeon then embedded a wire or lead from the defibrillator into the chest and grafted it onto the heart. Needless to say, this was quite a traumatic procedure for the patient and resulted in substantial operative mortality. The early defibrillators certainly saved many, many more lives than they claimed; however, they were only able to deliver one type of energy shock to the patient's heart. The high-energy shock that these devices delivered was effective in some patients, but not all.

A second generation of implantable-defibrillators was approved for use in Europe in 1988 and in the U.S. in 1991. These devices could deliver both high- and low-energy shocks to the patient's heart and the physician could program them to maximize effectiveness.

The third generation of implantable defibrillators was approved for use in Europe in 1991 and in the U.S. in 1993. These were multiprogrammable. The physician could tailor the type of shock the defibrillator would deliver, according to the patient's needs, even after the device was implanted, through the use of an electronic wand. The defibrillator also had an internal memory that kept a record of the number times it had discharged, as well as several key statistics concerning the nature of the shock it had delivered. The physician could access this information with the wand. The defibrillator could also pace the patient's heartbeat; it incorporated recent advancements in pacing technology that allowed the device to correct for both slow- and rapid-beating problems.

The physician used either epicardial or endocardial leads to attach third-generation defibrillators to the heart. He grafted epicardial leads onto the heart muscle by means of screw-in or stab-tab electrodes. This type of lead required a thoractomy, or open chest procedure. Endocardial leads, on the other had, could be threaded through the patient's blood vessels to the heart. Because these leads stay inside the blood vessels, there is no reason to open the chest. Endocardial leads were not originally approved for use with third-generation defibrillators in the U.S., but became available in December 1993. Endocardial leads were first widely available in Europe in late 1991, two years before they were widely available in the U.S.

The clinical evidence in favor of endocardial leads over epicardial leads is extremely strong. A clinical study carried out at 125 participating hospital centers demonstrated that 4.2 percent of patients receiving the epicardial leads died within 30 days following surgery, and only 0.8 percent of patients receiving the endocardial leads died during the same period. Two years after surgery, 87.6 percent of the patients receiving endocardial leads were alive, but only 81.9 percent of patients with epicardial leads were still alive. The medical characteristics of patients in both groups were similar. Other studies have also demonstrated the superiority of endocardial leads, exhibiting a differential in survival rates of about 4 percent.

The fourth generation of implantable defibrillators is much smaller than the previous three. These can be implanted in the chest, under the pectoral muscle, much like a conventional pacemaker. This greatly reduces the length of the leads required and results in a smaller incision. The devices can send out a more efficient type of energy wave that allows the use of endocardial leads in nearly all patients. This new wave, which is biphasic, achieves the same results as the formerly used monophasic waves, but at substantially lower energy levels and with fewer electrodes. The gains in efficiency allow near-universal use of endocardial leads. Another result of the enhancement in efficiency is that the device needs far less testing while the patient is on the operating table. This leads to a reduction in the time the patient is in surgery and should decrease several other complications.

Operative mortality with this fourth-generation device again fell, this time to less than 0.5 percent. The smaller device is also said to be much more comfortable for the patient than the bulkier devices previously implanted in the abdomen. Fourth-generation defibrillators were first approved for use in Europe in October 1993 and in the U.S. in March 1995.

It is evident that during the last several years European consumers have had earlier access to the latest model of implantable defibrillators than American consumers. In fact, American consumers were one full product cycle behind their European counterparts for most of the past five years. Given the improvements in patient survival for each generation of the device, this is hardly a trivial issue. It is estimated that in the early 1990s roughly 13,200 Americans received defibrillators each year, and that the figure reached 20,000 by the mid-1990s.

Because of the regulatory lags outlined earlier, it can be estimated that 1,206 Americans died who, statistics indicate, would not have died if the same device that was available in Europe had been available in the U.S. The two-year regulatory lags in approving endocardial leads led to 1,056 of these deaths, and the 18-month regulatory lag in the approval of fourth-generation defibrillators was responsible for the remaining 150 deaths. Once again, the price of inefficient regulation carried a heavy human cost for American heart patients.

Mr. COATS. Let me yield the floor, because I do not think I will speak again, but not before commending the chairman of the committee, who has persisted with the patience here that is remarkable. He has persisted because he believes that this is an important thing to move forward on, that this issue is important to the health and safety and lives of Americans. I appreciate his effort and work and his cooperation and his standing tall with us even though it has not been easy.

So I thank the chairman, The Senator from Vermont, and, in view of that, yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER (Ms. COLLINS). The Senator from Vermont.

Mr. JEFFORDS. Madam President, I want to thank the Senator from Indiana for bringing to the awareness of my colleagues what the other side of the story is with respect to the famous 404 provision relative to devices.

I only add, as I would point out, there are some 6,000 devices approved each year, and during the period of the last 5 years around 30,000, of which there were only 5 or 6 that were found to have had problems after approval. So I want to try to get the dimensions of this problem which has really dominated our time.

I thank the Senator from Indiana.

Madam President, I ask unanimous consent that the statement of the managers be printed in the RECORD.

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

STATEMENT OF THE MANAGERS

After the mark-up of S. 830, supporters of the bill, the minority, and the FDA were able to come to agreement on several provisions, previously the subject of disagreement, on the basis of new legislative history. Other new provisions were agreed to which require accompanying legislative history. The following substitutes for the language in the committee report for S. 830, which shall not be considered part of the legislative history of this bill on the topics discussed below.

SECTION 601—MINOR MODIFICATIONS

The Committee changed section 601 only as that section relates to manufacturing changes, and this statement only supplants prior legislative history to the extent such history describes and explains manufacturing changes to approved PMA devices covered by the markup version of 601(c). Section 601 now better reflects the Committee's desire to ensure a workable means of expediting the clearance of significant manufacturing changes. The provision permits manufacturers to submit a notice to FDA describing manufacturing changes, summarizing data and information supporting the changes, and asserting that the changes were made in accordance with current good manufacturing practices. Before commercially distributing a device subject to such manufacturing changes, the manufacturer must wait 30 days from the date of the Secretary's receipt of the notice. If within the 30 day period the manufacturer receives from the Secretary a written statement that the notice is inadequate, the device may not be distributed until sufficient information is added to the notice to make it adequate within the meaning of the notice requirements of this subsection.

The Secretary will also have the option of requesting PMA supplements for the manufacturing changes identified in notices. If such a request is made, the Secretary will have 135 days from the date of receipt of the manufacturing supplement to approve or deny it. However, to the extent that a notice satisfies the content requirements for a manufacturing supplement, the time used by the Secretary for reviewing the notice will be deducted from the 135 day review period. For example, if the Secretary used 30 days to review a notice and requested a PMA manufacturing supplement, then the Secretary would have 105 days to review the supplement from the day of its receipt by the Secretary. The Committee expects that the Secretary commonly will permit manufacturing changes through the 30 day notice procedure after gaining experience with the procedures outlined by this subsection and with the performance of regulated persons. Important to the Committee's consideration in advancing this approach to manufacturing changes was the Secretary's recent implementation of pre-production design controls which require consideration of manufacturing specifications in the overall design evaluation of a device.

SECTION 604—AUTOMATIC CLASS III DESIGNATION

Section 604 includes a process that permits the Secretary to classify devices based on the Act's risk-based classification criteria when a device is found to be not substantially equivalent to a predicate devise. Specifically, thirty days after receipt of a not substantially equivalent determination, the person receiving the Secretary's classification order may request that the Secretary make a risk based classification determination for the person's device, if the type of device had not been previously classified. The manufacturer should provide information to assist the Secretary in making the risk-based classification. The Secretary will then determine the device's classification based on the classification definitions in section 513(a)(1) and any material provided for the Secretary's review. These classification definitions have been used by the Secretary to classify or reclassify over a thousand types of devices.

Within 60 days of the above request, the Secretary must make a classification determination, placing the device into one of three statutory device classes. If the device is placed into classes I or II, it may be commercially distributed immediately. Of course, like any device, devices classified into class I or II under section 604 will be subject to all provisions of the Act. However, if the device is placed in class III, its status will remain unchanged from its not substantially equivalent designation; that is, the device will be classified into class III and will require an approved premarket application under section 515 before marketing.

Once a device is classified into class I or II under section 604, it becomes a predicate for future premarket notification submissions. Persons who file reports under section 510(k) may demonstrate the substantial equivalence of newer devices to these predicates in the same manner as under current law.

The Committee realizes that ''special controls'' can be controls or a variety of controls that will assist in providing a reasonable assurance of device safety and effectiveness. When conducting a classification review under this section, the Secretary may classify a device into class II even when special controls do not yet exist.

Importantly, the fact that a device is subject to a special control under this section does not mean that enforcement authority over such controls in other parts of the Act become ineffective. For example, postmarket surveillance and labeling can be special controls. Nonetheless, postmarket surveillance is still enforceable as a misbranding under section 502(t) and specified labeling instructions remain enforceable under either section 502(a) or 502(f)(1) as misbrandings, depending on the labeling control at issue.

The Committee included section 604 to avoid the needless expenditure of the Secretary's resources that would occur if lower risk devices were subjected to premarket approval reviews under section 515 because such devices were unique and found to be not substantially equivalent to a predicate device. The Committee also believes that section 604 may permit the Secretary to avoid time and resource consuming substantial equivalence determinations that rely on remote predicates. The committee does not intend that this provision will alter the Act's substantial equivalence provisions or the Secretary's longstanding approach to the 510(k) classification process.

In sum, insofar as special controls are referenced in section 604, the committee intends to clearly communicate that any special control is enforceable to the extent enforcement authority specifically addressing such controls exists in the Act. Special controls that are voluntary, for example standards recognized by FDA under section 205 or agency guidance documents, may not be required to demonstrate substantial equivalence or, more generally, compliance with any requirements under the Act; however, alternate means of achieving compliance must be demonstrated by regulated persons.

SECTION 612—HEALTH CARE ECONOMIC INFORMATION

The purpose of section 612 is to make it possible for drug companies to provide information about the economic consequences of the use of their products to parties that are charged with making medical product selection decisions for managed care or similar organizations. Such parties include formulary committees, drug information centers, and other multidisciplinary committees within health care organizations that review scientific studies and technology assessments and recommend drug acquisition and treatment guidelines. The provision is limited to analyses provided to such entities because such entities are constituted to consider this type of information through a deliberative process and are expected to have the appropriate range of expertise to interpret health care economic information presented to them to inform their decision-making process, and to distinguish facts from assumptions. This limitation is important because it will ensure that the information is presented only to parties who have established procedures and skills to interpret the methods and limitations of economic studies. The provision is NOT intended to permit manufacturers to provide such health care economic information to medical practitioners who are making individual patient prescribing decisions nor is it intended to permit the provision of such information in the context of medical education.

Health care economic information is defined as an analysis that identifies, measures, or compares the economic consequences of the use of the drug to the use of another drug or another health care intervention or no intervention. Incorporated into economic consequences are the costs of health outcomes. Data about health outcomes associated with the use of drug, other treatments, or no treatment are therefore incorporated into the economic analysis. This provision limits such incorporation to health outcomes that are directly related to the approved use of the drug and are based on competent and reliable scientific evidence. The provision presumes that the current standard practice of including full disclosure of all assumptions and health outcomes used in the economic analysis will continue.

The type of health care economic information that can be provided pursuant to this section is that which is directly related to an approved labeled indication. To illustrate this point, economic claims based on preventing disease progression would ordinarily not be considered to be directly related to an approved indication for the treatment of

symptoms of a disease, for a drug for which the use in prevention of disease progression has not been approved. For example, rheumatoid arthritis drugs are approved for the treatment of symptoms and not for the prevention of deformity. Therefore, economic claims based in part on an assumption of prevention of deformity would not be considered directly related to the approved indications for these drugs.

Similarly, economic claims based on prolonging patient survival would not be considered directly related and would not, therefore, be permitted under this subsection, for agents approved for the symptomatic treatment of heart failure, but not approved for prolonging survival in heart failure patients. This provision also is NOT intended to provide manufacturers a path for promoting off label indications or claiming clinical advantages of one drug over another when such claims do not satisfy FDA's evidentiary standards for such claims.

However, the provision would permit health care economic information that includes reasonable assumptions about health care economic consequences derived from, but not explicitly cited in, the approved indication that is supported by competent and reliable scientific evidence. The nature of the evidence needed will depend on how closely related the assumptions are to the approved indication and to the health significance of the assumptions. For example, modeling the resource savings from tight control of blood sugar in Type 1 diabetes with insulin therapy could include costs savings associated with the prevention of retinopathy (an eye disease) and nephropathy (kidney disease) based on well-controlled study(ies) that demonstrate that control of blood sugar levels with insulin leads to a reduction of such consequences. Because prevention of retinopathy and nephropathy could not simply be assumed to be a result of blood sugar control, these prevention claims would have to be shown by well-controlled study(ies) before inclusion as health care outcome assumptions.

In contrast, economic claims that model, based on observational studies in a population of women, the economic consequences of prevention of fractures due to osteoporosis would be permitted for drugs already approved for prevention of fractures due to osteoporosis. This is possible because observational data may be considered competent and reliable for making an assumption about the secondary consequences of an osteoporotic fracture once the primary prevention has been established. Similarly, the long-term economic consequences of the prevention of meningitis by haemophilus be influenza vaccine could be modeled using population-based data once the primary prevention claim is established.

The standard of competent and reliable scientific evidence (49 Fed. Reg. 30999—August 2, 1984) supporting health care economic information provided under this subsection takes into account the current scientific standards for assessing the various types of data and analyses that underlie such information. Thus, the nature of the evidence required to support various components of health care economic analyses depends on which component of the analysis is involved. For example, the methods for establishing the economic costs and consequences used to construct the health care economic information would be assessed using standards widely accepted by economics experts. The methods used in establishing the clinical outcome assumptions used to construct the health care economic analysis would be evaluated using standards widely accepted by experts familiar with evaluating the merits of clinical assessments. In addition, the evidence needed could be affected by other pertinent factors.

Under FDA's current postmarketing reporting regulations, health care economic information as defined in this section must be submitted to FDA at the time it is initially provided to a formulary committee or other similar entity. In addition, pursuant to this provision, FDA will have access, upon request, to any data or other information related to the substantiation of the health care economic information. Such information is evaluated by the Secretary to determine if the health care economic information meets the requirements of this section. This consists of, for example, health outcome data, health resource utilization data and other information related to the economic consequences of the use of the drug. It would not include, for example, confidential corporate financial data, including confidential pricing data.

SECTION 617—HEALTH CLAIMS

Section 617 of the bill amends section 403(r)(3) of the Act to authorize a health claim based upon a published authoritative statement of an authoritative body of the United States. Such a claim would be lawful if it meets the requirements of clause (C), including the requirement that the Secretary be notified 120 days prior to a claim appearing on a food in interstate commerce. It is expected that the Secretary will ensure that all relevant offices of the Department give sufficient priority to evaluating the information in the notice submitted under clause (C) so that only accurate and appropriate claims appear on food labels. Specifically, the Committee expects that where the Secretary determines that a claim should be modified or prohibited under clause (D), a regulation can be drafted by the Food and Drug Administration within 100 days, and that the remaining 20 days will be adequate for other necessary reviews, including review within FDA and within the Department. The Committee also expects that the Office of Management and Budget will either waive its review of a regulation promulgated under clause (D) or complete that review expeditiously. In the event that FDA must consult with the authoritative body whose statement forms the basis of the claim, the Committee expects that the authoritative body will give the highest priority to that consultation to facilitate, within the 120 day notification period, the resolution of any outstanding differences.

SECTION 619—POSITRON EMISSION TOMOGRAPHY

The Committee intends in section 619 to require FDA to develop a framework for the regulation of radiotracers used in positron emission tomography (PET) scans based on the unique characteristics of PET and taking into account, where appropriate, the differences between the limited quantities of PET radiotracers compounded by not for profit institutions, such as academic medical centers, and the larger quantities that may be produced by commercial PET centers.

The Committee has established a period of four years as a reasonable time period in which appropriate new regulatory procedures will be developed by FDA and any necessary applications submitted by PET centers. Until the expiration of that four year period, the Committee intends to require that PET radiotracers meet the standards set by the United States Pharmacopoeia (USP) for safety, efficacy and compounding, and that the FDA or state agencies will enforce the standards set by the USP. In addition, makers and users of PET radiotracers will continue to be subject to the requirements of the various state boards of medicine and pharmacy which they are currently required to meet.

USP standards are recognized in the Food, Drug, and Cosmetic Act (FDCA) in the adulteration and misbranding sections of the Act (Secs. 501(b) and 502 respectively). USP establishes standards for marketed drugs in the U.S. It first provided standards for PET pharmaceuticals in 1988. During these years, USP standards have served to standardize and help assure the quality of these items and protect the public health. USP establishes standards or drugs through a rigorous peer reviewed process, and the FDA provides input and comment to USP as part of this process.

Section 619(a)(1) amends the FDCA to add a definition of a ''compounded positron emission tomography drug'' to mean a PET drug and associated software and hardware which has been compounded in accordance with state law by or on the order of a practitioner licensed in that State or in a federal facility in accordance with the law of the State in which it is located.

Section 619(b)(1) amends the FDCA to provide that a compounded PET drug is adulterated, and thus subject to regulatory and/or legal action by FDA, if it is compounded, processed, packed, or held other than in accordance with the PET compounding standards and the official monographs of the USP.

Section 619(b)(2) provides that the amendment effected by section 619(b)(1) shall cease to be effective four years after the date of enactment of this act, or two years after the adoption by FDA of the requirements specified in section 619(c), which occurs later.

Section 619(c)(1) requires that, no later than two years after the enactment of this act, FDA shall establish appropriate procedures for the approval of PET drugs pursuant to section 505 of the FDCA and appropriate current good manufacturing practice standards for such drugs. In both instances, the Committee intends that FDA shall take due account of any relevant differences between non-profit institutions that compound PET drugs for their own patients and commercial manufacturers of such drugs. FDA is directed to consult with patient advocacy groups, professional associations, manufacturers and physicians and scientists licensed to make and/or use PET drugs prior to establishing the procedures and requirements contemplated by this provision.

Section 619(c)(2) provides that FDA shall not require the submission of a new drug application for an abbreviated new drug application pursuant to section 505 of the FDCA for PET drugs which meet the appropriate USP standards referenced by section 619(b)(1) for a period of four years after the enactment of this act, or for two years after the establishment of the procedures and requirements under section 619(c)(1), whichever occurs later. The Committee intends that FDA shall use up to two years of the four year period to consult with the groups mentioned above and to formulate its procedures and requirements. Thereafter, the Committee intends that a period of one year be allowed to prepare and submit any necessary applications. Finally, FDA is given one year to review and act upon the applications. The Committee would expect that FDA would take no action against an applicant if, at the end of the four year period, the agency has neither approved nor issued a not approvable letter in response to an application filed within one year after the agency's procedures for PET drugs have been promulgated.

Section 619(d) requires the revocation of certain Federal Register notices which announced a rule inconsistent with this legislation.

PET is an imaging technique that produces a computerized image (scan) using small quantities of a radioactive tracer to measure biochemical activity in the body. It has been demonstrated to be an effective method of separating benign from malignant lesions,

staging the degree of metastasis, determining therapeutic effectiveness and identifying early recurrence of disease in several types of cancer, including lung, breast, colorectal, head and neck. In addition, PET has a high degree of accuracy in identifying early signs of coronary artery disease and in assessing whether cardiac tissue is alive following a heart attack. In more than one million uses of PET tracers in Europe and one million in the United States, the Committee is unaware of any reported instance of an adverse reaction to PET radiotracers. PET radiopharmaceuticals have been used in patients in the United States for over 30 years. Recent research and advances in imaging technology have enhanced the clinical importance of PET.

PET radiotracers are unique among radiopharmaceuticals because of their short half-lives, ranging from 30 seconds to 110 minutes. Therefore, most PET radiotracers are made using a cyclotron which is at or near the PET site, and most are made up on an individual dose basis upon the prescription of a licensed physician. At present, there are 70 PET centers in the United States, almost all of which are part of academic medical centers. PET technology and its applications were developed in large part with almost $2 billion in federal research funds. Yet, while PET is widely used in Europe, its benefits have not been widely available to American patients, mainly because of lack of reimbursement and inappropriate and costly regulations promulgated by FDA.

Under current FDA requirements, PET centers which compound PET radiopharmaceuticals on an individual dose basis would be required to meet FDA's Current Good Manufacturing Practices (CGMP) and to file NDA's and ANDA's for each type of PET tracer and for each indication for which the tracer might be used. This is the same type of regulation which the FDA applies to large pharmaceutical manufacturers.

Academic medical centers are facing unprecedented cost pressures. Without regulatory relief and expanded reimbursement, particularly from the Medicare program, many PET centers are likely to close, and the benefits of PET will be unavailable to the taxpayers who funded their development. For example, the University of California at Los Angeles estimated that FDA's new PET regulations would cost the University at least $300,000 for a single application for a single use of a PET radiotracer.

The Committee intends that adoption of this section will permit FDA to establish a regulatory framework for PET drugs that will enable PET centers to continue to make this valuable technology available to patients at reasonable cost and assure that the public health will be protected. The Committee also expects that the Health Care Financing Administration will, until four years after the enactment date, consider PET drugs which meet USP standards under the provisions of this section to be approved by FDA for purposes of Medicare reimbursement.

SECTION 807—NATIONAL UNIFORMITY

Warnings

New Section 761 provides for national uniformity for OTC drugs for human use. Under this section state and local governments may not in general have requirements for OTC drugs that are different from or in addition, or otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 or the Fair Packaging and Labeling Act.

Section 761(c)(2) makes it clear that the scope of national uniformity extends to any state requirement upon a manufacturer or distributor to mandate, by any method of communication, a warning of any kind. Such a requirement might relate to a warning on the label, in labeling, through posters or advertising, in letters or other mailing, or in any other form of public notification. Similarly, the provision applies to all forms of required warnings, not just those formally designated as a ''warning.'' It includes any statement, vignette, or other representation which indicates, directly or by implication, that the drug presents or may present a hazard to health or safety. For public health reasons, any warning of any kind, in any type of public communication, should be uniform throughout the country.

The reference to ''a warning of any kind'' is intended to make clear that a state requirement is preempted if it relates to a warning, regardless of whether the state requirement is described as a ''warning.'' For example, if the substance of a state requirement is to mandate a warning, it would be subject to preemption even if it were called a ''notification'' or ''information'' requirement.

It should be noted that the provision would not prevent the states from undertaking unilateral action to issue their own public statements in the form of health department releases, public service announcements, or public education campaigns to alert state consumers about its concerns about an OTC drug.

Exceptions

Subsection (d) deals with the situation where a drug is neither subject to a new drug application (NDA) or a final OTC drug monograph, and therefore has not been the subject of a full review by FDA of all applicable regulatory requirements. Until that FDA review occurs, national uniformity only applies where a state requirement relates to the same subject as a federal regulation or the same subject as a federal statutory amendment made on or after the date of enactment, but is different from, or in addition to that specific federal requirement. Where there is no such specific federal requirement and the drug is not subject to an NDA or a final monograph, the state remains free to impose its own requirement.

Thus, a state generally can impose a requirement on the content or labeling of a product not the subject of a final monograph. But a state cannot establish a different requirement (warning or otherwise) for a drug not subject to a final monograph where a final federal regulation on the subject is in place. For example, alcohol containing OTC drug products intended for ingestion (whether or not the subject of a final monograph) must meet the requirements of a final federal regulation which specifies maximum permissible concentrations of alcohol. A state could not issue a different regulation on that subject even if the state regulation applied only to products not subject to a final monograph. A similar situation is presented by FDA's proposed regulation requiring massive and in-depth changes in labeling format for OTC drugs. That proposal applies to all OTC drugs whether or not they are subject to a final monograph and therefore when final would preempt any different or additional state requirements.

Once FDA has conducted its full review in the form of an NDA or final OTC drug monograph, the FDA regulatory program will have a general preemptive effect for drugs subject to an NDA or final monograph, no state may enact any additional or different requirement that is of the type imposed by the three designated federal statutes. States may enforce identical provisions, but not requirements that are in addition to, different from, or otherwise not identical with the federal requirements. The full FDA review involved in an NDA or final monograph, along with the requirements of other applicable FDA regulations assures that all appropriate regulatory requirements including those involving safety, effectiveness, manufacturing, packaging, and labeling, are all in place for OTC drug products. For that reason, no other state requirements will be permitted.

Thus, generally (unless another final federal regulation applies) a state can require a warning for a drug that is not subject to an NDA or a final monograph, because FDA has not yet had an opportunity to conduct a full review of all potential warnings applicable to the drug. Once FDA approves an NDA or promulgates a final OTC drug monograph for the drug, however, no state may thereafter require any form of warning on any subject, through any form of public communication, unless it is identical with whatever warning is required by FDA. Additional or different warnings would thereafter be precluded.

SECTION 811—INFORMATION EXCHANGE

Incentives for Research

It is the Committee's belief that section 771 will provide health care practitioners important scientific information about uses that are not included in the approved labeling of drugs, biologics, and devices. We recognize, however, that our goal should also be to ensure that these new uses get onto the product label. That is why we have incorporated strong incentives to conduct the research needed to get those uses on the label. Pursuant to subsection (a)(3)(A), a manufacturer who seeks to disseminate information about a new use must either certify that it will file a supplemental application for the new use (if the studies have already been completed) or must submit a proposed protocol and schedule for conducting the necessary studies and a certification that a supplemental application will be filed. If the studies are completed at the time dissemination begins, a supplemental application must be filed within 6 months from the date of the initial dissemination. If the manufacturer commits to conduct the studies, a supplemental application must be filed within 3 years, unless the Secretary determines that more time is needed to complete the studies and submit a supplemental application. The Secretary may grant an extension of the three year period if the manufacturer has acted with due diligence to conduct the studies in a timely manner, but such extension may not exceed two years.

Although our goal is to ensure that the research is done to get new uses on the product label, we also recognize that there may be limited circumstances when it is appropriate to exempt a manufacturer from the requirement to file a supplemental application. Subsection (a)(3)(C) provides that a manufacturer may file a request for an exemption from the requirement if such manufacturer can demonstrate (I) that due to the size of the patient population or lack of potential benefit to the sponsor, the cost of obtaining clinical information and submitting a supplemental application is economically prohibitive, or (ii) it would be unethical to conduct the studies necessary to obtain adequate evidence for approval of a supplemental application.

In making the determination of whether to grant an exemption pursuant to subsection (a)(3)(C), the Secretary may consider, among other things, the following factors, if relevant, whether:

(1) the new use meets the requirements of section 186(t)(2)(B) of the Social Security Act;

(2) a medical specialty society that is represented in or recognized by the Council of Medical Specialty Societies (or is a subspecialty of such society) or is recognized by

the American Osteopathic Association, has found that the new use is consistent with sound medical practice;

(3) the new use is described in a recommendation or medical practice guidelines of a Federal health agency, including the National Institutes of Health, the Agency for Health Care Policy and Research, and the Centers for Disease Control and Prevention of the Department of Health and Human Services;

(4) the new use is described in one of three compendia: The U.S. Pharmacopeia—Drug Information; the American Medical Association Drug Evaluations; or the American Hospital Association Formulary Service Drug Information;

(5) the new use involves a combination of products of more than one sponsor of a new drug application, a biological license application, a device premarket notification, or a device premarket approval application; and

(6) the patent status of the product.

Subsection (a)(3)(D) requires manufacturers who commit to conduct studies to obtain evidence on new uses to provide the Secretary with periodic reports that describe the status of the studies. The reports required by this provision are not intended to be burdensome. In many cases it would be sufficient for manufacturers to provide brief updates on the status of the studies. In general, the purpose of this provision is to keep the Secretary apprised of how patient enrollment is proceeding, any significant problems that could affect the manufacturers' ability to complete the studies, and expected completion dates.

Additional Information

The principal policy considerations that underlie this provision are the facilitation of greater access to timely and accurate information to health care providers. Coupled with this goal is a recognition that the FDA has a responsibility to protect the public health. Thus, the discretionary authority of the Secretary to offer objective statements on the proposed dissemination and to require the manufacturer to disseminate additional information to achieve objectivity and balance is preserved.

It is important to recognize that it has been the long held view of Congress that the FDA cannot, and should not, regulate the practice of medicine. Thus, the FDA has no authority or jurisdiction to regulate how physicians prescribe approved drugs. This means that physician prescribing of off label uses of approved products is not within the jurisdiction of the FDA. In this case, because the physician is receiving information from a drug sponsor (whose conduct is within the jurisdiction of the FDA) the FDA has a role to play with respect to assuring balanced and objectivity necessary to fulfill its statutory mission. Because health care providers retain responsibility of making treatment decisions with respect to individual patients, the FDA's role with respect to individual treatment decisions based on peer reviewed articles and textbooks is advisory. In that advisory capacity the FDA will take steps to make sure that the amount of information given to the provider is useful, useable, and in compliance with this section. This requirement should not be read as requiring the FDA to comment on each and every proposed dissemination, rather this authority will likely be used in the limited circumstances in which balance can not be fully met by the options listed above of appending other journal articles or data or analyses. The intent is that the statement be limited to objective and scientific information and not present an opportunity to editorialize independently-derived scientific information. The statement is intended to provide significant scientific information to the health care providers.

New Information

This section offers a safeguard to assure the health care provider community that a disseminated journal article or textbook which discusses an off label use will trigger an update requirement in the event that the Secretary determines that there is a risk that the drug may not be effective or may present a significant risk to public health. The new information submitted by the manufacturer will be in a form prescribed by the Secretary in regulations. The Committee notes that manufacturers are already legally required by section 314.81 of volume 21 of the Code of Federal Regulations to submit annual reports to the Secretary. As opposed to the comprehensive data required under section 314.81, this requirement is limited to data on safety and efficacy. The Committee assumes that this requirement will not be burdensome, rather tailored to meet the public health responsibilities to be exercised by the Secretary. In addition, after the Secretary makes a finding under this provision the Secretary is required to consult with the manufacturer before determining what corrective actions are commensurate with the public health need of the affected health care provider community and what is in the best interests of potentially affected patients.

Rule of Construction

Subsection (d) provides that nothing in section 771 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner. The Committee has an interest in ensuring that current agency policies that encourage scientific exchange are not being modified by section 771. At the same time, insofar as the Secretary may currently have authority in other sections of the statute to restrict a manufacturer's dissemination of information in response to an unsolicited request from a health care practitioner, nothing in section 771 is intended to change or limit that authority.

Establishment of List of Articles and Textbooks Disseminated and List of Providers That Received Articles and Reference Textbooks

In order to effectively implement the authority of the Secretary to require corrective actions be taken by the manufacturer, the regulations promulgated by the Secretary may include record keeping requirements to make sure that such corrective actions are effective. These record keeping provisions should be tailored to meet the underlying purpose of the provision requiring corrective action. For example, in the case of new information under Section 771 that requires an update of a disseminated article, it may be appropriate to require the publication of an advertisement in the journal of a specific medical specialty society; or, in other cases, a ''Dear Doctor'' letter may be appropriate. It should not be necessary for manufacturers to keep a list of all providers who receive information disseminated under this section, if the company is willing to notify by letter or advertisement a larger group of health care providers in order to implement a corrective action.

PDUFA SIDELETTER

Ms. MIKULSKI. Madam President, I would like to have the chairman's understanding of the letter to be submitted by the Secretary of Health and Human Services concerning the performance goals of the FDA in connection with the reauthorization of the Prescription Drug User Fee Act of 1997, PDUFA.

Mr. JEFFORDS. I thank the Senator from Maryland for raising this very important point. As with the 1992 law, I intend that the FDA's performance goals that have been worked out between FDA and industry in the PDUFA reauthorization be covered in a separate letter. The letter will be sent by Secretary Shalala to Chairman BLILEY and me, as well as the distinguished ranking members of the House Commerce Committee, Mr. DINGELL, and our committee, Mr. KENNEDY.

This letter is referenced in the findings section of the user fees provisions of the bill. It will spell out in detail the performance goals that FDA has agreed to meet for each of the 5 years of the reauthorized user fee law.

I consider the provisions that will be in the Secretary's letter and attachment to be as mandatory as if they were in the statute itself. I expect the FDA will treat them as such just as it has with the provisions in the 1992 letter.

Ms. MIKULSKI. Mr. Chairman, I agree completely with what you just stated. The provisions that have been negotiated between FDA and industry and set forth in the sideletter from the Secretary are a key part of PDUFA. These provisions cover electronic submissions, meeting management goals, clinical holds, major dispute resolution, special protocol question assessment and agreement, and additional procedures, such as action letters.

Not only should these performance goals be considered fully binding on the agency, they should be considered as minimum, not maximum commitments. If the agency can do better, it should. I know that FDA will do its best to exceed the performance goals and other matters spelled out in the letter, just as it has exceeded its commitments in the 1992 PDUFA letter.

EFFECTIVE AND AGGRESSIVE OVERSIGHT OF THE FDA

Mr. JEFFORDS. I yield to the Senator from Washington, a member of the Senate Labor and Human Resources Committee for purposes of engaging in a colloquy.

Mrs. MURRAY. As a new member of the Senate Labor and Human Resources Committee I have spent the last 8 months coming up to speed on the FDA, reform proposals and the impact of these proposals. I have met with groups representing all sides on these issues—from the biotech industry to groups representing patients. I have tried to keep an open mind and work to find acceptable solutions to the many problems pointed out by industry and the patient groups. There appears to be a general mistrust among all interested parties. As a result each side is concerned about going too far—industry is concerned about burdensome and unnecessary regulation by FDA and the patients are concerned about effective regulation of the industry. It appears that this general mistrust is based on past experiences and each side can give numerous examples.

My objective was to revitalize the FDA to give it the regulatory flexibility to effectively regulate the pharmaceutical and medical device industry without jeopardizing timely approval of safe and effective lifesaving drugs and devices. At the same time, I am well aware of the prominent public health role played by the FDA—it is after all, a public health agency, not a drug or device manufacturer. My support for real reforms by no means says that I did not support an aggressive public health agency role for the FDA.

Several weeks ago, I met directly with several biotech companies in the State of Washington. As I sat at the table listening to their concerns I was struck by the amount of experience at the table and level of integrity that many of the companies are known for. I am proud to represent these companies that are on the cutting edge of medical technology and have contributed significantly to improving health care for all Americans. I knew that those companies would not market a dangerous, life threatening drug or device; that none of these companies deliberately act to falsify clinical data or would refuse to complete clinical trials. I knew that these companies were more concerned with getting their lifesaving technologies to patients than simply making a profit. They know the value of one's reputation and are truly proud of the lifesaving work they have done. Sadly, however, not all companies have the same commitment to the patient's health and are allowing stockholders, not scientists, to make decisions. Because of this, I am asking for the Chairman's commitment that the Senate Labor and Human Resources Committee will retain a strong and aggressive oversight role.

We are making some sweeping and some may argue dramatic changes in the way the FDA operates. We need to be sure that these changes are positive and that FDA has the resources and ability to remain an effective public health agency. If we detect future problems or conflicts, I need your commitment and support for swift and thorough hearings. I need to know that we will continue to monitor the FDA, and if legislative revisions are necessary to protect the public health, we will act with great speed. There is probably no other Member more hopeful that some of these reforms will means that patients get access to safe and effective drugs and devices sooner, but I also know that we cannot forget the past. There are certainly many examples of situations where the public health was put into jeopardy by unscrupulous pharmaceutical and medical device manufacturers. I need your assurances that if problems arise we will act to address any potential threat to the public health.

Mr. JEFFORDS. I share the Senator's goal of ensuring a strong FDA and believe the modernization and revitalization provisions included in S. 830 make for a better FDA, not a weaker one. Like you I have had the opportunity to meet with industry groups here in Washington and with consumers, patients, and physicians both here and at home in Vermont. All of these interested parties have made important points about how to modernize the agency while ensuring that its stellar standard for public safety remain as strong as ever. Though Vermont doesn't have any of these large industries regulated by the FDA, all of us use their products. The people and the patient advocates of Vermont have told me that more needs to be done to ensure their timely access to the best therapies available. I believe we have accomplished that with this bill.

I think that the Senator from Washington would agree that it's important to put aside once and for all that consumers, patients, and physicians universally oppose this measure. Vermont patient groups and their members—and I'm sure you have heard from your constituents—have told me that they support this effort to modernize the FDA. The Vermont Epilepsy Association, the Vermont Medical Society, the Vermont Association for the Deaf, the Vermont Board of Pharmacy, the Vermont Alliance for the Mentally Ill, and the Epilepsy Foundation of Vermont have all urged passage of the measure. At the national level we have heard from innumerable groups that support S. 830 and urge its passage. For example, the National Health Council—which includes the Arthritis Foundation, the National Multiple Sclerosis Society, and the Leukemia Society among its over 100 member organizations—took out a full-page advertisement in the Roll Call newspaper urging that the Senate move forward with this legislation.

I agree with my colleague from Washington and you can be assured that if problems do arise, I would act quickly to address any threat to the public health. Simply because we are authorizing PDUFA for 5 years does not mean that we cannot change other sections of the Food, Drug and Cosmetic Act. It could also turn out that some of these reforms, like expanded third party review for medical devices, will become such a success that the FDA will want to extend the program beyond the pilot phase.

Effective and aggressive oversight is one of the most important tools of the Labor and Human Resources Committee for making sure that the FDA can keep pace with the rapid changes in medical technology and still be a public health agency that is the envy of the world. I thank the Senator for her commitment to working toward real reforms that strengthen the FDA and the contributions she has made in crafting this bipartisan measure.

Mrs. MURRAY. I thank the Chairman for his support and commitment to a strong FDA and am grateful for his leadership on this legislation.

PHARMACY COMPOUNDING

Mr. KENNEDY. Madam President, I would like to engage my colleagues, Senator JEFFORDS, the distinguished chairman of the Labor and Resources Committee, and Senator HUTCHINSON, the distinguished Senator from Arkansas, regarding a provision in S. 830 pertaining to the practice of pharmacy compounding.

Mr. JEFFORDS. I would be pleased to enter into such a colloquy with the distinguished Senators from Massachusetts and Arkansas.

Mr. KENNEDY. First, I want to commend my colleagues and their staffs for their efforts in the difficult task of drawing the line between drug manufacturing and pharmacy compounding. Ordinary pharmacy compounding has been traditionally regulated by the States, but drug manufacturing, even when conducted by State-licensed pharmacists, is regulated under Federal law. Under current law, the Federal Food, Drug, and Cosmetic Act specifically exempts from the inspection and registration provisions of the act pharmacies that compound drugs for sale in the regular course of dispensing or selling drugs at retail. However, FDA and the courts that have addressed the matter interpret the act as not providing any general exemption from the new drug, adulteration, and misbranding provisions for drugs compounded by pharmacists. It is my understanding that section 809 of S. 830 would bring the legal status of compounding in line with FDA's longstanding enforcement policy of regulating only drug manufacturing, not ordinary pharmacy compounding. This legislation would, as I understand it, exempt drugs compounded in pharmacies from the new drug, and certain other, provisions of the act, but the exemption would not create a loophole that would allow unregulated drug manufacturing to occur under the guise of pharmacy compounding.

Mr. HUTCHINSON. As the sponsor of the amendment that became section 809 of S. 830, I concur with the distinguished ranking minority member of the Labor and Human Resources Committee that this legislation would ensure patient access to individualized drug therapy, and prevent unnecessary FDA regulation of health professional practice. This legislation would exempt pharmacy compounding from several regulatory requirements but would not exempt drug manufacturing from the act's requirements. The legislation also sets forth a number of conditions that would have to be met in order to qualify for the exemption from the act's requirements. I would note that the conditions established by section 809 should be used by the State boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to State-specific regulations. When a State board determines that certain compounding activities are outside the parameters established in section 809, that State board should refer the practitioners in question to the FDA for review.

Mr. KENNEDY. I thank the distinguished Senator from Arkansas for describing the reasons why this section is so important to patients and to the health professions. I want to especially commend his staff for working with mine to develop this legislation that exempts from Federal law the activities that are appropriately regulated by the States.

It is my understanding that some of the conditions are intended to ensure that the volume of compounding does not approach that ordinarily associated with drug manufacturing. Other conditions appear to be intended to ensure that the compounded drugs that qualify for the exemption have appropriate assurances of quality and safety since these compounded drugs would not be subject to the more comprehensive regulatory requirements that apply to manufactured drug products.

Mr. JEFFORDS. I believe the Senator is correct in his understanding.

Mr. DOMENICI. Madam President, I rise in support of S. 830, the FDA Modernization Act. This bill provides comprehensive—and long overdue reform to the FDA.

The primary focus of S. 830 is to streamline and strengthen the FDA's review and approval of lifesaving drugs and medical devices. One important mechanism for doing this is the Prescription Drug User Fee Act [PDUFA]. PDUFA authorizes the FDA to use fees collected from prescription drug manufacturers to expedite the FDA's review of drugs. The fees collected go to hiring new employees to increase the FDA's resources for reviewing new drugs.

With all of the advances in science and medicine, we must ensure the swift review of new drugs for life-threatening diseases. When there are backlogs and delays in drug approval, American lives can be lost. For example:

The 7-year delay in the FDA's eventual approval of beta blocker heart medicines cost the lives of 119,000 Americans; and

The FDA's 3½-year delay in approving the new drug Interleukin-2 (IL–2) cost 25,000 Americans to die of kidney cancer, even though the drug already had been approved for use in nine other countries.

This bill is good because it will give Americans access to lifesaving medication, without needless delay.

I would like to share with you the story of one man from my home State of New Mexico who would benefit from this bill.

Leonard Alderete is 39 years old and has lived in Albuquerque, NM all of his life. In 1987, Leonard was diagnosed HIV positive. Five years later, Leonard sought medical intervention because his condition worsened and he feared his life would end. Leonard began taking the standard AZT. In 1996, Leonard's health again took a downturn. Blood tests revealed that the virus had spread at an alarming rate through his system. In order to slow the spread of the virus, Leonard needed an aggressive treatment.

Leonard's doctor prescribed the drug regiment of 3TC, AZT, and Crixivan, which is also known as a triple cocktail. A key drug in this mixture is the protease inhibitor, Crixivan. Through PDUFA, Crixivan was made available to consumers within 3 months of its submission to the FDA. Shortly thereafter, Leonard began taking Crixivan.

Thanks to the ''triple cocktail,'' the virus is now below detectable levels. Although this is not a cure, it does provide Leonard hope—a more long-term hope for the future.

Leonard is a member of the Governor's task force on HIV/AIDS. He is the only member who has HIV. As a member of the Task Force, he advocates for the rights of those who are HIV infected—as well as those in the community who are affected.

Leonard has written, called, and even traveled to my office in Washington, DC two times this year to urge my support for this bill. Leonard provides testimonial for the importance of FDA reform, and especially PDUFA.

Fortunately, patients afflicted with AIDS as well as other life threatening diseases have a ''Leonard'' advocating for them. There are many other Leonards both silent and vocal all across the country who will benefit from this bill. It is on their behalf that I urge my colleagues to support S. 830.

Ms. MOSELEY-BRAUN. Madam President, I support S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997. I also want to commend Senators JEFFORDS and KENNEDY for their hard work on this legislation, and the compromises that will ultimately improve the FDA and improve the public's access to cutting edge medical technology.

Despite recent improvements, I am concerned that the length of time and amount of paperwork required for FDA approval of new products may still be excessive. For many companies desiring to market new products, application to the FDA is a formidable obstacle. In some cases, the length and complexity of the process can deter companies from even applying. This is a particularly troubling prospect given the increasing globalization of markets for health care products and food.

The FDA cannot continue to protect the public health through its traditional methods. Most industrialized and emerging nations participate in multilateral trade agreements that aim to reduce trade barriers. These agreements will continue to bring pressure on the FDA to harmonize its regulatory policies with other international safety and performance standards. The policies that have made the United States the ''gold standard'' in public health protection must be reformed to function properly in this global economy. This does not mean that we cannot continue to be the gold standard. It simply means that market forces will bring pressure on the FDA to implement policies that encourage the launching of new products in this country, as opposed to Europe, and ensures that the United States maintains its technical and scientific leadership in health disciplines.

As stewards of this generation, we must move to strike the balance between protecting the public health, fostering global trade under multilateral agreements, ensuring swift access to new health technology for Americans, and strengthening the U.S. technical and scientific leadership. S. 830 is a very good effort to balance those sometimes competing goals.

First, the bill reauthorizes the Prescription Drug User Fee Act [PDUFA] for an additional 5 years. PDUFA has been one the most successful pieces of governmental reform legislation. During the 5 years since we first passed PDUFA, the average approval time for pharmaceutical products has dropped over 40 percent. There is still more room for improvement. Many product reviews remain cumbersome, and applicants at times do not have a clear indication of the type of information necessary for FDA review.

S. 830 also makes considerable progress in expediting patients access to important new therapies and potentially life-saving experimental treatments. Just a few months ago, one of my constituents encountered considerable bureaucratic red-tape in her effort to access a potentially life-saving treatment for Hodgkin's disease. Only after countless appeals by my office and hundreds of my constituents did the FDA acquiesce. The troubling part of this incident was that the FDA had approved the same treatment for other patients several years prior. This is not to say that the people who work at the FDA were not following their current guidelines. They were probably following the guidelines to the letter. But the spirit of the FDA's mission was utterly lost in the process. S. 830 makes the much needed reforms.

Along the same lines, the bill also establishes a national registry of clinical trials. The primary impediment to patients access to potentially life-saving treatment is not the FDA but actually a lack of knowledge about ongoing research. A national database, which patients can access, will greatly assist people across the Nation who are searching for hope for their illnesses. This important reform is long overdue and absolutely necessary to continue providing Americans the best in medical treatment and technology.

Finally, the bill strikes an appropriate balance between protecting the public interests and allowing manufacturers to share important off-label use information with providers. It would have been a grave mistake to either prevent the distribution of off-label use information or not allow the FDA to play a vital role in ensuring the adequacy of information being distributed by manufacturers. I know that a lot of work went into the compromise

reached regarding off-label usage information and the agreement greatly benefits the American public.

I would like to congratulate the architects of legislation including patient and industry groups who worked so hard to achieve balance. Patients groups are to be especially congratulated for their steadfast pursuit of this reform. Just 2 weeks ago, I met with some of my constituents who have multiple sclerosis and amyotrophic lateral sclerosis—also known as Lou Gehrig's disease. Their message was loud and clear—pass FDA reform now. This is a resounding message that I cannot ignore.

Madam President, it is equally important to say that this legislation is not meant as an attack on the efforts of the women and men who work at FDA. I have great respect for the role that the agency and its employees play in protecting consumers from unsafe and ineffective healthcare, food, and cosmetic products. The FDA has taken a number of steps over the last several years to streamline administrative functions and work better with industry and consumers to facilitate the availability of cutting edge medical technology. The success that FDA has achieved in reducing the time to review new drugs and get potentially lifesaving therapies on the market is laudable. The reviewers at FDA should take pride in these accomplishments. This legislation simply builds on those reforms.

My support for S. 830 should not be construed as a complete endorsement of the bill. This is not a perfect piece of legislation. There are features that patient advocates, industry, and regulators simply do not support. Senator KENNEDY has done a good job of highlighting some of the issues and there have been a number of amendments accepted that further improve the bill.

I am particularly concerned that the bill does not adequately address food safety, which will certainly emerge as a major public health issue. Most of the recent criticism of the FDA has focused on the biologics and medical technology areas. Regulation of imported food products will probably be the pressing issue of the next millennium. As more imported agricultural products find their way to American tables, there will be more pressure upon FDA to act to prevent tainted products from getting to the market.

Nonetheless, reform is absolutely necessary and S. 830 is a good start in that direction. This bill represents a full year of work by stakeholders aimed at reaching compromise legislation. The bill does not contain the draconian hammer provisions that made many of us reluctant to support FDA reform last year. I am happy to have a bill that I can support and that I truly believe moves the country in the right direction. S. 830 is good for patients, good for the industry, and good for the Nation's global competitiveness. I hope that my colleagues will join me in supporting this important legislation.

Mr. MCCONNELL. Madam President, in 1906, Congress approved the first national statute to prevent the sale of adulterated and misbranded food and drugs. Since then, the FDA's responsibility to protect the health and safety of American consumers from unsafe products has expanded to cover over one-third of the products sold in our Nation.

While medical research and technological developments have revolutionized our Nation's capacity to advance the public health, the FDA's adherence to bureaucratic and inefficient practices threatens to undermine the potential benefit of these hard-earned innovations. In the 1950's, it took a new drug or medical device approximately 8 years or less to achieve FDA approval. Today, the average time for approval runs between 12 to 15 years. Over the course of 20 years, the FDA's product approval system has undergone careful study by Congress, investigational committees, and the FDA itself, and each has identified key areas of reform that would enhance FDA performance.

This week, the U.S. Senate considers vital legislation to ensure that the FDA can successfully fulfill its core mission to protect public health and safety through priority management, timely review of product applications, and effective use of expert resources. S. 830, the Food and Drug Administration Modernization and Accountability Act, reflects the fundamental recommendation of the Advisory Committee on the Food and Drug Administration that the FDA ''should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people.'' The Advisory Committee noted that product approval ''can be as important as preventing the marketing of harmful or ineffective products, . . . especially . . . for people with life-threatening illnesses and for diseases for which alternative therapies have not been approved.'' In other words, antiquated procedures that promote unnecessary delays in the review of new products and therapies fail to promote the public health.

In recent weeks, misinformation regarding the purpose and application of S. 830 reforms has been disseminated. As a supporter of S. 830 and a member of the Senate Committee on Labor and Human Resources, I want to clarify the objectives of this important legislative initiative.

First, this bill clearly sets forth the FDA's mission to protect the public health by ensuring products meet appropriate regulatory standards, and to act promptly and efficiently in its review of clinical research and other information relevant to the marketing of approved products.

Second, S. 830 responds to increasing public concern on the lack of access to investigational products for patients suffering from serious or life-threatening diseases. The FDA has established programs for the compassionate use of investigational products, however, only a limited number of patients have benefited from these opportunities. This bill will enable any patient with a seriously debilitating or immediately life-threatening condition to gain access to an investigational drug or device if the request is made by a licensed physician and the product's use meets the FDA's standards for expanded access. S. 830 also improves patient access to new therapies through a new fast-track drug approval process.

Third, the bill addresses key deficiencies in the assessment of pharmaceutical effects on children. Currently, there is no systematic means for testing drug safety and efficacy for pediatric use. S. 830 will allow the Secretary to request pediatric clinical trials for new drug applications and provide an extra 6 months of market exclusivity to manufacturers who voluntarily meet conditions under the trial program.

Fourth, this measure will improve the availability of health care economics information for medical providers, and create data bases about on-going research and clinical trials for new lifesaving therapies for patients. Access to clear, concise information will help both health care professionals and patients identify the best course of medical treatment available.

Fifth, S. 830 contains a series of reforms to assure that the FDA utilizes the scientific expertise of qualified Federal agencies, like the National Institutes of Health, and accredited outside organizations in order to improve the timeliness and quality of product reviews. The bill also contains reforms to ensure that the application process for new products is governed by consistent and equitable regulatory requirements in the areas of product classification, review, and approval.

Sixth, this measure reaffirms the FDA's accountability for the performance of its Federal obligations. As a member of the Senate Appropriations Subcommittee for Agriculture, I have repeatedly questioned the FDA regarding its failure to prioritize resources for the fulfillment of its statutory requirements. In response to these concerns, S. 830 requires the FDA to develop a clear plan outlining how it will comply with its obligations under Federal statute, and report to Congress annually on the plan's implementation. In addition, the FDA must streamline and update procedures for product review and inspection so its resources are applied cost effectively.

Seventh, S. 830 contains targeted reforms for food regulation. The bill simplifies the approval process for indirect food contact substances. It provides a more reasonable standard for the use of bona fide health claims based on the authoritative recommendations of qualified scientific bodies, such as the National Institutes of Health and the Centers for Disease Control and Prevention. While food reforms take on a minor role in this bill, I look forward

to working with my fellow members on legislation that will more thoroughly address the regulatory concerns of the food industry.

Finally, S. 830 reauthorizes the Prescription Drug User Fee Act. In 1992, the FDA and pharmaceutical industry agreed to the collection of additive user fees to pay for the additional staff needed to rectify delays in the review of new drug applications. This reauthorization proposal seeks to build upon those successes through new performance goals and equipment modernization plans. PDUFA serves as a clear example that the FDA can work with regulated industry and consumers to advance the public health through priority management and efficient use of resources.

Madam President, S. 830 has been formed brick by brick from inclusive, bipartisan negotiations by representatives of the FDA, the Clinton administration, the U.S. Senate, industry, and consumer groups. The purpose of this bill is not to weaken the FDA's ability to defend the public health, but rather to enhance its capacity to fulfill this statutory obligation. Whether the issue is food safety or a breakthrough medical treatment, our Nation's researchers will only be successful if the FDA is prepared to effectively respond to the quickening pace of scientific discovery. S. 830 lays this essential foundation for the FDA's future, and I urge my colleagues to join in its approval.

Mr. REED. Madam President, I rise today to address S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997. This is an important bill with serious implications for the health of the American people.

The FDA is responsible for assuring that the Nation's food supply is pure and healthy as well as providing a guarantee that drugs and medical devices are safe and effective. The FDA has an immense impact on the lives of all Americans. Few government agencies provide this kind of important protection for the American people. Indeed, the FDA's mandate requires it to regulate over one-third of our Nation's products. Daily, the FDA faces the delicate balance between ensuring that patients have swift access to new drugs and devices, while guaranteeing that those new products are safe and effective.

S. 830 contains many positive elements. It reauthorizes the important Prescription Drug User Fee Act, one of the most effective regulatory reforms ever enacted. S. 830 also includes a number of provisions that will improve and sensibly streamline the regulation of prescription drugs, biologic products, and medical devices. I believe that these important reforms to the operation of the Food and Drug Administration will increase its efficiency and speed the delivery of important new medical treatments to patients.

One of the most important elements of this legislation is the reauthorization of the Prescription Drug User Fee Act, often referred to as PDUFA. PDUFA established an important partnership between the agency and the industry, and has successfully streamlined the drug approval process.

I am pleased that S. 830 will provide expedited access to investigational therapies. This provision builds on current FDA programs related to AIDS and cancer drugs. Another important element will allow designation of some drugs as fast track drugs, thus facilitating development and expediting approval of new drugs for the treatment of serious or life-threatening conditions. The bill will also require the Secretary of the Department of Health and Human Services to establish a database on the status of clinical trials relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. Patients have long deserved access to such information, and I am pleased that this bill provides it.

S. 830 is the result of ongoing negotiations both prior to and subsequent to the markup of the legislation. Through this process, a number of provisions that seriously threatened public health and safety were dropped or otherwise resolved. I am particularly pleased that improvements made since the markup include important protections to the third party review process. Important changes have also been made to provisions regarding health claims for food products, health care economic claims and a number of other provisions in the original legislation.

Yet, there was one important change that was not made to S. 830. Yesterday, along with Senators KENNEDY, BINGAMAN, and DURBIN, I offered an amendment that would make a change on device labeling claims—an issue that has been identified by the Secretary of HHS as worthy of a recommendation to the President to veto this bill. Although our amendment did not prevail, I am still hopeful that this issue can be resolved as the bill continues through the legislative process.

In effect, the bill limits the FDA's current authority to ask device manufacturers for safety data. It prohibits the FDA from considering how a new device could be used if the manufacturer has not included that use in the proposed labeling application. As a general matter, the FDA does not consider uses that the manufacturer has not included in its proposed labeling materials. However, there are instances when the label does not tell the whole story. It is these instances—when the label is false or misleading—that our amendment addressed.

I am disappointed that we were not able to resolve this one issue, because the rest of the bill is worthy of support. However, I am unable to support this bill today because the device labeling issue remains unresolved. This matter is too important to the health and safety of Americans to vote for S. 830 at this time.

I look forward to working with my colleagues to resolve the issue of the FDA's authority in the device approval process. And when this issue is resolved, I am prepared to vote in favor of this bill.

Mrs. BOXER. Madam President, I want to begin my remarks by acknowledging the tremendous amount of work both Senator JEFFORDS and Senator KENNEDY have put into this bill. I know there are a few issues where there is still disagreement. I also realize that some of my colleagues may be offering amendments which they believe will strengthen the bill.

On balance, however, I believe this is a good bill that will have a very positive impact on helping to streamline and expedite some of the FDA review processes; and thus, help patients get access to new and promising treatments and devices in a safe, efficient, and expeditious manner. There is no agency within the Federal Government which has as direct or significant an impact on the American people as the Food and Drug Administration.

The FDA is responsible for ensuring the foods that we eat are safe, wholesome, sanitary, and properly labeled, that the drugs that we take, and that we give our pets, are safe and effective and that there is a reasonable assurance that the medical devices which we use are safe and effective. I believe the FDA has done, and continues to do, a tremendous job in carrying out this mission—it is internationally recognized as the gold standard for the approval of medical products.

The most important aspect of any FDA reform bill must be public safety. We have the safest food, drugs, and medical devices of any country in the world; and nothing we do should ever undermine this—period.

I also believe, however, that rapid technological advancements being made by biotechnology companies, and others, necessitate, and allow for, an expeditious product review and approval process. Obviously, this product review and approval process must simultaneously assure safety and efficacy. Again, safety and efficacy should not be compromised.

Let me share with my colleagues an example of the technological advances being made by the biotechnology industry. Affymax, a biotechnology company located in my home State of California, has developed a technology to speed-up the analysis of drug and biological compounds.

Affymax is a leader in the emerging field of combinatorial chemistry. Combinatorial chemistry functions by creating large numbers of diverse compounds to test against different disease targets. Affymax combines chemistries, sophisticated software and innovative molecular biology techniques to rapidly analyze and synthesize these potentially useful drug and biological compounds.

I know about this process because I had the pleasure of seeing it when I

toured Affymax's laboratories last year. Affymax has greatly accelerated the pace of drug discoveries by developing high technology automated machines which can synthesize and screen 10,000 compounds in just one week. The same testing, previously done in test tubes and petri dishes, used to take about 5 years.

These are the kinds of advancements which I believe make it necessary for the FDA to streamline its process, in those areas which can be streamlined, so that patients may get safe and effective products as expeditiously as possible. There are literally hundreds of thousands of patients around the country waiting for the next new and promising drug therapy and/or device to be approved.

There are, of course, other very important aspects of this bill. Not the least of which is the reauthorization of the Prescription Drug User Fee Act—commonly referred to as PDUFA.

PDUFA is generally considered the most successful piece of FDA reform legislation in recent history. It enables the FDA to collect user fees from pharmaceutical and biotechnology companies. Those fees are used to pay the salaries of hundreds of additional product reviewers and to fund product review. As a result, the FDA is able to speed-up its drug approval process and to more expeditiously get new and promising drug therapies, and medical devices, to those that need them.

By all measures, PDUFA has been enormously successful. One measure of that success is the assertion by all parties involved—the FDA, patients, prescription drug manufacturers, consumer groups, and policymakers—that the program has worked. Certainly any program that receives the unanimous support of industry, consumer groups, the FDA, and policymakers must be extremely beneficial and should continue to be supported.

This bill has other constructive elements as well. For example, the bill allows for expedited access to investigational drug therapies and for the expanded humanitarian use of devices. The bill also provides an incentive for drug manufacturers to conduct studies which support the safety and effectiveness of pediatric drugs and it provides for expanded collaboration and communication between the FDA and device manufacturers.

The pediatric drug provision in this bill is especially important inasmuch as the overwhelming number of drugs on the market today are not tested for safety and effectiveness on children. It is important, therefore, that we provide drug manufacturers an incentive to test their products on children.

I believe this provision, which gives drug manufacturers an additional 6 months of market exclusivity, is a reasonable and appropriate incentive, and will be a first step toward getting more drugs labeled for pediatric use. A very important and significant goal.

I am also excited about the provision in this bill which allows for expanded communication and collaboration between the FDA and device manufacturers. It is important that device manufacturers and FDA examiners, early on in the review process, clearly establish the type of scientific evidence that will be necessary to demonstrate device effectiveness. Not only will this provision help bring about increased clarity and certainty in the review process, it will also help speed safe and effective devices to market. I believe this is especially important given the rapid technological advancements being made in this area.

Finally, I want to thank Senators GREGG and JEFFORDS for working with me to ensure that California's proposition 65 will not be preempted by the uniformity provisions of this bill. California's proposition 65 was passed by California voters in 1986 and requires that persons who expose others to certain levels of carcinogens or reproductive toxins give a clear and reasonable warning.

Proposition 65 has successfully reduced toxic contaminants in a number of consumer products sold in California and it has even led the FDA to adopt more stringent standards for some consumer products. For example, proposition 65 has been used successfully to reduce toxic contaminants in ceramic dishware and in lead-foil wine bottle caps. Notably, the FDA followed the lead of California in both those instances. In fact, the FDA has adopted a standard completely barring the use of lead-foil wine bottle caps pursuant to California's agreement with the wine industry to convert to tin or plastic bottle caps. So I am very pleased that the FDA reform bill now being debated will exempt California's proposition 65.

As I stated at the outset, I believe, on balance, this is a good bill and will be beneficial in helping to get safe and effective drugs and devices to the American people in a more expeditious manner.

Mrs. FEINSTEIN. Madam President, S. 830, the bill before us today, will improve the tools used by the Federal Food and Drug Administration to bring more, safe and effective drugs, biologics and medical devices to the American people more quickly.

FDA is one of our Government's most important agencies because FDA approves life-saving medicines and devices and FDA protects us from unsafe and ineffective medicines and devices. Thanks to FDA, products like defective heart pacemakers, dangerous intrauterine devices, and overheating infant incubators are not sold.

FDA's 2,100 scientists and 7,000 other employees monitor about $1 trillion worth of products each year, inspect over 15,000 facilities a year, and examine about 80,000 product samples. FDA finds about 3,000 products a year unfit for consumers and detains 30,000 imports a year at ports of entry.

HOPE FOR CURES FOR DISEASES

Millions of Americans have serious, debilitating illnesses for which there is no treatment or cure. There are 3,000 to 4,000 genetic diseases alone. Cancer kills half a million Americans per year. Diabetes afflicts 15 million Americans a year, half of whom do not even know they have it. Fifteen thousand American children die every year. And, for children, the rates of asthma, bronchitis, sinusitis, heart murmurs, epilepsy, and anemia are on the rise. We put our faith in the medical industry and Government to find cures and therapies. Americans want an FDA that brings safe and effective drugs to market as quickly as possible to alleviate suffering, pain, and disease and to prevent death.

The bulk of the bill before us today, a bill to accelerate the approval of prescription drugs, biologics, and devices, is an important bill to the Nation and especially to my State. It is a good bill, except for section 807, ''National Uniformity'', provisions that could interfere with California's efforts to protect the public health laws.

CALIFORNIA'S ROLE

California is the Nation's premier medical technology base, public and private. Many of the Nation's leading drug, biotech, and device companies collaborate with the State's nine academic medical centers and conduct some of the world's leading health research. The UC system has spawned 30 Nobel laureates. Forty percent of California's biotech companies were started by UC scientists.

The Nation's largest concentration of health care technology companies is in California who employ 165,000 people. California's 900 health care technology companies are producing leading edge products, for example, the first new therapy for cystic fibrosis in 30 years, Genentech; technology that enables doctors to do heart surgery without opening the chest cavity, Heartport; a cancer drug that is genetically engineered and stimulates the bone marrow to produce important white blood cells, Amgen; and linear accelerators for treating cancer, Varian, and intraocular eye lenses, Allergan.

California produces 19 percent of all U.S. medical instruments, 20 percent of all diagnostic materials, and 13 percent of all biologics. There are 915 drugs, biologics, and devices under development in my State.

So the bill before us is important to both the human health and the economic health of the Nation and of California.

KEY PROVISIONS

The bill includes several improvements over current law that will bring more drugs, medical devices, and biotech products to people more quickly:

1. Extends User Fees: Extends for 5 years the Prescription Drug User Fee Act to accelerate drug and biologics approvals. The prescription drug user fees, enacted in 1992, have enabled FDA to hire 600 additional drug reviewers and FDA has cut drug approval times almost in half, from 29.2 months in 1992

to 15.5 months in 1996, according to the drug industry. This means that patients have had access to drugs almost a year sooner. These include a new class of drugs for asthma; a new treatment for multiple sclerosis; five new cancer drugs; the first new insulin product in 14 years; and three new antiviral medicines for AIDS, including two protease inhibitors.

This bill reflects the agreement of the drug and biotech industries to pay over $500 million in new user fees over the next 5 years, which could bring to the public 1,000 medicines now in the pipeline. These renewed user fees could help FDA cut drug approval times even more, an additional 10 to 16 months.

2. Clinical Trials Database (the Feinstein-Snowe bill): Requires NIH to establish a database, including a 1–800 number, for patients and medical providers to obtain information on clinical trials on serious and life-threatening diseases. This provision incorporates S. 87, a bill I introduced with Senator SNOWE, last August, was suggested by one of my constituents in a hearing of the Senate Cancer Coalition, which I co-chair. Facilitating access to information can help patients and their doctors learn about research underway and can expand the pool of research participants.

4. Pediatric Drugs: Provides 6 months of additional market exclusivity of a drug when the manufacturer, at the request of the FDA, conducts pediatric studies to support pediatric labeling for a drug.

According to the American Academy of Pediatrics, only 20 percent of drugs have been tested and proven to be safe and effective for use in infants and children. This creates serious problems for pediatricians who must prescribe with inadequate information or deny children important therapies. In a July 24 letter to me, they give the example of asthma and say that in most children it manifests itself by age five, but there is only one asthma drug labeled for children under age five.

5. Accelerating Approvals: The bill includes a number of provisions designed to modernize, streamline, and accelerate the drug and device approval process. For example, it allows products manufactured at a small or pilot facility to demonstrate safety and efficacy prior to scaling up to full manufacturing, unless FDA determines that a full-scale facility is necessary to ensure safety and effectiveness.

For biotech products, it establishes one license, rather than the current two, covering both the biologics or product license and the plant's manufacturing processes license . For medical devices it requires FDA to meet with manufacturers to establish the type of scientific data needed to demonstrate efficacy of the device and it requires FDA and the applicant to meet to evaluate the status of an application 100 days after submitting applications.

PREEMPTING CALIFORNIA'S PUBLIC HEALTH LAWS

California has a long history of regulating nonprescription drugs and cosmetics and has led the Nation in many instances in protecting the public in these areas. For example, in 1981, California adopted a requirement that nonprescription drugs carry a label warning pregnant or nursing women to consult with their physician or pharmacist prior to using a drug. In the following year, FDA adopted the California requirement.

But section 807 of the bill, titled ''National Uniformity,'' restricts States' actions by prohibiting States from establishing or continuing, for nonprescription drugs, any requirement that is ''different from or in addition to or that is otherwise not identical with'' a Federal requirement. For cosmetics, Section 807 prohibits states from establishing or continuing requirements for packaging and labeling that are ''different from or in addition to or that is otherwise not identical with'' a Federal requirement.

California Attorney General Lungren, in a July 14 letter, cites the Sherman Food, Drug, and Cosmetic Law as an example. He argues, ''* * * we are concerned that this provision may be construed to preempt States from imposing any requirements on cosmetics or over-the-counter drugs, and could therefore prevent the State of California from enforcing significant laws dealing with the health and safety of its citizens in the absence of a specific FDA exemption.''

The California Department of Health Services has also raised concerns about the preemption language, concern about the bill's impact on their ability to protect the public health. I believe in allowing States to enact stronger laws to protect the health of citizens and introduced an amendment on September 15 to allow California's laws to stand.

I appreciate the colloquy of my colleague and the bill manager, Senator JEFFORDS, that clarifies the extent of preemption intended by the authors of the bill. Senator JEFFORDS clarified that it is not the intent of this bill to prohibit the state from issuing public statements to warn the public about public health dangers. He said that it is not the intent of the bill to preempt State enforcement authority such as California's power to embargo products and to license and annually inspect facilities. On advertising, he stated that it is not the intent of the bill to affect State laws that prohibit false and misleading advertising or to prohibit unsubstantiated claims for nonprescription drugs. My office will remain in communication with the State to determine if problems develop and work with Senators JEFFORDS and KENNEDY in this regard.

The bill does include, at my request, an explicit protection—an exemption from preemption—for California's ''Proposition 65,'' a ballot initiative enacted in 1986 on a 63 to 37 percent vote which requires anyone exposing someone to chemicals known to cause cancer or birth defects to give a warning. Attorney General Lungren wrote on July 14 to Senator JEFFORDS, ''S. 830 [as reported from the Labor Committee] would, in the absence of specific FDA exemption, appear to prevent the State of California from enforcing both the Sherman Food, Drug and Cosmetic Law as well as Proposition 65, a state 'Right to Know' statute, passed by the voters of California in 1986. * * * We therefore respectfully urge you to seek modification of your bill to address this issue.''

Proposition 65 has provided important protections to the public and has prompted manufacturers to reformulate products. Because of this law, for example, manufacturers removed toluene from nail polish, lead from antacids, and calcium supplements and leadfoil from wine bottles. I am pleased that the Senate agreed with my request to explicitly exempt proposition 65, preserving this important California law, and I thank my colleagues for their support.

I believe it is wrong to preempt California's progressive drug and cosmetic laws. The citizens of my State have chosen to safeguard the public health through a strong State law and I have worked to protect our State's laws in this bill.

CONCLUSION

By extending prescription drug user fees, we can give FDA some of the resources it needs to bring products to the public and alleviate human suffering. I hope that this bill can move quickly to enactment so that the public will have a strong FDA.

Mr. WELLSTONE. Madam President, I take this opportunity to thank my colleagues for all of the hard work that they have done on S. 830, the FDA Modernization and Improvement Act of 1997. Senator JEFFORDS has provided his leadership in bringing this legislation forward, and my other colleagues have worked to negotiate agreement on provisions where there was concern. I would like to thank Senator COATS, who was true to his word that he would work with us to come to an agreement on third party issues, and Senator GREGG, who worked to reach a compromise on the national uniformity provision.

It is my belief that we can provide medical products to consumers in a more timely manner through many of the provisions in this bill, while retaining significant consumer protections. Many of the provisions in S. 830 will take a significant step toward addressing Americans' concerns with the FDA. The legislation would improve the predictability, timeliness and focus of the regulatory process for medical products. The legislation would also improve communication and collaboration between the FDA and the regulated industries. I strongly endorse the view that these objectives can be met

and unnecessary regulatory burdens can be minimized without compromising the quality of the reviews.

My colleagues and I have worked very hard on bringing forward needed reform proposals with respect to the review and approval of medical devices. We have negotiated many of the original provisions in the bill to the point that we have reached agreement on them, and can join together in supporting them. We have taken into consideration the comments and concerns of consumers and industry in order to present a bill that will improve the review and approval processes.

As you know, I have always been and will continue to be a strong consumer advocate. I think that S. 830 provides many things for consumers and will help to bring them medical therapies that are safe and effective in a more timely fashion. This is especially true with respect to devices. This is the part of the bill on which I have focused the bulk of my attention, and I do think that a large number of concerns that I and some of my colleagues, in particular Senator KENNEDY, had have been addressed.

There has been a great deal of discussion and debate about section 404 of the bill, which deals with labeling for intended use of devices. This issue is highly technical, but it is clear that all of us have the same goals in mind: First, to provide a degree of consistency in the way devices are reviewed by individual reviewers, so that reviewers do not try to second guess an honest manufacturer with respect to the intended use of a device, and second, to prevent the very few companies who might try to avoid presenting the FDA with adequate data about safety and effectiveness from having their devices classified and brought to market under the 510(k) process. I do not believe that the provision in this bill prohibits the FDA from exercising its authority to not find a device substantially equivalent to its predicate device when there are technological differences that raise new issues of safety and effectiveness. But obviously, there are differences of opinion with respect to this provision. Since we all agree on the goals that we are trying to achieve, I think that there must be a way of clarifying the authority of the FDA in a way that is satisfactory to everyone.

The Reed-Kennedy amendment offered one option, but this option is not the appropriate one. Several other suggestions for language to clarify this have been offered, but none capture what we are all trying to do. Rather than reiterate all of the arguments that were stated in the debate over the past several days, I will ask that my colleagues who are appointed as conferees work together to ensure that this provision is worded to make clear that it will penalize anyone who tries to get around the law, but will not penalize those who are complying with the intent of Congress and the law.

Madam President, as I have said before, I think this is an important piece of legislation. It is clearly important that we reauthorize and improve PDUFA, and that we work to bring safe and effective medical therapies to the public in a timely manner. Again, I would like to thank my colleagues, especially Senator JEFFORDS and Senator KENNEDY and their staff members for all of their efforts on this bill. I would also like to thank the consumer groups for their input, and the administration for its assistance in the negotiations process. I trust that the conferees will keep the importance of this bill in mind as they negotiate to bring the final legislation to the floor for passage.

Mr. JEFFORDS. I ask unanimous consent that a letter from the Nonprescription Drug Manufacturers Association to Senator LOTT be printed in the RECORD.

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

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION,
Washington, DC, September 15, 1997.

Hon. TRENT LOTT
U.S. Senate, Washington, DC.

DEAR SENATOR LOTT: In a letter to you dated September 4, the National Governors' Association (NGA), National Conference of State Legislatures (NCSL) and Association of State and Territorial Health Officials (ASTHO) stated their opposition to the national uniformity provision (§761) in S. 830, the Prescription Drug User Fee Act (PDUFA) and FDA modernization legislation. Unfortunately, their letter contained several incorrect and misleading statements concerning nonprescription, over-the-counter (OTC) medicines and the application of the national uniformity provision. In order to set the record straight on this important issue, I offer the following comments.

1. NATIONAL UNIFORMITY FOR OTC DRUGS WILL PROTECT THE PUBLIC HEALTH AND SAFETY

One national, uniform system of regulation for OTC drugs protects the interests of all American consumers. There is simply no difference in the safety, effectiveness, and proper labeling of OTC drugs from one state to another. An OTC drug that is safe, effective, and properly labeled for a consumer in Louisiana is safe, effective, and properly labeled for a consumer in Massachusetts, and vice versa.

Allowing states to establish a patchwork of different requirements for OTC drugs makes no sense. It would even be detrimental, resulting, for example, in confusion as consumers are confronted with different labels for the very same OTC drug obtained in different states. Moreover, non-uniform laws for OTCs would drive up consumer expense through the costs of different and inconsistent state requirements for testing, labeling, and packaging, and through disruption of the distribution for products required to meet as many as 50 disparate state systems.

The authors assert that there is no evidence that shows a need to preempt state laws regulating OTC drugs. Attachment A lists several examples of state proposals, which, if enacted, would have disrupted national uniformity.

2. IMPORTANT STATE INTERESTS WOULD BE FULLY PROTECTED UNDER S. 830

The authors mistakenly say that states would be prevented from effectively addressing compelling OTC drug problems unique to their states under S. 830. They particularly criticize the exemption procedure in S. 830. The exemption provision enables a state to petition FDA to depart from the single uniform national standard for an OTC drug. The preparation and submission of an exemption petition will not be a very burdensome or expensive process, and FDA can be expected to rule on such petitions promptly. Moreover, the three requirements for exemption from uniformity for a state are logical. If the public interest represented by the state proposal is already protected, there is no need for a state exemption to protect it. As interstate products, OTC drugs could not and should not violate other applicable federal laws. The prohibition against unduly burdening interstate commerce simply requires a sensible balancing of competing interests.

The authors also claim that states would be prohibited from taking action on their own even where there are compelling local conditions. They argue that states are expected to address compelling local conditions and that the Constitution already prohibits state laws that unduly burden state commerce. Therefore, they argue that the preemption provision of S. 830 is unneeded, and that states should not be required to petition FDA for exemptions from preemption.

The authors' premises are flawed. States are not limited to laws that address ''compelling'' local conditions. They have broad police powers to enact laws that deal with any legitimate issue. Moreover, they can pass laws that affect not just local conditions but regional and national ones as well. When analyzed under the ''dormant'' Commerce Clause, state laws enjoy a presumption of validity, and they will not be invalidated unless they impose burdens on interstate commerce that are clearly excessive in comparison to their benefits. This is a very different test from the one embodied in the national uniformity provision of S. 830 for OTC drugs.

A state law that does address a compelling local condition and does not unduly burden interstate commerce would be eligible for FDA consideration of an exemption petition. Many state laws, however, will not meet such a test and therefore should not be permitted to stand. The only way to distinguish one type of law from the other is to establish an exemption petition procedure. The petition process would not be expected to be burdensome, as described above.

Apart from the exemption procedure from preemption in S. 830, states would retain full authority to take action in emergency and (non-emergency) situations involving OTC drugs as follows: First, the bill would not affect the right of a state to take action immediately, without consultation with FDA, to deal with an authentic local emergency involving a nonprescription drug, such as outbreak of an abuse problem. If there is a true local emergency, as the authors acknowledge, the state could take immediate action to place a nonprescription drug on prescription status until the problem abates: And as noted below, some states have done that in the case of ephedrine-containing OTC drug products.

Second, the bill would prevent the states from undertaking unilateral action, again without consultation with the FDA, to issue their own public statements in the form of health department releases, public service announcements, or other public education campaigns to alert state consumers about its concerns about an OTC drug. The bill would simply prevent the states from imposing 50 different notification requirements on the OTC maker, whether in labeling, packaging or other form of public communication, which would disrupt the longstanding national system of review and marketing for nonprescription drugs.

Third, the bill would not prevent the states from utilizing their enforcement authority to take immediate action against an OTC drug that was adulterated, misbranded, or otherwise out of compliance with laws that are the same as federal laws.

Fourth, as recognized by the authors, the states can also require an OTC drug to be dispensed only by prescription.

3. STATES CAN PETITION FOR ADOPTION OF THEIR IDEAS AS THE NATIONAL UNIFORM STANDARD

The authors comment that FDA lacks adequate resources to act and states must be permitted to provide ''important protections'' FDA is unable to provide. This is specious. FDA has not failed to act in any case in the OTC area where action was otherwise warranted, on the basis of resources. FDA regulation of OTC drugs under the OTC Review, for example, is unrivaled in the world as the most comprehensive system of safety, effectiveness, and labeling review of its kind ever undertaken. Similarly, FDA is currently embarked upon a mammoth program to completely overhaul and standardize the format and content of all OTC drug labels.

The authors' argument also ignores the fundamental policy embodied in the national uniformity provision—that FDA is a national expert agency that should set national standards. The states remain laboratories of good ideas, which FDA can adopt as national standards or allow to take effect locally if they qualify for an exemption. But there is no constitutional or policy reason to prefer 50 mini-FDAs over a singly national one.

The bill would preserve the states right to petition the FDA to adopt a state proposal as the uniform national standard for OTC drugs. If a state believes it has an innovative idea for protection of the nation's OTC drug consumers as a whole that is superior to protection provided by FDA, it can petition FDA to adopt the idea as the national standard. That way, potential improvements in the OTC regulatory system can be evaluated by all interested parties against the background of the overall FDA regulatory program for OTC drugs. If FDA concludes that the state's proposal is the right one, then it can adopt it as the national standard.

4. STATES WOULD NOT BE PREEMPTED IN REGULATION OF DIETARY SUPPLEMENTS OR OTHER KINDS OF FOODS

The authors mistakenly assume that dietary supplement state regulation and other health food regulation would be affected by preemption. Neither dietary supplements nor foods of any kind, including dietary supplements or health foods containing ephedrine, would be covered by the OTC drug preemption provision of S. 830. Thus, none of the state laws cited by the authors in Louisiana, New York, Michigan, Maryland, Vermont, Washington, or Minnesota, would be preempted by S. 830 because there is no preemption of food laws.

5. STATES WOULD NOT BE PREEMPTED FROM REGULATING OTC DRUGS OTHER THAN WITH RESPECT TO THE FEDERAL LAWS GOVERNING OTCS THAT ARE SPECIFICALLY ENUMERATED IN S. 830

With respect to ephedrine-containing OTC drug products, contrary to the authors' statements, no state has imposed any labeling or packing restrictions on these products different from or beyond those imposed by the FDA. Some states have taken action on some OTC ephedrine products to place certain products on a controlled substance schedule, to place ephedrine on prescription status, to limit access to adults, and to prohibit possession of large quantities of the drug with intent to make methamphetamine. None of these state laws or actions would be preempted by the national provision of S. 830, because they are not laws enumerated in the section 807 of the bill (Sec. 761(a)(1)(B)).

6. ALL OTC DRUGS ARE SUBJECT TO THE SAME EXACTING FDA SAFETY, EFFECTIVENESS AND LABELING REQUIREMENTS

The authors make an unfounded and alarmist assertion that as more medications are switched from prescription to OTC status, consumers, especially the elderly and youth, are placed at greater risk. All nonprescription drugs, whether brought to market by being switched from prescription status, or marketed as OTC drugs from the outset, are subject to the same high and exacting standards for safety, effectiveness, and labeling. Indeed, nonprescription drugs are required to have an especially wide margin of safety precisely because they are intended to be purchased and used by consumers without the intervention of a doctor.

7. NATIONAL UNIFORMITY IS SUPPORTED BY MANY STATE AND NATIONAL ORGANIZATIONS AND SEVERAL FORMER FDA COMMISSIONERS

Support for national uniformity of OTC medicines is widespread and continues to grow. Over 90 organizations including the American Medical Association, National Consumers League, United Seniors Health Cooperative, as well as several state pharmacy, medical and retail organizations are in favor of one, uniform system of regulation for these important products. In addition, four former FDA Commissioners support this provision. (See Attachment B.)

Thank you for considering our views on this important subject. We urge you to continue your support for national uniformity for OTC medicines.

Sincerely,

JAMES D. COPE.
President.

Attachments: (A) Examples of State Proposals That Would Disrupt National Uniformity; (B) Organizations Supporting National Uniformity.

ATTACHMENT A

EXAMPLES OF STATE PROPOSALS THAT WOULD DISRUPT NATIONAL UNIFORMITY

The authors state that there is no evidence that there is a need for pre-exemption of state laws that seek to regulate OTC drug packaging and labeling. That quite simply is not true!. Here are just a few examples of state proposals that would, if enacted, disrupt national uniformity.

First, in 1993 alone, three states proposed to require bittering agents in certain OTC medicines sold in those states to deter childhood poisonings and overdoses. These state bills received consideration despite the federal CPSC's rejection of bittering agents under the Poison Prevention Packaging Act in favor of child resistant packaging and consumer education to address the problem.

Second, in the 1990s, at least fifteen state legislatures have considered legislation to require ''environmentally-friendly packaging'' of OTC drugs, that would mandate certain recycled content levels and plastic resins. These proposals would have conflicted with FDA's safety requirements that certain drugs be packaged only in ''virgin'' materials to prevent adulteration of the drugs. In some cases, these various proposals would conflict with each other as well.

Third, numerous states have proposed to require certain language and label warnings on OTC drugs that add additional, inconsistent and confusing precautions to these labels, in addition to the lengthy and comprehensive labeling requirements imposed by the FDA. Where would this extra room on OTC labels come from to accommodate all the suggestions that would be imposed by 50 states? Most OTC drugs are relatively small products, and thus have very limited label space.

OTC drug labels contain much FDA required information essential to their safe and proper use; therefore state-by-state proposals requiring additional label information obscure FDA-mandated warnings. Such proposals must be viewed in the context of the available label space. FDA makes these judgments recognizing the need for judicious use of scarce label space. Examples of these state-by-state proposed requirements include:

Conflicting proposed legislation in various states that would require—(1) the word ''poison'' along with antidote, (2) a ''Mr. Yuk'' symbol affixed to the label, (3) a special poison warning including a dark green background, and (4) a black ''X''—each of these different state proposals seek to address the same problem of childhood poisonings; label disclaimers that the elderly should disregard label dosages and consult a physician before taking any OTC drug, despite an absence of any scientific evidence that drug absorption or metabolism is connected to turning 65 years old; label disclosure that a certain product was tested on animals in its development, even though the FDA may require animal testing of the drug prior to its use in humans; label warnings that a product is unsuitable for disposal on land or in water; one state's attempt to require extensive label cautions on fluoride-containing toothpastes that fluoride is an enzymatic and protoplasmic poison 15 times more poisonous than arsenic; and initiatives or legislation in ten states that would have required special label warnings that certain ingredients may be carcinogens, even where the FDA has reviewed the drug and determined that it is safe and effective at the levels that the ingredient is used in that product. These states would reject the FDA's careful risk/benefit analysis of medications in favor of scaring consumers even where only trace quantities of the substance are present.

One can easily understand the confusion to consumers that would result if these warnings showed up on products in one state but not on the same identical product destined for another state. If any of the above ideas are good ones, they should be considered by FDA; receive comments from the public, the states, and the industry; and if they are determined to be sound public policy, they should be made national requirements.

There is absolutely a need for national uniformity to prevent such state proposals from disrupting commerce and confusing consumers.

ATTACHMENT B

ORGANIZATIONS SUPPORTING NATIONAL UNIFORMITY

American Association of Colleges of Pharmacy; American Beauty Association; American Medical Association; American Society of Health-System Pharmacists; Area Agencies on Aging Association of Michigan; Arizona Retailers Association; Associated Food Dealers of Michigan; Association of Commerce and Industry of New Mexico; California Arthritis Foundation Council; California Chapters of the National Association of Pediatric Nurse Associates & Practitioners; California Coalition of Hispanic Organizations; Central Ohio Retail Grocers Association; Chain Drug Marketing Association, Inc.; Citizens for the ''Right to Know''; and Congress of California Seniors.

Congress of California Seniors—Los Angeles; Connecticut State Medical Society; Florida Medical Association; Food Marketing Institute; Generic Pharmaceutical Industry Association; Giant Food, Inc.; Gulf Coast

Grocers Association (Texas); Health Advocacy Services (California); Independent Cosmetic Manufacturers & Distributors, Inc.; Indiana Manufacturers Association; Indiana Retail Council; Industry and Commerce Association of South Dakota; Interamerican College of Physicians and Surgeons; Iowa Retail Federal, Inc.; and Maryland Association of Chain Drug Stores.

Maryland Retailers Association; Medical Society of the State of New York; Medical Society of Virginia; Michigan Chamber of Commerce; Michigan Distributors and Venders Association, Inc.; Michigan State Medical Society; Minnesota Chamber of Commerce; Minnesota Grocers Association; Minnesota Retail Merchants Association; Mississippi Wholesale Distributors Association; Missouri Grocers Association; Missouri Retailers Association; Missouri State Medical Association; National Association of Chain Drug Stores; and National Association of Manufacturers.

National Coalition of Hispanic Health and Human Services; National Community Pharmacists Association; National Consumers League; National Council on the Aging; National Hispanic Council on Aging; National Retail Federation; National Wholesale Druggists' Association; New Hampshire Medical Society; New Mexico Pharmaceutical Association; Nonprescription Drug Manufacturers Association; North Carolina Retail Merchants Association; Ohio Council of Retail Merchants; Ohio Grocers Association; Ohio Wholesale Druggists Association; and Pennsylvania Association of Chain Drug Stores, Inc.

Philadelphia Association of Retail Druggists; Philadelphia College of Pharmacy; Retail Merchants Association of New Hampshire; Retailers Association of Massachusetts; Robbie Vierra-Lambert Spinal Cord Organization for Regaining Excellence; Safety & Health Council of New Hampshire; Safeway, Inc.; Senior Medication Awareness & Training Coalition, Sickle Cell Disease Association of America, Inc.; South Dakota Pharmacists Association; Tennessee Association of Business; Tennessee Grocers Association; Texas Association of Business & Chambers of Commerce; Texas Food Industry Association; and The 60 Plus Association.

United Seniors Association; United Seniors Health Cooperative; United States Hispanic Chamber of Commerce; Ukrop's; Vermont Board of Pharmacy; Vermont Chamber of Commerce; Vermont Grocers Association; Vermont Medical Society; Virginia Chamber of Commerce; Virginia Manufacturers Association; Virginia Pharmacists Association; Virginia Retail Merchants Association; Washington Retailers Association's Retail Pharmacy Council; Washington State Medical Association; White House Conference on Small Business, New Jersey Delegation; Wisconsin Grocers Association, Inc.; and Wisconsin Manufacturers and Commerce.

FORMER FDA COMMISSIONERS SUPPORTING NATIONAL UNIFORMITY

Charles C. Edwards, M.D.; Arthur Hull Hayes, Jr., M.D.; Donald Kennedy, Ph.D.; and Herbert Ley, Jr., M.D.

Mr. JEFFORDS. Madam President, we are nearing the end of the debate. I have no more requests for time that I am aware of. So I will make some comments and then go into a quorum call. But I want to alert Senators that if I do not have a request within the next 10 minutes, it is my intention to yield back the remainder of my time, assuming the minority would do the same thing, so that we can expedite the process and the movement of legislation through the Senate.

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

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

Mr. JEFFORDS. Madam President, I yield 6 minutes to the Senator from Arkansas.

CONSTITUTIONALITY OF MINING AMENDMENT

Mr. BUMPERS. Madam President, I rise today because I believe the Senate set a terrible precedent last Thursday when it voted to uphold a point of order that was made against an amendment that Senator GREGG and I offered to H.R. 2107, the Interior appropriations bill. This amendment proposed to collect the royalty from hardrock mining operations on public land and a reclamation fee from hardrock mining operations on land that was patented pursuant to the 1872 mining law. The receipts collected from the royalty and reclamation fee would have been deposited in a trust fund to be used to reclaim abandoned hardrock mines in the West.

Opponents of my amendment, in an attempt to prevent Senators from going on record in support of an effort to make the mining industry help pay for the environmental disasters it has created, raised a point of order arguing that the reclamation fee constituted a tax proposed by the Senate and thus the amendment violated the origination clause of the Constitution; that is, that all revenue measures must originate in the House. Unfortunately, the Senate voted to uphold the point of order even though the amendment was not even close to being unconstitutional.

The Supreme Court has held on numerous occasions that while a tax provision may not originate in the Senate, a governmental fee can. ''A statute that creates a particular governmental program and that raises revenue to support that program, as opposed to a statute that raises revenue to support government generally, it is not a 'bill for raising revenue' within the meaning of the origination clause.'' That is confirmed in United States versus Munoz-Florez. My amendment would have imposed a royalty and a fee in order to directly fund the reclamation of abandoned hardrock mines. It was not intended to raise revenues for the Treasury.

In fact, Madam President, the Parliamentarian has already ruled that the reclamation fee provision does not constitute a tax when the Parliamentarian referred S. 326, which includes the very same reclamation fee proposal that I had, to the Senate Energy and Natural Resources Committee rather than the Finance Committee. The House Parliamentarian made the very same ruling when he referred the House companion to S. 326 to the House Natural Resources Committee rather than the Ways and Means Committee.

I find it perplexing that anybody could argue that the amendment that Senator GREGG and I offered to the Interior appropriations bill could possibly constitute a tax. However, even if that were the case, it ought to be noted that the Interior appropriations bill originated in the House of Representatives in accordance with the origination clause of the Constitution. It does not matter that the amendment was offered in the Senate as long as the bill originated in the House. In *Flint* v. *Stone Tracy Company*, 220 U.S. 107 (1911), the Supreme Court ruled that legislation which created the tax on corporations complied with the origination clause even though the corporate tax was proposed by the Senate as a substitute to an inheritance tax that was included in the bill as reported by the House.

The fact that H.R. 2107 was reported by the Appropriations Committee rather than the Finance Committee is not relevant. The Senate has in the past added an amendment which modified the Tax Code to an appropriations bill. For example, in 1982 the Senate added a provision to the supplemental appropriations bill which limited the availability of certain tax deductions for Members of Congress.

Madam President, Senate rules do not permit the Parliamentarian to rule when a point of order is made against an amendment on constitutional grounds. If the Parliamentarian had been able to rule, the point of order would not have even been made and the decision would not have been close. Instead, the point of order was made with the knowledge that Senators would be able to defeat the Bumpers-Gregg amendment without actually going on record in support of allowing mining companies to continue acquiring billions of dollars worth of minerals from the taxpayers of this country without compensation and leaving those same taxpayers with environmental disasters to clean up.

Mr. President, I yield the floor.

Mr. JEFFORDS. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. DEWINE). The clerk will call the roll.

The bill clerk proceeded to call the roll.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

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